# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Amendment No. 1

to

Form S-1
REGISTRATION STATEMENT
UNDER

THE SECURITIES ACT OF 1933

# SUCAMPO PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**(State or Other Jurisdiction of Incorporation or Organization)

2834

(Primary Standard Industrial Classification Code Number) 13-3929237 (IRS Employer Identification Number)

4733 Bethesda Avenue, Suite 450 Bethesda, Maryland 20814 (301) 961-3400

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Sachiko Kuno, Ph.D.
President and Chief Executive Officer
Sucampo Pharmaceuticals, Inc.
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(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

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Approximate date of commencement of proposed sale to public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o
If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o
If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier registration statement for the same offering. o
If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier registration statement for the same offering. o

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

(SUBJECT TO COMPLETION)

Preliminary Prospectus Dated August 11, 2006



# **Class A Common Stock**

PHARMACEUTICALS, INC.

This is the initial public offering of our class A common stock. No public market currently exists for our class A common stock. We are offering all of the shares of class A common stock offered by this prospectus. We anticipate that the public offering price will be between \$ and \$ per share. After the offering, the market price for our shares may be outside this range.

We have applied to have our class A common stock approved for quotation on The NASDAQ Global Market under the symbol "SCMP."

Investing in our class A common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our class A common stock in "Risk Factors" beginning on page 8 of this prospectus.

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds, before expenses, to us	\$	\$

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We have granted the underwriters the right to purchase up to an additional shares of our class A common stock to cover overallotments. The underwriters can exercise this right at any time within 30 days after the offering. The underwriters expect to deliver the shares of class A common stock to investors on or about , 2006.

# Banc of America Securities LLC Deutsche Bank Securities Leerink Swann & Company

, 2006

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with information or information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of our class A common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. In this prospectus, unless otherwise stated or the context otherwise requires, references to "Sucampo," "we," "us," "our" and similar references refer to Sucampo Pharmaceuticals, Inc. and its combined affiliated companies, Sucampo Pharma Europe Ltd. and Sucampo Pharma, Ltd.

 $AMITIZA^{TM}$  and our logo are our trademarks and  $SUCAMPO^{\circledcirc}$  is our registered trademark. Each of the other trademarks, trade names or service marks appearing in this prospectus belongs to its respective holder.

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### NOTICE TO INVESTORS

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

#### **SUMMARY**

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all of the information that is important to you. Before investing in our class A common stock, you should read this prospectus carefully in its entirety, especially the risks of investing in our class A common stock that we discuss under "Risk Factors," and our combined financial statements and related notes beginning on page F-1.

#### Sucampo Pharmaceuticals, Inc.

Sucampo Pharmaceuticals, Inc. is an emerging pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. The therapeutic potential of prostones was first identified by one of our founders, Dr. Ryuji Ueno. We believe that most prostones function as activators of cellular ion channels and, as a result, may be effective at promoting fluid secretion and enhancing cell protection, which may give them wide-ranging therapeutic potential, particularly for age-related diseases. We are focused on developing prostones with novel mechanisms of action for the treatment of gastrointestinal, respiratory, vascular and central nervous system diseases and disorders for which there are unmet or underserved medical needs and significant commercial potential.

#### **AMITIZA**

In January 2006, we received marketing approval from the U.S. Food and Drug Administration, or FDA, for our first product AMITIZA™ (lubiprostone) for the treatment of chronic idiopathic constipation in adults. AMITIZA is the only prescription product for the treatment of chronic idiopathic constipation that has been approved by the FDA for use by adults of all ages, including those over 65 years of age, and that has demonstrated effectiveness for use beyond 12 weeks. Studies published in *The American Journal of Gastroenterology* estimate that approximately 42 million people in the United States suffer from constipation. Based on these studies, we estimate that approximately 12 million people can be characterized as suffering from chronic idiopathic constipation.

We also plan to pursue marketing approval for AMITIZA for additional constipation-related gastrointestinal indications with large, underserved markets. We are currently conducting two pivotal Phase III clinical trials of AMITIZA for the treatment of irritable bowel syndrome with constipation, for which we expect results in the first quarter of 2007. In addition, we plan to begin Phase II/III pivotal clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction by early 2007.

We are party to a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, to jointly develop and commercialize AMITIZA for chronic idiopathic constipation, irritable bowel syndrome with constipation, opioid-induced bowel dysfunction and other gastrointestinal indications in the United States and Canada. We have the right to co-promote AMITIZA along with Takeda in these markets. We and Takeda initiated commercial sales of AMITIZA in the United States for the treatment of chronic idiopathic constipation in April 2006. Takeda is marketing AMITIZA broadly to office-based specialty physicians and primary care physicians. We are complementing Takeda's marketing efforts by promoting AMITIZA through a specialty sales force in the institutional marketplace, including specialist physicians based in academic medical centers and long-term care facilities.

### **Additional Compounds**

Our additional compounds in development include:

• SPI-8811 for the treatment of ulcers induced by non-steroidal anti-inflammatory drugs, or NSAIDs, portal hypertension, non-alcoholic fatty liver disease, cystic fibrosis and chronic obstructive pulmonary disease. We have completed Phase I trials of SPI-8811 for NSAID-induced ulcers and a Phase IIa trial for cystic fibrosis. We plan to commence a Phase II clinical trial of SPI-8811 to treat NSAID-induced ulcers in early 2007, a Phase I/II proof-of-concept study of SPI-8811 in patients with portal

hypertension in 2007 and a Phase IIb trial of SPI-8811 for cystic fibrosis in 2007. SPI-8811 is in the preclinical stage for other indications.

• SPI-017 for the treatment of peripheral arterial and vascular disease and central nervous system disorders. Initially, we are working on the development of an intravenous formulation of SPI-017 for the treatment of peripheral arterial disease. We also are developing an oral formulation of SPI-017 for the treatment of Alzheimer's disease. We plan to initiate Phase I clinical trials of the intravenous formulation of SPI-017 in early 2007 and the oral formulation in mid to late 2007.

### **Our Strategy**

Our goal is to become a leading pharmaceutical company focused on discovering, developing and commercializing proprietary drugs based on prostones to treat diseases and disorders for which there are unmet or underserved medical needs and significant commercial potential. Our strategy to achieve this objective includes the following key elements:

- Focus on the commercial launch of AMITIZA in the United States for the treatment of chronic idiopathic constipation in adults.
- Develop AMITIZA for the treatment of additional indications and discover, develop and commercialize other prostone product candidates. We believe that our focus on prostones may offer several potential advantages, including:
  - novel mechanisms of action;
  - wide-ranging therapeutic potential;
  - our discovery and development experience with prostones; and
  - patent protection.
- Target large and underserved markets.
- Seek marketing approval for AMITIZA and our other product candidates in Europe and the Asia-Pacific region.
- Focus on our core discovery, clinical development and commercialization activities.
- Grow through strategic acquisitions and in-licensing opportunities.

#### **Related-Party Arrangements**

We hold an exclusive worldwide royalty-bearing license from Sucampo AG, a Swiss patent-holding company, to develop and commercialize AMITIZA and all other prostone compounds covered by patents and patent applications held by Sucampo AG. We are obligated to assign to Sucampo AG all patentable improvements that we make in the field of prostones, which Sucampo AG will in turn license back to us on an exclusive basis. With respect to any prostone compound other than AMITIZA, SPI-8811 and SPI-017, if we have not performed preclinical testing and generated specified pharmacological and toxicity data for such compound during the period that ends on the later of September 30, 2011 or three months after the date upon which Drs. Kuno and Ueno no longer control our company, then the commercial rights to that compound will revert to Sucampo AG, subject to a one-year extension in the case of any compound that we designate as one for which we intend in good faith to perform the required testing within that year. We refer to the end of this period as the Sucampo AG reversion date.

We are party to exclusive supply arrangements with R-Tech Ueno, Ltd., or R-Tech, a Japanese pharmaceutical manufacturer, to provide us with clinical and commercial supplies of AMITIZA and clinical supplies of our product candidates SPI-8811 and SPI-017. These arrangements include provisions requiring R-Tech to assist us in connection with applications for marketing approval for these compounds in the United States and elsewhere, including assistance with regulatory compliance for chemistry, manufacturing and controls.

Our two founders, Dr. Sachiko Kuno and Dr. Ryuji Ueno, together, directly or indirectly, own all of the stock of Sucampo AG and a majority of the stock of R-Tech. Drs. Kuno and Ueno also are executive officers, directors and controlling stockholders of our company and are married to each other.

#### **Our Dual Class Capital Structure**

We have two classes of common stock authorized, class A common stock and class B common stock. Holders of class A common stock and class B common stock have identical rights, except that holders of class A common stock are entitled to one vote per share and holders of class B common stock are entitled to ten votes per share on all matters on which stockholders are entitled to vote.

Immediately following the closing of this offering, we will have outstanding shares of class A common stock and 3,081,300 shares of class B common stock. The class B common stock will represent approximately % of the combined voting power of our outstanding common stock immediately following this offering. All of the shares of class B common stock are owned by S&R Technology Holdings, LLC, an entity wholly owned and controlled by Drs. Kuno and Ueno. As a result, Drs. Kuno and Ueno will be able to control the outcome of all matters upon which our stockholders vote, including the election of directors, amendments to our certificate of incorporation and mergers or other business combinations.

We will not be authorized to issue additional shares of class B common stock after this offering except in limited circumstances such as a stock split of both classes of common stock or a stock dividend made in respect of both classes of common stock. Shares of class B common stock will automatically be converted into shares of class A common stock upon transfer, with limited exceptions for transfers to family trusts. In addition, all remaining outstanding shares of class B common stock will automatically be converted into shares of class A common stock upon the death, legal incompetence or retirement from our company of both Drs. Kuno and Ueno or at such time as the number of outstanding shares of class B common stock is less than 20% of the number of outstanding shares of class A and class B common stock together.

In this prospectus, we refer to our authorized class A common stock and class B common stock together as our common stock.

#### **Risks Associated With Our Business**

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. Since our formation, we have incurred significant operating losses and, as of March 31, 2006, we had an accumulated combined deficit of \$27.0 million. We expect to incur additional losses and may never achieve or maintain profitability. Our success depends on the successful commercialization of AMITIZA for the treatment of chronic idiopathic constipation in adults and other indications for which we are developing this drug. We have limited experience commercializing drug products. If we are not successful in making the transition from a pre-commercial stage company to a commercial company, our ability to become profitable will be compromised. We are highly dependent upon the continued service of Drs. Kuno, our president and chief executive officer, and Ueno, our chief scientific and chief operating officer. We depend significantly upon our collaboration with Takeda, and the successful commercialization of AMITIZA will depend to a large degree upon the effectiveness of Takeda's sales force. Our agreement with Takeda provides that it may be terminated by either party if we fail to receive marketing approval from the FDA for AMITIZA for the treatment of irritable bowl syndrome with constipation and if we and Takeda do not thereafter agree on an alternative development and commercialization strategy. We have no manufacturing capabilities and rely exclusively upon R-Tech for the manufacture of AMITIZA and other prostone product candidates. Our preclinical studies may not produce successful results and our clinical trials may not demonstrate safety and efficacy in humans, which could impair our ability to develop additional indications for AMITIZA and to develop and commercialize other product candidates.

### **Our Corporate Information**

We were incorporated under the laws of Delaware in December 1996. Our principal executive offices are located at 4733 Bethesda Avenue, Suite 450, Bethesda, Maryland 20814, and our telephone number is (301) 961-3400. Prior to the closing of this offering, we will acquire all of the capital stock of two affiliated European and Asian operating companies, Sucampo Pharma Europe Ltd., or Sucampo Europe, and Sucampo Pharma, Ltd., or Sucampo Japan, that are under common control with us. At that time, Sucampo Europe and Sucampo Japan will become wholly owned subsidiaries of our company.

The Offering

Class A common stock we are offering

shares

Common stock to be outstanding after this offering:

Class A shares
Class B 3,081,300 shares

Total shares

Voting rights One vote for each share of class A common stock and ten votes for each share of

class B common stock on all matters on which stockholders are entitled to vote.

Use of proceeds We estimate that the net proceeds from this offering will be approximately

\$ million, or approximately \$ million if the underwriters exercise their overallotment option in full, assuming an initial public offering price of \$ per share, after deducting estimated underwriting discounts and commissions and offering expenses payable by us. We expect to use these net proceeds to fund: development activities for AMITIZA, SPI-8811 and SPI-017; expansion of our sales and marketing infrastructure; additional clinical trials and sales and marketing efforts by our European and Asian operating subsidiaries; development of other prostone compounds; and working capital, capital expenditures and other general corporate purposes, which may include the acquisition or in-license of complementary

technologies, products or businesses. See "Use of Proceeds."

Risk factors See "Risk Factors" and the other information included in this prospectus for a

discussion of factors you should carefully consider before deciding to invest in shares

of our class A common stock.

Proposed NASDAQ Global Market symbol SCMP

The number of shares of our class A and class B common stock to be outstanding after this offering is based on shares outstanding as of May 31, 2006. The number of shares to be outstanding after this offering excludes:

- 253,600 shares of our class A common stock issuable upon the exercise of stock options outstanding as of May 31, 2006 at a weighted average exercise price of \$41.88 per share; and
- an aggregate of 1,500,000 shares of class A common stock reserved for future issuance under our equity compensation plans as of the completion of this offering.

Unless otherwise noted, all information in this prospectus assumes:

- no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase up to shares of class A common stock to cover over-allotments;

• completion of the	automatically upon the closing of this offering; and acquisition by our company of two affiliated European and Asian operating companies, Su	campo Europe and
Sucampo Japan, a appearing elsewh to completion of	ere in this prospectus, which acquisition has been approved by our board of directors and we this offering. Following this acquisition, Sucampo Europe and Sucampo Japan will be whol	ip Reorganization' ill be completed p
of our company.		

### **Summary Combined Financial Data**

The following is a summary of our combined financial information. You should read this information together with our combined financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus.

Prior to the closing of this offering, we will acquire all of the capital stock of Sucampo Europe and Sucampo Japan. Accordingly, in this prospectus, except as otherwise expressly provided, we have presented financial information that reflects our financial position, results of operations and cash flows on a combined basis with these two operating companies.

Historical net (loss) income per share information is not presented due to the stock outstanding from multiple issuers, reflecting the combined nature of our financial statements. Please see note 3 to our combined financial statements appearing at the end of this prospectus for an explanation of the method used to calculate the pro forma net (loss) income per share and the number of shares used in the computation of pro forma per share amounts.

The pro forma balance sheet data set forth below gives effect to our issuance in April 2006 of 52,795 shares of class A common stock in a private placement transaction, and our receipt of \$4.5 million in net proceeds from that transaction.

The pro forma as adjusted balance sheet data set forth below gives further effect to our issuance and sale of shares of class A common stock in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and offering expenses payable by us.

			Three Months Ended			
	Years Ended December 31,			March 31,		
	2003	2004	2005	2005	2006	
		(in thousands	share data)			
Statement of operations data:						
Revenues	\$ 4,125	\$ 2,665	\$47,007	\$14,636	\$25,708	
Operating expenses:						
Research and development	18,444	14,036	29,888	6,920	6,120	
Selling, general and administrative	7,447	8,227	8,116	1,485	3,770	
Milestone royalties — related parties			1,500	500	1,250	
Operating (loss) income	(21,767)	(19,598)	7,503	5,731	14,568	
Total non-operating (expense) income, net	(250)	(56)	990	(73)	425	
(Loss) income before taxes	(22,017)	(19,654)	8,493	5,658	14,993	
Income tax provision		_	(1,768)	(558)	(3,728)	
Net (loss) income	\$ (22,017)	\$ (19,654)	\$ 6,725	\$ 5,100	\$11,265	
Basic pro forma net (loss) income per share	\$ (5.24)	\$ (4.66)	\$ 1.60	\$ 1.21	\$ 2.67	
Diluted pro forma net (loss) income per share	\$ (5.24)	\$ (4.66)	\$ 1.55	\$ 1.18	\$ 2.59	
Pro forma weighted average common shares outstanding — basic	4,205	4,213	4,213	4,214	4,214	
Pro forma weighted average common shares outstanding — diluted	4,205	4,213	4,331	4,317	4,343	

		As of March 31, 2006			
	Actual		o Forma n thousands)	Pro Forma As Adjusted	
Balance sheet data:		·			
Cash and cash equivalents	\$ 44,352	\$	48,840		
Short-term investments	28,537		28,537		
Working capital	49,941		54,429		
Total assets	75,247		79,735		
Total liabilities	49,201		49,201		
Accumulated deficit	(27,046)		(27,046)		
Total stockholders' equity	26,046		30,534		

#### **RISK FACTORS**

Investing in our class A common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information included in this prospectus, including the combined financial statements and related notes appearing at the end of this prospectus, before deciding to invest in our class A common stock. If any of the following risks actually occur, they may materially harm our business, prospects, financial condition and results of operations. In this event, the market price of our class A common stock could decline and you could lose part or all of your investment.

### **Risks Related to Our Limited Commercial Operations**

We have historically incurred significant losses and we might not achieve or maintain operating profitability.

We have only recently initiated commercial sales of our first product, AMITIZA, for the treatment of chronic idiopathic constipation in adults, and we have not yet recorded any product revenues. Since our formation, we have incurred significant operating losses and, as of March 31, 2006, we had an accumulated combined deficit of \$27.0 million. Our combined net losses were \$22.0 million in 2003 and \$19.7 million in 2004. Although we had combined net income of \$6.7 million in 2005 and \$11.3 million in the quarter ended March 31, 2006, this was attributable to our receipt of one-time milestone payments totaling \$30.0 million in 2005 and \$20.0 million in the quarter ended March 31, 2006. Our historical losses have resulted principally from costs incurred in our research and development programs and from our general and administrative expenses. We expect to continue to incur significant and increasing expenses for at least the next several years as we continue our research activities and conduct development of, and seek regulatory approvals for, additional indications for AMITIZA and for other drug candidates. Under our collaboration agreement with Takeda, Takeda reimbursed us for the first \$30.0 million in research and development expenses we incurred related to AMITIZA for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation, and we are now responsible for the next \$20.0 million. Takeda's reimbursement obligation covered substantially all of our research and development expenses for AMITIZA through 2005, by which time Takeda had satisfied its full \$30.0 million reimbursement obligation. Accordingly, the unreimbursed portion of our research and development expenses will significantly increase in 2006. Whether we are able to achieve operating profitability in the future will depend upon our ability to generate revenues that exceed our expenses. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and maintain profitability, the market value of our class A common stock will decline and you could lose all or a part of your investment.

If we are unable to successfully commercialize our first product, AMITIZA, for the treatment of chronic idiopathic constipation in adults or other indications for which we are developing this drug, or experience significant delays in doing so, our ability to generate product-based revenues and achieve profitability will be jeopardized.

In the near term, our ability to generate product-based revenues will depend on the successful commercialization and continued development of AMITIZA. We expect to record our first product revenue from AMITIZA in the quarter ending June 30, 2006. The commercial success of AMITIZA will depend on several factors, including the following:

- the effectiveness of Takeda's sales force, as supplemented by the specialty sales force we have engaged, in marketing and selling AMITIZA in the United States for the treatment of chronic idiopathic constipation in adults;
- the ability of R-Tech, which has the exclusive right to manufacture and supply AMITIZA, or any substitute manufacturer to supply quantities sufficient to meet market demand and at acceptable levels of quality and price;
- acceptance of the product within the medical community and by third party payors;

- successful completion of clinical trials of AMITIZA for the treatment of other constipation-related gastrointestinal indications beyond chronic idiopathic constipation; and
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities for the treatment of other indications, including marketing approval in the United States and Europe for AMITIZA to treat irritable bowel syndrome with constipation.

If we are not successful in commercializing AMITIZA for the treatment of chronic idiopathic constipation or other indications, or are significantly delayed in doing so, our business will be materially harmed.

We have limited experience commercializing drug products. If we are not successful in making the transition from a pre-commercial stage company to a commercial company, our ability to become profitable will be compromised.

For most of our operating history, we have been a pre-commercial stage company. We are in the process of transitioning to a company capable of supporting commercial activities, and we may not be successful in this transition. Our operations to date have been limited to organizing and staffing our company, developing prostone technology, undertaking preclinical and clinical trials of our product candidates and coordinating the U.S. regulatory approval process for AMITIZA for the treatment of chronic idiopathic constipation in adults. To make the transition to a commercial company, we will need to develop internally, or contract with third parties to provide us with, the capabilities to manufacture a commercial scale product and to conduct the sales and marketing activities necessary for successful product commercialization. While we expect R-Tech to perform these manufacturing functions and Takeda to perform many of these sales and marketing functions with respect to the sale of AMITIZA in the United States, we may nevertheless encounter unforeseen expenses, difficulties, complications and delays as we establish these commercial functions for AMITIZA and for other products for which we may receive regulatory marketing approval. As we continue to develop and seek regulatory approval of additional product candidates and additional indications for AMITIZA, and to pursue regulatory approvals for AMITIZA and other products outside the United States, it could be difficult for us to obtain and devote the resources necessary to successfully manage our commercialization efforts. If we are not successful in completing our transition to a commercial company, our ability to become profitable will be jeopardized and the market price of our class A common stock is likely to decline.

### Risks Related to Employees and Managing Growth

If we are unable to retain our president and chief executive officer and chief scientific and operating officer and other key executives, we may not be able to successfully develop and commercialize our products.

We are highly dependent on Dr. Sachiko Kuno, our president and chief executive officer, and Dr. Ryuji Ueno, our chief scientific and operating officer, and the other principal members of our executive and scientific teams, including Mariam Morris, our chief financial officer, Brad Fackler, our executive vice president of commercial operations, Gayle Dolecek, our senior vice president of research and development, Kei Tolliver, our vice president of business development and business operations, and Charles Hrushka, our vice president of marketing. The loss of the services of any of these persons might impede the achievement of our product development and commercialization objectives. We have employment agreements with these executives, but these agreements are terminable by the employees on short or no notice at any time without penalty to the employee. We do not maintain key-man life insurance on any of our executives.

If we fail to attract, retain and motivate qualified personnel, we may not be able to pursue our product development and commercialization programs.

Recruiting and retaining qualified scientific and commercial personnel, including clinical development, regulatory, and marketing and sales executives and field personnel, will be critical to our success. If we fail to recruit and then retain these personnel, our ability to pursue our clinical development and product commercialization programs will be compromised. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar

personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions.

We expect to expand our development, regulatory, sales and marketing, and finance and accounting capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, sales and marketing and finance and accounting. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We have identified material weaknesses in our internal control over financial reporting and those of Sucampo Europe and Sucampo Japan. If we fail to achieve and maintain effective internal control over financial reporting, we could face difficulties in preparing timely and accurate financial reports, which could lead to delisting of our class A common stock from The NASDAQ Global Market, to which we have applied to have our class A common stock approved for quotation, result in a loss of investor confidence in our reported results and cause the price of our class A common stock to fall.

In connection with the anticipated acquisition of Sucampo Europe and Sucampo Japan and our preparation of audited financial information for those two entities for the year ended December 31, 2005, we identified control deficiencies related to those entities that constitute material weaknesses in the design and operation of our internal controls over financial reporting.

In general, a material weakness is defined as a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of annual or interim financial statements will not be prevented or detected. The material weaknesses we identified are as follows:

- We did not maintain effective controls over the completeness and accuracy of revenue recognition. Specifically, effective controls were not designed and in place to adequately review contracts for the accuracy and proper cut-off of revenue recognition at Sucampo Europe and Sucampo Japan. This control deficiency resulted in adjustments to the revenue and deferred revenue accounts. Additionally, this control deficiency could result in a misstatement of the revenue and deferred revenue accounts that would result in a material misstatement to our interim or annual financial statements that would not be prevented or detected.
- We did not maintain effective controls over the completeness and accuracy of the accounting for debt instruments. Specifically, effective controls were not designed and in place to adequately review debt agreements of Sucampo Europe and Sucampo Japan for the proper accounting implications, or to ensure appropriate communication within our company regarding the existence of all debt agreements. This control deficiency resulted in adjustments to accounts payable, other liabilities and notes payable accounts. Additionally, this control deficiency could result in a misstatement of accounts payable, other liabilities and notes payable accounts that would result in a material misstatement to our interim or annual financial statements that would not be prevented or detected.
- We did not maintain effective controls over the preparation, review and presentation of the financial information prepared in accordance with U.S. generally accepted accounting principles reflecting Sucampo Europe and Sucampo Japan's operations. Specifically, effective controls were not designed and in place to adequately review, analyze and monitor these affiliates' financial information, nor did we have a standard reporting format for these affiliates, accounting procedures and policies manuals, formally documented controls and procedures or a formal process to review and analyze financial information of these affiliates. This control deficiency resulted in adjustments to revenue, deferred

revenue, accounts payable, other liabilities and notes payable accounts, as well as the statement of cash flows. Additionally, this control deficiency could result in a misstatement in a number of our financial statement accounts, including the statement of cash flows, resulting in a material misstatement to our interim or annual financial statements that would not be prevented or detected.

If we are unable to remediate these material weaknesses, we may not be able to accurately and timely report our financial position, results of operations or cash flows as a public company. Becoming subject to the public reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, upon the completion of this offering will intensify the need for us to report our financial position, results of operations and cash flows on an accurate and timely basis. Because we and Sucampo Europe and Sucampo Japan have not historically been managed by the same management group and because we have never had to prepare financial statements which included other entities, we may not be able to prepare complete and accurate financial statements on a timely basis, which could result in delays in our public filings and ultimately delisting of our class A common stock from its principal trading market, which will be The NASDAQ Global Market if our application to have our class A common stock approved for quotation is approved.

The remediation of our internal control over financial reporting as described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" is currently ongoing. We cannot assure you that we will be able to remediate these weaknesses. If we are not able to remediate these weaknesses, our ability to accurately and timely report our financial position, results of operations or cash flows could be impaired.

#### The requirements of being a public company may strain our resources and distract management.

As a public company, we will incur significant legal, accounting, corporate governance and other expenses that we did not incur as a private company. We will be subject to the requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, the NASDAQ Global Market, to which we have applied to have our class A common stock approved for quotation, and other rules and regulations. These rules and regulations may place a strain on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Sarbanes-Oxley requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We currently do not have an internal audit group. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to devote significant resources and management oversight. As a result, management's attention may be diverted from other business concerns. In addition, we will need to hire additional accounting staff with appropriate public company experience and technical accounting knowledge and we cannot assure you that we will be able to do so in a timely fashion.

These rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

### **Risks Related to Product Development and Commercialization**

Commercial rights to some prostone compounds will revert back to Sucampo AG in the future unless we devote sufficient development resources to those compounds during the next several years; if any of the compounds that revert back to Sucampo AG subsequently become valuable compounds, we will have lost the commercial rights to those compounds and will not be able to develop or market them, and the reverted compounds could ultimately compete with compounds we are developing or marketing.

Sucampo AG has granted to us an exclusive worldwide license to develop and commercialize products based upon Sucampo AG's extensive portfolio of U.S. and foreign patents and patent applications relating to

prostone technology. To retain our license rights to any prostone compounds other than AMITIZA, SPI-8811 and SPI-017, we are required to perform preclinical testing over a specified period on those compounds and to generate specified pharmacological and toxicity data. The specified period ends on the later of September 30, 2011 or three months after the date upon which Drs. Kuno and Ueno no longer control our company. At the end of the specified period, Sucampo AG can terminate our license with respect to any compounds as to which we have not performed the required testing, except for any compounds we designate as compounds for which we intend in good faith to perform the required testing within the following twelve months. At the end of that twelve-month period, Sucampo AG may terminate our license as to any of the designated compounds for which we have not performed the required testing.

We will need to focus our development resources and funding on a limited number of compounds during the specified period. The decision whether to commit development resources to a particular compound will require us to determine which compounds have the greatest likelihood of commercial success. Dr. Ueno and his staff will be primarily responsible for making these decisions on our behalf. Dr. Ueno and his wife, Dr. Kuno, indirectly own all the stock of Sucampo AG. In this process, we will likely commit resources to some compounds that do not prove to be commercially feasible and we may overlook other compounds that later prove to have significant commercial potential. If we do not identify and commit resources to one of these valuable compounds, the commercial rights with respect to the compound will eventually revert back to Sucampo AG. After the reversion of these rights to Sucampo AG, we will have no ability to develop or commercialize the compound. Although Sucampo AG will be prohibited from developing products that compete with our products prior to the Sucampo AG reversion date, thereafter they will be free to develop competitive products. In addition, although Sucampo AG will be prohibited from marketing products that compete with our products for 21 months after the Sucampo AG reversion date, after that date Sucampo AG will be permitted to market products, including products covered by the reverted license rights, in competition with us.

If our preclinical studies do not produce successful results or if our clinical trials do not demonstrate safety and efficacy in humans, our ability to develop additional indications for AMITIZA and to develop and commercialize other product candidates will be impaired.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Preclinical and clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and as a result we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we consider to be promising. For example, the efficacy results in two of our Phase IIa trials of SPI-8811, specifically the trials for the treatment of non-alcoholic fatty liver disease and for the treatment of cystic fibrosis, were inconclusive. Therefore, further clinical testing will be required in connection with the development of this compound for these indications;
- enrollment in our clinical trials may be slower than we currently anticipate, resulting in significant delays, or participants may drop out of our clinical trials at rates that are higher than we currently anticipate;
- we might have to suspend or terminate our clinical trials if we discover that the participating patients are being exposed to unacceptable health risks;

- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we currently anticipate;
- we might have difficulty obtaining sufficient quantities of the product candidate being tested to complete our clinical trials;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable; and
- the effects of our product candidates may not be the desired or anticipated effects or may include undesirable side effects, or the product candidates may have other unexpected characteristics. For example, in preclinical tests of AMITIZA, the drug demonstrated a potential to cause fetal loss in guinea pigs and, as a result, its label includes cautionary language as to its use by pregnant women.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing or if the results of these trials or tests are not positive or are only modestly positive, we may:

- be delayed in obtaining marketing approval for our product candidates;
- · not be able to obtain marketing approval; or
- obtain approval for indications that are not as broad as those for which we apply.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

We are required to conduct supplemental post-marketing clinical trials of AMITIZA and we may elect to perform additional clinical trials for other indications or in support of applications for regulatory marketing approval in jurisdictions outside the United States. These supplemental trials could be costly and could result in findings inconsistent with our historic U.S. clinical trials.

In connection with our marketing approval for AMITIZA for the treatment of chronic idiopathic constipation in adults, we committed to the FDA to conduct post-marketing studies of the product in pediatric patients and in patients with renal and hepatic impairment. In the future, we may be required, or we may elect, to conduct additional clinical trials of AMITIZA. In addition, if we seek marketing approval from regulatory authorities in jurisdictions outside the United States, such as the European Medicines Agency, or EMEA, they may require us to submit data from supplemental clinical trials in addition to data from the clinical trials that supported our U.S. filings with the FDA. Any requirements to conduct supplemental trials would add to the cost of developing our product candidates. Additional or supplemental trials could also produce findings that are inconsistent with the trial results we have previously submitted to the FDA, in which case we would be obligated to report those findings to the FDA. This could result in new restrictions on AMITIZA's existing marketing approval for chronic idiopathic constipation in adults or could force us to stop selling AMITIZA altogether. Inconsistent trial results could also lead to delays in obtaining marketing approval in the United States for other indications for AMITIZA or for other product candidates, could cause regulators to impose restrictive conditions on marketing approvals and could even make it impossible for us to obtain marketing approval. Any of these results could materially impair our ability to generate revenues and to achieve or maintain profitability.

If we are unable to establish sales and marketing capabilities or successfully use third parties to market and sell our products, we may be unable to generate sufficient product revenues to become profitable.

We currently have very limited sales and distribution capabilities and little experience in marketing and selling pharmaceutical products. To achieve commercial success for AMITIZA and any other approved

products, we must either develop a sales and marketing organization or outsource these functions to third parties. There are risks associated with either of these alternatives. For example, developing a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing capabilities were delayed, we would incur related expenses too early relative to the product launch. This may be costly, and our investment would be lost if we could not retain our sales and marketing personnel.

We have entered into a joint collaboration and license agreement with Takeda for the commercialization of AMITIZA for gastrointestinal indications in the United States and Canada. Takeda will market AMITIZA for the treatment of chronic idiopathic constipation in adults broadly to office-based specialty physicians and primary care physicians in the United States. We have also entered into an agreement with Ventiv Commercial Services, LLC, or Ventiv, to provide us with a specialty sales force to market AMITIZA to hospital-based specialist physicians and long-term care facilities. The Takeda sales force dedicated to selling AMITIZA will be significantly larger than our contract sales force, and we will therefore be heavily dependent on the marketing and sales efforts of Takeda. If our contract specialty sales force is not effective, or if Takeda is less successful in selling AMITIZA than we anticipate, our ability to generate revenues and achieve profitability will be significantly compromised.

# We face substantial competition which may result in others discovering, developing or commercializing products earlier or more successfully than we do.

The development and commercialization of pharmaceutical products is highly competitive. We expect to face intense competition with respect to AMITIZA and our other product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than AMITIZA or the other product candidates that we are developing or that would render AMITIZA or our other product candidates obsolete or uncompetitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours or achieve product commercialization before we do. If any of our competitors develops a product that is more effective, safer or more convenient for patients, or is able to obtain FDA approval for commercialization before we do, we may not be able to achieve market acceptance for our products, which would impair our ability to generate revenues and recover the substantial developments costs we have incurred and will continue to incur.

There are currently approved therapies for the diseases and conditions addressed by AMITIZA. For example, Zelnorm®, which is marketed by Novartis Pharmaceuticals Corporation, has been approved both for the treatment of chronic idiopathic constipation in adults under 65 years of age and for the short-term treatment of irritable bowel syndrome with constipation in women. In addition, the osmotic laxatives MiraLax™ (polyethylene glycol 3350), which is marketed by Braintree Laboratories, Inc., and lactulose, which is produced by Solvay S.A., have each been approved for the treatment of occasional constipation.

Several companies also are working to develop new drugs and other therapies for these same diseases and conditions. Some of these potential competitive drug products include:

- Drugs targeting serotonin receptors for the treatment of irritable bowel syndrome with constipation, such as Renzapride, being developed by Alizyme plc and currently in Phase III clinical trials; and
- Opioid antagonists such as Entereg® (alvimopan), being developed by Adolor Corporation and currently in Phase III clinical trials, and methylnaltrexone, being developed by Progenics Pharmaceuticals, Inc. and currently in Phase III clinical trials, each for the treatment of opioid-induced bowel dysfunction.

We face similar competition from approved therapies and potential drug products for the diseases and conditions addressed by SPI-8811 and SPI-017, and are likely to face significant competition for any other product candidates we may elect to develop in the future.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

# The commercial success of AMITIZA and any other products that we may develop will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

AMITIZA and any other products that we bring to the market may not gain acceptance by physicians, patients, healthcare payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate sufficient product revenues to become profitable. The degree of market acceptance of AMITIZA and any other products approved for commercial sale will depend on a number of factors, including:

- the prevalence and severity of any side effects. For example, the most common side effects reported by participants in our clinical trials of AMITIZA were nausea, which was reported by 31% of trial participants, and diarrhea and headache, both of which were reported by 13% of trial participants;
- the efficacy and potential advantages over alternative treatments;
- the competitiveness of the pricing of our products;
- the relative convenience and ease of administration of our products compared with other alternatives;
- the timing of the release of our products to the public compared to alternative products or treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- the level of third party coverage or reimbursement.

# If we are unable to obtain adequate reimbursement from third party payors for AMITIZA and any other products that we may develop, or acceptable prices for those products, our revenues and prospects for profitability will suffer.

Our revenues and ability to become profitable will depend heavily upon the availability of adequate reimbursement for the use of our products from governmental and other third party payors, both in the United States and in foreign markets. Reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- · cost effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or other third party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some product uses that are approved by the FDA or comparable authorities. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. If we are not able to obtain coverage and profitable reimbursement promptly from government-funded and

private third party payors for our products, our ability to generate revenues and become profitable will be compromised.

# Recent federal legislation will increase the pressure to reduce prices of prescription drugs paid for by Medicare, which could limit our ability to generate revenues.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we will be required to sell products to Medicare recipients through drug procurement organizations operating pursuant to this legislation. These organizations will negotiate prices for our products, which are likely to be lower than those we might otherwise obtain. Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as AMITIZA and the other product candidates that we are developing.

Legislation has been proposed from time to time that would permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices at which we sell our products and impair our ability to derive revenues from these products.

Legislation has been introduced from time to time in the U.S. Congress that would permit more widespread re-importation of drugs from foreign countries into the United States. This could include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decrease in the price we receive for any approved products, which, in turn, could impair our ability to generate revenues. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales.

#### Foreign governments tend to impose strict price controls, which may limit our ability to generate revenues.

In some foreign countries, particularly Japan and the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable in particular countries or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenue in these countries will be compromised.

# If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure, both from the testing of our product candidates in human clinical trials and from the sale of AMITIZA and any other drugs we may sell in the future. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for AMITIZA or any other product that we may develop;
- injury to our reputation;
- · withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;

- · loss of revenue; and
- the inability to continue to commercialize AMITIZA or to commercialize any other product that we may develop.

We currently have product liability insurance that covers our clinical trials and our commercial sales of AMITIZA up to an annual aggregate limit of \$20.0 million and subject to a per claim deductible. We do not currently have product liability insurance covering clinical trials in pediatric patients, and we will need to negotiate coverage of this type before we commence pediatric trials of AMITIZA in January 2007. The amount or scope of our product liability insurance may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost, and we may not be able to obtain insurance coverage that will be adequate to cover any liability that may arise. We may not have sufficient resources to pay for any liabilities resulting from a claim beyond the limits of our insurance coverage. If we cannot protect against product liability claims, we or our collaborators may find it difficult or impossible to commercialize our products.

Our strategy of generating growth through acquisitions and in-licenses may not be successful if we are not able to identify suitable acquisition or licensing candidates, to negotiate the terms of any such transaction or to successfully manage the integration of any acquisition.

As part of our business strategy, we intend to pursue strategic acquisitions and in-licensing opportunities with third parties to complement our existing product pipeline. We have no experience in completing acquisitions with third parties to date and we may not be able to identify appropriate acquisition or licensing candidates or to successfully negotiate the terms of any such transaction. The licensing and acquisition of pharmaceutical and biological products is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products in the pharmaceutical field, and they may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. If we are unable to successfully complete acquisitions or in-licensing transactions for suitable products and product candidates, our prospects for growth could suffer.

Even if we are successful in completing one or more acquisitions, the failure to adequately address the financial, operational or legal risks of these transactions could harm our business. To finance an acquisition, we could be required to use our cash resources, issue potentially dilutive equity securities or incur or assume debt or contingent liabilities. Accounting for acquisitions can require impairment losses or restructuring charges, large write-offs of in-process research and development expense and ongoing amortization expenses related to other intangible assets. In addition, integrating acquisitions can be difficult, and could disrupt our business and divert management resources. If we are unable to manage the integration of any acquisitions successfully, our ability to develop new products and continue to expand our product pipeline may be impaired.

We may need substantial additional funding and be unable to raise capital when needed, which could force us to delay, reduce or abandon our commercialization efforts or product development programs.

We expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution of AMITIZA. In addition, we expect our research and development expenses to increase in connection with our ongoing activities. We may need substantial additional funding and be unable to raise capital when needed or on attractive terms, which would force us to delay, reduce or abandon our commercialization efforts or development programs.

We have financed our operations and internal growth principally through private placements of equity securities, payments received under our collaboration agreement with Takeda and milestone and other payments from Sucampo AG and R-Tech. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents and internally generated funds that we anticipate from AMITIZA

product sales, will be sufficient to enable us to fund our operating expenses for the foreseeable future. Our future funding requirements, however, will depend on many factors, including:

- actual levels of AMITIZA product sales;
- the cost of commercialization activities, including product marketing, sales and distribution;
- the scope and results of our research, preclinical and clinical development activities;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- the costs involved in obtaining and maintaining proprietary protection for our products, technology and know-how, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in businesses, products and technologies;
- the success of our collaboration with Takeda; and
- our ability to establish and maintain additional collaborations.

If we are required to raise additional funds from external sources, we might accomplish this through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities, you may experience dilution. The holders of any new equity securities we issue may have rights, preferences or privileges that are senior to yours. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights and related intellectual property to our technologies, research programs, products or product candidates.

#### Risks Related to Our Dependence on Third Parties, Including Related Parties

We have no manufacturing capabilities and are dependent upon R-Tech to manufacture and supply us with our product and product candidates. If R-Tech does not manufacture AMITIZA or our other product candidates in sufficient quantities, at acceptable quality levels and at acceptable cost and if we are unable to identify a suitable replacement manufacturer, our sales of AMITIZA and our further clinical development and commercialization of other products could be delayed, prevented or impaired.

We do not own or operate manufacturing facilities and have little experience in manufacturing pharmaceutical products. We currently rely, and expect to continue to rely, exclusively on R-Tech to supply Takeda and us with AMITIZA, SPI-8811 and SPI-017 and any future prostone compounds that we may determine to develop or commercialize. We have granted R-Tech the exclusive worldwide right to manufacture and supply AMITIZA until 2026, and we do not have an alternative source of supply for AMITIZA. We also do not have an alternative source of supply for SPI-8811 or SPI-017, which R-Tech manufactures and supplies to us. If R-Tech is not able to supply AMITIZA or these other compounds on a timely basis, in sufficient quantities and at acceptable levels of quality and price and if we are unable to identify a replacement manufacturer to perform these functions on acceptable terms, sales of AMITIZA would be significantly impaired and our development programs could be seriously jeopardized.

The risks of relying solely on R-Tech for the manufacture of our products include:

- we rely solely on R-Tech for quality assurance and their continued compliance with regulations relating to the manufacture of pharmaceuticals;
- R-Tech's manufacturing capacity may not be sufficient to produce commercial quantities of our product, or to keep up with subsequent increases in the quantities necessary to meet potentially growing demand;

- R-Tech may not have access to the capital necessary to expand its manufacturing facilities in response to our needs;
- in light of the complexity of the manufacturing process for prostones, if R-Tech were to cease conducting business, or if its operations were to be interrupted, it would be difficult and time consuming for us to find a replacement supplier and the change would need to be submitted to and approved by the FDA;
- R-Tech has substantial proprietary know-how relating to the manufacture of prostones and, in the event we must find a replacement or supplemental manufacturer or we elect to contract with another manufacturer to supply us with products other than AMITIZA, we would need to transfer this know-how to the new manufacturer, a process that could be both time consuming and expensive to complete;
- R-Tech may experience events, such as a fire or natural disaster, that force it to stop or curtail production for an extended period; and
- R-Tech could encounter significant increases in labor, capital or other costs that would make it difficult for R-Tech to produce our products cost-effectively.

In addition, R-Tech currently uses one supplier for the primary ingredient used in the manufacture of prostones. R-Tech could experience delays in production should it become necessary to switch its source of supply for this ingredient to another supplier or to manufacture the ingredient itself.

Our current and anticipated future dependence upon R-Tech for the manufacture of our products and product candidates may adversely affect our future revenues, our cost structure and our ability to develop product candidates and commercialize any approved products on a timely and competitive basis. In addition, if R-Tech should cease to manufacture prostones for our clinical trials for any reason, we likely would experience delays in advancing these trials while we seek to identify and qualify replacement suppliers. We may be unable to obtain replacement supplies on a timely basis, on terms that are favorable to us or at all.

#### We and R-Tech are dependent upon a single contract manufacturer to complete the final stage of manufacture of AMITIZA.

R-Tech has subcontracted with a single contract manufacturer to encapsulate the bulk form AMITIZA supplied by R-Tech into gelatin capsules and to package the final product for distribution in the United States. If this subcontractor experiences difficulties or delays in performing these services for any reason, our ability to deliver finished product to physicians and patients will be impaired during the period in which R-Tech seeks a replacement manufacturer, which could cause us to lose revenues. In addition, any change in the party providing encapsulation of AMITIZA would need to be approved by the FDA, and any change in the party packaging the product would need to be submitted to and reviewed by the FDA, which could increase the time required to replace this subcontractor should that become necessary.

# R-Tech and any other third party manufacturer of our products and product candidates are subject to significant regulations governing manufacturing facilities and procedures.

R-Tech, R-Tech's subcontractors and suppliers and any other manufacturer of our products or product candidates may not be able to comply with the FDA's current good manufacturing practice, or cGMP, regulations, other U.S. regulations or similar regulatory requirements in force outside the United States. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products approved for sale. In addition, the FDA may at any time audit or inspect a manufacturing facility to ensure compliance with cGMP. Our failure, or the failure of R-Tech, R-Tech's subcontractors and suppliers or any other third party manufacturer we use, to comply with applicable manufacturing regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates.

If it were to become necessary for us to replace R-Tech as contract manufacturer of our product and product candidates, we would compete with other products for access to appropriate manufacturing facilities and the change would need to be submitted to and approved by the FDA. Among manufacturers that operate under cGMP regulations, there are a limited number that would be both capable of manufacturing for us and willing to do so.

# We depend significantly on our collaboration with Takeda, and may depend in the future on collaborations with other third parties, to develop and commercialize our product candidates.

A key element of our business strategy is to collaborate where appropriate with third parties, particularly leading pharmaceutical companies, to develop, commercialize and market our products and product candidates. We are currently party to a 16-year joint collaboration and license agreement with Takeda for the development and commercialization of AMITIZA for gastrointestinal indications in the United States and Canada.

Our agreement with Takeda provides that it may be terminated by either party if we fail to receive marketing approval from the FDA for AMITIZA for the treatment of irritable bowel syndrome with constipation and if we and Takeda do not thereafter agree on an alternative development and commercialization strategy. If Takeda were to terminate the agreement under these conditions, we would likely realize significantly lower revenues from sales of AMITIZA for the treatment of chronic idiopathic constipation until we could find a replacement marketing organization or develop our own, and our ability to continue our development program for AMITIZA for other gastrointestinal indications could be seriously compromised.

The success of our collaboration arrangement will depend heavily on the efforts and activities of Takeda. The risks that we face in connection with this collaboration, and that we anticipate being subject to in any future collaborations, include the following:

- our joint collaboration agreement with Takeda is, and any future collaboration agreements that we may enter into are likely to be, subject to termination under various circumstances;
- Takeda and other future collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us;
- Takeda and other future collaborators may underfund or not commit sufficient resources to the testing, marketing, distribution or other development of our products;
- Takeda and other future collaborators may not properly maintain or defend our intellectual property rights or may utilize our
  proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or
  expose us to potential liability; and
- Takeda and other future collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities from time to time, including following mergers and consolidations, which have been common in recent years in these industries.

The ability of our products and product candidates to reach their potential could be limited if Takeda or any other future collaborators decrease or fail to increase spending relating to such products, fail to dedicate sufficient resources to promoting our products or change their business focus.

We rely upon a third party contract sales company to provide our contract sales force focused on the institutional market for AMITIZA in the United States, and we have limited control over the sales representatives employed by this company.

To complement Takeda's sales efforts, we have entered into an agreement with Ventiv to provide us with a specialty sales force to market AMITIZA to hospital-based specialist physicians and long-term care facilities. This contract sales force consists entirely of Ventiv employees and, although our own employees will be involved in monitoring this sales force, we will have limited control over their activities. This contract sales force may not be effective, and our ability to terminate individual sales representatives or our relationship with

Ventiv will be limited. We do not have any experience managing a contract sales force and we may not be successful in this effort. If our contract sales force is not effective, our ability to generate revenues and achieve profitability may be significantly compromised.

# Because we rely upon third parties to provide the sales representatives marketing AMITIZA, we may face increased risks arising from their misconduct or improper activities, which would harm our business.

Because we will have only limited capacity to monitor the sales efforts of Takeda's and Ventiv's employees, we may be exposed to increased risks arising from any misconduct or improper activities of these employees, including the potential off-label promotion of our products or their failure to adhere to standard requirements in connection with product promotion. Any such improper activities could hurt our reputation, cause us to become subject to significant liabilities and otherwise harm our business.

# We may not be successful in establishing additional collaborations, which could compromise our ability to develop and commercialize products.

If we are unable to reach new agreements with suitable collaborators, we may fail to meet our business objectives for the affected product or program. We face significant competition in seeking appropriate collaborators. Moreover, these collaboration arrangements are complex and time-consuming to negotiate and document. We may not be successful in our efforts to establish additional collaborations or other alternative arrangements. The terms of any additional collaborations or other arrangements that we establish may not be as favorable to us as we anticipate. Moreover, these collaborations or other arrangements may not be successful.

# We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily or may fail to meet established deadlines for the completion of these trials.

We generally do not have the independent ability to conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions, and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not carry out their contractual duties or meet expected deadlines, we will be delayed in obtaining, or may not be able to obtain, regulatory approvals for our product candidates and will be delayed in our efforts to, or may not be able to, successfully commercialize our product candidates.

In addition, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

# Conflicts of interest may arise between us and Sucampo AG or R-Tech, and these conflicts might ultimately be resolved in a manner unfavorable to us.

Our founders, Dr. Sachiko Kuno and Dr. Ryuji Ueno, together wholly own Sucampo AG and own a majority of the stock of R-Tech. Dr. Ueno also is a director of Sucampo AG. Dr. Kuno and Dr. Ueno are married to each other. Ownership interests of our founders in the stock of R-Tech or Sucampo AG, or Dr. Ueno's service as a director of our company while at the same time serving as a director of Sucampo AG, could give rise to conflicts of interest when faced with a decision that could favor the interests of one of the affiliated companies over another. In addition, conflicts of interest may arise with respect to existing or possible future commercial arrangements between us and R-Tech or Sucampo AG in which the terms and

conditions of the arrangements are subject to negotiation or dispute. For example, conflicts of interest could arise over matters such as:

- disputes over the cost or quality of the manufacturing services provided to us by R-Tech with respect to AMITIZA, SPI-8811 and SPI-017;
- a decision whether to engage R-Tech in the future to manufacture and supply compounds other than AMITIZA, SPI-8811 and SPI-017;
- decisions as to which particular prostone compounds, other than AMITIZA, SPI-8811 or SPI-017, we will commit sufficient
  development efforts to so that commercial rights to those compounds will not revert back to Sucampo AG at the Sucampo AG
  reversion date; or
- business opportunities unrelated to prostones that may be attractive both to us and to the other company.

# If United States or foreign tax authorities disagree with our transfer pricing policies, we could become subject to significant tax liabilities.

We are a member of an affiliated group of entities, including Sucampo AG and R-Tech, each of which is directly or indirectly controlled by Drs. Kuno and Ueno. We have had and will continue to have significant commercial transactions with these entities. Furthermore, following the closing of this offering, we will operate two foreign subsidiaries, Sucampo Japan and Sucampo Europe. We expect to enter into commercial transactions with each of these entities on an ongoing basis. As a result of these transactions, we will be subject to complex transfer pricing regulations in both the United States and the other countries in which we and our affiliates operate. Transfer pricing regulations generally require that, for tax purposes, transactions between our affiliates and us be priced on a basis that would be comparable to an arm's length transaction and that contemporaneous documentation be maintained to support the related party agreements. To the extent that United States or any foreign tax authorities disagree with our transfer pricing policies, we could become subject to significant tax liabilities and penalties related to prior, existing and future related party agreements.

### **Risks Related to Our Intellectual Property**

If we are unable to obtain and maintain proprietary protection for the intellectual property relating to our technology and products, the value of our technology and products will be adversely affected and our ability to derive revenue from our products would be impaired.

Our success depends in part on our ability, and that of Sucampo AG, to obtain and maintain proprietary protection for the technology and know-how upon which our products are based, to operate without infringing on the proprietary rights of others and to prevent others from infringing on our proprietary rights. The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our intellectual property will depend on our success, in conjunction with Sucampo AG, in obtaining effective claims and enforcing those claims once granted. The scope of protection afforded by a set of patent claims is subject to inherent uncertainty unless the patent has already been litigated and a court has ruled on the meaning of the claim language and other issues affecting how broadly a patent claim can be enforced. In some cases, we license patent applications from Sucampo AG instead of issued patents, and we do not know whether these patent applications will result in the issuance of any patents. Our licensed patents may be challenged, invalidated or circumvented, which could limit the term of patent protection for our products or diminish our ability to stop competitors from marketing related products. In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of Sucampo AG's patents and our intellectual property or narrow the scope of the protection provided by these patents. Accordingly, we cannot determine the degree of future protection for our proprietary rights in the licensed patents and patent applications. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, a related patent may expire or

may remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

The patents we license from Sucampo AG also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our Sucampo AG can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

# Confidentiality agreements with our employees and other precautions may not be adequate to prevent disclosure of our proprietary information and know-how.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how developed both by Sucampo AG and by us. We and Sucampo AG seek to protect our respective proprietary technology and processes, in part, by confidentiality agreements with our respective employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. These agreements or security measures may be breached, and we and Sucampo AG may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we or Sucampo AG are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could compromise our ability to produce revenue and achieve profitability.

## If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Our research, development and commercialization activities and those of Sucampo AG, as well as any products or product candidates resulting from these activities, may infringe or be alleged to infringe patents or patent applications owned or controlled by other parties. These third parties could bring claims against us or one of our collaborators that would require us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or one of our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we or one of our collaborators may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or a collaborator were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or one of our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

### We may be subject to other patent related litigation or proceedings that could be costly to defend and uncertain in their outcome.

In addition to infringement claims against us, we may become a party to other patent litigation and proceedings, including interference proceedings declared by the United States Patent and Trademark Office or opposition proceedings in the European Patent Office regarding intellectual property rights with respect to our products and technology, as well as other disputes with licensees, licensors or others with whom we have

contractual or other business relationships for intellectual property. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could negatively affect our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management resources.

#### Risks Related to Regulatory Approval and Oversight

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate.

Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Our future products may not be effective, may be only moderately effective or may prove to have undesirable side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited in scope or subject to restrictions or post-approval commitments that render the product not commercially viable. If any regulatory approval that we obtain is delayed or is limited, we may decide not to commercialize the product candidate after receiving the approval.

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

AMITIZA and any other product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

We may experience unanticipated safety issues with our products after they are approved for marketing, which could harm our business and our reputation.

Because AMITIZA and our other product candidates are based on newly discovered prostone technology with novel mechanisms of action, there may be long-term safety risks associated with these products that are not identifiable or well-understood at early stages of development and commercialization. Later discovery of previously unknown problems with our products, manufacturers or manufacturing processes may result in:

- restrictions on such products, manufacturers or manufacturing processes;
- · warning letters;
- withdrawal of the products from the market;
- · refusal to approve pending applications or supplements to approved applications that we submit; and
- voluntary or mandatory product recalls.

# Failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our products outside the United States.

We intend to market our products both domestically and outside the United States. In order to market our products in the European Union, Japan and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

We may not be able to obtain orphan drug exclusivity for our product candidates. If our competitors are able to obtain orphan drug exclusivity for a product that is the same drug as one of our product candidates and we cannot show that our product candidate is clinically superior, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including Europe and the United States, may designate drugs that target relatively small patient populations as orphan drugs. We have received an orphan drug designation from the FDA for the oral formulation of our product candidate SPI-8811 for the treatment of cystic fibrosis and we may pursue orphan drug designation for additional product candidates, Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity. The exclusivity applies only to the indication for which the drug has been designated and approved. The applicable exclusivity period is seven years in the United States, but this period may be interrupted if a sponsor of a competitive product that is otherwise the same drug for the same use can show that its drug is clinically superior to our orphan drug candidate. The European exclusivity period is ten years, but may be reduced to six years if a drug no longer meets the criteria for orphan drug designation, including where it is shown that the drug is sufficiently profitable so that market exclusivity is no longer justified. In addition, European regulations establish that a competitor's marketing authorization for a similar product with the same indication may be granted if there is an insufficient supply of the product or if another applicant can establish that its product is safer, more effective or otherwise clinically superior. Obtaining orphan drug exclusivity for SPI-8811, both in the United States and in Europe, may be important to its success. If a competitor obtains orphan drug exclusivity for a product competitive with SPI-8811 before we do and if the competitor's product is the same drug with the same indication as ours, we would be excluded from the market, unless we can show that our drug is safer, more effective or otherwise clinically superior. Even if we obtain orphan drug exclusivity for SPI-8811 for

these indications, we may not be able to maintain it if a competitor with a product that is otherwise the same drug can establish that its product is clinically superior.

We must comply with federal, state and foreign laws, regulations, and other rules relating to the health care business, and, if we are unable to fully comply with such laws, regulations and other rules, we could face substantial penalties.

We are or will be directly, or indirectly through our customers, subject to extensive regulation by the federal government, the states and foreign countries in which we may conduct our business. The laws that directly or indirectly affect our ability to operate our business include the following:

- the federal Medicare and Medicaid Anti-Kickback law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;
- other Medicare laws, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- the federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- the federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and
- state and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations.

If our operations are found to be in violation of any of the laws, regulations, rules or policies described above or any other law or governmental regulation to which we or our customers are or will be subject, or if the interpretation of the foregoing changes, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations would harm our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions may be open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert management resources from the operation of our business and damage our reputation.

### Risks Related to the Offering

After this offering, our founders will maintain the ability to control all matters submitted to stockholders for approval, which could result in actions of which you or other stockholders do not approve.

When this offering is completed, Dr. Sachiko Kuno, our president, chief executive officer and a director, and Dr. Ryuji Ueno, our chief operating officer, chief scientific officer and a director, will together beneficially own 683,665 shares of class A common stock and 3,081,300 shares of class B common stock, representing % of the combined voting power of our outstanding common stock. As a result, Drs. Kuno and Ueno acting by themselves will be able to control the outcome of all matters that our stockholders vote upon, including the election of directors, amendments to our certificate of incorporation, and mergers or other business combinations. The concentration of ownership and voting power also may have the effect of delaying

or preventing a change in control of our company and could prevent stockholders from receiving a premium over the market price if a change in control is proposed.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our class A common stock may be lower as a result.

There are provisions in our certificate of incorporation and by-laws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our class A common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents contain other provisions that could have an anti-takeover effect, including:

- the high-vote nature of our class B common stock;
- following the conversion of all shares of class B common stock into class A common stock, only one of our three classes of directors will be elected each year;
- following the conversion of all shares of class B common stock into class A common stock, stockholders will not be entitled to remove directors other than by a 75% vote and for cause;
- following the conversion of all shares of class B common stock into class A common stock, stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our class A common stock. These provisions may also prevent changes in our management.

### If you purchase shares of class A common stock in this offering, you will suffer immediate dilution of your investment.

We expect the initial public offering price of our class A common stock to be substantially higher than the net tangible book value per share of our class A common stock. Therefore, if you purchase shares of our class A common stock in this offering, you will pay a price per share that substantially exceeds our pro forma net tangible book value per share after this offering. To the extent outstanding options or warrants are exercised, you will incur further dilution. Based on an assumed initial public offering price of \$ per share, the midpoint of the range set forth on the cover of this prospectus, you will experience immediate dilution of \$ per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the initial public offering price. In addition, purchasers of class A common stock in this offering will have contributed approximately % of the aggregate price paid by all purchasers of our common stock but will own only approximately % of our common stock outstanding after this offering.

In addition, as of May 31, 2006, we had outstanding stock options to purchase an aggregate of 253,600 shares of class A common stock at a weighted average exercise price of \$41.88 per share. To the extent these outstanding options are exercised, there will be further dilution to investors in this offering.

#### An active trading market for our class A common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our class A common stock will be determined through negotiations with the underwriters and may bear no relationship to the price at which the class A common stock will trade upon completion of this offering. Although we have applied to have our class A common stock quoted on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our class A common stock does not develop, it may be difficult to sell shares you purchase in this offering without depressing the market price for the shares or to sell your shares at all.

#### Because our stock price may be volatile, purchasers of our class A common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their class A common stock at or above the initial public offering price. The market price for our class A common stock may be influenced by many factors, including:

- failure of AMITIZA or other approved products, if any, to achieve commercial success;
- results of clinical trials of our product candidates or those of our competitors;
- the regulatory status of our product candidates;
- the success of competitive products or technologies;
- regulatory developments in the United States and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- the ability of R-Tech to manufacture our products to commercial standards in sufficient quantities;
- actual or anticipated fluctuations in our quarterly financial results;
- · variations in the financial results of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations; and
- general economic, industry and market conditions.

### We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our class A common stock. The failure by our management to apply these funds effectively could result in financial losses, cause the price of our class A common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

### We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on our capital stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our class A common stock will be your sole source of gain for the foreseeable future.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future. This could cause the market price of our class A common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our class A common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our class A common stock in the public market following this offering, the market price of our class A common stock could decline significantly. Upon completion of this offering, we will have outstanding shares of common stock, assuming no exercise of outstanding options. Of these shares, shares sold in this offering will be freely tradable, additional shares of common stock will be available for sale in the public market 90 days after the date of this prospectus, and additional shares of common stock will be available for sale in the public market 180 days after the date of this prospectus following the expiration of lock-up agreements between our stockholders and the underwriters. The representatives of the underwriters may release these stockholders from their 180-day lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of shares in the public market. Moreover, after this offering, holders of an aggregate of 794,307 shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register the shares of class A common stock that we may issue in the future under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the 180-day lock-up agreements with our underwriters.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our plans for selling and marketing AMITIZA in the United States for treatment of chronic idiopathic constipation in adults and our plans to seek regulatory approval to market AMITIZA in jurisdictions outside the United States;
- our plans to develop other indications for AMITIZA;
- our plans to develop SPI-8811 and SPI-017 and potentially other compounds;
- our collaborative arrangement with Takeda;
- our ongoing and planned research programs and clinical trials;
- the timing of and our ability to obtain and maintain regulatory approvals;
- the rate and degree of market acceptance and clinical utility of our products;
- our ability to quickly and efficiently develop clinical candidates;
- our marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
- our belief that the net proceeds from this offering, together with our existing cash and cash equivalents and internally generated funds from AMITIZA product sales, will be sufficient to enable us to fund our operating expenses for the foreseeable future.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

#### **USE OF PROCEEDS**

We expect to use the net proceeds from this offering as follows:

- approximately \$20.0 million to fund our share of development activities for AMITIZA for the treatment of additional gastrointestinal indications, which we expect will enable us to complete the two ongoing pivotal Phase III clinical trials and one follow-on safety study of AMITIZA for the treatment of irritable bowel syndrome with constipation;
- up to \$1.0 million to fund our share of two post-marketing studies of AMITIZA to evaluate its safety in patients with renal and hepatic impairment;
- approximately \$20.0 million to fund development activities for SPI-8811 and SPI-017, which we expect will enable us to complete at least the following development efforts:
  - a Phase II clinical trial of SPI-8811 for the prevention and treatment of NSAID-induced ulcers;
  - a Phase I/II proof-of-concept study of SPI-8811 in patients with portal hypertension;
  - a Phase IIb clinical trial of SPI-8811 for cystic fibrosis; and
  - Phase I clinical trials of an intravenous formulation of SPI-017 for peripheral arterial and vascular disease and stroke;
- up to \$25.0 million to fund: expansion of our sales and marketing infrastructure in the United States; additional clinical trials and sales and marketing efforts by Sucampo Europe and Sucampo Japan; and development activities for prostone compounds other than AMITIZA, SPI-8811 and SPI-017;
- up to \$3.0 million to fund costs in connection with:
  - a potential move of our headquarters facility, including costs for furniture, fixtures and equipment; and
  - computers, software and information technology to support growth in our business; and
- any balance to fund working capital, capital expenditures and other general corporate purposes, which may include the acquisition or in-license of complementary technologies, products or businesses.

This expected use of proceeds from this offering represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures may vary significantly depending upon numerous factors, including the progress of our development and commercialization efforts, the progress of our clinical trials and our operating costs and capital expenditures. As a result, we will retain broad discretion in the allocation of the net proceeds from this offering. We have no current understandings, commitments or agreements to acquire or in-license any technologies, products or businesses.

Pending use of the proceeds from this offering, we intend to invest the proceeds in short-term, investment-grade, interest-bearing instruments.

### **DIVIDEND POLICY**

We have never paid or declared any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to fund the growth and development of our business, and we do not anticipate paying any cash dividends in the foreseeable future.

### **CAPITALIZATION**

The following table sets forth our cash and cash equivalents, short-term investments and capitalization as of March 31, 2006:

- on an actual basis; and
- on a pro forma basis to give effect to:
  - *Pro Forma I:* our issuance in April 2006 of 52,795 shares of class A common stock in a private placement transaction, and our receipt of \$4.5 million in net proceeds from that transaction; and
  - *Pro Forma II:* that private placement transaction, as well as the issuance of 211,765 shares of our class A common stock in exchange for all of the shares of Sucampo Europe and Sucampo Japan, and the related elimination of their equity, and the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 378,000 shares of class A common stock upon the closing of this offering; and
- on a pro forma as adjusted basis to give effect to the sale of shares of class A common stock in this offering at an assumed initial public offering price of \$ per share, after deducting estimated underwriting discounts and commissions and offering expenses payable by us.

You should read this table together with our combined financial statements and the related notes appearing elsewhere in this prospectus and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of March 31, 2006						
		Actual	Pro Forma I (in th		Pro Forma II housands)		Pro Forma As Adjusted
Cash and cash equivalents	\$	44,352	\$	48,840	\$	48,840	\$
Short-term investments		28,537		28,537		28,537	
Notes payable — related parties, net of current portion	\$	3,752	\$	3,752	\$	3,752	\$
Stockholders' equity:				,			
Series A convertible preferred stock, \$0.01 par value; 3,780 shares issued and outstanding actual and proforma I; no shares issued and outstanding pro							
forma II and pro forma as adjusted		20,288		20,288		_	
Class A common stock, \$0.01 par value; 769,662 shares issued and outstanding actual; 822,457 shares issued and outstanding pro forma I; 1,412,222 shares issued and outstanding pro forma II; and shares issued							
and outstanding pro forma as adjusted		8		8		14	

As	of	Marc	h	31.	2006

						Pro Forma
	Actual	Pro	Forma I	Pro Form	a II	As Adjusted
			(in th	ousands)		
Class B common stock, \$0.01 par value;						
3,081,000 shares outstanding actual, pro forma I, pro						
forma II and pro forma as adjusted	31		31		31	
Common stock, Sucampo Japan, \$420.65 par value;						
1,000 shares issued and outstanding actual and pro						
forma I; no shares issued and outstanding pro						
forma II and pro forma as adjusted	421		421		_	
Common stock, Sucampo Europe, \$1.53 par value;						
5,000 shares issued and outstanding actual and pro						
forma I; no shares issued and outstanding pro						
forma II and pro forma as adjusted	8		8		_	
Additional paid-in capital	32,436		36,924	57	,635	
Accumulated other comprehensive loss	(99)		(99)		(99)	
Accumulated deficit	(27,046)		(27,046)	(27	,04 <u>6</u> )	
Total stockholders' equity	26,046		30,533	30	,533	
Total capitalization	\$ 29,798	\$	34,285	\$ 34	,285	\$

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share of class A common stock would increase or decrease cash and cash equivalents and short-term investments by \$ million, and increase or decrease additional paid-in capital, total stockholders' equity and total capitalization by a total of \$ million, assuming that the number of shares of class A common stock offered by us, as set forth on the cover page of this prospectus, remains the same. The information discussed in this paragraph is illustrative only and following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

The number of shares in the table above excludes:

- 171,000 shares of our class A common stock issuable upon the exercise of stock options at a weighted average exercise price of \$21.05 per share; and
- an aggregate of 1,500,000 shares of class A common stock reserved for future issuance under our equity compensation plans as of the completion of this offering.

#### DILUTION

If you invest in our class A common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our class A common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our pro forma net tangible book value as of March 31, 2006 was approximately \$29.6 million, or approximately \$6.59 per share of common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets less total liabilities, after giving effect to our receipt of \$4.5 million of net proceeds from our private placement sale of class A common stock in April 2006, divided by the number of shares of class A and class B common stock outstanding after giving effect to our issuance of 52,795 shares of class A common stock in our private placement financing in April 2006, the issuance of 211,765 shares of our class A common stock in exchange for all of the shares of Sucampo Europe and Sucampo Japan and the related elimination of their equity and the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 378,000 shares of class A common stock upon the closing of this offering.

After giving effect to the issuance and sale of the shares of class A common stock in this offering, at an assumed initial public offering price of \$ per share, less the estimated underwriting discounts and commissions and offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2006 would have been \$ , or \$ per share of class A and class B common stock. This represents an immediate increase in net tangible book value per share of \$ to existing stockholders and immediate dilution of \$ per share to new investors. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by a new investor. The following table illustrates the per share dilution without giving effect to the over-allotment option granted to the underwriters:

Assumed initial public offering price per share of class A common stock	\$
Pro forma net tangible book value per share as of March 31, 2006	\$
Increase per share attributable to new investors	
Pro forma as adjusted net tangible book value per share after this offering	 
Dilution per share to new investors	\$

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share of class A common stock would increase or decrease the pro forma as adjusted net tangible book value per share after this offering by \$ per share and the dilution per share to new investors in this offering by \$ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

If the underwriters exercise their over-allotment option in full, our pro forma as adjusted net tangible book value will increase to \$ per share, representing an immediate increase to existing stockholders of \$ per share and an immediate dilution of \$ per share to new investors. If any shares are issued in connection with outstanding options, you will experience further dilution.

The following table summarizes as of March 31, 2006, on the pro forma basis described above, the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid by the existing stockholders and by new investors in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range listed on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and other expenses of this offering.

	Total Class A Class B Sh		Total Consider	ation	Aver	age Price
	Number	%	Amount	%	Per	Share
Existing stockholders	4,493,522	%	\$ 55,311,899	%	\$	12.31
New investors						
Total		100%	\$	100%		

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share of class A common stock would increase or decrease the total consideration paid by new investors by \$ million, and increase or decrease the percent of total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The table above is based on shares outstanding as of March 31, 2006 and excludes:

- 171,000 shares of our class A common stock issuable upon the exercise of stock options at a weighted average exercise price of \$21.05 per share; and
- an aggregate of 1,500,000 shares of class A common stock reserved for future issuance under our equity compensation plans as of the completion of this offering.

If the underwriters' over-allotment option is exercised in full, the following will occur:

- the percentage of shares of common stock held by existing stockholders will decrease to number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors will be increased to common stock outstanding after this offering.

#### SELECTED COMBINED FINANCIAL DATA

You should read the following selected combined financial data in conjunction with our combined financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. Prior to the closing of this offering, we will acquire all of the capital stock of Sucampo Europe and Sucampo Japan. Accordingly, in this prospectus we have presented financial statements that reflect our financial position, results of operations and cash flows on a combined basis with these two operating companies. We have derived the following combined financial data as of December 31, 2004 and 2005 and for the three years ended December 31, 2005 from combined financial statements audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm. Combined balance sheets as of December 31, 2004 and 2005 and the related combined statements of operations, of changes in stockholders' (deficit) equity and of cash flows for each of the three years in the period ended December 31, 2005 and notes thereto appear elsewhere in this prospectus. We have derived the following combined financial data as of December 31, 2002 and 2003 and for the year ended December 31, 2002 from unaudited combined financial statements, which are not included in this prospectus. We have derived the following financial data as of December 31, 2001 and for the year then ended from audited financial statements, which are not included in this prospectus. We have derived the following combined financial data as of March 31, 2006 and for the three months ended March 31, 2006 and 2005 from unaudited combined financial statements, which appear elsewhere in this prospectus, which we have prepared on the same basis as the audited combined financials statements and which, in the opinion of our management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the results for the unaudited interim periods. Interim financial results are not necessarily indicative of results to be expected for the full year or for any future reporting period.

		Year E	Ended Decemb	per 31,			nths Ended h 31,
	2001	2002	2003	2004	2005	2005	2006
			(in thousand	s, except per	share data)		
Statement of operations data:							
Revenues	\$10,104	\$ 8,097	\$ 4,125	\$ 2,665	\$47,007	\$ 14,636	\$25,708
Operating expenses:							
Research and development	6,241	12,549	18,444	14,036	29,888	6,920	6,120
Selling, general and administrative	5,244	6,536	7,447	8,227	8,116	1,485	3,770
Milestone royalties — related parties					1,500	500	1,250
Total operating expenses	11,485	19,085	25,891	22,263	39,504	8,906	11,140
Operating (loss) income	(1,381)	(10,988)	(21,767)	(19,598)	7,503	5,731	14,568
Total non-operating income (expense), net	186	7,721	(250)	(56)	990	(73)	425
(Loss) income before taxes	(1,195)	(3,267)	(22,017)	(19,654)	8,493	5,658	14,993
Income tax benefit (provision)	776	(681)			(1,768)	(558)	(3,728)
Net (loss) income	\$ (419)	\$ (3,948)	\$(22,017)	\$(19,654)	\$ 6,725	\$ 5,100	\$ 11,265
Basic pro forma net (loss) income per share	\$ (0.24)	\$ (1.01)	\$ (5.24)	\$ (4.66)	\$ 1.60	\$ 1.21	\$ 2.67
Diluted pro forma net (loss) income per share	\$ (0.24)	\$ (1.01)	\$ (5.24)	\$ (4.66)	\$ 1.55	\$ 1.18	\$ 2.59
Pro forma weighted average common shares							
outstanding — basic	1,751	3,910	4,205	4,213	4,213	4,214	4,214
Pro forma weighted average common shares							
outstanding — diluted	1,751	3,910	4,205	4,213	4,331	4,317	4,343

	2001	2005	As of March 31, 2006			
Balance sheet data:						
Cash and cash equivalents	\$13,760	\$31,393	\$ 19,070	\$ 21,918	\$ 17,436	\$ 44,352
Short-term investments	_	_	_	3,000	28,435	28,537
Working capital	9,950	27,850	14,834	14,956	22,083	49,942
Total assets	16,299	32,455	20,072	26,826	47,933	75,247
Notes payable — related parties, current	237	250	271	4,040	848	850
Notes payable — related parties, net of current portion	483	241	3,352	2,326	2,546	3,752
Total liabilities	5,116	4,463	14,196	40,549	52,597	49,201
Accumulated equity (deficit)	582	(3,366)	(25,382)	(45,036)	(38,311)	(27,046)
Total stockholders' equity (deficit)	11,183	27,992	5,876	(13,723)	(4,664)	26,046

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our combined financial statements and the related notes and other financial information appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Information for the three months ended March 31, 2005 and 2006 is derived from our unaudited financial statements.

#### Overview

We are an emerging pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. In January 2006, we received marketing approval from the FDA for our first product, AMITIZA, for the treatment of chronic idiopathic constipation in adults.

We are party to a collaboration and license agreement with Takeda to jointly develop and commercialize AMITIZA for chronic idiopathic constipation, irritable bowel syndrome with constipation, opioid-induced bowel dysfunction and other gastrointestinal indications in the United States and Canada. We have the right to co-promote AMITIZA along with Takeda in these markets. We and Takeda initiated commercial sales of AMITIZA in the United States for the treatment of chronic idiopathic constipation in adults in April 2006

Because we have only recently initiated commercial sales of AMITIZA for the treatment of chronic idiopathic constipation in adults, we had not generated any product revenues as of March 31, 2006. Since inception we have incurred operating losses and, as of March 31, 2006, we had an accumulated combined deficit of \$27.0 million. Our combined net losses were \$22.0 million in 2003 and \$19.7 million in 2004. We recognized combined net income of \$6.7 million in 2005 and \$11.3 million in the quarter ended March 31, 2006. The historical combined losses resulted principally from costs incurred in our research and development programs and from our general and administrative expenses. We expect to continue to incur significant and increasing expenses for the next several years as we continue to expand our research and development activities, seek regulatory approvals for additional indications for AMITIZA and augment our sales and marketing capabilities. Whether we are able to sustain profitability will depend upon our ability to generate revenues in the future that exceed these expenses. In the near term, our ability to generate product revenues will depend primarily on the successful commercialization and continued development of additional indications for AMITIZA.

We hold an exclusive worldwide royalty-bearing license from Sucampo AG to develop and commercialize AMITIZA and all other prostone compounds covered by patents and patent applications held by Sucampo AG. We are obligated to assign to Sucampo AG all patentable improvements that we make in the field of prostones, which Sucampo AG will in turn license back to us on an exclusive basis. If we have not committed specified development efforts to any prostone compound other than AMITIZA, SPI-8811 and SPI-017 by the end of a specified period, which ends on the later of September 30, 2011 or three months after the date upon which Drs. Kuno and Ueno no longer control our company, then the commercial rights to that compound will revert to Sucampo AG, subject to a one-year extension in the case of any compound that we designate in good faith as planned for development within that year.

Prior to the closing of this offering, we will acquire all of the capital stock of two affiliated European and Asian operating companies, Sucampo Europe and Sucampo Japan, that are under common control with us. At that time, Sucampo Europe and Sucampo Japan will become wholly owned subsidiaries of our company. Accordingly, in this prospectus we have presented financial statements that reflect our financial position, results of operations and cash flows on a combined basis with these two operating companies, and this

management's discussion and analysis of financial condition and results of operations discusses such combined financial statements.

#### **Our Clinical Development Programs**

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

- AMITIZA. In connection with our marketing approval for AMITIZA for the treatment of chronic idiopathic constipation in adults, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in pediatric patients and in patients with renal and hepatic impairment. We plan to initiate these studies by January 2007. In addition, we are developing AMITIZA to treat irritable bowel syndrome with constipation and opioid-induced bowel dysfunction. We are currently conducting two pivotal Phase III clinical trials of AMITIZA for the treatment of irritable bowel syndrome with constipation, and we also are conducting a follow-on safety study to assess the long-term use of AMITIZA as a treatment for this indication. We expect results of these two Phase III pivotal trials and the follow-on safety study in the first quarter of 2007. If the results of these trials are favorable, we plan to seek marketing approval for AMITIZA in the United States as well as Europe and Japan for the treatment of this disorder. We believe we can pursue marketing approval of this indication in the United States by filing a supplement to our existing new drug application, or NDA, for AMITIZA. We plan to initiate Phase II/III pivotal clinical trials of AMITIZA for treatment of opioid-induced bowel dysfunction by early 2007. Our collaboration and co-promotion arrangement with Takeda also covers these additional indications for AMITIZA.
- SPI-8811. We are developing orally administered SPI-8811 to treat various gastrointestinal and liver disorders, including NSAID-induced ulcers, portal hypertension, non-alcoholic fatty liver disease and gastrointestinal disorders associated with cystic fibrosis. We also are planning to develop an inhaled formulation of SPI-8811 for the treatment of respiratory symptoms of cystic fibrosis and chronic obstructive pulmonary disease. Our near term focus is on the development of SPI-8811 as a treatment for NSAID-induced ulcers. We have completed Phase I clinical trials of SPI-8811 in healthy volunteers and plan to initiate a Phase II clinical trial of this product candidate for the treatment of NSAID-induced ulcers in early 2007. We also plan to initiate a Phase I/II proof-of-concept study of SPI-8811 in patients with portal hypertension in 2007.
- **SPI-017.** We are developing SPI-017 to treat vascular disease and central nervous system disorders. We are initially focused on developing an intravenous formulation of this product candidate for the treatment of peripheral arterial disease. We also are developing an oral formulation of SPI-017 for the treatment of Alzheimer's disease. We plan to initiate Phase I clinical trials of the intravenous formulation of SPI-017 in early 2007 and the oral formulation in mid to late 2007.

## Financial Terms of our Collaboration with Takeda

We entered into our collaboration agreement with Takeda in October 2004 following completion of our Phase III clinical trials for chronic idiopathic constipation. Under the terms of the agreement, we have received a variety of payments and will have the opportunity to receive additional payments in the future.

## **Up-front Payment**

Upon signing the agreement with Takeda, we received a nonrefundable up-front payment of \$20.0 million, which we deferred and which is being recognized as contract revenue ratably over the 16-year life of the agreement.

#### **Product Development Milestone Payments**

We have also received the following nonrefundable payments from Takeda reflecting our achievement of specific product development milestones:

- \$10.0 million upon the filing of the NDA for AMITIZA to treat chronic idiopathic constipation in March 2005;
- \$20.0 million upon the initiation of our Phase III clinical trial related to AMITIZA for the treatment of irritable bowel syndrome with constipation in May 2005; and
- \$20.0 million upon the receipt of approval from the FDA for AMITIZA for the treatment of chronic idiopathic constipation in adults in January 2006.

We recognized these payments as milestone revenue in full upon our achievement of the applicable milestone.

In addition, our collaboration agreement requires that Takeda pay us up to an additional aggregate of \$90.0 million conditioned upon our achievement of future regulatory milestones relating to AMITIZA. We would recognize these payments as milestone revenue in full upon our achievement of the applicable milestone.

## Research and Development Cost-Sharing for AMITIZA

Our collaboration agreement with Takeda provides for the sharing between Takeda and us of the costs of our research and development activities for AMITIZA in the United States and Canada as follows:

- Takeda was responsible for the first \$30.0 million in research and development expenses we incurred after October 2004 related to AMITIZA for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation. We received reimbursement payments from Takeda of \$1.5 million in 2004 and \$28.5 million in 2005. We have deferred recognition of these payments and are currently recognizing the revenue using the straight-line method over the life of the development cycle, which we have estimated will continue through December 2006, with the exception that we do not recognize revenue in any period to the extent that it resulted in cumulative recognized revenue exceeding cumulative reimbursable expenses incurred. As of March 31, 2006, we had recognized an aggregate of \$19.6 million of the total \$30.0 million we have received and had deferred revenues of \$10.4 million.
- We are responsible for the next \$20.0 million in research and development expenses we incur related to AMITIZA for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation. Thereafter, any expenses in excess of \$50.0 million are shared equally between Takeda and us. Because we have received reimbursements of \$30.0 million from Takeda, we are now responsible for the next \$20.0 million of these expenses. We do not expect aggregate expenses necessary to complete development of AMITIZA for these two indications will exceed the \$20.0 million for which we are solely responsible.
- For research and development expenses relating to changing or expanding the labeling of AMITIZA to treat chronic idiopathic constipation and irritable bowel syndrome with constipation, Takeda is responsible for 70% of these expenses and we are responsible for 30%. We have not incurred any expenses of this nature to date. However, in connection with our marketing approval for AMITIZA for the treatment of chronic idiopathic constipation in adults, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in patients with renal and hepatic impairment. The expenses of these studies will be shared 70% by Takeda and 30% by us. We plan to initiate these studies by January 2007.
- The expense of Phase IV clinical trials of AMITIZA for the treatment of chronic idiopathic constipation in pediatric patients that we expect to initiate by January 2007 will be borne by Takeda in full.
- For expenses in connection with additional clinical trials required by regulatory authorities relating to AMITIZA to treat chronic idiopathic constipation or irritable bowel syndrome with constipation, Takeda

and we are responsible to share these expenses equally. We have not incurred any expenses of this nature to date.

- Takeda is responsible for the first \$50.0 million in expenses we incur related to the development of AMITIZA for each gastrointestinal indication other than chronic idiopathic constipation and irritable bowel syndrome with constipation, and any expenses in excess of \$50.0 million are shared equally between Takeda and us. We plan to initiate clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction by early 2007. Currently, we do not anticipate the aggregate expenses necessary to complete our development of AMITIZA for this indication will exceed the \$50.0 million for which Takeda is responsible.
- Takeda is responsible for the first \$20.0 million in expenses we incur related to the development of each new formulation of AMITIZA, and any expenses in excess of \$20.0 million are shared equally between Takeda and us. We have not incurred any expenses of this nature to date, and we have no plans to develop new formulations of AMITIZA.

## Co-Promotion Reimbursement

In connection with our exercise of our co-promotion rights under the collaboration agreement, Takeda agreed to reimburse us for a portion of our expenses related to our specialty sales force. We estimate that these reimbursements will cover approximately 80% of the costs for our current sales force of 38 contract sales representatives provided under our contract with Ventiv, an independent contract sales organization. Through March 31, 2006, we had not received any reimbursement for these expenses because our sales representatives did not commence their activities until April 2006.

### **Royalty Payments**

Takeda is obligated to pay us a varying royalty based on a percentage of the net sales revenue from the sale of AMITIZA in the United States and Canada. The actual percentage will depend on the level of net sales revenue during each calendar year. All sales of AMITIZA in the United States and Canada, including those arranged by our specialty sales force, will be made through Takeda. Through March 31, 2006, we had not received any royalties from Takeda because commercial sales did not commence until April 2006.

# **Commercialization Milestone Payments**

Our collaboration agreement also requires Takeda to pay us up to an additional aggregate of \$50.0 million conditioned upon the achievement of specified targets for annual net sales revenue from AMITIZA in the United States and Canada.

## **Option Payment**

In November 2004, we received \$5.0 million from Takeda as an option payment to continue negotiations for the joint development and commercialization of AMITIZA for gastrointestinal indications in additional territories. In the event that these negotiations failed to produce a definitive agreement by specified dates, the terms of the option required us to repay \$2.5 million of the original \$5.0 million option payment to Takeda. As to the \$2.0 million of the option payment relating to joint development and commercialization in Asia, we recorded \$1.0 million as current deferred revenue and \$1.0 million as other short-term liabilities in 2004. As to the \$3.0 million of the option payment relating to Europe, the Middle East and Africa, we recorded \$1.5 million as long term deferred revenue and \$1.5 million as other long-term liabilities in 2004. The option right for Asia expired during 2005, at which time we repaid \$1.0 million to Takeda and recognized the remaining \$1.0 million as contract revenue. The option right for Europe, the Middle East and Africa expired during the first quarter of 2006, at which time we repaid \$1.5 million to Takeda and recognized the remaining \$1.5 million as contract revenue.

#### Financial Terms of our License from Sucampo AG

Under our license agreement with our affiliate, Sucampo AG, we are required to pay Sucampo AG 5% of every development milestone payment we receive from a sublicensee, such as Takeda. We also are obligated to make the following milestone payments to Sucampo AG:

- \$500,000 upon initiation of the first Phase II clinical trial for each compound in each of three territories covered by the license: North, Central and South America, including the Caribbean; Asia; and the rest of the world; and
- \$1.0 million for the first NDA filing or comparable foreign regulatory filing for each compound in each of these three territories.

In addition, we are required to pay Sucampo AG, on a country-by-country basis, royalty payments of 6.5% of net sales for every product covered by existing patents and, if applicable, thereafter 4.25% of net sales for every product candidate covered by new or improvement patents assigned by us to Sucampo AG. With respect to sales of AMITIZA in North, Central and South America, including the Caribbean, the rates for these royalty payments are set at 3.2% and 2.1% of net sales, respectively. The royalties that we pay to Sucampo AG are based on total product net sales, whether by us or a sublicensee, and not on amounts actually received by us.

We paid Sucampo AG \$1.0 million, reflecting 5% of the \$20.0 million up-front payment that we received from Takeda with respect to AMITIZA in October 2004. This payment was characterized as deferred licensing fees and is being expensed as selling, general and administrative expenses ratably over the life of the contract with Takeda through 2020.

We also have paid Sucampo AG \$2.5 million, reflecting 5% of the aggregate of \$50.0 million of development milestone payments that we received from Takeda through March 31, 2006, and \$250,000 upon marketing approval of AMITIZA by the FDA for the treatment of chronic idiopathic constipation in adults. These payments were characterized as milestone royalties to related parties and were expensed as incurred.

#### Supply Agreement with R-Tech

We entered into an exclusive supply arrangement with our affiliate, R-Tech, in March 2003. In return for the exclusive right to manufacture and supply clinical and commercial supplies of AMITIZA and a second prostone compound that we are no longer developing in North, Central and South America, including the Caribbean, R-Tech agreed to make the following milestone payments to us:

- \$1.0 million upon entry into the arrangement, which we received in March 2003;
- \$2.0 million upon commencement of a first Phase II clinical trial relating to AMITIZA to treat irritable bowel syndrome with constipation, which we received in April 2003; and
- \$3.0 million upon commencement of a first Phase II clinical trial for the other compound, which we received in 2003. On March 31, 2005, after evaluating the Phase II study results, we determined to discontinue any further research and development related to this compound and will not receive any further payments in respect of this compound.

We evaluated the \$6.0 million in cash receipts from R-Tech and determined these payments were made for the exclusive right to supply inventory to us and, accordingly, should be deferred until commercialization of the drugs begins. We also were unable to accurately apportion value between AMITIZA and the other compound based on the information available to us and determined that the full \$6.0 million deferred amount should be amortized over the contractual life of the relationship, which we concluded was equivalent to the commercialization period of AMITIZA and the other compound. Accordingly, the entire \$6.0 million is reflected as deferred revenue at March 31, 2006, and we will begin recognizing this revenue during the quarter ending June 30, 2006 ratably over the remaining life of our supply agreement with R-Tech through 2026. This revenue will be characterized as contract revenue from related parties.

The supply agreement also requires payment of a specified transfer price in respect of supplies of AMITIZA. Takeda is obligated to make such payment, without reimbursement from us, in respect of commercial supplies of AMITIZA for the territory covered by our collaboration with Takeda.

In June 2005, Sucampo Europe entered into an exclusive supply agreement with R-Tech. In return for the exclusive right to manufacture and supply clinical and commercial supplies of AMITIZA in Europe, the Middle East and Africa, R-Tech agreed to pay us \$2.0 million in anticipation of entering into this agreement, which we received in March 2005. We determined that this payment should be deferred until commercialization of AMITIZA begins within the specified territory and, accordingly, the entire \$2.0 million is reflected as deferred revenue at March 31, 2006.

#### **Discontinued Ophthalmic Collaborative Relationship**

On February 1, 1999, we entered into a five-year collaboration agreement with an unrelated third party, which established a long-term alliance for the development and commercialization of drugs to treat ophthalmic diseases. Under this arrangement, we agreed to conduct preclinical tests, clinical tests and other research and development for designated compounds, all of which were unrelated to prostones. In turn, we received nonrefundable payments totalling \$8.0 million. We recognized these payments ratably over the term of the project, which approximated the term of the agreement. We recognized \$1.6 million in revenue under this agreement in 2003 and \$67,000 in 2004, which we characterized as contract revenue. All revenues related to this agreement were recognized by the first quarter of 2004. We determined not to continue this relationship, and we allowed the collaboration agreement to expire in 2004.

## **Critical Accounting Policies and Estimates**

This discussion and analysis of our financial condition and results of operations is based upon our combined financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our combined financial statements requires us to make estimates and judgments that affect our reported assets, liabilities, revenues and expenses. Actual results may differ significantly from those estimates under different assumptions and conditions.

We regard an accounting estimate or assumption underlying our financial statements as a critical accounting estimate if:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are described in more detail in note 2 of our combined financial statements.

## Revenue Recognition

We have historically generated revenue from two primary sources: (1) research and development arrangements providing for upfront payments and milestone payments and (2) research and development cost-sharing under our joint collaboration and license agreement with Takeda. In addition, we expect to begin receiving royalty payments from Takeda for the joint commercialization of AMITIZA in the second quarter of 2006. We recognize revenue from these sources in accordance with Staff Accounting Bulletin, or SAB, 104, "Revenue Recognition", Emerging Issues Task Force, or EITF, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables", and EITF No. 99-19, "Reporting Revenue Gross as a Principal Versus Net as an Agent".

We recognize up-front licensing fees, which are recorded as contract revenue, as revenue on the straight-line basis over the estimated performance period under the applicable agreement.

In the case of up-front option fees we receive related to potential joint collaboration and license agreements, we commence revenue recognition upon the exercise of the option and we continue recognition over the estimated service period. Alternatively, if the option expires unexercised, we then recognize the fees as revenue immediately upon the expiration of the option.

We follow the substantive milestone method for recognizing contingent payments. If a milestone payment is earned related to our performance, we evaluate whether substantive effort was involved in achieving the milestone. Factors we consider in determining whether a milestone is substantive and therefore can be accounted for separately from an up-front payment include assessing the level of risk and effort in achieving the milestone, the timing of its achievement relative to the up-front payment and whether the amount of the payment was reasonable in relation to our level of effort. If these criteria are met, we recognize the milestone payment when it is earned. If these criteria are not met, we would be required to defer revenue from the milestone payment and recognize it ratably over the contractual life of the agreement.

We recognize reimbursement of research and development costs under our agreement with Takeda as revenue using a proportional performance method in accordance with SAB 104. While we provide multiple services under this agreement, there is insufficient evidence of the fair values of each of the individual services. Therefore, we recognize revenue on a straight-line basis over the development activity period, which we have estimated will be completed at the end of 2006. We believe a straight-line basis is representative of the pattern in which performance takes place. The revenue recognized in any period is limited to the lesser of the cumulative straight-line basis amount through that period or the cumulative reimbursable portion of the research and development costs actually incurred through that period. We have determined, in accordance with EITF 99-19, that we are acting as a principal in this arrangement and, as such, we have recorded reimbursements of these development costs as revenues.

We account for cost-sharing revenue related to development activities under research and development and consulting arrangements with related parties under the proportional performance method. Under this method, cost-sharing payments received in advance of performance are recorded as deferred revenue and recognized as contract revenue to related parties over the applicable performance period. The application of this revenue recognition method is based on the proportional costs incurred against total expected costs relative to the respective cost-sharing arrangement.

Beginning in the second quarter of 2006, we will begin to receive royalty payments from Takeda relating to net sales of AMITIZA. Because of the lack of historical data regarding sales returns, we will not recognize as revenue any royalty payments related to the portion of sales by Takeda that are subject to a right of return until the right of return lapses.

Beginning in the second quarter of 2006, we will also receive reimbursement of selling and marketing expenses from Takeda. We have determined, in accordance with EITF 99-19, that we are acting as a principal in this arrangement and, as such, we will record reimbursements of these amounts as revenues.

## **Accrued Expenses**

As part of our process of preparing our combined financial statements, we are required to estimate accrued expenses. This process involves reviewing and identifying services which have been performed by third parties on our behalf and determining the value of these services. Examples of these services are payments to clinical investigators, professional fees, such as accountants' and attorneys' fees, and payments to contracted service organizations. In addition, we make estimates of costs incurred to date but not yet invoiced to us in relation to external contract research organizations and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs, when evaluating the adequacy of the accrued liabilities. We must make significant judgments and estimates in determining the accrued balance in any accounting period.

In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by the service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event we do not

identify costs that have begun to be incurred or we under-estimate or over-estimate the level of services performed or the costs of such services, our reported expenses for the relevant period would be too low or too high. We must also sometimes make judgments about the date on which services commence, the level of services performed on or before a given date and the cost of such services. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

## **Stock-Based Compensation**

We have elected to follow Accounting Principles Board Opinion, or APB, No. 25, "Accounting for Stock Issued to Employees", and related interpretations in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under Statement of Financial Accounting Standards, or SFAS, No. 123, "Accounting for Stock-Based Compensation Accounting Principles Board Opinion" through December 31, 2005. Accordingly, we have not recorded stock-based compensation expense for stock options issued to employees in fixed amounts with exercise prices at least equal to the fair value of the underlying common stock on the date of grant, including those granted in 2004. We did not award stock options to employees during 2003, 2005 or the quarter ended March 31, 2006. In note 2 to our combined financial statements included later in this prospectus, we provide pro forma disclosures for the years presented in accordance with SFAS 123 and related pronouncements.

We account for transactions with non-employees in which services are received in exchange for equity instruments under EITF 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services". Under this guidance, the transactions are based on the fair value of the services received from the non-employees or the fair value of the equity instruments issued, whichever is more reliably measured. The three factors which most affect stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded, the vesting term of the options and the volatility of such fair value. Accounting for these equity instruments requires us to determine the fair value of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating stock-based compensation expenses.

Given the lack of an active public market for our common stock, our board of directors determined the fair value of our common stock for stock option awards. Our board of directors determined this fair value by considering a retrospective valuation obtained from a valuation specialist during 2005. In establishing the estimates of fair value, the specialist considered the guidance set forth in the AICPA Practice Guide, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation", or AICPA Practice Guide, and made retrospective determinations of fair value. The valuation was considered by our board of directors to determine the fair value of the common stock underlying stock options awarded to non-employees in 2005.

Determining the fair value of our common stock requires making complex and subjective judgments. Our approach to valuation is based on a discounted future cash flow approach that uses our estimates of revenue, driven by assumed market growth rates, and estimated costs as well as appropriate discount rates. These estimates are consistent with the plans and estimates that we use to manage our business. There is inherent uncertainty in making these estimates. Although it is reasonable to expect that the completion of this offering will add value to the shares because they will have increased liquidity and marketability, the amount of additional value cannot be measured with precision or certainty.

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123R, "Share-Based Payment", or SFAS 123R, a revision of SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS 123R requires companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use APB 25's intrinsic method of accounting for share-based payments. The standard generally allows two alternative transition methods in the year of adoption — prospective application and retroactive application with restatement of prior financial statements to include the same amounts that were previously included in the pro forma disclosures. On January 1, 2006, we adopted SFAS 123R using the prospective method of implementation. According to the prospective method, the previously issued financial statements will not be

adjusted. The adoption of this pronouncement will not have any financial impact on our combined financial statements until new stock option awards are granted to employees because all outstanding stock options at January 1, 2006 were fully vested and no options were granted during the three months ended March 31, 2006.

We implemented SFAS 123R utilizing the prospective transition method. Under this method, we will recognize compensation expense for all share-based payment awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R.

For recording our stock-based compensation expense under SFAS 123R, we have chosen to use:

- the straight-line method of allocating compensation cost under SFAS 123R;
- the Black-Scholes model as our chosen option-pricing model;
- the simplified method to calculate the expected term for options as discussed under SAB No. 7, "Share-Based Payment"; and
- an estimate of expected volatility based on the historical volatility of similar entities whose share prices are publicly available.

The result of the adoption of SFAS 123R did not affect our combined financial statements for the periods presented because all outstanding stock options as of January 1, 2006 were fully vested and there were no new stock options awarded to employees or modifications to outstanding stock options during the three months ended March 31, 2006. Also, prior periods do not need to be restated for this adoption when the prospective method is chosen.

#### **Income Taxes**

As part of the process of preparing our combined financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. We follow SFAS No. 109, "Accounting for Income Taxes". This process requires us to estimate our actual current tax exposure while assessing our temporary differences resulting from the differing treatment of items for tax and accounting purposes. These differences have resulted in deferred tax assets and liabilities. As of December 31, 2005, we had foreign net operating loss carryforwards will begin to expire on December 31, 2010. As of December 31, 2005, we had general business tax credits of \$3.3 million, which also may be available to offset future income tax liabilities and will expire if not utilized at various dates beginning December 31, 2022. We have recorded a full valuation allowance as an offset to our net deferred tax assets due to the uncertainty in determining the timing of the realization of the tax benefit. In the event that we determine that we will be able to realize all or a portion of these assets, we will make an adjustment to the valuation allowance. The Tax Reform Act of 1986 contains provisions that may limit our ability to use our credits available in any given year in which there has been a substantial change in ownership interest, as defined. The realization of the benefits of the tax credits is dependent on sufficient taxable income in future years. Lack of earnings, a change in the ownership of our company, or the application of the alternative minimum tax rules could adversely affect our ability to utilize these tax credits.

## **Related Party Transactions**

As part of our operations, we enter into transactions with our affiliates. At the time of the transaction, we estimate the fair market value of the transaction based upon estimates of net present value or comparable third party information. For material transactions with our foreign subsidiaries and affiliates, we have had transfer pricing studies performed to ensure that the terms of transactions are similar to those that would have prevailed had the entities not been affiliated.

#### **Combined Results of Operations**

#### Comparison of three months ended March 31, 2005 and March 31, 2006

#### Revenue

The following table summarizes our combined revenues for the three months ended March 31, 2005 and 2006:

Three Months End		
March 31,		
2005 20		
(in thousands)		
\$10,000	\$20,000	
4,287	3,869	
309	1,809	
40	30	
\$14,636	\$25,708	
	Marc 2005 (in thou \$10,000 4,287 309 40	

Total combined revenues were \$25.7 million for the three months ended March 31, 2006 compared to \$14.6 million for the three months ended March 31, 2005, an increase of \$11.1 million. This increase was due primarily to an increase of \$10.0 million in milestone revenue.

Milestone revenues in the three months ended March 31, 2005 reflected our receipt from Takeda of a \$10.0 million milestone payment upon the filing of the NDA for AMITIZA to treat chronic idiopathic constipation in adults in March 2005. Milestone revenues in the three months ended March 31, 2006 reflected the \$20.0 million milestone payment we received from Takeda in January 2006 for the NDA approval of AMITIZA. We recognized these payments in full as revenues upon their receipt.

Revenues from reimbursement of research and development costs represent payments we receive from Takeda in reimbursement of a portion of research and development expenses we incur for AMITIZA. In the three months ended March 31, 2005, we recognized \$4.3 million of cost reimbursements from Takeda. During the three months ended March 31, 2006, we recognized \$3.9 million of cost reimbursements, reflecting a portion of the cost reimbursement payments we had received from Takeda in 2005. Our recognition of this amount in the first quarter of 2006 reduced our deferred revenue balance relating to Takeda reimbursements to \$10.4 million. Depending on the clinical trial results associated with irritable bowel syndrome with constipation, we may need to reevaluate the expected time line for the project to which these reimbursements relate, which could require us to extend the deferral of this revenue.

Contract revenue reflects a portion of the \$20.0 million up-front payment we received from Takeda upon the execution of our collaboration and license agreement with them in October 2004. We are recognizing this up-front payment as revenue ratably over the 16-year life of the agreement. Contract revenue for the three months ended March 31, 2006 also includes \$1.5 million in previously deferred revenue that we recognized upon the expiration of the option granted to Takeda for joint development and commercialization rights for AMITIZA in Europe, Africa and the Middle East. Contract revenue was \$1.8 million for the three months ended March 31, 2006 compared to \$309,000 for the three months ended March 31, 2005, an increase of \$1.5 million. This increase was attributable to the \$1.5 million we recognized upon the option expiration.

Contract revenue from related parties represents reimbursement of costs incurred by us on behalf of affiliated companies for research and development consulting, patent maintenance and certain administrative costs. These revenues are recognized in accordance with the terms of the contract or project to which they relate. Contract revenue from related parties was \$30,000 for the three months ended March 31, 2006 compared to \$40,000 for the three months ended March 31, 2005, an increase of \$10,000.

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

Research and development expenses represent costs incurred in connection with the in-licensing of our compounds, clinical trials, activities associated with regulatory filings and manufacturing efforts. Currently, we outsource our clinical trials to independent contract research organizations in order minimize our overhead. We expense our research and development costs as incurred.

Total combined research and development expenses for the three months ended March 31, 2006 were \$6.1 million compared to \$6.9 million for the three months ended March 31, 2005, a decrease of \$800,000. The higher costs in the first quarter of 2005 reflect the significant research and development expenses incurred by us during that period in connection with the filing of the NDA for AMITIZA to treat chronic idiopathic constipation in adults and the initiation of Phase III clinical trials of AMITIZA for the treatment of irritable bowel syndrome with constipation. In the first quarter of 2006, our only research and development expenses were those associated with the ongoing Phase III clinical trials of AMITIZA for the treatment of irritable bowel syndrome with constipation.

We consider the continued development of our product pipeline crucial to our success, and we anticipate that our research and development costs will continue to increase as we advance our research and development activities associated with our product candidates.

Following the closing of this offering, approximately three employees of Sucampo AG will become employees of Sucampo Japan, and we will assume the filing and maintenance costs relating to the patent portfolio licensed by us from Sucampo AG. In addition, following this offering, we will be obligated under our license agreement with Sucampo AG to incur at least \$1.0 million annually to develop compounds other than AMITIZA, SPI-8811 and SPI-017. We estimate that these costs will increase our research and developments expenses by approximately \$1.7 million per year.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- the potential benefits of our product candidates over other therapies;
- our ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;
- future clinical trial results;
- the terms and timing of regulatory approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of expenses for salaries and related personnel expense, corporate activities and costs associated with sales and marketing activities.

The following summarizes our combined selling, general and administrative expenses for the three months ended March 31, 2005 and 2006:

		nths Ended		
	Marc	March 31,		
	2005	2006		
	(in tho	usands)		
Salaries, benefits and related costs	\$ 1,057	\$ 1,782		
Legal and consulting expenses	140	926		
Stock-based compensation	9	_		
Other operating expenses	279	1,062		
Total	\$ 1,485	\$ 3,770		

Combined selling, general and administrative expenses were \$3.8 million for the three months ended March 31, 2006 compared to \$1.5 million for the three months ended March 31, 2005, an increase of \$2.3 million. This increase was due primarily to expenses in the first quarter of 2006 associated with our sales and marketing function, which did not exist in the first quarter of 2005, increases in operational headcount, rent for additional leased office space and a one-time 5% bonus payment to our employees upon receipt of marketing approval for AMITIZA to treat chronic idiopathic constipation in adults.

Combined sales and marketing expenses were \$650,000 for the three months ended March 31, 2006. We had no sales and marketing expenses for the three months ended March 31, 2005. We anticipate significant increases in our combined sales and marketing expenses for 2006 related to the following activities:

- the hiring during the first quarter of 2006 of a director of branding, a national sales director, four regional sales managers and one analyst;
- our contract with Ventiv to provide us with a 38 representative specialty sales force, which began service in the field in April 2006; and
- continuing and increased costs for market research and analysis, advertising expenses, marketing and promotional materials, product samples and other costs associated with our recent launch of AMITIZA.

# Milestone Royalties to Related Parties

In the three months ended March 31, 2006, we paid Sucampo AG \$1.0 million, reflecting the 5% we owed them in respect of the \$20.0 million milestone payment we received from Takeda during that period, and a \$250,000 milestone payment for regulatory approval of AMITIZA. In the three months ended March 31, 2005, we paid Sucampo AG \$500,000, reflecting the 5% we owed them in respect of the \$10.0 million milestone payment we received from Takeda during that period. These payments to Sucampo AG are characterized as milestone royalties to related parties. We expense these payments when the related milestone is achieved.

#### Non-Operating Income and Expense

The following table summarizes our combined non-operating income and expense for the three months ended March 31, 2005 and 2006:

	Three Mon	nths Ended
	Marc	ch 31,
	2005	2006
	(in thou	usands)
Interest income	\$ 80	\$ 305
Interest expense	(84)	(20)
Other income (loss)	(68)	140
Total, net	\$ (72)	\$ 425

Combined interest income was \$305,000 for the three months ended March 31, 2006 compared to \$80,000 for the three months ended March 31, 2005, an increase of \$226,000. The increase was primarily due to an increase in the funds available for investment as a result of our receipt of milestone payments from Takeda in March 2005, May 2005 and January 2006. Interest expense was \$20,000 for the three months ended March 31, 2006 compared to \$84,000 for the three months ended March 31, 2005, a decrease of \$64,000. This decrease reflected our repayment in full in the first quarter of 2005 of three-year convertible bonds issued in 2004 by Sucampo Japan to S&R Technology Holdings, LLC.

#### **Income Taxes**

The income tax provision for the three months ended March 31, 2006 was \$3.7 million compared to \$558,000 for the three months ended March 31, 2005. The increase of \$3.1 million resulted from an increase in income (loss) before income taxes of \$9.3 million and an increase in the effective income tax rate. The increase in the effective income tax rate related to changes in the projected income tax expense computed on an annual basis as of March 31, 2005 compared to March 31, 2006. The significant changes in the computation of the effective income tax rate related to net operating losses and general business credits.

# Comparison of years ended December 31, 2004 and December 31, 2005

#### Revenues

The following table summarizes our combined revenues for the years ended December 31, 2004 and 2005:

		Ended nber 31,
	2004	2005 ousands)
Milestone revenue	\$ —	\$30,000
Reimbursement of research and development costs	1,482	14,672
Contract revenue	275	2,237
Contract revenue — related parties	411	98
Other — gain on sale of patent to related party	497	_
Total	\$2,665	\$47,007

Total combined revenues were \$47.0 million in 2005 compared to \$2.7 million in 2004, an increase of \$44.3 million. This increase was due primarily to our receipt of \$30.0 million in milestone revenue in 2005 as well as an increase of \$13.2 million in research and development reimbursement.

The milestone revenue in 2005 reflected our receipt from Takeda of a \$10.0 million milestone payment upon the filing of the NDA for AMITIZA to treat chronic idiopathic constipation in adults in March 2005 and a \$20.0 million milestone payment upon the initiation of our Phase III clinical trial related to AMITIZA for the treatment of irritable bowel syndrome with constipation in May 2005. We recognized these payments in full as revenues upon their receipt.

We received \$1.5 million from Takeda as reimbursement of research and development costs in 2004, all of which we recognized in 2004. We received \$28.5 million from Takeda in 2005, but only recognized \$14.7 million, resulting in deferred revenue of \$13.8 million as of December 31, 2005.

We recognized contract revenue of \$208,000 in 2004 and \$1.2 million in 2005 with respect to the up-front payment received from Takeda. The unrecognized deferred revenue related to this up-front payment was \$18.6 million as of December 31, 2005. Contract revenue in 2004 also included the \$67,000 we recognized with respect to the terminated ophthalmic collaboration agreement. Contract revenue in 2005 included \$1.0 million in previously deferred revenue that we recognized during this period upon the expiration of the option granted to Takeda for joint development and commercialization rights for AMITIZA in Asia.

We received \$411,000 in contract revenue from related parties in 2004, including \$324,000 from Sucampo AG for consulting services and \$87,000 from R-Tech for manufacturing and research and development consulting services. We received \$98,000 of contract revenue from related parties in 2005, reflecting payments from R-Tech for manufacturing and research and development consulting services.

In 2004, we also recognized a one-time gain of \$497,000 upon the sale to Sucampo AG of U.S. patents relating to RESCULA. As a result of declining royalty revenues associated with these patents, we determined that we would be unable to recover the original \$954,865 purchase price paid for these patents and sold our rights in them to Sucampo AG.

## Research and Development Expenses

Total combined research and development expenses were \$29.9 million in 2005 compared to \$14.0 million in 2004, an increase of \$15.9 million. This increase was due primarily to costs associated with the commencement in May 2005 of two pivotal Phase III clinical trials of AMITIZA for the treatment of irritable bowl syndrome with constipation and a related follow-on safety trial.

In 2005, we incurred \$2.2 million in research and development expenses for services performed by third party consultants, whom we compensated by granting stock options at the time services were rendered. We determined the value of these options to be \$2.2 million, and we recognized the related expense in full in the period of the grant.

#### Selling, General and Administrative Expenses

The following summarizes our combined selling, general and administrative expenses for the years ended December 31, 2004 and 2005:

Vears Ended

	Tears I	mucu
	Decemb	er 31,
	2004	2005
	(in thou	sands)
Salaries, benefits and related costs	\$4,160	\$3,784
Legal and consulting expenses	2,131	1,719
Stock-based compensation	68	138
Other operating expenses	1,868	2,475
Total	\$8,227	\$8,116

Combined selling, general and administrative expenses were \$8.1 million in 2005 compared to \$8.2 million in 2004, a decrease of \$110,000. Stock-based compensation was \$138,000 in 2005 compared to \$68,000

in 2004, an increase of \$70,000. This increase was due primarily to a modification in 2005 of the vesting of previously issued stock options and the resulting stock-based compensation expense in 2005.

Combined sales and marketing expenses were \$200,000 for 2005 compared to zero for 2004. The expenses in 2005 were primarily attributable to the following:

- the hiring of two members of our senior marketing staff, consisting of a vice-president of marketing and sales, hired in September 2005, and a director of marketing, hired in June 2005; and
- expenses for market research and analysis conducted in anticipation of potential marketing approval by the FDA of AMITIZA for the treatment of chronic idiopathic constipation in adults.

## Milestone Royalties to Related Parties

During 2005, we paid Sucampo AG \$1.5 million reflecting the 5% we owed them in respect of the \$30.0 million of milestone payments we received from Takeda during the year. We made no milestone royalty payments during 2004.

#### Non-Operating Income and Expense

The following table summarizes our combined non-operating income and expense for the years ended December 31, 2004 and 2005:

	Years Decem	Ended ber 31,
	2004	2005
	(in thou	usands)
Interest income	\$ 96	\$1,046
Interest expense	(173)	(311)
Other income	21	255
Total, net	<u>\$ (56)</u>	\$ 990

Combined interest income was \$1.0 million in 2005 compared to \$96,000 in 2004, an increase of \$950,000. The increase was primarily due to an increase in the funds available for investment as a result of our receipt of milestone payments from Takeda of \$10.0 million in March 2005 and \$20.0 million in May 2005. We invested these funds in short-term auction-rate securities. Interest expense was \$311,000 in 2005 compared to \$173,000 in 2004, an increase of \$138,000. The increase in other income was due primarily to foreign currency transaction gains of \$248,000 during 2005. This increase was attributable to increased borrowings under notes to related parties.

### **Income Taxes**

The income tax provision was \$1.8 million for the year December 31, 2005 compared to \$0 for the year ended December 31, 2004. The increase of \$1.8 million resulted from income we recognized during the year ended December 31, 2005 for tax purposes, against which we were not able to offset tax loss carryforwards. Our U.S. tax loss carryforwards were fully utilized as of December 31, 2005.

## Comparison of years ended December 31, 2003 and December 31, 2004

#### Revenues

The following table summarizes our combined revenues for the years ended December 31, 2003 and 2004:

	Years	Ended
	Decen	nber 31,
	2003	2004
	(in the	ousands)
Reimbursement of research and development costs	\$ —	\$1,482
Contract revenue	1,636	275
Contract revenue — related parties	2,489	411
Other — gain on sale of patent to related party	<u> </u>	497
Total	\$4,125	\$2,665

Total combined revenues were \$2.7 million in 2004 compared to \$4.1 million in 2003, a decrease of \$1.4 million.

In 2004, we recognized \$1.5 million in cost reimbursements from Takeda. We did not receive any cost reimbursements from Takeda in 2003.

Contract revenue in 2004 was \$275,000 compared to \$1.6 million in 2003, a decrease of \$1.4 million. This decrease reflected a reduction in our recognition of the deferred revenue from the up-front payment relating to our discontinued ophthalmic collaboration agreement from \$1.6 million in 2003 to \$67,000 in 2004, offset in part by the recognition of \$208,000 of contract revenue in 2004 relating to the up-front payment from Takeda.

Contract revenue from related parties was \$411,000 in 2004 compared to \$2.5 million in 2003, a decrease of \$2.1 million. This decrease was attributable to the termination in August 2003 of a services agreement with R-Tech under which we provided marketing and regulatory support for RESCULA.

In 2004, we recognized a one-time gain of \$497,000 upon the sale to Sucampo AG of patents relating to RESCULA. We received no similar revenue in 2003.

## Research and Development Expenses

Combined research and development expenses were \$14.0 million in 2004 compared to \$18.4 million in 2003, a decrease of \$4.4 million. This decrease was primarily due to the completion in September 2003 of the second of our two pivotal Phase III clinical trials to assess AMITIZA for the treatment of chronic idiopathic constipation in adults.

## Selling, General and Administrative Expenses

The following table summarizes our combined selling, general and administrative expenses for the years ended December 31, 2003 and 2004:

	Years En	ded
	December	r 31,
	2003	2004
	(in thousa	nds)
Salaries, benefits and related costs	\$4,383	\$4,160
Legal and consulting expenses	1,060	2,131
Stock-based compensation	16	68
Other operating expenses	1,988	1,868
Total	\$7,447	\$8,227

Combined selling, general and administrative expenses in 2004 were \$8.2 million compared to \$7.4 million in 2003, an increase of \$779,000. This increase was due primarily to legal and administrative costs in 2004 associated with the negotiation of our joint collaboration and license agreement with Takeda.

## Non-Operating Income and Expenses

The following table summarizes our combined non-operating income and expenses for the years ended December 31, 2003 and 2004:

		Ended ıber 31,
	2003	2004
	(in tho	usands)
Interest income	\$ 146	\$ 96
Interest expense	(142)	(173)
Other income (loss)	(254)	21
Total, net	<u>\$(250)</u>	\$ (56)

Combined interest income was \$96,000 in 2004 compared to \$146,000 in 2003, a decrease of \$50,000. The decrease was due primarily to our lower cash balance throughout 2004 compared to 2003. Combined interest expense was \$173,000 in 2004 compared to \$142,000 in 2003, an increase of \$31,000. This increase was due primarily to Sucampo Europe entering into a \$1.0 million note agreement with Sucampo AG and incurring related interest expenses. Other losses in 2003 primarily consisted of foreign currency transaction losses of \$270,000.

## **Reportable Geographic Segments**

We have determined that we have three reportable geographic segments based on our method of internal reporting, which disaggregates business by geographic location. These segments are the United States, Europe and Japan. We evaluate the performance of these segments on the basis of income from operations. The following is a summary of financial information by reportable segment.

Uni	ited States	Europe Japan (in thousands)				Combined
\$	24,178	\$ 1,500	\$ 30	\$		\$ 25,708
	13,242	1,345	(20)		_	14,567
	13,560	1,354	79			14,993
	71,713	893	2,666		(25)	75,247
\$	14,596	\$ —	\$ 40	\$	_	\$ 14,636
	6,221	(423)	(68)		_	5,730
	6,262	(597)	(7)		_	5,658
\$	45,909	\$ —	\$ 1,098	\$	_	\$ 47,007
	8,136	(1,475)	843		_	7,504
	8,919	(1,439)	1,011		_	8,493
	45,314	1,363	2,576		(1,320)	47,933
\$	2,996	\$ —	\$ 82	\$	(413)	\$ 2,665
	(15,742)	(2,424)	(1,432)		(1)	(19,599)
	(15,887)	(2,628)	(1,139)		_	(19,654)
	20,920	2,481	5,090		(1,665)	26,826
\$	2,649	\$ —	\$ 5,138	\$	(3,662)	\$ 4,125
	(21,542)	(425)	200		_	(21,767)
	(21,607)	(435)	25		_	(22,017)
	\$ \$ \$	\$ 14,596 6,221 6,262 \$ 45,909 8,136 8,919 45,314 \$ 2,996 (15,742) (15,887) 20,920 \$ 2,649 (21,542)	\$ 24,178 \$ 1,500 13,242 1,345 13,560 1,354 71,713 893 \$ 14,596 \$ — 6,221 (423) 6,262 (597) \$ 45,909 \$ — 8,136 (1,475) 8,919 (1,439) 45,314 1,363 \$ 2,996 \$ — (15,742) (2,424) (15,887) (2,628) 20,920 2,481 \$ 2,649 \$ — (21,542) (425)	\$ 24,178 \$ 1,500 \$ 30 \$ 13,242 1,345 (20) 13,560 1,354 79 71,713 893 2,666 \$ 14,596 \$ — \$ 40 6,221 (423) (68) 6,262 (597) (7) \$ 45,909 \$ — \$ 1,098 8,136 (1,475) 843 8,919 (1,439) 1,011 45,314 1,363 2,576 \$ 2,996 \$ — \$ 82 (15,742) (2,424) (1,432) (15,887) (2,628) (1,139) 20,920 2,481 5,090 \$ \$ 2,649 \$ — \$ 5,138 (21,542) (425) 200	United States     Europe (in thousands)     Japan (in thousands)     Elir (in thousands)       \$ 24,178     \$ 1,500     \$ 30     \$ 13,242     1,345     (20)     13,560     1,354     79     79     71,713     893     2,666     2,666     2,666     2,666     2,666     2,666     2,666     3,68     3,2666     3,68	\$ 24,178 \$ 1,500 \$ 30 \$ — 13,242 1,345 (20) — 13,560 1,354 79 — 71,713 893 2,666 (25)  \$ 14,596 \$ — \$ 40 \$ — 6,221 (423) (68) — 6,262 (597) (7) —  \$ 45,909 \$ — \$ 1,098 \$ — 8,136 (1,475) 843 — 8,919 (1,439) 1,011 — 45,314 1,363 2,576 (1,320)  \$ 2,996 \$ — \$ 82 \$ (413) (15,742) (2,424) (1,432) (1) (15,887) (2,628) (1,139) — 20,920 2,481 5,090 (1,665)  \$ 2,649 \$ — \$ 5,138 \$ (3,662) (21,542) (425) 200 —

## **Liquidity and Capital Resources**

## Sources of Liquidity

We require cash principally to meet our operating expenses. As of March 31, 2006, we had \$4.6 million of debt to related parties and minimal commitments for capital expenditures. We have financed our operations since inception with a combination of private placements of equity securities, up-front and milestone payments received from Takeda, R-Tech and the third party with whom we entered into our discontinued ophthalmic collaboration, and research and development expense reimbursements from Takeda. From inception through March 31, 2006, we had raised net proceeds of \$50.8 million from private equity financings. From inception through March 31, 2006, we had also received an aggregate of \$110.5 million in up-front, milestone, option and expense reimbursement payments from third parties. We operated profitably in the quarter ended March 31, 2006 and the year ended December 31, 2005, principally as a result of the milestone payments that we received in these periods from Takeda. As of March 31, 2006, we had cash and cash equivalents and short-term investments of \$72.9 million. In light of the recent AMITIZA product launch, we anticipate generating internal cash from AMITIZA sales beginning with the quarter ending June 30, 2006.

#### Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2003, 2004 and 2005 and the three months ended March 31, 2005 and 2006:

	7	Years Ended		Three	Months
	Ι	December 31,			
	2003	2004	2005	2005	2006
			(in thous	sands)	
Cash (used in) provided by:					
Operating activities	\$ (15,167)	\$ 3,210	\$ 23,816	\$1,414	\$ 6,527
Investing activities	(85)	(3,016)	(25,474)	2,983	(108)
Financing activities	2,658	2,292	(2,278)		20,501
Effect of exchange rates	271	362	(545)	(265)	(4)
Net (decrease) increase in cash and cash equivalents	\$ (12,323)	\$ 2,848	\$ (4,482)	\$4,132	\$26,916

## Three months ended March 31, 2006

Net cash provided by operating activities was \$6.5 million for the three months ended March 31, 2006. This reflected net income of \$11.3 million, an increase in our accounts payable and accrued expenses of \$1.6 million primarily related to the research and development expenditures for our trials of AMITIZA for the treatment of irritable bowel syndrome with constipation. These amounts were offset in part by a decrease in our other liabilities and deferred revenue of \$6.8 million, which related primarily to repaying Takeda the \$1.5 million refundable portion of an option payment and our expenses of \$5.3 million in connection with our trials of AMITIZA for the treatment of irritable bowel syndrome with constipation.

Net cash used in investing activities was \$108,000 for the three months ended March 31, 2006. This reflected our purchase of auction rate securities.

Net cash provided by financing activities was \$20.5 million for the three months ended March 31, 2006. This reflected \$19.4 million in net proceeds raised in a private placement sale of 229,412 shares of class A common stock and \$1.2 million in funds received from borrowings under related party debt instruments as well as \$156,000 of expenses incurred for our planned initial public offering.

#### Year ended December 31, 2005

Net cash provided by operating activities was \$23.8 million for the year ended December 31, 2005. This reflected net income of \$6.7 million, an increase in our deferred revenue of \$13.6 million for research and development obligations paid by Takeda and \$2.3 million of non-cash in stock-based compensation charges.

Net cash used in investing activities was \$25.5 million for the year ended December 31, 2005, reflecting our net purchase of \$25.4 million in auction rate securities.

Net cash used in financing activities was \$2.3 million for the year ended December 31, 2005, reflecting our repayment of related party debt.

## Year ended December 31, 2004

Net cash provided by operating activities was \$3.2 million for the year ended December 31, 2004. This reflected a net loss of \$19.7 million and an increase in our deferred revenue of \$21.5 million arising primarily from up-front payments and research and development obligations paid by Takeda.

Net cash used in investing activities was \$3.0 million for the year ended December 31, 2004, reflecting our purchase of auction rate securities.

Net cash provided by financing activities was \$2.3 million for the year ended December 31, 2004, reflecting funds received from borrowings under related party debt instruments.

#### Year ended December 31, 2003

Net cash used in operating activities was \$15.2 million for the year ended December 31, 2003. This reflected a net loss of \$22.0 million due to increases in our research and development expenditures associated with Phase III trials of AMITIZA for the treatment of chronic idiopathic constipation in adults and Phase II trials of AMITIZA for the treatment of irritable bowel syndrome with constipation. We also had an increase in our accounts payable and accrued expenses of \$1.8 million and deferred revenue of \$4.6 million, resulting from payments received in respect of our exclusive supply agreement with R-Tech.

Net cash used in investing activities was \$85,000 for the year ended December 31, 2003, reflecting our purchase of property and equipment.

Net cash provided by financing activities was \$2.7 million for the year ended December 31, 2003, reflecting funds we received from borrowings under related party debt instruments.

## **Commitments and Contingencies**

Our principal outstanding contractual obligations relate to our office leases in Bethesda, Maryland, England and Japan and notes payable to related parties. The following table summarizes our significant contractual obligations at December 31:

	2006	2007	<u>2008</u> (in thou	2009 sands)	<u>2010</u>	Total
Contractual obligations:						
Operating leases	\$ 455	\$ 448	\$407	\$373	\$ 61	\$1,744
Notes payable — related parties	848	2,546	_	_	_	4,602
Total	\$1,303	\$2,994	\$407	\$373	\$ 61	\$6,346

The above table does not include:

- Contingent milestone and royalty obligations under our license agreement with Sucampo AG. These obligations are described in more detail above, and include obligations to pay Sucampo AG:
  - 5% of every development milestone payment we receive from a sublicensee;
  - \$500,000 upon initiation of the first Phase II clinical trial for each compound in each of the three territories covered by the license;
  - \$1.0 million for the first NDA filing or comparable foreign regulatory filing for each compound in each of these three territories; and
  - royalty payments ranging from 2.1% to 6.5% of net sales of products covered by patents licensed to us by Sucampo AG.
- Our share of research and development costs for AMITIZA. As of March 31, 2006, we had not incurred any portion of these costs. We expect to incur approximately \$20.0 million of costs in connection with the development of AMITIZA for irritable bowel syndrome with constipation and expect to incur additional costs in connection with the development of AMITIZA for other indications, such as opioid-induced bowel dysfunction.
- Expenses under agreements with contract research organizations for clinical trials of our product candidates. The timing and amount of these disbursements are based on a variety of factors, such as the achievement of specified milestones, patient enrollment, services rendered or the incurrence of expenses by the contract research organization. As a result, we must reasonably estimate the potential timing and

amount of these payments. We estimate that our current commitments to contract research organizations to be approximately \$3.1 million for 2006 and \$730,000 for 2007.

In addition, the FDA has required us to perform two post-marketing studies to evaluate the safety of AMITIZA in patients with renal and hepatic impairment. Under our collaboration agreement with Takeda, the costs for these studies will be shared 70% by Takeda and 30% by us. We do not anticipate our portion of these expenses will exceed \$5.0 million.

#### **Funding Requirements**

In addition to our normal operating expenses, we estimate that our specific funding requirements through 2007 will include:

- Approximately \$20.0 million to complete the two ongoing pivotal Phase III clinical trials and one follow-on safety study of AMITIZA for the treatment of irritable bowel syndrome with constipation. We expect to complete these studies in 2006.
- Up to \$1.0 million to fund our 30% share of the two post-marketing studies of AMITIZA to evaluate its safety in patients with renal and hepatic impairment. We expect to initiate these studies by January 2007.
- Approximately \$20.0 million to fund development activities for SPI-8811 and SPI-017, which we expect will enable us to complete at least the following development efforts:
  - a Phase II clinical trial of SPI-8811 for the prevention and treatment of NSAID-induced ulcers, which we plan to commence in early 2007;
  - a Phase I/II proof-of-concept study of SPI-8811 in patients with portal hypertension, which we plan to commence in 2007;
  - a Phase IIb clinical trial of SPI-8811 for cystic fibrosis, which we plan to commence in 2007; and
  - Phase I clinical trials of an intravenous formulation of SPI-017 for peripheral arterial and vascular disease and stroke, which we
    plan to commence in early 2007;
- Up to \$25.0 million to fund: expansion of our sales and marketing infrastructure in the United States; additional clinical trials and sales and marketing efforts by Sucampo Europe and Sucampo Japan; and development activities for prostone compounds other than AMITIZA, SPI-8811 and SPI-017;
- Up to \$3.0 million to fund costs in connection with:
  - a potential move of our headquarters facility, including costs for furniture, fixtures and equipment; and
  - computers, software and information technology to support growth in our business.

Takeda will fund 100% of the Phase IV clinical trials of AMITIZA for the treatment of chronic idiopathic constipation in pediatric patients that we expect to initiate by January 2007. Takeda is also responsible for the first \$50.0 million in expenses we incur related to the development of opioid-induced bowel dysfunction, including the Phase II/III pivotal clinical trials we plan to initiate by early 2007. We do not expect the aggregate expenses necessary to complete our development of AMITIZA for this indication will exceed the \$50.0 million for which Takeda is responsible.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents and internally generated funds from AMITIZA product sales, will be sufficient to enable us to fund our operating expenses for the foreseeable future. We have based this estimate on assumptions that may prove to be wrong. There are numerous risks and uncertainties associated with AMITIZA product sales and with the development and commercialization of our product candidates. Our future capital requirements will depend on many factors, including:

• the level of AMITIZA product sales;

- the scope, progress, results and costs of preclinical development and laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual propertyrelated claims;
- the extent to which we acquire or invest in businesses, products and technologies; and
- our ability to establish and maintain collaborations, such as our collaboration with Takeda.

In particular, we could require external sources of funds for acquisitions that we determine to make in the future.

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Except for development funding by Takeda, we do not currently have any commitments for future external funding.

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

## **Related Party Transactions**

Under our license agreement with our affiliate Sucampo AG, we are required to make specified milestone and royalty payments. We estimated the fair value of this arrangement based upon like-kind third party evidential matter for the transaction. When we entered into this agreement, we performed an economic analysis of the transaction to ensure that we were receiving a return on our investment equivalent to that of other pharmaceutical companies. In addition, we performed a transfer pricing study and economic analysis to ensure that the agreement did not conflict with taxing guidelines.

Under our exclusive supply agreement with R-Tech, R-Tech made milestone payments to us totaling \$6.0 million. We recorded the full \$6.0 million representing these payments in deferred revenue as of March 31, 2006. When we entered into this agreement, we evaluated the net present value of the supply agreement, based upon anticipated cash flows from the successful development and commercialization of the compounds it covers, to determine the current value of the transaction. Additionally, we performed a transfer pricing study and economic analysis to ensure the agreement did not conflict with taxing guidelines.

For information regarding additional related party transactions, see notes 7 and 8 to our combined financial statements appearing at the end of this prospectus.

Changes in the application of domestic or foreign taxing regulations and interpretation of related party transactions with foreign entities could affect the extent to which taxing authorities agree that these transactions are on an arm's length basis.

## **Quantitative and Qualitative Disclosures About Market Risk**

Our exposure to market risk is currently confined to our cash and cash equivalents and investments in auction-rate securities. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculative or trading purposes. Because of the short-term maturities of our cash and cash

equivalents, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

#### **Effects of Inflation**

Our most liquid assets are cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our intellectual property. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our balance sheets. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

## **Effects of Foreign Currency**

We currently incur a portion of our operating expenses in the United Kingdom and Japan. The reporting currency for our consolidated financial statements is U.S. Dollars. As such, our results of operations could be adversely effected 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.

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

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

## **Accounting Pronouncements**

In December 2004, the FASB issued SFAS No. 123(R), which requires companies to expense the estimated fair value of employee stock options and similar awards. SFAS No. 123(R) replaces SFAS No. 123 and supersedes APB Opinion No. 25. In March 2005, the SEC issued SAB Bulletin No. 107, which generally provides the SEC staff's views regarding SFAS No. 123(R). SAB 107 provides guidance on how to determine the expected volatility and expected term inputs into a valuation model used to determine the fair value of share-based payments. SAB 107 also provides guidance related to numerous aspects of the adoption of SFAS No. 123(R) such as income taxes, capitalization of compensation costs, modification of share-based payments prior to adoption and the classification of expenses. We will apply the principles of SAB 107 in conjunction with our adoption of SFAS No. 123(R).

As of January 1, 2006, we adopted the provisions of SFAS No. 123(R) using a modified prospective method. There was no impact to our combined financial statements as a result of this adoption. Under the modified prospective method, SFAS No. 123(R), which provides changes to the methodology for valuing share-based compensation among other changes, will apply to new awards and to awards outstanding on the effective date that are subsequently modified or cancelled. Compensation expense for outstanding awards for which the requisite service has not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under SFAS No. 123.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3", or SFAS 154. This statement replaces APB Opinion No. 20, "Accounting Changes", and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements", and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS 154 applies to all voluntary changes in accounting principle and requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. This statement also requires that a change in depreciation, amortization or depletion method for long-lived, non-

financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 as of January 1, 2006 did not have a material effect on our combined financial statements.

In November 2005, the FASB Staff issued FASB Staff Position, or FSP, FAS 115-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments", or FSP FAS 115-1. FSP FAS 115-1 addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. This FSP also includes accounting considerations subsequent to the recognition of other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP amends FASB Statements No. 115, "Accounting for Certain Investments in Debt and Equity Securities", and No. 124, "Accounting for Certain Investments Held by Not-for-Profit Organizations", and APB Opinion No. 18, "The Equity Method of Accounting for Investments in Common Stock". The guidance in this FSP must be applied to reporting periods beginning after December 15, 2005. The adoption of FSP FAS 115-1 as of January 1, 2006 did not have a material effect on our combined financial statements.

In June 2006, the FASB Staff issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes", or FIN 48, which clarifies the accounting treatment for uncertain tax positions. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that we recognize in the financial statements the impact of a tax position if that position is more likely than not to be sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on de-recognition, balance sheet classification, interest and penalties, accounting in interim periods and footnote disclosures. We will be required to adopt FIN 48 as of January 1, 2007 and we are in the process of determining the impact, if any, of the adoption of FIN 48 on our combined financial statements.

#### **Internal Control Over Financial Reporting**

In connection with the anticipated acquisition of Sucampo Europe and Sucampo Japan and our preparation of audited financial information for those two entities for the year ended December 31, 2005, we identified control deficiencies relative to those entities that constitute material weaknesses in the design and operation of our internal control over financial reporting.

In general, a material weakness is defined as a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of annual or interim financial statements will not be prevented or detected. The material weaknesses we identified are as follows:

- We did not maintain effective controls over the completeness and accuracy of revenue recognition. Specifically, effective controls were not designed and in place to adequately review contracts for the accuracy and proper cut-off of revenue recognition at Sucampo Europe and Sucampo Japan. This control deficiency resulted in adjustments to the revenue and deferred revenue accounts. Additionally, this control deficiency could result in a misstatement of the revenue and deferred revenue accounts that would result in a material misstatement to our interim or annual financial statements that would not be prevented or detected.
- We did not maintain effective controls over the completeness and accuracy of the accounting for debt instruments. Specifically, effective controls were not designed and in place to adequately review debt agreements of Sucampo Europe and Sucampo Japan for the proper accounting implications, or to ensure appropriate communication within our company regarding the existence of all debt agreements. This control deficiency resulted in adjustments to accounts payable, other liabilities and notes payable accounts. Additionally, this control deficiency could result in a misstatement of accounts payable, other liabilities and notes payable accounts that would result in a material misstatement to our interim or annual financial statements that would not be prevented or detected.

• We did not maintain effective controls over the preparation, review and presentation of the financial information prepared in accordance with U.S. generally accepted accounting principles reflecting Sucampo Europe and Sucampo Japan operations. Specifically, effective controls were not designed and in place to adequately review, analyze and monitor these affiliates' financial information, nor did we have a standard reporting format for these affiliates, accounting procedures and policies manuals, formally documented controls and procedures or a formal process to review and analyze financial information of these affiliates. This control deficiency resulted in adjustments to revenue, deferred revenue, accounts payable, other liabilities and notes payable accounts, as well as the statement of cash flows. Additionally, this control deficiency could result in a misstatement in a number of our financial statement accounts, including the statement of cash flows, resulting in a material misstatement to our interim or annual financial statements that would not be prevented or detected.

Sucampo Europe and Sucampo Japan collectively accounted for 2.3% of our total combined revenues in the year ended December 31, 2005 and 6.0% for the three months ended March 31, 2006.

If we are unable to remediate these material weaknesses, we may not be able to accurately and timely report our financial position, results of operations or cash flows as a public company. Becoming subject to the public reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, upon the completion of this offering will intensify the need for us to report our financial position, results of operations and cash flows on an accurate and timely basis.

To remediate these material weaknesses, we intend to:

- following completion of the acquisition, transfer control of the books and records of Sucampo Europe and Sucampo Japan to our headquarters;
- following completion of the acquisition, transfer the authority to enter into contracts and to incur indebtedness from Sucampo Europe and Sucampo Japan to our headquarters;
- establish and implement formal processes for communicating financial and operating information from Sucampo Europe and Sucampo Japan to our headquarters;
- establish and implement formal processes for analyzing accounting for contracts and debt agreements;
- establish corporate level procedures for review of the accuracy and proper cut-off of revenue recognition at Sucampo Europe and Sucampo Japan; and
- establish and implement standard reporting processes for these entities, an accounting procedures and policies manual for each entity, formally documented controls and procedures for each entity, and a formal process to review and analyze financial information we receive from each entity.

Our remediation efforts are underway and we expect to complete them by December 31, 2006. We cannot assure you, however, that we will not encounter unexpected difficulties or delays in completing this process. If we are not able to remediate these weaknesses, this could impair our ability accurately and timely to report our financial position, results of operations or cash flows.

#### **BUSINESS**

#### Overview

We are an emerging pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. The therapeutic potential of prostones was first identified by one of our founders, Dr. Ryuji Ueno. We believe that most prostones function as activators of cellular ion channels and, as a result, may be effective at promoting fluid secretion and enhancing cell protection, which may give them wide-ranging therapeutic potential, particularly for age-related diseases. We are focused on developing prostones with novel mechanisms of action for the treatment of gastrointestinal, respiratory, vascular and central nervous system diseases and disorders for which there are unmet or underserved medical needs and significant commercial potential.

In January 2006, we received marketing approval from the U.S. Food and Drug Administration, or FDA, for our first product, AMITIZA™ (lubiprostone), for the treatment of chronic idiopathic constipation in adults of all ages. AMITIZA is the only prescription product for the treatment of chronic idiopathic constipation that has been approved by the FDA for use by adults of all ages, including those over 65 years of age, and that has demonstrated effectiveness for use beyond 12 weeks. Constipation becomes chronic when a patient suffers specified symptoms for more than 12 non-consecutive weeks within a 12-month period and is idiopathic if it is not caused by other diseases or by use of medications. Studies published in *The American Journal of Gastroenterology* estimate that approximately 42 million people in the United States suffer from constipation. Based on these studies, we estimate that approximately 12 million people can be characterized as suffering from chronic idiopathic constipation. In an additional study published in *The American Journal of Gastroenterology*, 91% of physicians expressed a desire for better treatment options for constipation.

AMITIZA increases fluid secretion into the intestinal tract by activating specific chloride channels in cells lining the small intestine. This increased fluid level softens the stool, facilitating intestinal motility and bowel movements. In addition, AMITIZA improves symptoms associated with chronic idiopathic constipation, including straining, hard stools, bloating and abdominal pain or discomfort.

We are party to a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, to jointly develop and commercialize AMITIZA for chronic idiopathic constipation, irritable bowel syndrome with constipation, opioid-induced bowel dysfunction and other gastrointestinal indications in the United States and Canada. We have the right to co-promote AMITIZA along with Takeda in these markets. We and Takeda initiated commercial sales of AMITIZA in the United States for the treatment of chronic idiopathic constipation in April 2006. Takeda is marketing AMITIZA broadly to office-based specialty physicians and primary care physicians. We are complementing Takeda's marketing efforts by promoting AMITIZA through a specialty sales force in the institutional marketplace, including specialist physicians based in academic medical centers and long-term care facilities. This institutional market is characterized by a concentration of elderly patients, who we believe will be a key market for AMITIZA to treat gastrointestinal indications, and by physicians who are key opinion leaders in the gastrointestinal field.

We also plan to pursue marketing approval for AMITIZA for additional constipation-related gastrointestinal indications with large, underserved markets. We are currently conducting two pivotal Phase III clinical trials and a long-term safety trial of AMITIZA for the treatment of irritable bowel syndrome with constipation, for which we expect results in the first quarter of 2007. In addition, we plan to begin Phase II/III pivotal clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction by early 2007. According to the American College of Gastroenterology, irritable bowel syndrome affects approximately 58 million people in the United States, with irritable bowel syndrome with constipation accounting for approximately one-third of these cases. We also plan to pursue marketing approval for AMITIZA in Europe and the Asia-Pacific region for appropriate gastrointestinal indications based on local market disease definitions and the reimbursement environment.

In addition, we are developing other prostone compounds for the treatment of a broad range of diseases. The most advanced of these programs are:

- SPI-8811 for the treatment of ulcers induced by non-steroidal anti-inflammatory drugs, or NSAIDs, portal hypertension, non-alcoholic fatty liver disease, cystic fibrosis and chronic obstructive pulmonary disease. We have completed Phase I clinical trials of SPI-8811 in healthy volunteers and plan to initiate a Phase II clinical trial of this product candidate for the treatment of NSAID-induced ulcers in early 2007. We also plan to initiate a Phase I/II proof-of-concept study of SPI-8811 in patients with portal hypertension in 2007.
- SPI-017 for the treatment of peripheral arterial and vascular disease and central nervous system disorders. Initially, we are working on the development of an intravenous formulation of SPI-017 for the treatment of peripheral arterial disease. We also are developing an oral formulation of SPI-017 for the treatment of Alzheimer's disease. We plan to initiate Phase I clinical trials of the intravenous formulation of SPI-017 in early 2007 and the oral formulation in mid to late 2007.

We hold an exclusive worldwide royalty-bearing license from Sucampo AG, a Swiss patent-holding company, to develop and commercialize AMITIZA and all other prostone compounds covered by patents and patent applications held by Sucampo AG. We are obligated to assign to Sucampo AG all patentable improvements that we make in the field of prostones, which Sucampo AG will in turn license back to us on an exclusive basis. If we have not committed specified development efforts to any prostone compound other than AMITIZA, SPI-8811 and SPI-017 by the end of a specified period, which ends on the later of September 30, 2011 or three months after the date upon which Drs. Kuno and Ueno no longer control our company, then the commercial rights to that compound will revert to Sucampo AG, subject to a one-year extension in the case of any compound that we designate in good faith as planned for development within that year. We refer to the end of this period as the Sucampo AG reversion date.

We are party to exclusive supply arrangements with R-Tech Ueno, Ltd., or R-Tech, a Japanese pharmaceutical manufacturer, to provide us with clinical and commercial supplies of AMITIZA and clinical supplies of our product candidates SPI-8811 and SPI-017. These arrangements include provisions requiring R-Tech to assist us in connection with applications for marketing approval for these compounds in the United States and elsewhere, including assistance with regulatory compliance for chemistry, manufacturing and controls. Drs. Ueno and Kuno together, directly or indirectly, own all of the stock of Sucampo AG and a majority of the stock of R-Tech. Drs. Kuno and Ueno are considering plans to reduce their equity ownership in R-Tech.

# **Product Pipeline**

The table below summarizes the development status of AMITIZA and our key product candidates. Other than AMITIZA, which is covered by our collaboration and license agreement with Takeda, we currently hold all of the commercialization rights to the prostone compounds in our product pipeline.

Product/ Product Candidate AMITIZA	Target Indication Chronic idiopathic constipation (adult)	<b>Development Phase</b> Marketed	Next Milestone —
	Chronic idiopathic constipation (pediatric)	Planning Phase IV pediatric trial	Phase IV pediatric trial planned to commence by January 2007
	Irritable bowel syndrome with constipation	Phase III	Phase III trial results expected in the first quarter of 2007
	Opioid-induced bowel dysfunction	Planning Phase II/III pivotal trial	Phase II/III pivotal trial planned to commence by early 2007
SPI-8811	Non-steroidal anti- inflammatory drug (NSAID) induced ulcers	Phase I testing completed	Phase II trial planned to commence in early 2007
	Portal hypertension	Preclinical testing completed	Phase I/II proof-of-concept study planned to commence in 2007
	Non-alcoholic fatty liver disease	Phase IIa trial completed	Pending availability of new diagnostic tool
	Cystic fibrosis (oral formulation)	Phase IIa trial completed	Phase IIb dose-ranging trial planned to commence in 2007
	Cystic fibrosis (inhaled formulation)	Preclinical	Finalize inhaled formulation
	Chronic obstructive pulmonary disease	Preclinical	Finalize inhaled formulation
SPI-017	Peripheral arterial and vascular disease	Preclinical	Phase I trials of intravenous formulation planned to commence in early 2007
	Stroke	Preclinical	Phase I trials of intravenous formulation planned to commence in early 2007
	Alzheimer's disease	Preclinical	Develop oral formulation and commence preclinical toxicology studies in late 2006

#### **Scientific Background of Prostones**

Prostones are a class of compounds derived from functional fatty acids that occur naturally in the human body. The therapeutic potential of prostones was first identified by Dr. Ueno. Fatty acids serve as fuel for energy production in cells in many organisms and are intermediates in the synthesis of other important chemical compounds. To date, two prostone products have received marketing approval: AMITIZA for the treatment of chronic idiopathic constipation and RESCULA® (unoprostone isopropyl) for the treatment of glaucoma. RESCULA, which was developed by R-Tech under the leadership of Drs. Ueno and Kuno, was the first commercially available prostone drug. RESCULA was first sold in Japan beginning in 1994 and is currently marketed in more than 40 countries worldwide. Although we do not hold any rights to RESCULA, we believe that the successful development of AMITIZA and RESCULA demonstrates the therapeutic potential of prostones.

#### **Ion Channel Activation**

Based on our preclinical and clinical studies, we believe that most prostones work as selective ion channel activators, which means that they promote the movement of specific ions into or out of cells. Ions are charged particles, such as sodium, potassium, calcium and chloride. The concentration of specific ions within particular types of cells is important to many vital physiological functions in the human body. Because ions cannot move freely across cell membranes, they must enter or exit a cell through protein structures known as ion channels. Ion channels, which are found in every cell in the body, span the cell membrane and regulate the flow of ions into and out of cells by opening and closing in response to particular stimuli. Each kind of ion moves through its own specific ion channel. Some molecular compounds, including some prostones, have been shown to activate or inhibit ion channels, thereby controlling the concentration of specific ions within cells. We believe that these prostones work selectively on specific ion channels and, as a result, can be targeted to induce very specific pharmacological activities without triggering other cellular activity that could lead to undesirable side effects

In preclinical *in vitro* tests on human cell lines with the three prostones that we are currently developing, AMITIZA, SPI-8811 and SPI-017, all three compounds selectively activated a specific ion channel known as the type-2 chloride channel, or ClC-2 channel. The ClC-2 channel is expressed in cells throughout the body and is one of the channels through which chloride ions move into and out of cells. Chloride channels regulate many essential physiological functions within cells, including cell volume, intracellular pH, cellular water and ion balance and regulation of cellular voltage and energy levels. We believe that AMITIZA is the first selective chloride channel activator approved by the FDA for therapeutic use in humans.

## **Potential Beneficial Effects of Prostones**

We believe that the method of action of prostones that serve as selective ion channel activators may result in the following beneficial effects:

- Enhancement of Fluid Secretion. Activating the movement of specific ions into and out of cells can promote the secretion of fluid into neighboring areas. For example, AMITIZA promotes fluid secretion into the small intestine by activating the ClC-2 channel in the cells lining the small intestine. Likewise, RESCULA is a potassium channel activator that works to treat glaucoma by increasing aqueous humor outflow in ocular cells in the eyes.
- *Recovery of Barrier Function*. Disruption of the barrier function in human cells can trigger cell damage by increasing the permeability of cells and tissue, thereby diminishing the body's first line of defense. Recently, protein complexes occurring between cells known as "tight junctions" have been found to play a critical role in the regulation of barrier function in the body. The ClC-2 channel plays an important role in the restoration of these tight junction complexes and in the recovery of barrier function in the body. In preclinical studies, AMITIZA appeared to accelerate the recovery of the disrupted barrier function through the restoration of the tight junction structure. We believe that this may be a result of AMITIZA's specific effects on the ClC-2 channel. We believe that other prostones that act as ClC-2 channel activators may have a similar barrier recovery function.

• Localized Activity. Because most prostones act through contact with cells, their pharmacological activity is localized in those areas where the compound is physically present in its active form. Because some prostones metabolize relatively quickly to an inactive form, we believe their pharmacological effects are not spread to other parts of the body. These properties allow some prostones to be targeted to specific types of cells in specific organs through different routes of administration. For example, when AMITIZA is taken orally, it arrives in the small intestine and liver while it is still active and begins to act on the cells lining those organs. By the time it is passed through to the large intestine, it appears to have been largely metabolized and is no longer active. Similarly, we believe that inhaled formulations of some prostones would act principally in the lungs and intravenous formulations would act principally in the vascular system, in each case without having systemic effects.

#### **Our Strategy**

Our goal is to become a leading pharmaceutical company focused on discovering, developing and commercializing proprietary drugs based on prostones to treat diseases and disorders for which there are unmet or underserved medical needs and significant commercial potential. Our strategy to achieve this objective includes the following key elements:

Focus on the commercial launch of AMITIZA in the United States for the treatment of chronic idiopathic constipation in adults. We initiated commercial sales of AMITIZA in the United States for the treatment of chronic idiopathic constipation in collaboration with Takeda in April 2006. Takeda is marketing AMITIZA broadly to office-based specialty physicians and primary care physicians. Pursuant to the terms of our collaboration and license agreement with Takeda, Takeda is providing a dedicated sales force of at least 200 people to promote AMITIZA and a supplemental sales force of 500 people to promote AMITIZA together with one other drug product. We are complementing Takeda's marketing efforts by promoting AMITIZA in the institutional marketplace through a specialty sales force consisting of 38 contract field sales representatives. This institutional market is characterized by a concentration of elderly patients, who we believe will be a key market for AMITIZA to treat gastrointestinal indications, and by physicians who are key opinion leaders in the gastrointestinal field. In connection with the commercial launch of AMITIZA, we have recruited experienced internal sales and marketing leadership and developed a marketing strategy and promotional materials for the commercialization of AMITIZA in our targeted institutional market.

**Develop AMITIZA for the treatment of additional indications and discover, develop and commercialize other prostone product candidates.** We are concentrating our development efforts on expanding the approved indications for AMITIZA and developing our product candidates SPI-8811 and SPI-017. We hold an exclusive worldwide royalty-bearing license from Sucampo AG to develop and commercialize each of these prostone compounds. In the future, we also expect to develop other proprietary prostones. We believe that our focus on prostones may offer several potential advantages, including:

- *Novel mechanisms of action*. We believe that AMITIZA, SPI-8811 and SPI-017 have, and that additional product candidates that we may develop in the future based on prostones may have, novel mechanisms of action, such as selective ClC-2 chloride channel activation, that offer physicians a new approach to treatment of targeted indications.
- *Wide-ranging therapeutic potential of prostones*. We believe that many prostones promote fluid secretion, enhance cell barrier protection and can be developed to target particular organs or systems of the body. As a result, we believe that we will be able to develop prostone drugs to treat multiple diseases and disorders of the gastrointestinal, respiratory, vascular and central nervous systems.
- *Our discovery and development experience with prostones*. We expect that our considerable experience with AMITIZA, as well as the knowledge gained by Drs. Ueno and Kuno in the development of RESCULA, will facilitate our discovery and clinical development of additional prostone compounds.
- *Patent protection*. AMITIZA, SPI-8811 and SPI-017 each are covered by composition-of-matter, method of use and other issued patents or patent applications in the United States, Europe and Japan.

*Target large and underserved markets.* We believe that drugs based on prostones may be able to address a variety of large markets characterized either by treatments with limited effectiveness or, in some cases, no treatment. In addition to AMITIZA for the treatment of chronic idiopathic constipation in adults, the indication for which it has been approved by the FDA, we are targeting:

- AMITIZA for the treatment of chronic idiopathic constipation in pediatric patients and for the treatment of irritable bowel syndrome with constipation and opioid-induced bowel dysfunction;
- SPI-8811 for the treatment of NSAID-induced ulcers, portal hypertension, non-alcoholic fatty liver disease, cystic fibrosis and chronic obstructive pulmonary disease; and
- SPI-017 for the treatment of peripheral arterial disease, stroke and Alzheimer's disease.

Seek marketing approval for AMITIZA and our other product candidates in Europe and the Asia-Pacific region. We plan to pursue marketing approval for AMITIZA and our other product candidates in markets outside the United States. To the extent possible, we intend to use the data from our U.S. clinical trials and the experience gained from the U.S. approval process to expedite the approval process in the European Union, Japan and other countries. If we receive marketing approval for our products outside the United States, we plan to retain co-commercialization rights and work with third-party pharmaceutical companies with marketing, sales and distribution capabilities in the relevant regions to commercialize these products.

Focus on our core discovery and clinical development and commercialization activities. Our business model is to devote our resources and efforts to discovering, developing and commercializing product candidates based on prostones, while outsourcing other, non-core business functions to third parties. Following this approach, we selectively collaborate with a number of third parties to assist us with these non-core business functions. These collaborators include:

- Our affiliate R-Tech, which manufacturers commercial and clinical supplies of AMITIZA and other prostone compounds for us;
- Takeda, with whom we are collaborating to market AMITIZA for the treatment of chronic idiopathic constipation in adults; and
- · Contract research organizations, whom we engage to perform preclinical and clinical trials of our product candidates.

We believe that applying our resources in this way allows us to concentrate on our core strengths while benefiting from the specialized expertise of our third-party collaborators.

*Grow through strategic acquisitions and in-licensing opportunities.* We intend to pursue strategic acquisitions and in-licensing opportunities to complement our existing product pipeline. We have significant experience in pharmaceutical research and product development, including clinical trials and regulatory affairs, and we have a specialty sales and marketing function focused on the institutional market. We believe that these capabilities will help us to identify attractive acquisition and in-licensing opportunities to build upon our core clinical development and commercialization capabilities.

## **Products and Product Candidates**

# AMITIZATM (lubiprostone)

#### Overview

We are developing AMITIZA for the treatment of multiple constipation-related gastrointestinal disorders. AMITIZA functions as a selective activator of the ClC-2 chloride channel through which negatively charged chloride ions flow out of the cells lining the small intestine and into the intestinal cavity. As these negatively charged chloride ions enter the intestine, positively charged sodium ions move through spaces between the cells into the intestine to balance the negative charge of the chloride ions. As these sodium ions move into the intestine, water is also allowed to pass into the intestine through these spaces between the cells. We believe

that this movement of water into the small intestine promotes increased fluid content, which in turn softens the stool and facilitates its movement, or motility, through the intestine.

## Chronic Idiopathic Constipation

On January 31, 2006, after a 10-month review, the FDA approved our new drug application, or NDA, for AMITIZA for the treatment of chronic idiopathic constipation in adults of all ages, including those over 65 years of age, without restriction as to duration of use. In collaboration with Takeda, we initiated commercial sales of AMITIZA in the United States for the treatment of chronic idiopathic constipation in April 2006. When used for this indication, AMITIZA gelatin capsules are taken orally twice daily in doses of 24 micrograms each.

*Disease Overview.* Constipation is characterized by infrequent and difficult passage of stool and becomes chronic when a patient suffers specified symptoms for over 12 non-consecutive weeks within a 12-month period. Chronic constipation is idiopathic if it is not caused by other diseases or by use of medications. Symptoms of chronic idiopathic constipation include straining, hard stools, bloating and abdominal pain or discomfort. Factors contributing to the development of chronic idiopathic constipation include a diet low in soluble and insoluble fiber, inadequate exercise, bowel disorders and poor abdominal pressure and muscular weakness.

Current Treatment. Some patients suffering from chronic idiopathic constipation can be successfully treated with lifestyle modification, dietary changes and increased fluid and fiber intake, and these treatments are generally tried first. For patients who fail to respond to these approaches, physicians typically recommend laxatives, most of which are available over-the-counter. The most commonly used laxatives can be categorized as stimulants, stool softeners, bulk-forming agents, osmotics or lubricants. Though somewhat effective in treating chronic idiopathic constipation, stimulants and stool softeners can be habit forming, while bulk-forming agents are often ineffective in patients with moderate-to-severe constipation. Osmotics, such as the prescription products MiraLax<sup>TM</sup> (polyethylene glycol 3350) and lactulose are labeled for use only for treating occasional constipation, not chronic idiopathic constipation, and they may cause fluid and electrolyte imbalance, which, if left untreated, can impair normal function of the nerves and muscles. In addition, lubricants, such as orally administered mineral oil, can be inconvenient and unpleasant for patients to ingest.

For those patients who fail to respond to laxatives, Zelnorm® (tegaserod maleate), a partial serotonin-receptor agonist, is often prescribed. Zelnorm, however, is not approved for administration to patients over 65 years of age and has been linked with incidents of ischemic colitis, a life-threatening inflammation of the large intestine caused by restricted blood flow, and other forms of intestinal ischemia. In addition, the effectiveness of Zelnorm for the treatment of chronic idiopathic constipation has not been studied beyond 12 weeks.

**Market Opportunity.** Studies published in *The American Journal of Gastroenterology* estimate that approximately 42 million people in the United States suffer from constipation. Based on these studies, we estimate that approximately 12 million people can be characterized as suffering from chronic idiopathic constipation. In an additional study published in *The American Journal of Gastroenterology*, 91% of physicians expressed a desire for better treatment options for constipation.

We believe that AMITIZA has a number of advantages over existing treatment options that could help it capture a significant portion of, and potentially expand, the existing market for chronic idiopathic constipation therapies. These advantages include the following:

- AMITIZA has been approved for administration to adults of all ages, including those over 65 years of age;
- · AMITIZA has been approved without limitation on duration of use; and
- AMITIZA has not been associated with the serious side effects observed with some other treatment options, such as ischemic
  colitis and electrolyte imbalance.

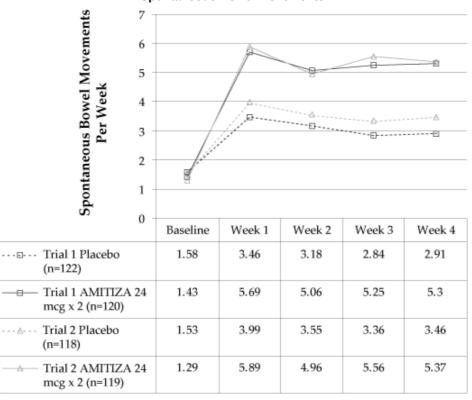
*Clinical Trial Results.* In connection with obtaining FDA marketing approval of AMITIZA, we conducted a comprehensive program of clinical trials of this drug for use in treating chronic idiopathic constipation. This clinical program included two Phase III pivotal trials and three long-term safety and efficacy trials.

Efficacy Results in Two Pivotal Clinical Trials. In August 2002 and September 2003, we completed two multi-center, double-blind, randomized, placebo-controlled, four-week, Phase III clinical trials of substantially identical design to assess the safety and efficacy of AMITIZA for the treatment of chronic idiopathic constipation. In each of these trials, we enrolled approximately 240 participants aged 18 or older with a history of chronic idiopathic constipation. The primary efficacy endpoint in these trials was the frequency of spontaneous bowel movements during the first week of treatment. Secondary efficacy endpoints included the frequency of spontaneous bowel movements during the second, third and fourth weeks of treatment, the percentage of participants with a spontaneous bowel movement within 24 hours after administration, the time to first spontaneous bowel movement and weekly subjective assessments by participants of average stool consistency, degree of straining, severity of constipation, overall treatment effectiveness and prevalence of other related symptoms, such as bloating and discomfort.

In these trials, AMITIZA met its primary efficacy endpoint with a high degree of statistical significance, increasing the frequency of spontaneous bowel movements during the first week of treatment by 64% in one pivotal trial and 48% in the second pivotal trial, in each case with a p-value less than or equal to 0.0001. In addition, on the basis of combined data from both pivotal trials, AMITIZA met all but one of the secondary efficacy endpoints with statistical significance for all treatment weeks. That one secondary efficacy endpoint, abdominal discomfort, showed statistically significant improvements only during the last two weeks of treatment with AMITIZA compared to placebo. The results of these trials were consistent in subpopulation analyses for gender, race and patients 65 years of age or older. We determined statistical significance based on a widely used, conventional statistical method that establishes the p-value of clinical results. Under this method, a p-value of 0.05 or less represents statistical significance, meaning that there is a less than one-in-twenty likelihood that the observed results occurred by chance.

The table below sets forth the mean number of spontaneous bowel movements for the intent-to-treat population in these two pivotal trials on a weekly basis for each of the four weeks of the trials. The intent-to-treat population for these trials consisted of all participants enrolled in the trials who were randomized and received at least one dose of AMITIZA or placebo with the last observation carried forward.

## AMITIZA for Chronic Idiopathic Constipation Pivotal Phase III Clinical Trial Results Weekly Number of Spontaneous Bowel Movements



In the table above, "n" indicates the number of participants in each treatment group.

Efficacy Results in Long-term Safety Trials. Between November 2001 and January 2005, we conducted three multi-center, openlabel, long-term clinical safety and efficacy trials of AMITIZA in patients with a history of chronic idiopathic constipation. The trials consisted of one six-month trial and two twelve-month trials and enrolled a total of 881 patients age 18 or older. The primary objective of these trials was to demonstrate the safety of AMITIZA when administered to participants in twice-daily doses of 24 micrograms each. A secondary objective was to provide further evidence of the long-term efficacy of AMITIZA in treating the symptoms of chronic idiopathic constipation. In these trials, AMITIZA produced statistically significant improvements from baseline in subjective assessments of constipation severity, abdominal bloating and abdominal discomfort over both the six-month and the twelve-month treatment periods with a p-value less than or equal to 0.0001. Subjective assessment of constipation severity was improved by an average of 1.47 points on a five-point scale in the six-month trial and 1.38 points in the twelve-month trial; subjective assessment of abdominal bloating was improved by an average of 0.98 points in the six-month trial and 1.00 points in the twelve-month trial; and subjective assessment of abdominal discomfort was improved by an average of 0.91 points in the six-week trial and 0.87 points in the twelve-month trial.

Safety Profile and Withdrawal Effects. AMITIZA was well tolerated in twice-daily doses of 24 micrograms each in an earlier Phase II trial, the two Phase III pivotal trials and the three long-term clinical safety and efficacy trials. These trials revealed no apparent increased risk of serious adverse events as a result of treatment with AMITIZA. The most common adverse events reported by participants in these six trials were nausea, which was reported by 31% of all trial participants, and diarrhea and headache, which were each reported by 13% of all trial participants. The incidence of nausea was lower among participants 65 years of age or older, with only 18.6% of those participants reporting this side effect. In addition, because AMITIZA demonstrated a potential to cause fetal loss in guinea pigs in preclinical studies, its label provides that it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The label further states that women who could become pregnant should have a negative pregnancy test prior to beginning therapy with the drug and should be capable of complying with effective contraceptive measures.

*Post-marketing Studies.* In connection with our marketing approval for AMITIZA for the treatment of chronic idiopathic constipation in adults, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in pediatric patients and in patients with renal and hepatic impairment. We currently are designing protocols for these studies and plan to commence the studies by January 2007.

#### Irritable Bowel Syndrome with Constipation

We are conducting two Phase III pivotal trials and a long-term safety trial of AMITIZA in men and women for the treatment of irritable bowel syndrome with constipation. In these trials, participants are taking AMITIZA gelatin capsules orally in twice daily doses of 8 micrograms each.

*Disease Overview.* Irritable bowel syndrome is a disorder of the intestines with symptoms that include severe cramping, pain, bloating and extreme changes of bowel habits, such as diarrhea or constipation. Patients diagnosed with irritable bowel syndrome are commonly classified as having one of three forms: irritable bowel syndrome with constipation, irritable bowel syndrome with diarrhea, or mixed-pattern irritable bowel syndrome alternating between constipation and diarrhea. Currently, irritable bowel syndrome in all its forms is considered to be one of the most common gastrointestinal disorders.

Current Treatment. Most treatment options for irritable bowel syndrome with constipation focus on separately addressing symptoms, such as pain or infrequent bowel movements. Some patients suffering from irritable bowel syndrome with constipation can be successfully treated with dietary measures, such as increasing fiber and fluid intake, and these treatments are generally tried first. If these measures prove ineffective, laxatives are frequently used for the management of this condition. Zelnorm is currently the only FDA-approved drug indicated for the treatment of irritable bowel syndrome with constipation, although its label limits its indication to short-term treatment of women. In December 2005, the European Medicines Agency refused marketing approval for Zelnorm for the treatment of irritable bowel syndrome with constipation in women, citing the inconclusiveness of clinical studies in demonstrating its effectiveness. In March 2006, the Agency denied an appeal of that decision.

*Market Opportunity.* According to the American College of Gastroenterology, irritable bowel syndrome affects approximately 58 million people in the United States, and irritable bowel syndrome with constipation accounts for approximately one-third of these cases.

**Development Status.** In June 2004, we completed a multi-center, double-blind, randomized, placebo-controlled, dose-response, 12-week Phase II clinical trial to assess the safety and efficacy of AMITIZA for the treatment of irritable bowel syndrome with constipation in daily doses of 16, 32 and 48 micrograms. In this trial, we enrolled approximately 200 participants meeting the International Congress of Gastroenterology's working criteria for the diagnosis of irritable bowel syndrome with constipation, referred to as the Rome II criteria. The objective of this trial was to evaluate the safety and efficacy of multiple dose levels of AMITIZA in this patient population in order to select the appropriate dose for Phase III pivotal studies.

The primary efficacy endpoint for this trial was a subjective assessment of changes in abdominal discomfort and pain during the first month of treatment. Secondary efficacy endpoints included subjective assessments of changes in abdominal discomfort and pain during the second and third months of treatment,

frequency of spontaneous bowel movements, subjective assessments of average stool consistency, degree of straining, abdominal bloating, severity of constipation and overall treatment effectiveness and subjective assessment of quality of life.

In this trial, AMITIZA demonstrated a statistically significant, dose-dependent trend in improvement in mean change from baseline abdominal discomfort and pain during the first month of treatment with a p-value of 0.0431. The term mean change from baseline refers to differences in patients' condition after treatment with the drug or the placebo compared to their condition before treatment. This dose-dependent trend in improvement in mean change from baseline also was statistically significant during the second month of treatment with a p-value of 0.0336. During the third month of treatment, the trend in favor of AMITIZA continued, but was not statistically significant.

In accordance with the trial's protocol, we conducted comparisons of specific doses of AMITIZA versus placebo to evaluate differences in patient's assessments of abdominal discomfort and pain before and after treatment. During the first month of treatment, only the 48 microgram dose demonstrated a statistically significant improvement over placebo in mean change from baseline, showing an improvement of 0.46 points for AMITIZA compared to an improvement of 0.19 for the placebo, and with a p-value of 0.0226. During the second month of treatment, improvements from baseline in all three doses were statistically significant compared with placebo, with improvements of 0.52 points at the 16 microgram dose of AMITIZA, 0.53 points at the 32 microgram dose and 0.54 points at the 48 microgram dose, compared to a 0.23 point improvement for the placebo, with p-values of 0.0392 for the 16 microgram dose, 0.0331 for the 32 microgram dose and 0.0277 for the 48 microgram dose. The mean change from baseline compared with placebo in the 32 microgram dose during the first month of treatment was not statistically significant. Accordingly, as provided in the trial protocol, we initially did not test the 16 microgram dose compared to placebo for the first month of treatment. However, we subsequently performed a comparison that demonstrated a statistically significant improvement from baseline abdominal discomfort and pain in the 16 microgram dose during the first month of treatment compared with placebo, with an improvement of 0.45 points for AMITIZA compared to 0.19 points for placebo, and with a p-value of 0.033. Several secondary efficacy endpoints, including frequency of spontaneous bowel movements, subjective assessments of average stool consistency, degree of straining, abdominal bloating and severity of constipation, also showed overall dose-dependent trends that were statistically significant for at least two of the three months of treatment.

Although AMITIZA was well tolerated at all doses in this trial, the 16 microgram daily dose produced the best overall balance of safety and efficacy, with participants in the 32 and 48 microgram treatment groups generally more likely to discontinue treatment due to adverse events. The only adverse events that were dose-dependent and occurred more frequently in the AMITIZA treatment group than in the placebo treatment group were nausea, which was reported by 19% of participants dosed at 16 micrograms and 18% of participants dosed at 32 micrograms, and diarrhea, which was reported by 14% of participants dosed at 16 micrograms and 12% of participants dosed at 32 micrograms.

Based on the results of this Phase II trial, we initiated two pivotal Phase III clinical trials of AMITIZA in men and women for irritable bowel syndrome with constipation in May 2005, each involving 570 or more participants meeting the Rome II criteria for irritable bowel syndrome with constipation at 65 investigative study sites in the United States. We enrolled the last participant for these trials in April 2006. These Phase III pivotal trials are designed as double-blind, randomized, 12-week clinical trials to demonstrate the efficacy and safety of AMITIZA for the treatment of symptoms of irritable bowel syndrome with constipation using twice daily doses of 8 micrograms each, or 16 micrograms total. The primary efficacy endpoint for these trials is a subjective assessment of the participant's overall relief from the symptoms of irritable bowel syndrome with constipation. The secondary efficacy endpoints are similar to those for our Phase II clinical trials of AMITIZA for this indication and involve subjective assessments of such factors as abdominal discomfort and pain, bloating, stool consistency and quality of life components. The first of the two pivotal studies is being followed by a randomized withdrawal period to assess the effects, if any, associated with withdrawal of AMITIZA over a four-week period. We also are conducting an additional follow-on safety study to assess the long-term use of AMITIZA as a treatment for this indication. We expect to announce the preliminary results of these two Phase III pivotal trials and the follow-on safety trial in the first quarter of 2007.

If the results of our Phase III pivotal trials are favorable, we intend to pursue marketing approval for AMITIZA in the United States as well as Europe and Japan for the treatment of this indication. We believe we can pursue marketing approval for this indication in the United States by filing a supplement to our existing NDA for AMITIZA. In connection with seeking marketing approval for AMITIZA in Europe and Japan, we anticipate that additional clinical studies will be required.

## **Opioid-Induced Bowel Dysfunction**

We plan to initiate Phase II/III pivotal clinical trials of orally administered AMITIZA gelatin capsules for the treatment of opioid-induced bowel dysfunction by early 2007.

*Disease Overview.* Opioid-induced bowel dysfunction comprises a variety of gastrointestinal side effects stemming from the use of narcotic medications such as morphine and codeine, which are referred to as opioids. Physicians prescribe opioids for patients with advanced medical illnesses, such as cancer and AIDS, patients undergoing surgery and patients who experience chronic pain. Despite their pain-relieving effectiveness, opioids are known to produce gastrointestinal effects that lead to opioid-induced constipation, including inhibition of large intestine motility, decreased gastric emptying and hard stools.

**Current Treatment.** There are currently no FDA-approved products that are specifically indicated for treatment of opioid-induced bowel dysfunction. Current treatment options for opioid-induced bowel dysfunction include the use of stool softeners, enemas, suppositories and peristaltic stimulants such as senna, which stimulate muscle contractions in the bowel. The effectiveness of these products for the treatment of opioid-induced bowel dysfunction is limited due to the severity of the constipation caused by opioids. In addition, physicians often cannot prescribe peristaltic stimulants for the duration of narcotic treatment because of the potential for dependence upon these stimulants. As a result, patients frequently must discontinue opioid therapy and endure pain in order to obtain relief from opioid-induced bowel dysfunction.

*Market Opportunity.* According to the American Pain Foundation, over 50 million Americans suffer from chronic pain, and nearly 25 million Americans experience acute pain each year due to injuries or surgery. Opioid pain relievers are widely prescribed for these patients, many of whom also develop opioid-induced bowel dysfunction. We believe over three million people in the United States currently suffer from opioid-induced bowel dysfunction.

Opioid drugs are known to increase absorption of electrolytes, including chloride, in the small intestine, contributing to the constipating effects of these analgesics. We believe that AMITIZA, as a chloride channel activator, may directly counteract this side effect without interfering with the analgesic benefits of opioids. As a result, we believe that AMITIZA, if approved for the treatment of opioid-induced bowel dysfunction, could hold a competitive advantage over drugs that do not work through this mechanism of action.

**Development Status.** We have completed preclinical studies of AMITIZA as a potential therapy for opioid-induced bowel dysfunction in a model of morphine-induced constipation in mice. In these studies, AMITIZA was shown to improve intestinal transit time and did not result in any reduction of the analgesic effect of morphine. Based on these preclinical results, we have determined to pursue development of AMITIZA as a treatment for opioid-induced bowel dysfunction.

## SPI-8811

### Overview

We are developing the prostone compound SPI-8811 for oral administration to treat various gastrointestinal and liver disorders, including NSAID-induced ulcers, non-alcoholic fatty liver disease and portal hypertension. We also plan to develop an inhaled formulation of SPI-8811 for the treatment of respiratory disorders, such as cystic fibrosis and chronic obstructive pulmonary disease. We believe that SPI-8811, like AMITIZA, is an activator of the chloride ion channel ClC-2, which is known to be present in gastrointestinal, liver and lung cells.

We completed two Phase I clinical trials of SPI-8811 in healthy volunteers in Japan in 1997. In these trials, orally administered SPI-8811 was generally well tolerated both when it was administered three times daily for a period of seven days at doses we expect to be clinically relevant and when it was administered in single doses that were significantly higher than those we expect to be clinically relevant. Several incidents of loose or watery stools were reported, but at doses higher than those we expect to use in planned additional clinical trials. No serious adverse events were experienced by any participants in these trials, and no participants withdrew from these trials due to adverse events, even at dose levels several times higher than what we expect to be clinically-relevant doses of SPI-8811.

## Non-Steroidal Anti-Inflammatory Drug-Induced Ulcers

We plan to initiate a Phase II clinical trial of SPI-8811 for the prevention and treatment of NSAID-induced ulcers in early 2007.

*Disease Overview.* NSAIDs, such as aspirin and ibuprofen, are among the most commonly prescribed drugs worldwide. They are used to treat common medical conditions, such as arthritis, headaches and fever. In addition, with the recent withdrawal from the marketplace of the COX-2 inhibitors Vioxx® (rofecoxib) and Bextra® (valdecoxib), which were widely prescribed for arthritis patients, an increased number of these patients are returning to NSAID therapy. However, gastrointestinal symptoms, such as gastric, or stomach, ulcers and bleeding, are major limiting side effects of long-term NSAID use.

Current Treatment. Current treatment options for NSAID-induced ulcers include products designed to prevent the formation of gastric ulcers during NSAID use and products that help to repair the damage of ulcers after they have developed. Cytotec® (misoprostol) is currently the only FDA approved product for the prevention of NSAID-induced gastric ulcers. It is sometimes marketed as a combination product with NSAIDs under the brand name Arthrotec®. However, Cytotec has been associated with severe diarrhea, particularly in higher doses, and its label restricts its use in women of childbearing potential, except in very limited circumstances, because it can cause abortion, premature birth and birth defects.

After NSAID-induced ulcers have developed, proton pump inhibitors, such as Nexium® (esomeprazole magnesium) and Prevacid® (lansoprazole), are prescribed to treat most gastric ulcer patients, either alone or in combination with other treatments. H2 blockers, such as Pepcid® (famotidine), Tagamet® (cimetidine) and Zantac® (ranitidine hydrochloride), help to reduce stomach acid and are typically prescribed as a second line of therapy for gastric ulcers, when proton pump inhibitors are not effective, or are used in conjunction with proton pump inhibitors. Although both proton pump inhibitors and H2 blockers can aid in the repair of existing gastric ulcers, neither of these drug categories has been shown to be effective in preventing ulcer development. Furthermore the therapeutic effects of these products are only observed at high doses and in some types of at-risk patients, such as those with a prior history of ulcers or those 65 years of age or older.

*Market Opportunity.* According to a study published in *Postgraduate Medicine*, approximately 13 million patients in the United States are regular users of NSAIDs. According to the American Chronic Pain Association, as many as 20% of patients who take NSAIDs daily may develop gastric ulcers. We believe that many patients treated with NSAIDs are not prescribed preventative treatment for gastric ulcers due to a combination of high cost, side effects and lack of a well established standard of care. We believe that these factors also limit the use of prescription products for the repair of gastric ulcers after they have developed. Based on SPI-8811's novel mechanism of action and protective activity in animal models, we believe that it may be effective at both preventing and treating NSAID-induced ulcers, but without the safety concerns and restrictions on use associated with existing treatment options.

**Development Status.** We have completed preclinical studies of SPI-8811 as a potential therapy for NSAID-induced ulcers. In preclinical tests in rats, SPI-8811 protected against formation of ulcers induced by indomethacin, an NSAID, and ulcers induced by stress and demonstrated an acceptable safety profile at what we believe are clinically relevant doses. In early 2007, we plan to initiate a Phase II clinical trial for SPI-8811. We expect that this Phase II trial will be a multi-center, randomized, placebo-controlled study to evaluate the effects of multiple doses of SPI-8811 for the treatment and prevention of ulcer formation following treatment with NSAIDs.

#### **Other Potential Indications**

**Portal Hypertension.** Portal hypertension is the build-up of pressure in the portal vein connecting the intestines and the liver and is caused by a narrowing of the blood vessel as a result of liver cirrhosis. Increased pressure in the portal vein can lead to the development of large, swollen veins in the esophagus, stomach and rectum which, if ruptured, can result in potentially life-threatening blood loss. According to a physician survey conducted by MEDACorp, an independent strategic consulting firm focused on the health care sector and a division of Leerink Swann & Co., Inc., one of the managing underwriters for this offering, approximately 4.0 million Americans suffer from liver cirrhosis, with approximately 1.5 million of those individuals also diagnosed with portal hypertension. Beta-adrenergic receptor blocking agents, or beta blockers, such as propranolol are the most common treatment for portal hypertension. Beta blockers help to relieve the effects of portal hypertension by lowering blood pressure throughout the body. However, these products are associated with increased risk of stroke and a number of other side effects, including, nausea, diarrhea, hypotension, heart failure, dizziness, fatigue, insomnia and depression, which may limit their use, particularly among elderly patients. In contrast to beta blockers, we believe that SPI-8811 may be effective at reducing portal hypertension without exhibiting many of the serious side effects associated with beta blockers.

In preclinical tests, SPI-8811:

- reduced liver blood flow associated with portal hypertension in two rodent models of the disease;
- increased cutaneous blood flow in two additional animal models in the presence of chemical agents known to constrict the peripheral vasculature; and
- reduced vascular resistance in the liver induced by a chemical agent in an isolated rat model.

We plan to initiate a Phase I/II proof-of-concept study of SPI-8811 in patients with portal hypertension in 2007.

Non-Alcoholic Fatty Liver Disease. Non-alcoholic fatty liver disease is characterized by elevations of specific liver enzymes in the absence of excessive alcohol intake or other chronic liver diseases. Although all levels of non-alcoholic fatty liver disease lead to fat accumulation in the liver, the more advanced versions of this disease, known as Type 3 and Type 4 non-alcoholic fatty liver disease, also involve fibrosis and greatly increase the risk of progressive liver disease, cirrhosis and liver-related death. There is currently no treatment available for non-alcoholic fatty liver disease and the market size is unknown. According to the National Institute of Diabetes and Digestive and Kidney Diseases, a division of the National Institutes of Health, approximately 10% to 20% of Americans are affected by fat in the liver, and this condition is becoming more common, possibly due to the greater number of Americans with obesity.

In preclinical studies of SPI-8811 as a potential treatment for non-alcoholic fatty liver disease in rodent models of liver damage, SPI-8811 was found to favorably alter various serum indicators of liver function and to reduce the severity of liver injury caused by hepatitis.

In June 2003, we completed a limited, 28-day Phase IIa trial to assess the safety and efficacy of orally administered SPI-8811 for the treatment of non-alcoholic fatty liver disease. The efficacy results of this trial were inconclusive, which we believe was likely the result of the trial's short treatment period and the fact that all but one of the participants in this trial suffered from Type 4 non-alcoholic fatty liver disease, the most severe form of the disease. Although we believe that further investigation of the role of SPI-8811 in the prevention or delay of non-alcoholic fatty liver disease progression is warranted, current techniques for studying this condition require a biopsy of the liver. As a result, we do not plan to pursue human clinical trials of SPI-8811 for the treatment of non-alcoholic fatty liver disease until such time as less invasive methods are developed for diagnosing the disease and evaluating its progress.

*Cystic Fibrosis.* Cystic fibrosis is a congenital disease that usually develops during childhood and causes pancreatic insufficiency and pulmonary disorder. The gene product responsible for cystic fibrosis is a protein called the cystic fibrosis transmembrane conductance regulator, or CFTR. CFTR is found in cells lining the internal surfaces of the lungs, salivary glands, pancreas, sweat glands, intestine and reproductive organs and acts as a channel transporting chloride ions out of the cell. Cystic fibrosis is caused by a defect in the CFTR

protein, which prevents the transport of chloride ions between cells, causing the body to develop thick, sticky mucus in the lungs, pancreas and liver. According to the Cystic Fibrosis Foundation, cystic fibrosis currently affects approximately 30,000 people in the United States and is usually diagnosed in infants and children.

In preclinical *in vitro* tests on human cell lines, SPI-8811 acted as an ion transport modulator, facilitating transport of chloride ions across cell membranes through the ClC-2 chloride channel, a transport process different from that which is defective in cystic fibrosis patients. We believe that the ability of SPI-8811 to activate chloride transport using an alternate chloride channel could potentially reverse the effects caused by the defective CFTR, reducing mucus viscosity and allowing increased clearance of mucus in the lungs, pancreas and liver.

In 2003, we conducted an open-label, dose-escalating Phase II safety and efficacy trial of orally administered SPI-8811 in 24 participants with documented cystic fibrosis. These participants were assigned to one of three dose cohorts at four sites in the United States and treated with SPI-8811 for seven days. The efficacy results of this Phase II trial were inconclusive, which we believe was likely due to the short duration of treatment, the rapid metabolization of the drug in the gastrointestinal tract and the limited number of participants enrolled in the trial. SPI-8811 was generally well tolerated by trial participants, although one participant experienced a serious adverse event and was hospitalized for exacerbation, or short-term worsening, of the disease, possibly as a result of treatment with SPI-8811. We plan to commence a Phase IIb dose-ranging trial of orally administered SPI-8811 for the treatment of gastrointestinal disorders associated with cystic fibrosis in 2007. In addition, we plan to develop an inhaled formulation of SPI-8811 for the treatment of respiratory symptoms of cystic fibrosis.

Chronic Obstructive Pulmonary Disease. Chronic obstructive pulmonary disease is characterized by the progressive development of airflow limitation in the lungs that is not fully reversible and encompasses chronic bronchitis and emphysema. According to the National Heart, Lung and Blood Institute, or the NHLBI, a division of the National Institutes of Health, approximately 12 million adults 25 years of age or older in the United States are diagnosed with chronic obstructive pulmonary disease. The NHLBI further estimates that approximately 24 million adults in the United States have evidence of impaired lung function, indicating in their view that this disease is underdiagnosed. Anticholinergics, smooth muscle relaxers that can help to widen air passageways to the lungs, have been the primary therapy to treat chronic obstructive pulmonary disease. Recently, combination agents, such as steroid/Beta-2 agonists, have enjoyed increased use as chronic obstructive pulmonary disease treatments. However, these treatments relieve only the symptoms of chronic obstructive pulmonary disease, such as chronic cough or shortness of breath, and have limited effect on reducing the incidence of exacerbation of the disease.

Because we believe that the method of action of SPI-8811 involves a barrier protection function resulting from chloride channel activation, we believe that it may be able to address multiple respiratory treatment needs, including treatment of exacerbations, chronic excessive mucus secretion and the mucus component of chronic bronchitis. In pharmacological testing using an inhaled formulation of SPI-8811 in a guinea pig model of acute bronchitis, SPI-8811 reduced cigarette smoke-induced airway resistance and restored forced expiratory volume. We plan to conduct additional preclinical testing of this inhaled formulation of SPI-8811 as a potential treatment for chronic obstructive pulmonary disease.

#### SPI-017

#### Overview

We are conducting preclinical development of SPI-017 for the treatment of peripheral arterial and vascular disease and central nervous system disorders. Initially, we are working on the development of an intravenous formulation of SPI-017 for the treatment of peripheral arterial disease. We also are developing an oral formulation of SPI-017 for the treatment of Alzheimer's disease. We plan to initiate Phase I clinical trials of the intravenous formulation of SPI-017 in early 2007 and the oral formulation in mid to late 2007.

In preclinical *in vitro* tests on human cell lines, SPI-017 activated chloride channels in very low concentrations on a variety of cells found in the central nervous system and peripheral blood vessels. We are currently evaluating the safety profile of SPI-017 in preclinical toxicology studies.

#### **Potential Indications**

**Peripheral Arterial and Vascular Disease.** Peripheral arterial disease, which also is sometimes referred to as peripheral vascular disease, is a chronic condition that results from narrowing of the vessels that supply blood to the stomach, kidneys, arms, legs and feet. Peripheral arterial disease is caused by the build-up of fatty deposits, or plaque, in the inner walls of the arteries as a result of a vascular condition known as atherosclerosis. This build-up of plaque restricts the flow of blood throughout the body, particularly in the arms and legs, and can lead to painful cramping and fatigue after exercise. The American Heart Association estimates that peripheral arterial disease affects as many as 8 million to 12 million people in the United States.

Anti-platelet medications, vasodilators and prostaglandins represent the most frequently prescribed treatments for peripheral arterial disease, but they have little or no impact on symptoms or the underlying atherosclerotic process. Palux® (alprostadil) and Liple® (alprostadil) are used for the treatment of chronic arterial occlusion in Japan, but are not currently available in the United States. In addition, Palux and other prostaglandin E1 drug products should not be administered to patients with bleeding disorders or patients being treated with chronic anti-platelet medications, such as aspirin, due to the detrimental effect of these products on platelet aggregation. Despite the need for additional treatments, we believe that few novel therapies are being explored.

In preclinical animal studies, intravenously administered SPI-017 counteracted blood vessel constriction induced by a chemical agent without significantly affecting blood pressure. In addition, in preclinical animal studies, SPI-017 had no effect on platelet aggregation. We believe that this may suggest that SPI-017, unlike Palux and other prostaglandin E1 drugs, could be used to treat patients with bleeding disorders or patients being treated with chronic anti-platelet medications. We are planning additional experiments to further test the activity of SPI-017 in animal models of peripheral arterial disease.

**Stroke.** Ischemic stroke occurs when an artery that supplies blood to the brain becomes blocked due to a blood clot or other blockage or when blood flow is otherwise reduced as a result of a heart condition. During ischemic stroke, a high rate of damage of neuronal cells in the brain usually leads to permanent functional loss. The American Heart Association estimates that approximately 700,000 patients in the Unites States suffer strokes annually, 88% of which are ischemic strokes.

The thrombolytic Activase® (alteplase, recombinant) is the principal drug currently used to treat acute ischemic stroke in the United States. To be effective, treatment with Activase must be initiated within three hours after the onset of stroke symptoms. In addition, because Activase is contraindicated in patients with intracranial hemorrhaging or active internal bleeding, treatment should be initiated only after exclusion of these conditions.

In animal studies, intravenously administered SPI-017 reduced the extent of cerebral tissue damage in experimentally induced ischemic stroke in rats. In these studies, intravenous SPI-017 administered shortly after the restoration of blood flow also significantly reduced the extent of tissue damage. We are planning additional animal tests to further define the time window for administration of SPI-017 and the concentration range.

**Alzheimer's Disease.** Alzheimer's disease is a chronic debilitating disease, with patients suffering from a progressive dementia over a number of years, ultimately resulting in severe incapacitation and a shortened lifespan. According to the Alzheimer's Association, there are approximately 4.5 million Alzheimer's disease patients in the United States.

While the causes of Alzheimer's disease are currently not well understood, it is widely recognized that particular regions of the brain may play a central role in memory. The brain comprises a complex network of neurons that enable memory, sensation, emotion and other cognitive functions. Neurons are highly specialized cells that are capable of communicating with each other through biochemical transmission across junctions called synapses. For this communication to occur, neurons secrete chemicals, known as neurotransmitters, that

bind to receptors on neighboring neurons. Coordinated communication across synapses is essential for the formation of memories.

Several classes of ion channels play a critical role in both the activation of neurons and in the secretion of neurotransmitters across synapses. In particular, some classes of potassium ion channels, sodium ion channels and calcium ion channels have been shown to be critical in the cascade of events that leads to the secretion of neurotransmitters in key regions of the brain associated with memory. We believe that some of these channels may be important in the process of memory formation and retention.

Preliminary data from a preclinical study of SPI-017 in a rat model of Alzheimer's disease suggests that orally administered SPI-017 may restore cognitive behavior. We are planning additional studies to further define the activity of SPI-017 in this animal model.

#### **Marketing and Sales**

We are co-promoting AMITIZA in the United States with Takeda. We plan to market other product candidates that we may bring to market through a combination of our own sales capabilities and co-marketing, co-promotion, licensing and distribution arrangements with third-party collaborators.

As we develop other products for commercialization, we intend to evaluate the merits of retaining commercialization rights for ourselves, entering into similar collaborative arrangements with leading pharmaceutical companies to help further develop and commercialize our product candidates or a combination of both. Our decision whether to enter into collaborative arrangements will be based on such factors as anticipated development costs, therapeutic expertise and the commercial infrastructure required to access a particular market. We expect that in many of these arrangements, we will seek to co-promote our products in the United States and, in some cases, other markets as part of our ongoing effort to build our internal sales and marketing capabilities.

As part of this strategy, we entered into a 16-year collaboration and license agreement with Takeda in October 2004 for the joint development and commercialization of AMITIZA for gastrointestinal indications in the United States and Canada. In early 2006, we exercised the co-promotion rights under our collaboration and license agreement with Takeda in order to begin developing a specialized sales force to market AMITIZA and other gastrointestinal-related products to complement Takeda's sales efforts. Our initial strategy is to focus our marketing and sales efforts on promoting AMITIZA in the institutional marketplace, including specialist physicians based in academic medical centers and long-term care facilities. This institutional market is characterized by a concentration of elderly patients, who we believe will be a key market for AMITIZA to treat gastrointestinal indications, and by physicians who are key opinion leaders in the gastrointestinal field. Takeda is marketing AMITIZA more broadly to office-based specialty physicians and primary care physicians. Pursuant to the terms of the collaboration and license agreement, Takeda is providing a dedicated sales force of at least 200 people to promote AMITIZA and a supplemental sales force of 500 people to promote AMITIZA together with one other drug product.

In late 2005 and early 2006, in anticipation of the launch of AMITIZA, we recruited an experienced sales and marketing management team comprising an executive vice president of marketing and sales, a marketing director, a director of medical marketing, a national sales director and four regional sales managers.

In addition, effective February 2006, we entered into a contract sales agreement with Ventiv Commercial Services, LLC, or Ventiv, under which Ventiv is providing us with a contract specialty sales force of 38 field sales representatives to market AMITIZA in our targeted institutional market. The sales representatives, who are employees of Ventiv, are marketing AMITIZA on a full-time basis. Under the terms of the agreement, Ventiv is responsible for training the sales representatives on applicable healthcare laws and regulations, and we are responsible for training them with respect to product-specific information. The agreement provides that we will pay Ventiv a flat monthly fee as well as periodic incentive fees upon the recruitment and maintenance of specified numbers of sales representatives over the term of the agreement. In addition, we are responsible for reimbursing Ventiv for specified pass-through expenses related to, among other things, travel, training and employee bonuses. Our agreement with Takeda provides that Takeda will fund a significant portion of our

contract sales force costs. The term of the agreement with Ventiv is through March 29, 2008. The agreement can be terminated by us without cause upon 90 days' notice to Ventiv anytime after April 17, 2007, by Ventiv if payment is not made within 30 days of invoice and by either party for a material breach of the agreement or in the case the other party becomes insolvent or is dissolved or liquidated.

We determined to engage a contract sales force through Ventiv, instead of recruiting a sales force of our own, to minimize the time necessary to launch an operational sales force following our receipt of marketing approval for AMITIZA from the FDA. In light of the size of the sales force, we also believed this approach was more cost effective in the short term than establishing our own sales force internally. In the future, we may recruit our own specialty sales force to supplement or replace the Ventiv sales force. In addition, under the terms of our agreement with Ventiv, we have the right to hire some or all of Ventiv's contract sales representatives as our own employees after the first anniversary of their deployment in the field, subject to 90 days' prior written notice and payment of a specified conversion fee to Ventiv.

#### **Takeda Collaboration**

In October 2004, we entered into a 16-year collaboration and license agreement with Takeda to jointly develop and commercialize AMITIZA for gastrointestinal indications in the United States and Canada. The agreement provides Takeda with exclusive rights within these two countries to develop and commercialize AMITIZA under all relevant patents, know-how and trademarks. Takeda does not have the right to manufacture AMITIZA. Instead, Takeda is required to purchase all supplies of the product from R-Tech under a related supply and purchase agreement.

Development Costs. The agreement provides for development cost-sharing arrangements in which Takeda funds all development costs for the development of AMITIZA as a treatment for chronic idiopathic constipation and irritable bowel syndrome with constipation up to \$30.0 million, of which we received the full amount in 2005. We are required to fund the next \$20.0 million in development costs for these two indications, and all development costs in excess of \$50.0 million are shared equally between Takeda and us. In addition, Takeda and we share equally in all external costs of regulatory-required studies up to \$20.0 million, with Takeda funding any remaining costs related to such studies. For any additional indications beyond chronic idiopathic constipation and irritable bowel syndrome with constipation and for new formulations of AMITIZA, Takeda has agreed to fund all development costs, including regulatory-required studies, to a maximum of \$50.0 million for each new indication and \$20.0 million for each new formulation. Takeda and we have agreed to share equally all costs in excess of these amounts. With respect to any studies required to modify or expand the label for AMITIZA for the treatment of chronic idiopathic constipation or irritable bowel syndrome with constipation, Takeda has agreed to fund 70% of the costs of such studies and we have agreed to fund the remainder. With respect to the development costs for AMITIZA for the treatment of chronic idiopathic constipation in pediatric patients, the joint commercialization committee described below has determined that such costs will be funded entirely by Takeda.

Commercialization Funding Commitment. Takeda is obliged to maintain a specific level of funding for activities in relation to the commercialization of AMITIZA. This funding obligation is \$10.0 million per year so long as marketing approval for the product in the United States is limited to the treatment of chronic idiopathic constipation. If we receive marketing approval in the United States for the treatment of irritable bowel syndrome with constipation and we and Takeda jointly determine to conduct a full-scale direct-to-consumer television advertising campaign for AMITIZA, Takeda's funding obligation for commercialization activities will increase to \$80.0 million per year for three years.

*Promotion and Marketing.* Takeda is required to provide a dedicated sales force of at least 200 people to promote AMITIZA and a supplemental sales force of 500 people to promote AMITIZA together with one other drug product. In addition, Takeda is required to perform specified minimum numbers of product detail meetings with health care professionals throughout the term of the agreement depending upon the indications for which AMITIZA has been approved.

*Co-Promotion Rights.* Under the agreement, we retained co-promotion rights, which we exercised in February 2006. In connection with our exercise of these rights, we agreed to establish our own specialty sales

force consisting of a team of approximately 38 field sales representatives provided under contract by Ventiv. The agreement provides that Takeda will fund a portion of our contract sales force costs, for a period of five years from the date we first deploy our sales representatives. We may increase the total number of our sales representatives and receive additional funding from Takeda for any related costs up to a specified annual amount, subject to the unanimous approval of the joint commercialization committee described below.

Medical and Scientific Activities. We also are entitled to receive cost reimbursement from Takeda on a case-by-case negotiated basis for a part of our commercialization efforts after launch with respect to specific medical and scientific activities undertaken by us. Takeda is to retain overall responsibility for managing these medical and scientific activities. We are responsible for the development of all publications directed at a scientific audience until January 31, 2007, with this work being reimbursed by Takeda up to a specified limit. We retain all intellectual property rights over the material in these publications. After January 31, 2007, Takeda will be primarily responsible for the development of these publications.

Licensing Fees, Milestone Payments and Royalties. Takeda made an up-front payment of \$20.0 million in 2004 and has paid total development milestone payments of \$50.0 million to date. Subject to reaching future development and commercial milestones, we are entitled to receive up to \$140 million in additional development and commercial milestone payments. In addition, upon commercialization of any product covered by the agreement, Takeda is required to pay us a quarterly royalty on net sales revenue on sales of the commercialized product.

Governance. Our collaboration with Takeda is governed by several committees consisting of an equal number of representatives from both companies. These consist of a joint steering committee, which resolves any conflicts arising within the other committees, a joint development committee, a joint commercialization committee and a joint manufacturing committee. In the case of a deadlock within the joint steering committee, our chief executive officer has the determining vote on matters arising from the joint development and manufacturing committees, while Takeda's representative has the determining vote on matters arising from the joint commercialization committee.

New Indications and Additional Territories. Under the agreement, Takeda has a right of first refusal to obtain a license to develop and commercialize AMITIZA in the United States and Canada for any new indications that we may develop. In addition, the agreement granted Takeda an option to exclusively negotiate with our affiliated European and Asian operating companies, Sucampo Europe and Sucampo Japan, to jointly develop and commercialize AMITIZA in two additional territories: Europe, the Middle East, and Africa; and Asia. With respect to the negotiation rights for Europe, the Middle East and Africa, Takeda was required to pay Sucampo Europe an option fee of \$3.0 million. In the event that these negotiations failed to produce a definitive agreement before we received marketing approval in the United States for AMITIZA for the treatment of chronic idiopathic constipation in adults, Sucampo Europe was required to repay Takeda \$1.5 million of the original option fee. With respect to the negotiation rights for Asia, Takeda was required to pay Sucampo Japan an option fee of \$2.0 million. In the event that these negotiations failed to produce a definitive agreement within twelve months, Sucampo Japan was required to repay Takeda \$1.0 million of the original option fee. By the first quarter of 2006, the option rights for both territories had expired without agreement and, accordingly, we repaid Takeda an aggregate of \$2.5 million of the original option fees.

*Term.* The Takeda agreement continues until 2020 unless earlier terminated. We may terminate the agreement if Takeda fails to achieve specific levels of net sales revenue, or if Takeda comes under the control of another party and launches a product competitive with AMITIZA. Alternatively, either party has the right to terminate the agreement in the following circumstances:

- a breach of the agreement by the other party that is not cured within 90 days, or 30 days in the case of a breach of payment obligations;
- a change of control of the other party in which the new controlling party does not expressly affirm its continuing obligations under the agreement;
- insolvency of the other party; or

• a failure to receive marketing approval from the FDA for AMITIZA for the treatment of irritable bowel syndrome with constipation and subsequent failure of the parties to agree on an alternative development and commercialization strategy.

## **Intellectual Property**

Our success depends in part on our ability, and that of Sucampo AG, to obtain and maintain proprietary protection for the technology and know-how upon which our products are based, to operate without infringing on the proprietary rights of others and to prevent others from infringing on our proprietary rights.

We hold an exclusive worldwide royalty-bearing license from Sucampo AG to develop and commercialize AMITIZA and all other prostone compounds covered by patents and patent applications held by Sucampo AG. We are obligated to assign to Sucampo AG all patentable improvements that we make in the field of prostones, which Sucampo AG will in turn license back to us on an exclusive basis. If we have not committed specified development efforts to any prostone compound other than AMITIZA, SPI-8811 and SPI-017 by the end of a specified period, which ends on the later of September 30, 2011 or three months after the date upon which Drs. Kuno and Ueno no longer control our company, then the commercial rights to that compound will revert to Sucampo AG, subject to a one-year extension in the case of any compound that we designate in good faith as planned for development within that year. Sucampo AG, wholly owned by Drs. Ryuji Ueno and Sachiko Kuno and based in Zug, Switzerland, is the patent holding company that maintains the patent portfolio derived from Dr. Ueno's research with prostone technology.

As of July 31, 2006, we had licensed from Sucampo AG rights to a total of 51 U.S. patents, 19 U.S. patent applications, 25 European Union patents, 14 European Union patent applications, 37 Japanese patents and 16 Japanese patent applications. Many of these patents and patent applications are counterparts of each other. Our portfolio of licensed patents includes patents or patent applications with claims directed to the composition of matter, including both compound and pharmaceutical formulation, or method of use, or a combination of these claims, for AMITIZA, SPI-8811 and SPI-017. Depending upon the timing, duration and specifics of FDA approval of the use of a compound for a specific indication, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act.

The patent rights relating to AMITIZA licensed by us consist of seven issued U.S. patents, three issued European Union patents and two issued Japanese patents relating to composition of matter and methods of use. These patent rights also include various U.S., European and Japanese patent applications relating to dosing, pharmaceutical formulation and other claims. The U.S. patent relating to composition of matter expires in 2020. The other U.S. and foreign patents expire between 2008 and 2022.

The patent rights relating to SPI-8811 licensed by us consist of eight issued U.S. patents, three issued European Union patents, and six issued Japanese patents relating to composition of matter and methods of use. These patent rights also include various U.S., European and Japanese patent applications relating to dosing regimes, pharmaceutical formulation and other claims. The U.S. patent relating to composition of matter expires in 2020. The other U.S. and foreign patents expire between 2008 and 2021.

The patent rights relating to SPI-017 licensed by us consist of nine issued U.S. patents, five issued European Union patents and five issued Japanese patents relating to methods of use. These patent rights also include various U.S., European and Japanese patent applications relating to composition of matter and methods of use. If the application for a U.S. patent relating to composition of matter were granted, this patent would expire in 2020. The U.S. patents relating to methods of use and the other U.S. and foreign patents expire between 2010 and 2020.

We are actively seeking to augment the patent protection of our licensed compounds by focusing on the development of new chemical entities, or NCEs, such as AMITIZA, SPI-8811 and SPI-017, which have not previously received FDA approval. Upon approval by the FDA, NCEs are entitled to market exclusivity in the United States with respect to generic drug products for a period of five years from the date of FDA approval, even if the related patents have expired.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success, in conjunction with Sucampo AG, in obtaining effective claims and enforcing those claims once granted. In some cases, we license patent applications instead of issued patents, and we do not know whether any of the patent applications will result in the issuance of any patents. Our licensed patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

## License from Sucampo AG

Prior to the closing of this offering, we will have entered into a restated license agreement with Sucampo AG. Under this agreement, Sucampo AG has granted to us a royalty-bearing, exclusive, worldwide license, with the right to sublicense, to develop and commercialize AMITIZA, SPI-8811 and SPI-017 and any other prostone compounds, other than RESCULA, subject to Sucampo AG's patents. Under the terms of the license, we are obligated to assign to Sucampo AG any patentable improvements derived or discovered by us relating to AMITIZA, SPI-8811 and SPI-017 through the term of the license. In addition, we are obligated to assign to Sucampo AG any patentable improvements derived or discovered by us relating to other licensed prostone compounds prior to the date which is the later of June 30, 2011 or the date on which Drs. Ueno and Kuno cease to control our company. All compounds assigned to Sucampo AG under this agreement will be immediately licensed back to us on an exclusive basis.

In consideration of the license, we are required to make milestone and royalty payments to Sucampo AG. The milestone payments include:

- a payment of \$500,000 upon the initiation of the first Phase II clinical trial for each compound in each of three territories covered by the license: North, Central and South America, including the Caribbean; Asia; and the rest of the world; and
- a payment of \$1.0 million for the first NDA filing or comparable foreign regulatory filing for each compound in each of the same three territories.

Upon payment of the above milestones, no further payments will be required either for new indications or formulations or for further regulatory filings for the same compound in additional countries within the same territory. In addition, we are required to pay Sucampo AG 5% of any up-front or milestone payments that we receive from our sublicensees.

Under the license, we also are required to pay Sucampo AG, on a country-by-country basis, ongoing patent royalties as follows:

- With respect to sales of licensed compounds covered by patents existing on the date of this offering, we are required to pay a royalty of 4.5% of net sales until the last existing patent covering each relevant compound has expired. With respect to sales of AMITIZA in North, Central and South America, including the Caribbean, this royalty is set at 2.2% of net sales.
- Thereafter, if we have assigned any relevant improvement patents to Sucampo AG with respect to a licensed compound, we are required to pay a royalty of 2.25% of net sales, or 1.1% of net sales in the case of sales of AMITIZA in North, Central and South America, including the Caribbean, until the last improvement patent covering each relevant compound has expired.
- With respect to sales of licensed compounds covered by new patents derived by us and assigned to Sucampo AG after the date of
  this offering, we are required to pay a royalty of 2.25% of net sales until the terms of the last new patent covering each relevant
  compound have expired.

In addition, we are required to pay Sucampo AG, on a country-by-country basis, a know-how royalty of 2% of net sales, or 1% of net sales in the case of sales of AMITIZA in North, Central and South America, including the Caribbean, until the fifteenth anniversary of the first sale of the respective compound. All royalties required to be paid under the license are based on total product net sales, whether by us or a sublicensee, and not on amounts actually received by us.

The license from Sucampo AG is perpetual as to AMITIZA, SPI-8811 and SPI-017 and cannot be terminated unless we default in our payment obligations to Sucampo AG. With respect to any other licensed prostone compounds, we are required to perform preclinical testing over a specified period on those compounds and to generate specified pharmacological and toxicity data. The specified period ends on the later of September 30, 2011 or three months after the date upon which Drs. Kuno and Ueno no longer control our company. At the end of the specified period, Sucampo AG can terminate our license with respect to any compounds as to which we have not performed the required testing, except for any compounds we designate as compounds for which we intend in good faith to perform the required testing within the following twelve months. At the end of the twelve-month period, Sucampo AG may terminate our license as to any of the designated compounds for which we have not performed the required testing.

We will need to focus our development resources and funding on a limited number of compounds during the specified period. The decision whether to commit development resources to a particular compound will require us to determine which compounds have the greatest likelihood of commercial success. Initially, Dr. Ueno and his staff will be primarily responsible for making these decisions on our behalf. To assist in this determination, we may in the future institute a management review process that will consist of a special committee of certain members of management, but that committee will not include Drs. Ueno and Kuno.

We retain the rights to any improvements, know-how or other intellectual property we develop that is not related to prostones. We also retain the rights to any improvements, know-how or other intellectual property we develop after the Sucampo AG reversion date, even if they are related to prostones.

The agreement provides that, until the later to occur of June 30, 2011 or until Drs. Ueno and Kuno cease to control our company, Sucampo AG may not develop or commercialize:

- any products with a primary mode of action substantially the same as that of any licensed compound; or
- any products licensed or approved for an indication for which a licensed compound is approved or under development.

Thereafter, Sucampo AG may undertake development of competing products but may not commercialize these products for an additional two years.

As part of this license, we have assumed the responsibility to pay the patent filing and maintenance costs related to the licensed rights. In return, we have control over patent filing and maintenance decisions. The

license agreement also specifies how we and Sucampo AG will allocate costs to defend patent infringement litigation brought by third parties and costs to enforce patents against third parties.

## **Manufacturing**

We do not own or operate manufacturing facilities for the production of commercial quantities of AMITIZA or preclinical or clinical supplies of the other prostone compounds that we are testing in our development programs. Instead, we rely, and expect to continue to rely, exclusively on our affiliate R-Tech to supply us with AMITIZA, SPI-8811 and SPI-017 and any future prostone compounds that we determine to develop or commercialize. Drs. Ueno and Kuno own, directly and indirectly, a majority of the stock of R-Tech.

Prior to the closing of this offering, we, together with our subsidiaries Sucampo Europe and Sucampo Japan, will have entered into an exclusive supply arrangement with R-Tech. Under the terms of this arrangement, we have granted to R-Tech the exclusive right to manufacture and supply AMITIZA to meet our commercial and clinical requirements worldwide until 2026. With the exception of the exclusive supply agreements with Takeda described below, R-Tech is prohibited from supplying AMITIZA to anyone other than us during this period. Our supply arrangement with R-Tech also provides that R-Tech will assist us in connection with applications for marketing approval for AMITIZA in the United States and elsewhere, including assistance with regulatory compliance for chemistry, manufacturing and controls. In consideration of these exclusive rights, R-Tech has paid to us \$8.0 million in upfront and milestone payments. Either we or R-Tech may terminate the supply arrangement with respect to us or one of our operating subsidiaries in the event of the other party's uncured breach or insolvency.

In anticipation of the commercial development of AMITIZA, Takeda, R-Tech and we entered into a 16-year supply agreement in October 2004, which was supplemented by a definitive supply and purchase agreement in January 2006. Under these agreements, R-Tech agreed to supply and Takeda agreed to purchase all of Takeda's commercial requirements, including product samples, for AMITIZA in the United States and Canada. Pursuant to the terms of these agreements, Takeda is required to provide R-Tech with a rolling 24-month forecast of its product and sample requirements and R-Tech is required to keep adequate levels of inventory in line with this forecast. In addition, these agreements require R-Tech to maintain a six-month supply of the active ingredient used in manufacturing AMITIZA and a six-month supply of AMITIZA in bulk form as backup inventory. Upon a termination of the collaboration and license agreement between Takeda and us, either Takeda or we may terminate these supply agreements by notice to R-Tech.

R-Tech is Takeda's and our sole supplier of AMITIZA. In the event that R-Tech cannot meet some or all of Takeda's or our demand, neither Takeda nor we have alternative manufacturing arrangements in place. However, we have the right to qualify a back-up supplier for AMITIZA and, in the event that R-Tech is unwilling or unable to meet our demand, we may purchase AMITIZA from this back-up supplier at our election. If we chose to qualify a back-up supplier, R-Tech will grant to that back-up supplier a royalty-free license to use any patents or know-how owned or controlled by R-Tech relating to the manufacturing process for AMITIZA and will provide, upon our reasonable request and at our expense, consulting services to the back-up supplier to enable it to establish an alternative manufacturing capability for AMITIZA.

R-Tech operates a cGMP compliant manufacturing facility near Osaka, Japan. In October 2005, R-Tech received approval from the FDA to manufacture AMITIZA at this facility. In addition, R-Tech manufactures its own prostone product RESCULA at this facility and has been the sole supplier of this product to the marketplace since 1994 without interruption.

Prior to the closing of this offering, we also will have entered into exclusive supply arrangements with R-Tech to provide us with clinical supplies of our product candidates SPI-8811 and SPI-017 and to assist us in connection with applications for marketing approval for these compounds in the United States and elsewhere, including assistance with regulatory compliance for chemistry, manufacturing and controls.

#### Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience, and resources provide us with competitive advantages, we face potential competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. AMITIZA and any other product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than AMITIZA or the other product candidates that we are developing. In addition, our ability to compete may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products. This may have the effect of making branded products less attractive, from a cost perspective, to buyers.

There are currently approved therapies for the diseases and conditions addressed by AMITIZA. For example, Zelnorm, which is marketed by Novartis Pharmaceuticals Corporation, has been approved both for the treatment of chronic idiopathic constipation in adults under 65 years of age and for the short-term treatment of irritable bowel syndrome with constipation in women. In addition, the osmotic laxatives MiraLax, which is marketed by Braintree Laboratories, Inc., and lactulose, which is produced by Solvay S.A., have each been approved for the treatment of occasional constipation.

Several companies also are working to develop new drugs and other therapies for these same diseases and conditions. Some of these potential competitive drug products include:

- Drugs targeting serotonin receptors for the treatment of irritable bowel syndrome with constipation, such as Renzapride, being developed by Alizyme plc and currently in Phase III clinical trials; and
- Opioid antagonists such as Entereg® (alvimopan), being developed by Adolor Corporation and currently in Phase III clinical trials, and methylnaltrexone, being developed by Progenics Pharmaceuticals, Inc. and currently in Phase III clinical trials, each for the treatment of opioid-induced bowel dysfunction.

We face similar competition from approved therapies and potential drug products for the diseases and conditions addressed by SPI-8811, SPI-017 and our other product candidates.

The key competitive factors affecting the success of all of our product candidates are likely to be their efficacy, safety, price and convenience.

#### **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, approval, manufacturing, labeling,

post-approval monitoring and reporting, packaging, promotion, storage, advertising, distribution, marketing and export and import of pharmaceutical products such as those we are developing. The process of obtaining regulatory approvals and the subsequent substantial compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

## **United States Government Regulation**

In the United States, the information that must be submitted to the FDA in order to obtain approval to market a new drug varies depending upon whether the drug is a new product whose safety and efficacy have not previously been demonstrated in humans or a drug whose active ingredients and certain other properties are the same as those of a previously approved drug. A product whose safety and efficacy have not previously been demonstrated in humans will follow the New Drug Application, or NDA, route.

## The NDA Approval Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and implementing regulations. Failures to comply with the applicable FDA requirements at any time during the product development process, approval process or after approval may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a hold on clinical trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The steps required before a drug may be marketed in the United States include:

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory practices regulations;
- submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin and which must include a commitment that an independent Institutional Review Board, or IRB, will be responsible for the review and approval of each proposed study and that the investigator will report to the IRB proposed changes in research activity;
- performance of adequate and well-controlled clinical trials in accordance with good clinical practices to establish the safety and efficacy of the product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluations of product chemistry, toxicology and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Preclinical testing generally continues after the IND is submitted. The IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. In other words, submission of an IND does not guarantee that the FDA will allow clinical trials to commence.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each site at which the study is conducted must approve the protocol, any amendments to the protocol and related materials such as informed consent documents and investigator brochures. All research subjects must provide their informed consent in writing.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I trials usually involve the initial introduction of the investigational drug into healthy volunteers to evaluate the product's safety, dosage tolerance and pharmacokinetics, or the process by which the product is absorbed, distributed, metabolized and eliminated by the body, and, if possible, to gain an early indication of its effectiveness.

Phase II trials usually involve trials in a limited patient population to:

- evaluate dosage tolerance and appropriate dosage;
- · identify possible adverse effects and safety risks; and
- provide a preliminary evaluation of the efficacy of the drug for specific indications.

Phase II trials are sometimes denoted as Phase IIa or Phase IIb trials. Phase IIa trials typically represent the first human clinical trial of a drug candidate in a smaller patient population and are designed to provide earlier information on drug safety and efficacy. Phase IIb trials typically involve larger numbers of patients and may involve comparison with placebo, standard treatments or other active comparators.

Phase III trials usually further evaluate clinical efficacy and test further for safety in an expanded patient population. Phase III trials usually involve comparison with placebo, standard treatments or other active comparators. These trials are intended to establish the overall risk-benefit profile of the product and provide an adequate basis for physician labeling.

Phase II and Phase III testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of research if the research is not being conducted in accordance with the IRB's requirements or if the research has been associated with unexpected serious harm to patients.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with other detailed information, including information on the chemistry, manufacture and composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. In most cases, a substantial user fee must accompany the NDA. The FDA will initially review the NDA for completeness before it accepts the NDA for filing. After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether a product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity.

Under the Pediatric Research Equity Act of 2003, or PREA, all NDAs or supplements to NDAs relating to a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is determined to be safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers, as it did in connection with our NDA for AMITIZA for the treatment of chronic idiopathic constipation. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Before approving an NDA, the FDA will inspect the facility or the facilities at which the product is manufactured. The FDA will not approve the product unless cGMP compliance is satisfactory. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

With respect to approval for a new indication where the product candidate is already approved for another indication, the results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA supplement. The FDA may deny approval of an NDA supplement if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or an additional pivotal Phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA supplement does not satisfy the criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

## **Post-Approval Requirements**

After regulatory approval of a product is obtained, we are required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, the FDA may require post marketing, or Phase IV, trials to assess the product's long-term safety or efficacy. In addition, holders of an approved NDA are required to report certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes certain procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, new government requirements, including those resulting from new legislation, may be established that could delay or prevent regulatory approval of our products under development.

## **Orphan Drug Designation**

We have received an orphan drug designation from the FDA for the oral formulation of our product candidate SPI-8811 for the treatment of cystic fibrosis and may pursue orphan drug designation for additional product candidates, as appropriate. The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition" that affects fewer than 200,000 individuals in the United States, or more than

200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation can provide opportunities for grant funding towards clinical trial costs, tax advantages and FDA user-fee benefits. In addition, if a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity or may receive approval of the same drug as the orphan drug product for a different indication.

## **Regulation Outside the United States**

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of countries outside the United States before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

#### Europe

To obtain regulatory approval of a drug under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by certain biotechnological processes and optional for those which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. All marketing authorizations for products designated as orphan drugs must be granted in accordance with the centralized procedure. The decentralized procedure provides for a member state, known as the reference member state, to assess an application, with one or more other, or concerned, member states subsequently approving that assessment. Under this procedure, an applicant submits an application, or dossier, and related materials including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment and related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to the public health, any disputed points may be referred to the European Commission, whose decision is binding on all member states.

The European Medicines Agency, or EMEA, grants orphan drug designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the European Union. In addition, orphan drug designation can be granted if the drug is intended for a life threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that sales of the drug in the European Union would be sufficient to justify developing the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the European Union of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients. Orphan drug designation provides opportunities for free protocol assistance, fee reductions for access to the centralized regulatory procedures before and during the first year after marketing authorization and 10 years of market exclusivity following drug approval. Fee reductions are not limited to the first year after authorization for

small and medium enterprises. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable that maintaining market exclusivity is not justified. In addition, European regulations establish that a competitor's marketing authorization for a similar product with the same indication may be granted if there is an insufficient supply of the product or if the competitor can establish that its product is safer, more effective or otherwise clinically superior.

#### Japan

In Japan, pre-marketing approval and clinical studies are required for all pharmaceutical products. The regulatory regime for pharmaceuticals in Japan has in the past been so lengthy and costly that it has been cost-prohibitive for many pharmaceutical companies. Historically, Japan has required that all clinical data submitted in support of a new drug application be performed on Japanese patients. Recently, however, as a part of the global drug harmonization process, Japan has signaled a willingness to accept United States or European Union patient data when submitted along with a bridging study, which demonstrates that Japanese and non-Japanese subjects react comparably to the product. This approach, which is executed on a case-by-case basis, may reduce the time required for approval and introduction of new products into the Japanese market.

Amendments to Japan's drug regulatory legislation went into effect in April 2005.

- Under the revised legislation, Japan adopted a marketing authorization process comparable to the European Union authorization and United States NDA. This is expected to allow greater flexibility on the part of Japanese manufacturers to efficiently organize their production/marketing activities.
- The amended legislation requires worldwide compliance with good manufacturing practice requirements by exporters of pharmaceutical products to Japan and detailed disclosure of the manufacturing process to the Japanese authorities, as well as to the importer in Japan.

The Japanese government has also announced that it intends during 2006 to introduce a new proprietary data exclusivity period of up to eight years in order to protect the value of clinical data.

## Regulation of the Health Care Industry

In addition to the regulatory approval requirements described above, we are or will be directly, or indirectly through our customers, subject to extensive regulation of the health care industry by the federal government and the states and foreign countries in which we may conduct our business. The laws that directly or indirectly affect our ability to operate our business include the following:

- the federal Medicare and Medicaid Anti-Kickback law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;
- other Medicare laws, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- the federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- the federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and
- state and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations.

If our operations are found to be in violation of any of these laws, regulations, rules or policies or any other law or governmental regulation to which we or our customers are or will be subject, or if interpretations of the foregoing change, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found non-compliant with applicable laws, they may be subject to sanctions.

## **Pharmaceutical Pricing and Reimbursement**

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through drug procurement organizations operating pursuant to this legislation. These organizations would negotiate prices for our products, which are likely to be lower than the prices we might otherwise obtain. Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals, including AMITIZA and the drug candidates that we are developing.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on pharmaceutical pricing.

Another development that may affect the pricing of drugs is proposed Congressional action regarding drug reimportation into the United States. Proposed legislation would allow the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs are sold at a lower price. If such legislation or similar regulatory changes were enacted, they could reduce the price we receive for any approved products, which, in turn, could adversely affect our revenues. Even without legislation authorizing reimportation, patients have been purchasing prescription drugs from Canadian and other non-United States sources, which has reduced the price received by pharmaceutical companies for their products.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions permit products to be marketed only after a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits.

In Japan, the National Health Ministry biannually reviews the pharmaceutical prices of individual products. In the past, these reviews have resulted in price reductions. In the 2004 biannual review, the Japanese government reduced the overall drug reimbursement rates. We expect a similar price review in 2006, in line with the government's previously announced plan for controlling health care costs. It is not possible to predict the outcome of this review, and it is possible that Japanese authorities will again reduce drug reimbursement rates, which could adversely affect the reimbursement levels for our products or product candidates.

# **Facilities**

Our principal facilities consist of approximately 12,766 square feet of office space located in Bethesda, Maryland. We occupy 11,166 square feet of this space under a lease that expires in November 2009 and 1,600 square feet of this space under a sublease that expires in December 2010. We are currently seeking to identify and lease a new headquarters location containing approximately 22,000 square feet of office space to support growth in our business. If we secure a new headquarters lease, we believe we will be able to sublease our current headquarters space for the duration of our current leases at little or no loss to us. We also rent space under short-term leases in London, England and Osaka, Japan.

#### **Employees**

As of May 31, 2006, we had 35 full-time employees, including 11 with doctoral or other advanced degrees. Of our workforce, 13 employees are engaged in research and development, seven are engaged in marketing and sales, and 15 are engaged in business development, legal, finance and administration. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

As of May 31, 2006, Sucampo Europe and Sucampo Japan each had one full-time employee.

# **Legal Proceedings**

We are not currently a party to any material legal proceedings.

#### MANAGEMENT

Our executive officers and directors, and their ages as of May 31, 2006, are as follows:

Name	Age	Position			
Sachiko Kuno, Ph.D.	51	President, Chief Executive Officer and Director			
Ryuji Ueno, M.D., Ph.D., Ph.D.	52	Chief Scientific Officer, Chief Operating Officer			
		and Chairman of the Board of Directors			
Mariam E. Morris	38	Chief Financial Officer and Treasurer			
Brad E. Fackler	52	Executive Vice President of Commercial Operations			
Gayle R. Dolecek	63	Senior Vice President of Research and Development			
Kei S. Tolliver	32	Vice President of Business Development and			
		Company Operations and Secretary			
Charles S. Hrushka	54	Vice President of Marketing			
Michael J. Jeffries(1)(2)(3)	63	Director			
Timothy I. Maudlin*	55	Director Elect			
Hidetoshi Mine(1)(2)(3)	55	Director			
V. Sue Molina*	58	Director Elect			
Gregory D. Perry(1)(2)(3)	45	Director			

Will join the board of directors in September 2006.

Sachiko Kuno, Ph.D. Dr. Kuno is a founder of our company and has been our President and Chief Executive Officer since July 2004. Dr. Kuno also served as founding Chief Executive Officer from December 1996 to November 2000. She has been a director since December 1996. Dr. Kuno has been a co-owner of our affiliate R-Tech since 1992 and served as its President and Chief Executive Officer from March 2003 to May 2004. Dr. Kuno also co-founded Sucampo AG together with Dr. Ueno in April 1998. In addition, Dr. Kuno served as head of clinical development for RESCULA and oversaw the drug's development and marketing approval in Japan for the treatment of glaucoma. Dr. Kuno received her Bachelors degree in Biochemistry and her Masters degree and Ph.D. in Industrial Biochemistry from Kyoto University. Dr. Kuno is married to Dr. Ueno.

Ryuji Ueno, M.D., Ph.D., Ph.D. Dr. Ueno is a founder of our company and has been our Chief Scientific Officer since August 2004 and our Chief Operating Officer since March 2006. Dr. Ueno also served as Chief Operating Officer from December 1996 to November 2000 and Chief Executive Officer from December 2000 to September 2003. Dr. Ueno has been a director since 1996 and Chairman of our Board of Directors since December 2000. Dr. Ueno co-founded our affiliate R-Tech in September 1989 and served as its President from 1989 to March 2003. Dr. Ueno also co-founded Sucampo AG in April 1998 and served as its President from October 2003 to May 2004. Dr. Ueno received his M.D. and a Ph.D. in medical chemistry from Keio University in Japan, and he received a Ph.D. in Pharmacology from Osaka University. Dr. Ueno is married to Dr. Kuno.

Mariam E. Morris. Ms. Morris has been our Chief Financial Officer and Treasurer since March 2006. From February 2004 to March 2006, Ms. Morris served as our Director of Finance. From January 2003 to February 2004, she worked as an independent consultant for AuditWatch, Inc., a training and consultancy firm for the audit profession. Ms. Morris was a supervising auditor with the public accounting firm of Snyder, Cohn, Collyer, Hamilton & Associates, P.C. from November 2001 to December 2002. Ms. Morris also was a senior auditor with the public accounting firm of PricewaterhouseCoopers LLP from September 2000 to October 2001. Ms. Morris is a certified public accountant and holds a B.B.A. degree in Accounting from Texas Tech University and a Master's degree in Taxation from Old Dominion University.

*Brad E. Fackler.* Mr. Fackler has been our Executive Vice President of Commercial Operations since September 2005. From January 2005 to September 2005, Mr. Fackler was Vice President of The Collaborative

<sup>(1)</sup> Member of Audit Committee.

<sup>(2)</sup> Member of Compensation Committee.

<sup>(3)</sup> Member of Nominating and Corporate Governance Committee.

Group, a specialty consultancy firm servicing the pharmaceutical industry. From September 2004 until January 2005, he was self-employed. From 1978 to September 2004, Mr. Fackler was a senior sales executive for Novartis Pharmaceuticals Corporation. Mr. Fackler holds a Bachelors degree in Life Science from Otterbein College and an M.B.A. degree from New York University, Leonard Stern School of Business.

*Gayle R. Dolecek*. Dr. Dolecek has been our Senior Vice President of Research and Development since May 2006. From August 1995 to April 2006, he was a Senior Consultant at AAC Consulting Group, Inc., a provider of regulatory consulting services to the pharmaceutical industry. Prior to 1995, Dr. Dolecek was an officer with the U.S. Public Health Service where he served in pharmacy and health service related positions. He completed his career with the government in the Food and Drug Administration as Director of Compendial Operations in the Center for Drug Evaluation and Research. Dr. Dolecek received his B.S./P.D. in Pharmacy from the University of Maryland and a M.P.H. in Health Services and Planning from the University of Hawaii.

*Kei S. Tolliver.* Ms. Tolliver has been our Vice President of Business Development and Company Operations and Secretary since March 2006. From October 2004 to March 2006, Ms. Tolliver was our Director of Business Development. Since joining our company in May 1998, Ms. Tolliver has held a number of positions within the Sucampo group of affiliated companies, including Director of Business, Development for S&R Technology Holdings, LLC, a position she has held since May 2002, supplemental director for Sucampo AG, a position she has held since September 2004, director of Sucampo Pharma, Ltd., a position she has held since July 2004, and General Manager and director of Sucampo Pharma Europe Ltd., a position she has held since January 2003. Ms. Tolliver holds a Bachelors degree in Political Science from West Virginia University.

Charles S. Hrushka. Mr. Hrushka has been our Vice President of Marketing since June 2006. From December 2005 to June 2006, Mr. Hrushka was our Director of Marketing. In October 2004, he co-founded Burren Pharmaceuticals, Inc., a specialty pharmaceutical company focused on gastroenterology, and served as its President and Chief Operating Officer until he joined our company in December 2005. From January 2001 to September 2004, he was the Managing Director of ScheBo\*Biotech USA Inc., a diagnostics company focusing on gastroenterology and oncology. Mr. Hrushka holds a Bachelors degree in Biology from Lynchburg College and an M.B.A. degree from Georgia State University, J. Mack Robinson College of Business.

*Michael J. Jeffries*. Mr. Jeffries has been a director since 2004. From January 1990 until his retirement in December 2005, Mr. Jeffries held various senior management positions at Osteotech, Inc., a medical technology company. These positions included Executive Vice President, a position he held from 1992 until his retirement, Chief Financial Officer, a position he held from 1990 until his retirement, and Secretary and director, positions he held from 1991 until his retirement. Mr. Jeffries received his B.B.A. degree from the City College of New York and his M.B.A. degree in Finance from Fordham University.

Timothy I. Maudlin. Mr. Maudlin will become a director in September 2006. Since 1989, Mr. Maudlin has been a managing partner of Medical Innovation Partners, a venture capital firm. Mr. Maudlin also served as a principal of Venturi Group, LLC, an incubator and venture capital firm, from 1999 to October 2001 and as chief financial officer of Venturi Group, LLC in 2002. Mr. Maudlin serves on the board of directors of Curative Health Services, Inc., a biopharmaceutical company. On March 24, 2006, Curative's board of directors authorized the filing of a voluntary petition for bankruptcy under Chapter 11. The petition was filed on March 27, 2006. Mr. Maudlin holds a B.A. from St. Olaf College and an M.M. from the Kellogg School of Management at Northwestern University.

Hidetoshi Mine. Mr. Mine has been a director since 2004. Mr. Mine has been the President and Chief Executive Officer at OPE Partners Limited, an investment firm, since August 2004. From January 2001 to July 2004, Mr. Mine was a Managing Director of the Principal Investment Team of Orix Corporation, a financial services firm. From April 1996 to December 2000, Mr. Mine was a Managing Director and Chief Executive Officer of Tokyo-Mitsubishi International (Singapore) Ltd. From November 1999 to October 2003, Mr. Mine was a director of the Singapore Exchange. Mr. Mine holds a Bachelors degree in Sociology from Hitotsubashi University in Tokyo.

*V. Sue Molina.* Ms. Molina will become a director in September 2006. From November 1997 until her retirement in May 2004, she was a tax partner at Deloitte & Touche LLP, an international accounting firm.

*Gregory D. Perry.* Mr. Perry served as Senior Vice President of Finance and Chief Financial Officer of Transkaryotic Therapies Inc., a biopharmaceutical company, from November 2004 until its acquisition by Shire Pharmaceuticals Group plc in July 2005. From May 2003, when he joined Transkaryotic, to November 2004, Mr. Perry served as Vice President, Finance, and Chief Financial Officer. From October 1998 to November 2002, Mr. Perry was employed by PerkinElmer, Inc., a provider of scientific instruments, consumables and services to the pharmaceutical, biomedical, environmental testing and general industrial markets, where he most recently served as Senior Vice President, Finance and Business Development, Life Sciences. Mr. Perry received his Bachelors degree in Economics and Political Science from Amherst College.

## **Board Composition**

Our board of directors is currently authorized to have five members and we currently have five members. The authorized number of directors may be changed only by resolution of the board of directors. The terms of service of each director will expire upon the election and qualification of successor directors at each annual meeting of our stockholders. Following the automatic conversion date, as described under "Description of Capital Stock — Common Stock," our directors may be removed only for cause and only by the affirmative vote of the holders of 75% or more of the combined voting power represented by our voting stock.

Upon the occurrence of any event that results in all the remaining class B common stock being automatically converted into class A common stock, or when there otherwise is no class B common stock outstanding, the board of directors will be immediately and automatically divided into three classes, class I, class II and class III, with each class serving staggered three-year terms. Class I directors will serve for a three year term beginning at the first annual meeting of stockholders following the automatic conversion date, class II directors will serve for a three year term beginning at the second annual meeting of stockholders following the automatic conversion date and class III directors will serve for a three year term beginning at the third annual meeting of stockholders following the automatic conversion date. Thereafter, upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

All current directors have been assigned prospectively to one of the classes as follows:

- the class I director will be Mr. Jeffries:
- the class II directors will be Dr. Ueno and Mr. Mine; and
- the class III directors will be Dr. Kuno and Mr. Perry.

Each new director will likewise be assigned prospectively to a class at the time he is nominated or appointed to the board. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management.

Our board of directors has reviewed, considered and discussed each director's relationships, either directly or indirectly, with our company and its subsidiaries and the compensation each director receives, directly or indirectly, from our company and its subsidiaries in order to determine whether such director meets the independence requirements of the applicable rules of the NASDAQ National Market and the applicable rules and regulations of the Securities Exchange Commission. Our board has determined that each of Messrs, Jeffries, Mine, and Perry qualify as independent under the NASDAQ and SEC rules. We refer to these directors as our independent directors. Upon the closing of this offering each of these independent directors will serve on one or more of our audit committee, compensation committee and nominating and corporate governance committees.

Except for Drs. Kuno and Ueno, there are no family relationships among any of our directors or executive officers.

#### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition of each committee will be effective upon closing of this offering.

#### **Audit Committee**

Messrs. Jeffries, Mine, and Perry will become members of our audit committee upon the closing of this offering. Our audit committee will assist our board of directors in its oversight of the integrity of our financial statements, our independent registered public accounting firm's qualifications and independence and the performance of our independent registered public accounting firm.

Upon the closing of this offering, our audit committee's responsibilities, as set forth in the written charter adopted by our board in June 2006, will include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of certain reports from our independent registered public accounting firm;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics:
- establishing policies and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our registered public accounting firm and management; and
- preparing the audit committee report required by Securities and Exchange Commission rules.

All audit services to be provided to us and all non-audit services, other than de minimus non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Mr. will chair the committee. Our board has determined that each member of the audit committee qualifies as an independent director under the applicable rules of the NASDAQ National Market and the applicable rules and regulations of the Securities Exchange Commission. Our board has also determined that each member of the audit committee is "financially literate" under the applicable NASDAQ rules and that both Messrs. Jeffries and Perry qualify as an "audit committee financial expert" under Securities and Exchange Commission rules by virtue of their experience described above.

## **Compensation Committee**

Messrs. Jeffries, Mine, and Perry will become members of our compensation committee upon the closing of this offering.

Mr. will chair the committee. Our board has determined that each member of our compensation committee qualifies as an independent director under the applicable NASDAQ rules. Our compensation committee will assist our board of directors in the discharge of its responsibilities relating to the compensation of our executive officers.

Upon the closing of this offering, our compensation committee's responsibilities, as set forth in the written charter adopted by the board in June 2006, will include:

• reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our chief executive officer and our other executive officers;

- overseeing and administering, and making recommendations to our board of directors with respect to, our cash and equity compensation plans;
- overseeing the evaluation of the performance of our senior executives;
- · reviewing and making recommendations to the board of directors with respect to director compensation; and
- preparing the compensation committee report required by Securities and Exchange Commission rules.

#### **Nominating and Corporate Governance Committee**

Messrs. Jeffries, Mine, and Perry will become members of our nominating and corporate governance committee upon the closing of this offering. Mr. will chair the committee. Our board has determined that each member of our nominating and corporate governance committee qualifies as an independent director under the applicable NASDAQ rules.

Upon the closing of this offering, our nominating and corporate governance committee's responsibilities will include:

- recommending to our board of directors the persons to be nominated for election as directors or to fill vacancies on the board of directors and to be appointed to each of the board of directors' committees;
- · reviewing and making recommendations to our board of directors with respect to management succession planning;
- · developing and recommending to our board of directors corporate governance principles and guidelines; and
- overseeing a periodic self-evaluation of our board of directors.

## **Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. None of the members of our compensation committee has ever been our employee.

## **Director Compensation**

In June 2006, our board of directors approved a compensation program pursuant to which we will pay each of our directors who is not an employee of, or a spouse of an employee of, our company, whom we refer to as our non-employee directors, an annual retainer of \$60,000 for service as a director. Each non-employee director will also receive a fee of \$1,000 for each meeting of the full board of directors or any committee of the board of directors attended by such non-employee director. We will reimburse each non-employee member of our board of directors for out-of-pocket expenses incurred in connection with attending our board and committee meetings.

# **Executive Compensation**

The following table sets forth the total compensation paid or accrued for the fiscal year ended December 31, 2005 to our chief executive officer and each of our four most highly compensated executive officers whose salary and bonus exceeded \$100,000 for the year ended December 31, 2005. We refer to these officers as our named executive officers.

# **Summary Compensation Table**

Name and Principal Position	Salary	Annual Compensation Bonus	All Other Compensation
Sachiko Kuno, Ph.D.	\$251,538	\$ 78,000	\$ 558(1)
President, Chief Executive Officer and Director			, ,
Ryuji Ueno, M.D., Ph.D., Ph.D.	374,807	117,000	972(2)
Chief Scientific Officer, Chief Operating Officer and Chairman of the			` ,
Board of Directors			
Mariam E. Morris	139,827	16,685	7,454 <sub>(3)</sub>
Chief Financial Officer and Treasurer			( )
Brad E. Fackler <sup>(4)</sup>	107,500	_	_
Executive Vice President of Commercial Operations			
Kei S. Tolliver	109,226	14,719	1,937 <sub>(5)</sub>
Vice President of Business Development and Company Operations and			
Secretary			

<sup>(1)</sup> Represents \$558 in matching contributions under our 401(k) plan.

## **Option Grants in Last Fiscal Year**

We made no grants of stock options to our executive officers during 2005.

<sup>(2)</sup> Represents \$972 in matching contributions under our 401(k) plan.

<sup>(3)</sup> Represents \$7,000 in matching contributions under our 401(k) plan and \$454 in life insurance premiums.

<sup>(4)</sup> Brad Fackler was appointed our Vice President of Commercial Operations in September 2005.

<sup>(5)</sup> Represents \$1,457 in matching contributions under our 401(k) plan and \$480 in life insurance premiums.

#### Aggregate Option Exercises in Last Fiscal Year and Year-End Option Values

The following table provides information about the number and value of options held by our named executive officers at December 31, 2005. There was no public trading market for our class A common stock as of December 31, 2005. Accordingly, as permitted by the rules of the Securities and Exchange Commission, we have calculated the value of unexercised in-the-money options at fiscal year-end assuming that the fair market value of our class A common stock as of December 31, 2005 was \$ per share, the midpoint of the price range on the cover of this prospectus, less the aggregate exercise price.

# Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

	Underlying	of Securities g Unexercised cember 31, 2005	Value of Unexercised In-the-Money Options at December 31, 2005	
<u>N</u> ame	Exercisable	Unexercisable	Exercisable	Unexercisable
Sachiko Kuno, Ph.D.	22,000	_	\$	\$
Ryuji Ueno, M.D., Ph.D., Ph.D.	62,000	_		
Mariam E. Morris	_	_	_	_
Brad E. Fackler	_	_	_	_
Kei S. Tolliver	_	_	_	_

#### **Employment Agreements**

Dr. Sachiko Kuno. Pursuant to an employment agreement effective June 16, 2006, we agreed to continue to employ Dr. Kuno as our Chief Executive Officer and President for a term of three years. This agreement renews automatically each year for a period of one year unless earlier terminated by Dr. Kuno or us. Under this agreement, Dr. Kuno is entitled to receive an annual base salary of \$380,000, to be reviewed annually by our compensation committee and our board of directors and increased, but not decreased unless agreed by Dr. Kuno and us. Dr. Kuno is also eligible for an annual bonus of up to 50% of her base salary as determined by our independent directors based on the compensation committee's assessment of Dr. Kuno's achievement of annual corporate objectives. In addition, Dr. Kuno is entitled to receive, at the discretion of our compensation committee, restricted stock grants, options to purchase shares of our class A common stock and other awards pursuant to our 2006 stock incentive plan once Dr. Kuno and Dr. Ueno own collectively less than 50% of our total equity, and also is eligible to participate in all employee benefit plans offered to other employees. In the event of a merger or sale of our company or the death of Dr. Kuno, all restricted stock and stock options issued to Dr. Kuno shall immediately vest. Upon termination or non-renewal by us of Dr. Kuno's employment other than for cause or upon termination by Dr. Kuno for specified good reasons, including diminution of authority and duties, Dr. Kuno will be entitled to receive a lump sum severance payment equal to 24 months of current base salary and to continue to receive full employment benefits for a period of 18 months after termination. If Dr. Kuno is terminated other than for cause within 18 months of a change of control of our company, she will be entitled to receive a lump sum severance payment equal to 48 months of current base salary. Under this agreement, Dr. Kuno has assigned to us all inventions conceived or reduced to practice during the term of her employment that make use of confidential information or trade secrets or which relate to our actual or anticipated research and development.

*Dr. Ryuji Ueno.* Pursuant to an employment agreement effective June 16, 2006, we agreed to continue to employ Dr. Ueno as our Chief Operating Officer and Chief Scientific Officer for a term of three years. This agreement renews automatically each year for a period of one year unless earlier terminated by Dr. Ueno or us. Under this agreement, Dr. Ueno is entitled to receive an annual base salary of \$450,000, to be reviewed annually by our compensation committee and our board of directors and increased, but not decreased unless agreed by Dr. Ueno and us. Dr. Ueno is also eligible for an annual bonus of up to 50% of his base salary as determined by our independent directors based on the compensation committee's assessment of Dr. Ueno's achievement of annual corporate objectives. In addition, Dr. Ueno is entitled to receive, at the discretion of our compensation committee, restricted stock grants, options to purchase shares of our class A common stock and

other awards pursuant to our 2006 stock incentive plan once Dr. Ueno and Dr. Kuno own collectively less than 50% of our total equity, and also is eligible to participate in all employee benefit plans offered to other employees. In the event of a merger or sale of our company or the death of Dr. Ueno, all restricted stock and stock options issued to Dr. Ueno shall immediately vest. Upon termination or non-renewal by us of Dr. Ueno's employment other than for cause or upon termination by Dr. Ueno for specified good reasons, including diminution of authority and duties, Dr. Ueno will be entitled to receive a lump sum severance payment equal to 24 months of current base salary and to continue to receive full employment benefits for a period of 18 months after termination. If Dr. Ueno is terminated other than for cause within 18 months of a change of control of our company, Dr. Ueno will be entitled to receive a lump sum severance payment equal to 48 months of current base salary. Under this agreement, Dr. Ueno has assigned to us all inventions conceived or reduced to practice during the term of his employment that make use of confidential information or trade secrets or which relate to our actual or anticipated research and development.

Other Executive Employment Agreements. We also have entered into employment agreements with certain of our executive officers. Under an employment agreement with Mariam E. Morris, effective June 16, 2006, we agreed to employ Ms. Morris as our Chief Financial Officer and Treasurer at an annual base salary of \$160,000. Under an employment agreement with Brad E. Fackler, effective June 16, 2006, we agreed to employ Mr. Fackler as our Executive Vice President of Commercial Operations at an annual base salary of \$220,000. Under an employment agreement with Gayle R. Dolecek, effective June 16, 2006, we agreed to employ Dr. Dolecek as our Senior Vice President of Research and Development at an annual base salary of \$135,000. Under an employment agreement with Kei S. Tolliver, effective June 16, 2006, we agreed to employ Ms. Tolliver as our Vice President of Business Development and Company Operations and Secretary at an annual base salary of \$112,832. Under an employment agreement with Charles S. Hrushka, effective June 16, 2006, we agreed to employ Mr. Hrushka as our Vice President of Marketing at an annual base salary of \$165,000.

Each of these agreements has a term of two years, and renews automatically each year for a period of one year unless earlier terminated by the executive or us. Annual salaries under the agreements are to be reviewed annually by our compensation committee and our board of directors and increased, but not decreased unless agreed by the executive and us. Pursuant to these agreements, each executive is also eligible for an annual bonus as determined by our compensation committee based on his or her contribution to our company's success. The agreements also provide for eligibility to receive, at the discretion of our compensation committee, restricted stock grants, options to purchase shares of our class A common stock and other awards pursuant to our 2006 stock incentive plan, and eligibility to participate in all employee benefit plans offered to other employees. In the event of a merger or sale of our company or the death of the executive, all restricted stock and stock options issued to the executive shall immediately vest. Upon termination or non-renewal by us of employment other than for cause or upon termination by the executive for specified good reasons, including diminution of authority and duties, the executive will be entitled to receive a lump sum severance payment equal to two months of current base salary and to continue to receive full employment benefits for a period of two months after termination. If the executive is terminated other than for cause within 18 months of a change of control of our company, he or she will be entitled to receive a lump sum severance payment equal to four months of current base salary. Under these agreements, each executive has assigned to us all inventions conceived or reduced to practice during the term of his or her employment that make use of confidential information or trade secrets or which relate to our actual or anticipated research and development.

# **Stock Option and Other Compensation Plans**

#### 2001 Stock Incentive Plan

Our 2001 stock incentive plan, as amended and restated from time to time, was initially adopted by our board of directors and approved by our stockholders in February 2001. The plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock and other stock-based awards. A maximum of 1,000,000 shares of class A common stock are authorized for issuance under our 2001 plan.

As of May 31, 2006, there were options to purchase 253,600 shares of class A common stock outstanding under the 2001 plan and options to purchase 1,000 shares of class A common stock had been exercised. After the effective date of the 2006 stock plan described below, we will make no further stock option or other equity grants under the 2001 plan.

In accordance with the terms of the 2001 plan, our board of directors has authorized a committee of our board to administer the plan. In accordance with the provisions of the plan, our board or such committee will select the recipients of awards and determine:

- the number of shares of class A common stock covered by options and the dates upon which the options become exercisable;
- the exercise price of options;
- the duration of options;
- the method of payment of the exercise price; and
- the number of shares of class A common stock subject to any restricted stock or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price.

In addition, our board of directors or any committee to which the board of directors delegates authority may, with the consent of the affected plan participants, amend outstanding awards.

Except as our board of directors or any committee to which the board of directors delegates authority may otherwise determine or provide in an award, awards shall not be transferred by the person to whom they are granted, except by the laws of descent and distribution, except that our board or such committee may authorize a participant to transfer options, other than incentive stock options, or designate a beneficiary to exercise the rights of the participant on the death of the participant. Each award shall be exercisable during the life of the participant only by the participant or by the participant's legal representative, if permissible under applicable law.

Upon a merger or other reorganization event, our board of directors or any committee to which the board of directors delegates authority, may adjust the 2001 plan and any outstanding options to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the plan as either our board or the committee deems equitable. Such adjustments may include, where appropriate, changes in the number and type of shares subject to the plan and the number and type of shares subject to outstanding awards.

#### 2006 Stock Incentive Plan

Our 2006 stock incentive plan was adopted by our board of directors on June 5, 2006 and approved by our stockholders on , 2006. The 2006 plan will become effective on the date that the registration statement of which this prospectus forms a part is declared effective. The 2006 plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock, stock appreciation rights, restricted stock units and other stock-based awards. Upon effectiveness, 1,000,000 shares of class A common stock will be reserved for issuance under the 2006 plan.

In addition, the 2006 plan contains an "evergreen provision" which allows for an annual increase in the number of shares available for issuance under the plan on the first day of each of our fiscal years during the period beginning in fiscal year 2006 and ending on the second day of fiscal year 2014. The annual increase in the number of shares shall be equal to the lower of:

- 5% of the number of shares of class A and class B common stock outstanding on the first day of the fiscal year; and
- · an amount determined by our board of directors.

In accordance with the terms of the 2006 plan, our board of directors has authorized our compensation committee to administer the plan. In accordance with the provisions of the plan, our compensation committee will select the recipients of awards and determine:

- the number of shares of class A common stock covered by options and the dates upon which the options become exercisable;
- the exercise price of options;
- the duration of options;
- the method of payment of the exercise price; and
- the number of shares of class A common stock subject to any restricted stock or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price.

In addition, our board of directors or any committee to which the board of directors delegates authority may, with the consent of the affected plan participants, amend outstanding awards.

The maximum number of shares of class A common stock with respect to which awards may be granted to any participant under the plan during any calendar year is 500,000 shares.

The maximum term of an option may not exceed ten years. Except as our board of directors or any committee to which the board of directors delegates authority may otherwise determine or provide in an award, awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an incentive stock option, pursuant to a qualified domestic relations order, and, during the life of the participant, shall be exercisable only by the participant.

Upon a merger or other reorganization event, our board of directors or any committee to which the board of directors delegates authority, may, in its sole discretion, take any one or more of the following actions pursuant to our 2006 plan, as to some or all outstanding awards:

- provide that all outstanding awards shall be assumed or substituted by the successor corporation;
- upon written notice to a participant, provide that the participant's unexercised options or awards will become exercisable in full and will terminate immediately prior to the consummation of such transaction unless exercised by the participant;
- provide that outstanding awards will become realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the reorganization event;
- in the event of a merger pursuant to which holders of our class A common stock will receive a cash payment for each share surrendered in the merger, make or provide for a cash payment to the participants equal to the difference between the merger price times the number of shares of our class A common stock subject to such outstanding awards (to the extent then exercisable at prices not in excess of the merger price), and the aggregate exercise price of all such outstanding awards, in exchange for the termination of such awards; and
- provide that, in connection with a liquidation or dissolution, awards convert into the right to receive liquidation proceeds.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights under each outstanding restricted stock award will continue for the benefit of the successor company and will apply to the cash, securities or other property into which our common stock is converted pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted stock award.

#### 2006 Employee Stock Purchase Plan

Our 2006 employee stock purchase plan was adopted by our board of directors on June 5, 2006 and approved by our stockholders on , 2006. The purchase plan will become effective on the date that the registration statement of which this prospectus forms a part is declared effective. Upon effectiveness, 500,000 shares of class A common stock will be reserved for issuance to participating employees under the purchase plan.

All of our employees, including our directors who are employees and all employees of any of our participating subsidiaries, who have been employed by us for at least three months prior to enrolling in the purchase plan, and whose customary employment is for more than 20 hours a week and for more than five months in any calendar year, will be eligible to participate in the purchase plan. Employees who would, immediately after being granted an option to purchase shares under the purchase plan, own 5% or more of the total combined voting power or value of our common stock will not be eligible to participate in the purchase plan.

We will make one or more offerings to our employees to purchase stock under the purchase plan. Offerings will begin on each January 1, April 1, July 1 and October 1, or the first business day thereafter, commencing October 1, 2007. Each offering commencement date will begin a three-month period during which payroll deductions will be made and held for the purchase of the common stock at the end of the purchase plan period.

On the first day of a designated payroll deduction period, or offering period, we will grant to each eligible employee who has elected to participate in the purchase plan an option to purchase shares of our common stock. The employee may authorize up to the lesser of (a) 10% of his or her compensation and (b) \$6,250 to be deducted by us during the offering period. On the last day of the offering period, the employee will be deemed to have exercised the option, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the purchase plan, the option exercise price shall be determined by our board of directors and shall not be less than the lower of 85% of the closing price, as defined in the purchase plan, of our class A common stock on the first day of the offering period or on the last day of the offering period. The plan establishes a default price of 95% of the closing price of our class A common stock on the last day of the offering period, but the board of directors may establish a larger discount, subject to the limits in the previous sentence. If the board of directors did elect to provide a larger discount, we would likely incur accounting charges.

Upon a merger or other reorganization event, our board of directors or any committee to which the board of directors delegates authority, may, in its sole discretion, take any one or more of the following actions pursuant to our purchase plan, as to some or all outstanding options to purchase stock:

- provide that all outstanding options shall be assumed or substituted by the successor corporation;
- upon written notice to a participating employee, provide that the employee's unexercised options will become exercisable to the extent of accumulated payroll deductions as of a date at least ten days before the consummation of such transaction, and will terminate as of the effective date of such transaction unless exercised by the employee;
- upon written notice to a participating employee, provide that the employee's unexercised options will be cancelled prior to the consummation of such transaction and that all accumulated payroll deductions will be returned to the employee;
- in the event of a merger pursuant to which holders of our class A common stock will receive a cash payment for each share surrendered in the merger, make or provide for a cash payment to the participating employees equal to the difference between the merger price times the number of shares of our class A common stock subject to such outstanding options (to the extent then exercisable at prices not in excess of the merger price), and the aggregate exercise price of all such outstanding options, in exchange for the termination of such options; and

• provide that, in connection with a liquidation or dissolution, options convert into the right to receive liquidation proceeds.

An employee who is not a participant on the last day of the offering period will not be entitled to exercise any option, and the employee's accumulated payroll deductions will be refunded. An employee's rights under the purchase plan will terminate upon voluntary withdrawal from the purchase plan at any time, or when the employee ceases employment for any reason, except that upon termination of employment because of death, the balance in the employee's account will be paid to the employee's beneficiary.

# Limitation of Liability and Indemnification of Officers and Directors

Our certificate of incorporation that will be in effect upon completion of this offering limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law. Our certificate of incorporation provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of their duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for voting or assenting to unlawful payments of dividends or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act or failure to act, or any cause of action, suit or claim that would accrue or arise prior to any amendment or repeal or adoption of an inconsistent provision. If the Delaware General Corporation Law is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the Delaware General Corporation Law.

In addition, our certificate of incorporation provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

There is no pending litigation or proceeding involving any of our directors or executive officers to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Since January 1, 2003, we have engaged in the following transactions with our directors, executive officers and holders of more than 5% of our voting securities and their affiliates.

# **Stock Issuances and Transfers**

From March 31, 2006 through April 12, 2006, we issued and sold 282,207 shares of our class A common stock at a price per share of \$85.00 for an aggregate purchase price of \$24.0 million. The following table sets forth the number of shares of our class A common stock sold to our 5% stockholders and their affiliates in these transactions.

	Number of Shares		
	of Class A	1	Aggregate
Name	Common Stock	Purchase Price	
OPE Partners Limited	70,588	\$	5,999,980
Tokio Marine and			
Nichido Fire Insurance Co., Ltd.	100,000		8,500,000
Mizuho Capital Co., Ltd.	35,295		3,000,075

On March 31, 2006, R-Tech Ueno, Ltd., or R-Tech, one of our principal stockholders and a company a majority of the stock of which is owned, directly and indirectly, by our founders Drs. Ueno and Kuno, sold a total of 134,100 shares of our class A common stock to three investors at a price per share of \$85.00 for an aggregate purchase price of \$11,398,500. Included in these sales were 70,588 shares of our class A common stock sold to OPE Partners Limited for an aggregate purchase price of \$5,999,980.

Mr. Hidetoshi Mine, one of our directors, is the Managing Director of Principal Investment at OPE Partners Limited.

Tokio Marine and Nichido Fire Insurance Co., Ltd. did not have a relationship with our company prior to its purchase of shares on March 31, 2006.

In connection with the issuance and transfer of the above described shares, we granted registration rights to the investors, made representations and warranties to them and waived rights of first refusal we had with respect to the shares transferred by R-Tech. For a more detailed description of the registration rights we have granted, see "Description of Capital Stock — Registration Rights".

### **Sucampo Group Reorganization**

On May 12, 2006, our board of directors approved a transaction to acquire all of the capital stock of our affiliated European and Asian operating companies, Sucampo Pharma Europe Ltd., or Sucampo Europe, and Sucampo Pharma, Ltd., or Sucampo Japan. Each of Sucampo Europe and Sucampo Japan is wholly owned, indirectly, by Drs. Ueno and Kuno. This transaction has not yet closed, but will be completed prior to the closing of this offering. Prior to the completion of this reorganization, we were conducting our operations as one of three related operating companies, each focused on developing and commercializing prostones licensed from Sucampo AG in separate territories.

In anticipation of this offering, our board approved the reorganization, which will involve:

- the issuance of 211,765 additional shares of our class A common stock to S&R Technology Holdings, LLC, an entity wholly owned by Drs. Ueno and Kuno and the sole stockholder of Sucampo Europe and Sucampo Japan, in exchange for the shares of these two companies, following which these two companies will be wholly owned subsidiaries of our company;
- the amendment of our license with Sucampo AG, as described more fully below, to provide that our company, together with its new wholly owned subsidiaries, has exclusive worldwide license rights to commercialize and develop AMITIZA, SPI-8811 and SPI-017 and all other prostone compounds covered by patents and patent applications held by Sucampo AG; and

• the transfer of personnel of Sucampo AG who perform research in the field of prostones to Sucampo Japan, the company that will be our Asian subsidiary following completion of the reorganization, and the assumption by us of the filing and maintenance costs relating to the patent portfolio licensed by us from Sucampo AG.

### License Agreements with Sucampo AG

We have entered into several transactions with Sucampo AG. Sucampo AG is wholly owned by Drs. Ueno and Kuno.

### SPI-8811 License

In November 2000, we entered into a license agreement with Sucampo AG which granted to us a royalty-bearing, exclusive license, with the right to sublicense, to develop and commercialize various prostone compounds, including SPI-8811, and accompanying knowhow in North and South America. In consideration of the license, we were required to make an upfront payment of \$250,000 to Sucampo AG in respect of SPI-8811 and a specified milestone payment upon the first NDA submission for this compound. Similar upfront and milestone payments were required for other compounds included in the license. In addition, we were required to pay Sucampo AG, on a country-by-country basis, a royalty of 6.5% of net sales for compounds covered by unexpired patents, or 3% of net sales for compounds not covered by unexpired patents. This royalty obligation was to continue until all patents covering compounds included in the license had expired or until ten years from the first commercial sale of a licensed product within the relevant country, whichever was later. Under the terms of the agreement, Sucampo AG was granted the right to utilize any know-how relating to licensed compounds developed by us during the term of the agreement. In addition, upon termination of the agreement for any reason, Sucampo AG was granted the right to purchase any regulatory approvals obtained by us for a licensed compound at fair market value.

# Sucampo AG License

In February 2004, together with Sucampo Europe and Sucampo Japan, we entered into a license agreement with Sucampo AG. The agreement granted to each company, within its respective territory, a royalty-bearing, exclusive license, with the right to sub-license, to develop and commercialize Sucampo AG's patent portfolio and accompanying know-how as it existed on September 1, 2003. Pursuant to this agreement, we were granted the right to develop and commercialize Sucampo AG's technology in North, Central and South America, including the Caribbean, while Sucampo Europe and Sucampo Japan were granted rights to develop and commercialize this technology in Asia, Europe and the rest of the world. Under the agreement, each company was obligated to assign to Sucampo AG any improvement patents that it developed from the licensed technology, which Sucampo AG would in turn license back to all three companies. The agreement also granted to each company an exclusive option to license all other future patents developed or acquired by Sucampo AG. In consideration of the license, each company was required to make specified milestone payments to Sucampo AG and pay Sucampo AG, on a country-by-country basis, a royalty of 6.5% of net sales. The agreement also provided for the sharing of certain regulatory information related to licensed technology between the three licensees and the payment of specified royalties in connection with shared information.

In January 2006, we paid Sucampo AG \$250,000 upon receipt of marketing approval from the FDA for AMITIZA for the treatment of chronic idiopathic constipation in adults.

# **AMITIZA License**

In October 2004, we entered into a license agreement with Sucampo AG which granted to us a royalty-bearing, exclusive license, with the right to sublicense, to develop and commercialize AMITIZA and accompanying know-how in North, Central and South America, including the Caribbean. Under the agreement, we were obligated to assign to Sucampo AG any improvement patents that we developed from AMITIZA, which Sucampo AG would in turn license back to us. In consideration of the license, we were required to make milestone payments to Sucampo AG upon obtaining marketing approval in the United States for each

new indication for AMITIZA and were required to pay Sucampo AG 5% of any up-front or milestone payments that we in turn received from our sublicensees. We also were required to pay Sucampo AG, on a country-by-country basis, a royalty of 3.2% of net sales.

In October 2004, we sublicensed AMITIZA and accompanying know-how to Takeda Pharmaceutical Company Limited, or Takeda, for marketing in the United States and Canada for the treatment of gastrointestinal indications, and received \$20.0 million in up-front payments. At that time, we paid Sucampo AG \$1.0 million, reflecting their 5% share of the up-front payment. Since October 2004, we also have paid Sucampo AG an aggregate of \$2.8 million, reflecting their 5% share of the aggregate of \$50.0 million of development milestones that we have received from Takeda through March 31, 2006 and the \$250,000 that we received from Takeda upon marketing approval for AMITIZA by the FDA for the treatment of chronic idiopathic constipation in adults.

### SPI-017 License

In April 2005, we entered into a letter of intent with Sucampo AG to license SPI-017 for development and commercialization in North, Central and South America, including the Caribbean. Upon signing the letter of intent, we paid Sucampo AG a \$400,000 non-refundable up-front payment.

In February 2006, we entered into a definitive license agreement with Sucampo AG with respect to SPI-017. Under this agreement, Sucampo AG granted to us a royalty-bearing, exclusive license, with the right to sublicense, to develop and commercialize SPI-017 and accompanying know-how in North, Central and South America, including the Caribbean. Sucampo AG also granted to us an exclusive option until February 2008 to license SPI-017 for development and commercialization outside of this territory. Pursuant to the agreement, we were obligated to assign to Sucampo AG any improvement patents that we developed from this compound, which Sucampo AG would in turn license back to us. In consideration of the license, we made an upfront payment of \$1.1 million to Sucampo AG. In addition, under the terms of the agreement, we were required to make specified milestone payments to Sucampo AG, or, in the event that we sublicensed any of our rights under the agreement to a third party, to pay Sucampo AG 5% of any up-front or milestone payments that we in turn received from our sublicensees. We also were required to pay Sucampo AG, on a country-by-country basis, a royalty of 6.5% of net sales.

### Restated Sucampo AG License

We, together with Sucampo Europe and Sucampo Japan, have entered into a restated license agreement with Sucampo AG, which will become effective immediately prior to the closing of this offering. This agreement supersedes all previous license and data sharing arrangements between the parties and functions as a master license agreement with respect to Sucampo AG's prostone technology. Under the agreement, Sucampo AG has granted to us and our wholly owned subsidiaries a royalty-bearing, exclusive, worldwide license, with the right to sublicense, to develop and commercialize AMITIZA, SPI-8811 and SPI-017 and all other prostone compounds covered by patents and patent applications held by Sucampo AG. For additional information regarding our restated license agreement with Sucampo AG, see "Business — License from Sucampo AG".

# Manufacturing Agreement with R-Tech Ueno, Ltd.

In June 2004, we entered into a 20-year exclusive supply agreement with R-Tech. Under this agreement we granted to R-Tech the exclusive right to manufacture and supply AMITIZA to meet our commercial and clinical requirements in North, Central and South America, including the Caribbean. In consideration of these exclusive rights, R-Tech has paid to us an aggregate of \$6.0 million in milestone payments as of March 31, 2006.

In June 2005, Sucampo Europe entered into an exclusive supply agreement with R-Tech on terms substantially similar to those described above to manufacture and supply AMITIZA to meet Sucampo Europe's commercial and clinical requirements in Europe, the Middle East and Africa. In consideration of these exclusive rights, R-Tech paid to Sucampo Europe a \$2.0 million up-front payment in March 2005 in anticipation of execution of the agreement.

We, Sucampo Europe and Sucampo Japan have each entered into new or restated supply agreements with R-Tech, which will become effective immediately prior to the closing of this offering. These agreements grant to R-Tech the exclusive right to manufacture and supply each company's commercial and clinical requirements for AMITIZA and clinical requirements for SPI-8811 and SPI-017. For additional information regarding our supply agreements with R-Tech, see "Business — Manufacturing".

### **Loans from Related Parties**

In October 2000, we entered into a note agreement with R-Tech pursuant to which we borrowed \$1.3 million. The rate of interest charged on the note was two percentage points per annum on the outstanding principal balance. Principal and interest were due in eight semi-annual installments of \$158,275 each, commencing on April 1, 2001. We repaid the note in full on December 31, 2004.

In August 2003, Sucampo Japan entered into a note agreement with Sucampo AG pursuant to which Sucampo Japan borrowed \$2.5 million. The rate of interest on the note originally was 1% in excess of the six-month Tokyo Interbank Offered Rate (TIBOR) per annum on the outstanding principal balance. Principal and interest were due within six months from the date of the agreement; however, the maturity date on the note was to be extended automatically for an additional six-month period, up to two years. In August 2005, Sucampo Japan executed an addendum to the note agreement that extended the term of the note until July 31, 2007. The rate of interest charged on the note also was amended and is now equal to the minimum rate of interest permitted by the Swiss Federal Tax Administration per annum on the outstanding principal balance. As of March 31, 2006, approximately \$2.5 million remained outstanding on the note

In February and March 2004, S&R Technology Holdings, LLC entered into two separate subscription agreements to purchase three-year convertible bonds issued by Sucampo Japan with an aggregate face value of \$1.0 million. Interest on the bonds was payable by Sucampo Japan every six months at a rate of 0.5% per annum, the market rate of interest in Japan. The bonds were convertible into common stock of Sucampo Japan at a specified conversion price per bond. Sucampo Japan repaid the bonds in full by December 2005 and all conversion rights were cancelled.

In May 2004, Sucampo Europe entered into a three-year loan facility agreement with S&R Technology Holdings, LLC pursuant to which Sucampo Europe borrowed \$603,919 in May 2004 and \$613,925 in July 2004. The rate of interest on the facility was Euro LIBOR plus 0.5% per annum. Principal and interest were repayable at any time during the three-year term of the facility, and the note was repaid in full in December 2005.

In July 2004, Sucampo Europe entered into a note agreement with Sucampo AG pursuant to which Sucampo Europe borrowed \$843,414. The rate of interest on the note was equal to the minimum rate of interest permitted by the Swiss Federal Tax Administration per annum on the outstanding principal balance. Principal and interest were due within six months from the date of the agreement; however, the maturity date on the note was to be extended automatically for an additional six-month period, up to two years. As of March 31, 2006, the note had been extended to July 1, 2006 and approximately \$850,000 remained outstanding on the note.

In February 2006, Sucampo Europe entered into a note agreement with Sucampo AG pursuant to which Sucampo Europe borrowed \$1.2 million. The rate of interest on the note was equal to the minimum rate of interest permitted by the Swiss Federal Tax Administration per annum on the outstanding principal balance. Principal and interest were due within six months from the date of the agreement; however, the maturity date on the note was to be extended automatically for an additional six-month period, up to two years. As of March 31, 2006, the note had been extended to July 1, 2007 and approximately \$1.2 million remained outstanding on the note.

### **Data Purchase Agreements**

In March 2003, we entered into a data purchase agreement with Sucampo Japan whereby we exchanged data related to our Phase II clinical trials of AMITIZA for the treatment of irritable bowel syndrome with

constipation for all non-clinical data owned by Sucampo Japan relating to AMITIZA and SPI-8811. In consideration for this exchange, we agreed to pay Sucampo Japan an aggregate of \$2.3 million in installment payments. Sucampo Japan in turn agreed to pay us the greater of \$1.0 million or 20% of the cost of conducting Phase II trials of AMITIZA for the treatment of irritable bowel syndrome with constipation on the earlier to occur of March 31, 2003 or commencement of the clinical trials. In addition, Sucampo Japan agreed to pay us 1.0% of future net sales of AMITIZA in Asia for the treatment of irritable bowel syndrome with constipation. During the first quarter of 2006, we paid Sucampo Japan the final installment of the \$2.3 million purchase price for its data. In 2003, Sucampo Japan paid us \$1.0 million for our data. AMITIZA has not been commercialized in Asia, and no royalties have been paid to us in respect of the product's sale in this territory.

In April 2003, we entered into a data purchase agreement with Sucampo Japan whereby we purchased all clinical and non-clinical data owned by Sucampo Japan relating to RUG-015, a prostone compound that we are no longer developing. In consideration for this data, we agreed to pay Sucampo Japan an aggregate of \$1.0 million in installment payments. In addition, we and Sucampo Japan agreed to share the costs of, and any data resulting from, the development of RUG-15 in the United States and entered into a joint development agreement in July 2003 to further clarify our rights and responsibilities in this regard. In January 2004, we paid Sucampo Japan the final installment of the \$1.0 million purchase price for the company's data. In March 2005, we determined to discontinue any further research and development related to RUG-015 and received no further cost reimbursements from Sucampo Japan in respect of this compound.

### **Research and Consulting Agreements**

In September 2002, we entered into a consulting agreement with R-Tech whereby R-Tech agreed to provide us with business advisory services for a specified quarterly fee. We paid an aggregate of \$480,000 in consulting fees to R-Tech under this agreement. The agreement was terminated in March 2004.

In October 2002, Sucampo Japan entered into a services agreement with R-Tech whereby Sucampo Japan agreed to perform marketing, regulatory and intellectual property support services for R-Tech relating to RESCULA for a specified monthly fee. Sucampo Japan received an aggregate of \$2.8 million in fees from R-Tech under this agreement. The agreement was terminated in August 2003.

In January 2003, Sucampo Japan entered into a services agreement with Sucampo AG whereby Sucampo Japan agreed to perform patent and trademark maintenance services for Sucampo AG for a specified monthly fee. Sucampo Japan received an aggregate of \$104,000 in fees from Sucampo AG under this agreement. The agreement was terminated in August 2003.

In September 2003, we entered into a research agreement with Sucampo AG whereby we agreed to perform pharmaceutical research services for Sucampo AG for a specified monthly fee. Under the terms of the agreement, all research and inventions conceived by Dr. Ueno during the term of the agreement were to be owned by Sucampo AG. We received an aggregate of \$324,000 in fees from Sucampo AG under this agreement in 2004. The agreement was terminated in August 2004.

In April 2005, we entered into a consulting agreement with Sucampo AG whereby Sucampo AG agreed to provide us with intellectual property advisory services for a specified monthly fee. As of March 31, 2006, we had paid an aggregate of \$60,000 in consulting fees to Sucampo AG under this agreement.

# Agency Agreements with Sucampo Europe and Sucampo Japan

In October 2004, we entered into an agency agreement with Sucampo Europe to negotiate on Sucampo Europe's behalf with Takeda for rights to jointly develop and commercialize AMITIZA for gastrointestinal indications in Europe, the Middle East and Africa. In consideration for our services, Sucampo Europe agreed to pay us 3.5% of the \$3.0 million option fee paid by Takeda to Sucampo Europe in respect of these negotiation rights. In the event that a collaboration and license agreement was entered into by Takeda and Sucampo Europe, without any repayment of the option fee, Sucampo Europe agreed to pay us an additional 3.5% agency fee. In December 2004, we received \$105,000 from Sucampo Europe as an initial agency fee. In

January 2006, the option between Takeda and Sucampo AG expired without agreement, and we received no further agency fees under this agreement.

In October 2004, we entered into an agency agreement with Sucampo Japan to negotiate on Sucampo Japan's behalf with Takeda for rights to jointly develop and commercialize AMITIZA for gastrointestinal indications in Asia. In consideration for our services, Sucampo Japan agreed to pay us 3.5% of the \$2.0 million option fee paid by Takeda to Sucampo Japan in respect of these negotiation rights. In the event that a collaboration and license agreement was entered into by Takeda and Sucampo Japan, without any repayment of the option fee, Sucampo Japan agreed to pay us an additional 3.5% agency fee. In December 2004, we received \$70,000 from Sucampo Japan as an initial agency fee. In October 2005, the option between Takeda and Sucampo AG expired without agreement, and we received no further agency fees under this agreement.

### **RESCULA Patent Disposal**

In October 2000, we purchased U.S. patents relating to RESCULA from R-Tech for a purchase price of \$954,865. As a result of declining royalty revenues associated with these patents, we determined that we would be unable to recover the costs of these patents from expected future cash flows and, in August 2004, assigned our rights in the RESCULA patents to Sucampo AG for a purchase price of \$497,000. We recognized \$36,409 in royalty revenues from the RESCULA patents in the year ended December 31, 2003 and no royalties from these patents in the year ended December 31, 2004.

# **Director Compensation**

See "Management — Director Compensation" for a discussion of compensation paid to our non-employee directors.

# **Executive Compensation and Employment Agreements**

See "Management — Executive Compensation" for additional information on compensation of our executive officers. Information regarding employment agreements with our executive officers is set forth under "Management — Employment Agreements."

### PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding the beneficial ownership of our class A and class B common stock as of May 31, 2006 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our class A common stock or our class B common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and named executive officers as a group.

The percentages shown are based on 1,412,222 shares of class A common stock and 3,081,300 shares of class B common stock outstanding as of May 31, 2006, after giving effect to the conversion of all outstanding shares of convertible preferred stock into 378,000 shares of class A common stock, which will occur automatically upon the closing of this offering, and the issuance of 211,765 shares of class A common stock in connection with our acquisition of Sucampo Europe and Sucampo Japan, but assuming no exercise of outstanding options, and shares of class A common stock outstanding after this offering, including the shares being offered for sale by us in this offering. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, and includes voting and investment power with respect to shares. The number of shares beneficially owned by a person includes shares subject to options held by that person that are currently exercisable or exercisable within 60 days of May 31, 2006. The shares issuable under those options are treated as if they were outstanding for computing the percentage ownership of the person holding those options but are not treated as if they were outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated below, to our knowledge, the persons or entities in this table have sole voting and investing power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law.

Except as otherwise set forth below, the address for the beneficial owner listed is c/o Sucampo Pharmaceuticals, Inc., 4733 Bethesda Avenue, Suite 450, Bethesda, Maryland 20814.

Beneficial Owner	Shares Beneficially Owned A Shares B Shares		Percentage Beneficially Prior to the A Shares	y Owned	Percentage of Shares Beneficially Owned After the Offering A Shares B Shares		of Total Voting Power after the Offering
5% holders:				,			
R-Tech Ueno, Ltd.(1) 10F, Yamato Life Insurance Building 1-1-7 Uchisaiwaicho, Chiyoda-ku Tokyo 100-0011 Japan	365,900	_	25.9%	_		_	%
S&R Technology Holdings, LLC(2) 7201 Wisconsin Avenue Suite 700 Bethesda, Maryland 20814	220,265	3,081,300	15.6	100.0%		100.0%	
OPE Partners Limited World Trade Center Building 37F 2-4-1 Hamamatsu-cho Minato-ku, Tokyo 105-6137 Japan	233,376(3)	_	16.5	_		_	
Astellas Pharma, Inc. 3-11 Nihonbashi-Honcho 2-chome Chuo-ku, Tokyo 103-8411 Japan	147,500	_	10.4	_		_	

Percentage

	Shares Ber Own	3	Percentage Beneficial Prior to th	ly Owned	Percentag Beneficia After th	of Total Voting Power after the	
Beneficial Owner	A Shares	B Shares	A Shares	B Shares	A Shares	B Shares	Offering
Tokio Marine and Nichido Fire Insurance Co., Ltd. West 14th Floor, Otemachi First Square 5-1, Otemachi 1-chome Chiyoda-ku, Tokyo 100-0004 Japan	100,000	_	7.1%	_		-	
Mizuĥo Capital Co., Ltd. 4-3, Nihonbashi-Kabutocho Chuo-ku, Tokyo 103-0026 Japan	90,595(4)	_	6.4	_		_	
Mitsubishi UFJ Capital Co., Ltd.(5) 2-14-1 Kyobashi, Kanematsu Building 9th Floor Chuo-Ku, Tokyo 104-0031 Japan	83,000	_	5.9	_		_	
Directors and Executive Officers:							
Sachiko Kuno	615,665(6)	3,081,300(7)	42.7	100.0%		100.0%	
Ryuji Ueno	654,165(8)	3,081,300(7)	44.2	100.0		100.0	
Mariam E. Morris	4,000(9)	_	*	_	*	_	
Brad E. Fackler	4,000(10)	_	*	_	*	_	
Gayle R. Dolecek	17,500(11)	_	*	_	*	_	
Kei S. Tolliver	3,750(12)	_	*	_	*	_	
Charles S. Hrushka	1,000(13)	_	*	_	*		
Michael J. Jeffries	_	_	_	_		_	
Timothy I. Maudlin**	_	_	_	_		_	
Hidetoshi Mine	233,376(14)	_	16.5	_		_	
V. Sue Molina**	_	_	_	_		_	
Gregory D. Perry	_	_	_	_		_	
All current executive officers and directors as a group (12 persons)	947,291(15)	3,081,300(7)	61.5	100.0		100.0	

Percentage

- (2) Voting and dispositive power with respect to the shares held by S&R Technology Holdings, LLC is shared by Dr. Sachiko Kuno and Dr. Ryuji Ueno.
- (3) Consists of 92,200 shares held by OPE Limited Partnership 1 and 141,176 shares held by OPE Limited Partnership 2. OPE Partners Ltd. is the general partner of both OPE Limited Partnership 1 and OPE Limited Partnership 2. Voting and dispositive power with respect to the shares held by each of these limited partnerships is shared by the seven managing members of OPE Partners Ltd., who are Hidetoshi Mine, one of our directors, Kenji Ogawa, Mitsunaga Tada, Kiyoyuki Katsumata, Koji Abe, Isao Nishimuta and Takumi Sakagami.
- (4) Consists of 51,230 shares held by Mizuho Capital Co., Ltd., 27,600 shares held by MHCC No. 3 Limited Liability Fund, and 11,765 shares held by Mizuho Capital No. 2 Limited Partnership. Osamu Kita, President of Mizuho Capital Co., Ltd., has sole voting and dispositive power over the shares held by Mizuho Capital Co., Ltd. and, in his capacity as President of Mizuho Capital Co., Ltd., the General Partner of Mizuho Capital No. 2 Limited Partnership and MHCC No. 3 Limited Liability Fund, also has sole voting and dispositive power over the shares held by those entities.
- (5) The president of Mitsubishi UFJ Capital Co., Ltd., Takao Wada, has voting power over the shares held by Mitsubishi UFJ Capital Co., Ltd. Investment power over the shares held by Mitsubishi UFJ Capital Co., Ltd. is held by its board of directors, which consists of Takao Wada, Kazuhiko Tokita, Takahiro Kagawa, Masahito Kawashima, Yasuhiko Arai, Tomohiko Ikeda, Akira Naito, Noriaki Hanamizu, Teruyuki Shirakawa, Kimitoshi Sato, Shotaro Yoshimura, and Eiichi Takahashi.

<sup>\*</sup> Represents beneficial ownership of less than 1%.

<sup>\*\*</sup> Will join the board of directors in September 2006.

<sup>(1)</sup> Voting and dispositive power with respect to the shares held by R-Tech Ueno, Ltd. is held by its board of directors, which consists of Shuji Inoue, Yukiko Hashitera, Yukihiko Mashima, Ryu Hirata, Yoshiaki Yamana and Toshio Iwasaki.

- (6) Includes 29,500 shares issuable upon exercise of stock options exercisable within 60 days of May 31, 2006. Also includes 220,265 shares held by S&R Technology Holdings, LLC and 365,900 shares held by R-Tech Ueno, Ltd., as to both of which Dr. Kuno shares voting and investment control.
- (7) Consists of 3,081,300 shares held by S&R Technology Holdings, LLC, as to which Drs. Kuno and Ueno share voting and investment control.
- (8) Includes 68,000 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2006. Also includes 220,265 shares held by S&R Technology Holdings, LLC and 365,900 shares held by R-Tech Ueno, Ltd., as to both of which Dr. Ueno shares voting and dispositive control.
- (9) Consists of 4,000 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2006.
- (10) Consists of 4,000 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2006.
- (11) Consists of 17,500 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2006.
- (12) Consists of 3,750 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2006.
- (13) Consists of 1,000 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2006.
- (14) Consists of 92,200 shares held by OPE Limited Partnership 1 and 141,176 shares held by OPE Limited Partnership 2. Mr. Mine is the President and one of the managing members of the general partner of both of these limited partnerships and, as such, shares voting and dispositive control of these shares.
- (15) Includes 127,750 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2006.

### **DESCRIPTION OF CAPITAL STOCK**

The following description of our common stock and provisions of our certificate of incorporation and by-laws are summaries and are qualified by reference to the certificate of incorporation and the by-laws that will be in effect upon completion of this offering. Copies of these documents have been filed with the Securities and Exchange Commission as exhibits to our registration statement, of which this prospectus forms a part. The description of the common stock reflects changes to our capital structure that will become effective upon the closing of this offering.

Upon the completion of this offering, our authorized capital stock will consist of 270,000,000 shares of class A common stock, par value \$0.01 per share, 75,000,000 shares of class B common stock, par value \$0.01 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share, all of which preferred stock will be undesignated.

### **Common Stock**

As of May 31, 2006, there were 822,457 shares of class A common stock outstanding held by 18 stockholders of record and 3,081,300 shares of class B common stock outstanding held by one stockholder of record. Based upon the number of shares outstanding as of that date, and giving effect to the conversion of all outstanding shares of convertible preferred stock into 378,000 shares of class A common stock, which will occur automatically upon the closing of this offering, the issuance of 211,765 shares of class A common stock in connection with our acquisition of Sucampo Europe and Sucampo Japan and the issuance of the shares of class A common stock offered by us in this offering, there will be shares of class A common stock and 3,081,300 shares of class B common stock outstanding upon the completion of this offering. All of our class B common stock is beneficially held by S&R Technology Holdings, LLC, an entity wholly owned and controlled by Drs. Kuno and Ueno.

Our common stock is divided into two classes, class A common stock and class B common stock. Holders of class A common stock and class B common stock have identical rights, except that holders of class A common stock are entitled to one vote per share held of record and holders of class B common stock are entitled to ten votes per share held of record on all matters submitted to a vote of the stockholders. The holders of class A common stock and the holders of class B common stock do not have cumulative voting rights. Directors are elected by a plurality of the votes of the shares present in person or by proxy at the meeting and entitled to vote in such election. Subject to preferences that may be applicable to any outstanding preferred stock, holders of class A common stock and class B common stock are entitled to receive ratably such dividends, if any, as may be declared by the board of directors out of funds legally available to pay dividends. Upon our liquidation, dissolution, or winding up, the holders of class A common stock and class B common stock are entitled to receive ratably all assets after the payment of our liabilities, subject to the prior rights of any outstanding preferred stock. Holders of class A common stock and class B common stock have no preemptive, subscription, redemption, or conversion rights, except the right to have class B common stock converted into class A common stock as described below. They are not entitled to the benefit of any sinking fund. The outstanding shares of common stock are, and the shares of class A common stock offered by us in this offering will be, when issued and paid for, validly issued, fully paid, and nonassessable. The rights, powers, preferences, and privileges of holders of class A common stock and class B common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Shares of class B common stock may be converted by their holder into a like number of shares of class A common stock at any time. In addition, any shares of class B common stock that are transferred after this offering will, immediately upon transfer, automatically convert into a like number of shares of class A common stock, except that a holder of the class B common stock may:

• transfer shares to a trust organized for the benefit of members of the families of Drs. Kuno and Ueno or for charitable purposes if either or both of Drs. Kuno or Ueno continue to control the trust after the transfer, subject to the shares later being automatically converted if the trust ceases to be controlled by either or both of Drs. Kuno or Ueno; or

• pledge shares to secure a bona fide loan, subject to the shares later being automatically converted if the pledgee forecloses on the shares

In addition, shares of class B common stock will convert automatically into a like number of shares of class A common stock upon the first to occur of the following events:

- the close of business on the day upon which one of the following events has occurred with respect to each of Dr. Kuno and Dr. Ueno:
  - her or his death;
  - her or his being judicially declared legally incompetent or the appointment of a conservator, receiver, custodian or guardian to supervise or control her or his financial affairs; or
  - she or he has ceased to be affiliated with our company as an employee, director or consultant; or
- the close of business on the day upon which the number of outstanding shares of class B common stock is less than 20% of the number of outstanding shares of class A and class B common stock together.

Once converted to class A common stock, the class B common stock will be cancelled and not reissued. Without separate class votes of the holders of each class of common stock, none of either the class A common stock or the class B common stock may be subdivided or combined unless the shares of the other class are subdivided or combined in the same proportion. The class B common stock is not being registered as part of this offering and currently we have no plans to do so in the future.

Without separate class votes of the holders of each class of common stock, we may not make any dividend or distribution to any holder of either class of common stock unless simultaneously with such dividend or distribution we make the same dividend or distribution with respect to each outstanding share of the other class of common stock; provided, however, that dividends of voting securities may differ in the same manner that the shares of class A and class B common stock differ. In the case of a dividend or other distribution payable in shares of a class of common stock, only shares of class A common stock may be distributed with respect to class B common stock. Whenever a dividend or distribution is payable in shares of a class of common stock, the number of shares of each class of common stock payable per shares of such class of common stock shall be equal in number.

In the event of a merger or consolidation of our company with or into another entity, whether or not our company is the surviving entity, the holders of class A common stock shall be entitled to receive the same per-share consideration as the per-share consideration, if any, received by any holder of the class B common stock in such merger or consolidation; provided, however, that if the merger consideration consists of voting securities, the terms of such securities may differ in the same manner that the class A and class B common stock differ.

No additional shares of class B common stock may be issued after this offering except in connection with a stock split or stock dividend on the class B common stock in which the class A common stock is similarly split or receives a similar dividend.

At present, there is no established trading market for the class A common stock. We have filed an application to list our shares of class A common stock on the NASDAQ Global Market under the symbol "SCMP".

# **Preferred Stock**

Under the terms of our certificate of incorporation, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon completion of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

## **Registration Rights**

Upon the closing of this offering, holders of an aggregate of 794,307 shares of our class A common stock will have the right to require us to register these shares under the Securities Act under specified circumstances. If we register any of our common stock, either for our own account or for the account of other securityholders, these stockholders are entitled to notice of the registration and to include their shares of common stock in the registration. In addition, these stockholders may from time to time make demand for registration on Form S-3, a short form registration statement, when we are eligible to use this form.

With specified exceptions, a holder's right to include shares in a registration is subject to the right of the underwriters to limit the number of shares included in this offering. All fees, costs and expenses of any of these registrations will be paid by us, and all selling expenses, including underwriting discounts and commissions, will be paid by the holders of the securities being registered.

### **Anti-Takeover Provisions**

### **Delaware Law**

We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 imposes a supermajority vote in order for a publicly held Delaware corporation to engage in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our board of directors or unless the business combination was approved by our board of directors prior to the time such person became interested. The vote required is two-thirds of the voting power not held by the interested stockholder. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" or the sale of more than 10% of our assets to the interested stockholder. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting power and any entity or person affiliated with or controlling or controlled by such entity or person.

# Future Staggered Board; Removal and Replacement of Directors

At such time as all the remaining class B common stock is converted into class A common stock, the board of directors will immediately and automatically be divided into three classes, class I, class II and class III, with each class serving staggered three-year terms, except that class I directors will serve an initial term ending at the first annual meeting of stockholders following the automatic conversion date, class II directors will serve an initial term ending at the second annual meeting of stockholders following the automatic conversion date and class III directors will serve an initial term ending at the third annual meeting of stockholders following the automatic conversion date.

Our certificate of incorporation and our by-laws provide that, following the automatic conversion date, directors may be removed only for cause and only by the affirmative vote of the holders of 75% or more of the combined voting power of our shares of capital stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and by-laws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

The future classification of our board of directors and the limitations on the ability of our stockholders to remove directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

# Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our certificate of incorporation and our by-laws provide that, following the automatic conversion date, any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our by-laws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our chairman of the board, our chief executive officer or our board of directors. In addition, our by-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to the board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

### Super-Majority Vote

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our by-laws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes which all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes which all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described in the prior two paragraphs or this paragraph.

### **Authorized but Unissued Shares**

The authorized but unissued shares of class A common stock and preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of The NASDAQ Global Market. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

# **Corporate Opportunities**

Our certificate of incorporation includes a provision, as permitted by the Delaware General Corporation Law, renouncing any interest or expectancy in business opportunities of entities controlled by Drs. Ueno and Kuno. This provision specifically carves out, and preserves our interest in, corporate opportunities relating to prostone compounds. The provision does not in any event override any contractual non-competition agreements among our company, Drs. Kuno and Ueno and any of their affiliated companies, such as the non-competition provisions of our agreement with Sucampo AG. This provision will expire at such time as all the remaining class B common stock is converted into class A common stock.

# **Transfer Agent and Registrar**

The transfer agent and registrar for the common stock will be

# **NASDAQ National Market**

We have applied to have our class A common stock approved for quotation on The NASDAQ Global Market under the Symbol "SCMP".

### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our class A common stock, and a liquid trading market for our class A common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding options, in the public market after this offering, or the anticipation of those sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities.

Upon the completion of this offering, we will have outstanding shares of class A common stock and 3,081,300 shares of class B common stock, after giving effect to the issuance of shares of class A common stock in this offering and assuming no exercise of the underwriters' over-allotment option and no exercise of options outstanding as of May 31, 2006. Each share of class A common stock is convertible into one share of class B common stock upon transfer with limited exceptions.

Of the shares to be outstanding after the completion of this offering, the shares of class A common stock sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining 3,903,757 shares of class A and class B common stock are "restricted securities" under Rule 144. Substantially all of these restricted securities will be subject to the 180-day lock-up period described below.

After the 180-day lock-up period, these restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act, which exemptions are summarized below.

### **Rule 144**

In general, under Rule 144, beginning 90 days after the date of this offering, a person who has beneficially owned shares of our common stock for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our class A common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume in our class A common stock on The NASDAQ Global Market during the four calendar weeks preceding the date of filing a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. Upon expiration of the 180-day lock-up period described below, shares of our class A common stock, including shares issuable upon conversion of shares of class B common stock, will be eligible for sale under Rule 144, excluding shares eligible for resale under Rule 144(k) as described below.

We cannot estimate the number of shares of class A common stock that our existing stockholders will elect to sell under Rule 144.

# Rule 144(k)

Subject to the lock-up agreements described below, shares of our common stock eligible for sale under Rule 144(k) may be sold immediately upon the completion of this offering. In general, under Rule 144(k), a person may sell shares of common stock acquired from us immediately upon the completion of this offering, without regard to manner of sale, the availability of public information about us or volume limitations, if:

- the person is not our affiliate and has not been our affiliate at any time during the three months preceding the sale; and
- the person has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than one of our affiliates.

Upon the expiration of the 180-day lock-up period described below, approximately eligible for sale under Rule 144(k).

shares of class A common stock will be

### **Rule 701**

In general, under Rule 701 of the Securities Act, any of our employees, officers, directors, consultants or advisors who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement is eligible to resell those shares 90 days after the effective date of this offering in reliance on Rule 144, but without compliance with specified restrictions, including the holding period, contained in Rule 144. Subject to the 180-day lock-up period described below, approximately shares of our class A common stock will be eligible for sale in accordance with Rule 701.

# **Lock-up Agreements**

We expect that the holders of all of our currently outstanding capital stock will agree that, without the prior written consent of Banc of America Securities LLC, they will not, during the period ending 180 days after the date of this prospectus, subject to exceptions specified in the lock-up agreements, sell, offer to sell, contract or agree to sell, hypothecate, pledge, grant any option to purchase or otherwise dispose of or agree to dispose of, directly or indirectly, or file a registration statement in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Exchange Act with respect to, our common stock or securities convertible into or exercisable or exchangeable for our common stock. Banc of America Securities LLC may, in its sole discretion, at any time and without notice, release for sale in the public market all or any portion of the shares subject to the lock-up agreements. For the purpose of allowing the underwriters to comply with NASD Rule 2711(f)(4), if, under specified circumstances, we release earnings or material news or make specified announcements that we will release earnings results, or a material event relating to us occurs, then the 180-day lock-up period will be extended up to 18 days following the date of release of the earnings results or the occurrence of the material news or event, as applicable.

Banc of America Securities LLC has no current intent or arrangement to release any shares subject to these lock-ups. The release of any lock-up will be considered on a case by case basis. In considering whether to release any shares, Banc of America Securities LLC would consider the particular circumstances surrounding the request, including but not limited to, the length of time before the lock-up expires, the number of shares requested to be released, the reasons for the request, and the possible impact on the market for our class A common stock.

# **Registration Rights**

Upon the closing of this offering, the holders of an aggregate of 794,307 shares of our class A common stock will have the right to require us to register these shares under the Securities Act under specified circumstances. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. Please see "Description of Capital Stock — Registration Rights" for additional information regarding these registration rights.

### **Stock Options**

As of May 31, 2006, we had outstanding options to purchase 253,600 shares of class A common stock, of which options to purchase 216,800 shares of class A common stock were vested. Following this offering, we intend to file registration statements on Form S-8 under the Securities Act to register all of the shares of class A common stock subject to outstanding options and options and other awards issuable pursuant to our equity compensation plans. Please see "Management — Stock Option and Other Compensation Plans" for additional information regarding these plans. Accordingly, shares of our common stock registered under the registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to those shares.

### UNDERWRITING

We are offering the shares of class A common stock described in this prospectus through a number of underwriters. Banc of America Securities LLC, Deutsche Bank Securities Inc. and Leerink Swann & Co., Inc. are the representatives of the underwriters. We have entered into a firm commitment underwriting agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has agreed to purchase, the number of shares of class A common stock listed next to its name in the following table:

<u>U</u> nderwriter	Number of Shares
Banc of America Securities LLC	
Deutsche Bank Securities Inc.	
Leerink Swann & Co., Inc.	
Total	

The underwriting agreement is subject to a number of terms and conditions and provides that the underwriters must buy all of the shares if they buy any of them. The underwriters will sell the shares to the public when and if the underwriters buy the shares from us.

The underwriters initially will offer the shares to the public at the price specified on the cover page of this prospectus. The underwriters may allow a concession of not more than \$ per share to selected dealers. The underwriters may also allow, and those dealers may re-allow, a concession of not more than \$ per share to some other dealers. If all the shares are not sold at the public offering price, the underwriters may change the public offering price and the other selling terms. The class A common stock is offered subject to a number of conditions, including:

- receipt and acceptance of the class A common stock by the underwriters; and
- the underwriters' right to reject orders in whole or in part.

Over-Allotment Option. We have granted the underwriters an over-allotment option to buy up to additional shares of our class A common stock at the same price per share as they are paying for the shares shown in the table above. These additional shares would cover sales of shares by the underwriters which exceed the total number of shares shown in the table above. The underwriters may exercise this option at any time within 30 days after the date of this prospectus. To the extent that the underwriters exercise this option, each underwriter will purchase additional shares from us in approximately the same proportion as it purchased the shares shown in the table above. If purchased, the additional shares will be sold by the underwriters on the same terms as those on which the other shares are sold. We will pay the expenses associated with the exercise of this option.

Discount and Commissions. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. These amounts are shown assuming no exercise and full exercise of the underwriters' option to purchase additional shares. We estimate that the expenses of the offering to be paid by us, not including underwriting discounts and commissions, will be approximately \$

	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

*Listing.* We have applied to have our class A common stock approved for quotation on the NASDAQ National Market under the symbol "SCMP".

*Stabilization.* In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our class A common stock, including:

• stabilizing transactions;

- short sales;
- syndicate covering transactions;
- imposition of penalty bids;
- and purchases to cover positions created by short sales.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our class A common stock while this offering is in progress. Stabilizing transactions may include making short sales of our class A common stock, which involves the sale by the underwriters of a greater number of shares of class A common stock than they are required to purchase in this offering, and purchasing shares of class A common stock from us or on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' over-allotment option referred to above, or may be "naked" shorts, which are short positions in excess of that amount. Syndicate covering transactions involve purchases of our class A common stock in the open market after the distribution has been completed in order to cover syndicate short positions.

The underwriters may close out any covered short position either by exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the over-allotment option.

A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the class A common stock in the open market that could adversely affect investors who purchased in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The representatives also may impose a penalty bid on underwriters and dealers participating in the offering. This means that the representatives may reclaim from any syndicate members or other dealers participating in the offering the underwriting discount, commissions or selling concession on shares sold by them and purchased by the representatives in stabilizing or short covering transactions.

These activities may have the effect of raising or maintaining the market price of our class A common stock or preventing or retarding a decline in the market price of our class A common stock. As a result of these activities, the price of our class A common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence the activities, they may discontinue them at any time. The underwriters may carry out these transactions on the NASDAQ Global Market, in the over-the counter market or otherwise.

Market Making. In connection with this offering, some underwriters and any selling group members who are qualified market makers on the NASDAQ Global Market may engage in passive market making transactions in our class A common stock on the NASDAQ Global Market. Passive market making is allowed during the period when the Securities and Exchange Commission's rules would otherwise prohibit market activity by the underwriters and dealers who are participating in this offering. Passive market making may occur during the business day before the pricing of this offering, before the commencement of offers or sales of the class A common stock. A passive market maker must comply with applicable volume and price limitations and must be identified as a passive market maker. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for our class A common stock; but if all independent bids are lowered below the passive market maker's bid, the passive market maker must also lower its bid once it exceeds specified purchase limits. Net purchases by a passive market maker on each day are limited to a specified percentage of the passive market maker's average daily trading volume in our class A common stock during the specified period and must be discontinued when that limit is reached. Passive market making may cause the price of our class A common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters and dealers are not required to engage in a passive market making and may end passive market making activities at any time.

*Discretionary Accounts*. The underwriters have informed us that they do not expect to make sales to accounts over which they exercise discretionary authority in excess of 5% of the shares of class A common stock being offered.

*IPO Pricing.* Prior to this offering, there has been no public market for our class A common stock. The initial public offering price will be negotiated between us and the representatives of the underwriters. Among the factors to be considered in these negotiations will be:

- the history of, and prospects for, our company and the industry in which we compete;
- our past and present financial performance;
- an assessment of our management;
- the present state of our development;
- the prospects for our future earnings;
- the prevailing conditions of the applicable United States securities market at the time of this offering;
- market valuations of publicly traded companies that we and the representatives of the underwriters believe to be comparable to us; and
- other factors deemed relevant.

The estimated initial public offering price range set forth on the cover of this preliminary prospectus is subject to change as a result of market conditions and other factors.

Lock-up Agreements. We, our directors and executive officers, all of our existing stockholders and all of our option holders have entered into lock-up agreements with the underwriters. Under these agreements, subject to exceptions, we may not issue any new shares of common stock, and those holders of stock and options may not, directly or indirectly, offer, sell, contract to sell, pledge or otherwise dispose of or hedge any common stock or securities convertible into or exchangeable for shares of common stock, or publicly announce the intention to do any of the foregoing, without the prior written consent of Banc of America Securities LLC for a period of 180 days from the date of this prospectus. This consent may be given at any time without public notice. In addition, during this 180-day period, we have also agreed not to file any registration statement for, and each of our officers and stockholders has agreed not to make any demand for, or exercise any right of, the registration of, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock without the prior written consent of Banc of America Securities LLC. In addition, for the purpose of allowing the underwriters to comply with NASD Rule 2711(f)(4), if, under specified circumstances, we release earnings results or material news or make specified announcements that we will release earnings results, or a material event relating to us occurs, then the 180-day lock-up period will be extended up to 18 days following the date of release of the earnings results or the occurrence of the material news or material event, if applicable.

Banc of America Securities LLC has no current intent or arrangement to release any shares subject to these lock-ups. The release of any lock-up will be considered on a case by case basis. In considering whether to release any shares, Banc of America Securities LLC would consider the particular circumstances surrounding the request, including but not limited to, the length of time before the lock-up expires, the number of shares requested to be released, the reasons for the request, and the possible impact on the market for our class A common stock.

*Indemnification.* We will indemnify the underwriters against some liabilities, including liabilities under the Securities Act. If we are unable to provide this indemnification, we will contribute to payments the underwriters may be required to make in respect of those liabilities.

Online Offering. A prospectus in electronic format may be made available on the web sites maintained by one or more of the underwriters participating in this offering. Other than the prospectus in electronic format, the information on any such web site, or accessible through any such web site, is not part of the prospectus. The representatives may agree to allocate a number of shares to underwriters for sale to their

online brokerage account holders. Internet distributions will be allocated by the underwriters that will make internet distributions on the same basis as other allocations. In addition, shares may be sold by the underwriters to securities dealers who resell shares to online brokerage account holders.

Conflicts/Affiliates. The underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which services they have received, and may in the future receive, customary fees. MEDACorp, a division of Leerink Swann & Co., Inc., one of the managing underwriters for this offering, has provided market research services to us in the past and may in the future provide such services.

European Economic Area. In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, an offer of the shares to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the relevant implementation date, make an offer of shares to the public in that Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity which has two or more of (a) an average of at least 250 employees during the last financial year; (b) a total balance sheet of more than €43,000,000 and (c) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts; or
- in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

France. No prospectus, including any amendment, supplement or replacement thereto, has been prepared in connection with the offering of the shares that has been approved by the *Autorité des marchés financiers* or by the competent authority of another state that is a contracting party to the Agreement on the European Economic Area and notified to the *Autorité des marchés financiers*; no shares have been offered or sold and will be offered or sold, directly or indirectly, to the public in France except to permitted investors, or Permitted Investors, consisting of persons licensed to provide the investment service of portfolio management for the account of third parties, qualified investors (*investisseurs qualifiés*) acting for their own account and/or investors belonging to a limited circle of investors (*cercle restreint d'investisseurs*) acting for their own account, with "qualified investors" and "limited circle of investors" having the meaning ascribed to them in Articles L. 411-2, D. 411-1, D. 411-2, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the French *Code Monétaire et Financier* and applicable regulations thereunder; none of this prospectus or any other materials related to the offering or information contained therein relating to the shares has been released, issued or distributed to the public in France except to Permitted Investors; and the direct or indirect resale to the public in France of any shares acquired by any Permitted Investors may be made only as provided by Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the French *Code Monétaire et Financier* and applicable regulations thereunder.

United Kingdom. Each underwriter acknowledges and agrees that:

• it has not offered or sold and will not offer or sell the shares other than to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments, as principal or as

agent, for the purposes of their businesses or who it is reasonable to expect will acquire, hold, manage or dispose of investments, as principal or agent, for the purposes of their businesses where the issue of the shares would otherwise constitute a contravention of Section 19 of the Financial Services and Markets Act 2000, or the FSMA, by us;

- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity, within the meaning of Section 21 of the FSMA, received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom or (ii) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order, all such persons together being referred to as relevant persons. The shares are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such shares will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

Italy. The offering of the shares has not been cleared by the Italian Securities Exchange Commission (Commissione Nazionale per le Società e la Borsa), or the CONSOB, pursuant to Italian securities legislation and, accordingly, has represented and agreed that the shares may not and will not be offered, sold or delivered, nor may or will copies of this prospectus or any other documents relating to the shares be distributed in Italy, except (i) to professional investors (operatori qualificati), as defined in Article 31, second paragraph, of CONSOB Regulation No. 11522 of July 1, 1998, as amended, or Regulation No. 11522, or (ii) in other circumstances which are exempted from the rules on solicitation of investments pursuant to Article 100 of Legislative Decree No. 58 of February 24, 1998, or the Financial Service Act, and Article 33, first paragraph, of CONSOB Regulation No. 11971 of May 14, 1999, as amended.

Any offer, sale or delivery of the shares or distribution of copies of this prospectus or any other document relating to the shares in Italy may and will be effected in accordance with all Italian securities, tax, exchange control and other applicable laws and regulations, and, in particular, will be: (i) made by an investment firm, bank or financial intermediary permitted to conduct such activities in Italy in accordance with the Financial Services Act, Legislative Decree No. 385 of September 1, 1993, as amended, or the Italian Banking Law, Regulation No. 11522, and any other applicable laws and regulations; (ii) in compliance with Article 129 of the Italian Banking Law and the implementing guidelines of the Bank of Italy; and (iii) in compliance with any other applicable notification requirement or limitation which may be imposed by CONSOB or the Bank of Italy.

Any investor purchasing the shares in the offering is solely responsible for ensuring that any offer or resale of the shares it purchased in the offering occurs in compliance with applicable laws and regulations.

This prospectus and the information contained herein are intended only for the use of its recipient and, unless in circumstances which are exempted from the rules on solicitation of investments pursuant to Article 100 of the "Financial Service Act" and Article 33, first paragraph, of CONSOB Regulation No. 11971 of May 14, 1999, as amended, is not to be distributed, for any reason, to any third party resident or located in Italy. No person resident or located in Italy other than the original recipients of this document may rely on it or its content.

Italy has only partially implemented the Prospectus Directive, the provisions under the heading "European Economic Area" above shall apply with respect to Italy only to the extent that the relevant provisions of the Prospectus Directive have already been implemented in Italy.

Insofar as the requirements above are based on laws that are superseded at any time pursuant to the implementation of the Prospectus Directive, such requirements shall be replaced by the applicable requirements under the Prospectus Directive.

### **LEGAL MATTERS**

The validity of the issuance of the class A common stock offered by us in this offering will be passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP, Washington, D.C. Cleary Gottlieb Steen & Hamilton LLP has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

### **EXPERTS**

The combined financial statements as of December 31, 2004 and 2005 and for each of the three years in the period ended December 31, 2005 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on their authority as experts in auditing and accounting.

### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act, with respect to the common stock offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules, and undertakings set forth in the registration statement. For further information pertaining to us and our common stock, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

You may read and copy all or any portion of the registration statement without charge at the public reference room of the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Copies of the registration statement may be obtained from the SEC at prescribed rates from the public reference room of the SEC at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. In addition, registration statements and certain other filings made with the SEC electronically are publicly available through the SEC's web site at http://www.sec.gov. The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the SEC.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Securities Exchange Act and, accordingly, will file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the SEC. You will be able to inspect and copy such periodic reports, proxy statements, and other information at the SEC's public reference room, and the web site of the SEC referred to above.

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# **Report of Independent Registered Public Accounting Firm**

To the Boards of Directors and Stockholders of Sucampo Pharmaceuticals, Inc.:

In our opinion, the accompanying combined balance sheets and the related combined statements of operations and comprehensive (loss) income, changes in stockholders' (deficit) equity and cash flows present fairly, in all material respects, the financial position of Sucampo Pharmaceuticals, Inc. and its affiliated companies (Sucampo Pharma Europe, Ltd. and Sucampo Pharma, Ltd.) (collectively, the "Company") at December 31, 2004 and December 31, 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP Baltimore, Maryland August 11, 2006

# **Combined Balance Sheets**

	Decem	ber 31,	March 31, 2006		
	2004	2005	Actual	Pro Forma	
			(unaudited)	(unaudited)	
ASSETS:					
Current assets:					
Cash and cash equivalents	\$ 21,917,693	\$ 17,436,125	\$ 44,351,759		
Short-term investments	3,000,000	28,435,058	28,537,326		
Accounts receivable	99,618	584,444	474,204		
Deferred tax assets	317,199	_	_		
Deferred licensing fees	61,860	61,860	61,860		
Prepaid expenses and other current assets	196,211	282,568	403,213		
Total current assets	25,592,581	46,800,055	73,828,362		
Property and equipment, net	200,712	177,460	166,013		
Deferred licensing fees, net of current portion	927,831	865,972	850,507		
Deposits and other assets	105,089	89,727	402,342		
Total assets	\$ 26,826,213	\$ 47,933,214	\$ 75,247,224		
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY:					
Current liabilities:					
Accounts payable	\$ 1,290,951	\$ 1,900,605	\$ 4,481,007		
Accrued expenses	1,728,577	2,083,214	1,124,459		
Deferred revenue — current	2,242,799	16,599,457	15,083,270		
Income taxes payable	302,276	1,766,172	2,348,064		
Notes payable — related parties — current	4,040,409	847,733	849,915		
Other current liabilities	1,031,336	1,520,174			
Total current liabilities	10,636,348	24,717,355	23,886,715		
Notes payable — related parties, net of current portion	2,326,480	2,545,800	3,751,800		
Deferred revenue, net of current portion	26,072,885	25,333,589	21,562,772		
Other liabilities	1,513,242				
Total liabilities	40,548,955	52,596,744	49,201,287		
Commitments and Contingencies (Note 6)					
<u> </u>					
Stockholders' (Deficit) Equity:					
Series A Convertible Preferred Stock, \$0.01 par value; 10,000 shares authorized;					
3,780 shares issued and outstanding at December 31, 2004 and 2005 and March 31, 2006	20 200 104	20 200 104	20 200 104	\$ -	
·	20,288,104	20,288,104	20,288,104	<b>5</b> —	
Class A Common Stock, \$0.01 par value; 5,000,000 shares authorized; 43,000, 540,250 and 769,662 shares issued and outstanding at December 31, 2004 and					
2005 and March 31, 2006, respectively	430	E 402	7,697	12 505	
Class B Common Stock, \$0.01 par value; 5,000,000 shares authorized;	430	5,403	7,097	13,595	
•					
3,581,300 shares issued and outstanding at December 31, 2004 and	35,813	30,813	30,813	30,813	
3,081,300 shares outstanding at December 31, 2005 and March 31, 2006	33,013	30,013	30,013	30,013	
Common Stock, Sucampo Pharma, Ltd. (SPL), \$420.65 par value; 4,000 shares authorized; 1,000 shares issued and outstanding at December 31, 2004 and 2005					
and March 31, 2006	420,650	420,650	420,650		
Common Stock, Sucampo Pharma Europe Ltd. (SPE), \$1.53 par value; 10,000 shares	420,030	420,030	420,030	_	
authorized; 5,000 shares issued and outstanding at December 31, 2004 and 2005					
and March 31, 2006	7,628	7,628	7,628		
Additional paid-in capital				E2 146 000	
Deferred compensation	10,749,914	12,989,723	32,436,404	53,146,888	
Accumulated other comprehensive loss	(61,828) (127,639)	(94,951)	(99,269)	(99,269	
Accumulated other comprehensive loss  Accumulated deficit					
	(45,035,814)	(38,310,900)	(27,046,090)	(27,046,090	
Total stockholders' (deficit) equity	(13,722,742)	(4,663,530)	26,045,937	\$ 26,045,937	
Total liabilities and stockholders' (deficit) equity	\$ 26,826,213	\$ 47,933,214	\$ 75,247,224		

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

# SUCAMPO PHARMACEUTICALS, INC. and AFFILIATED COMPANIES Combined Statements of Operations and Comprehensive (Loss) Income

	Year Ended December 31,				Three Months Ended March 31,		
	2003	3	2004	2005	2005	2006	
					(unaudited)	(unaudited)	
Revenues and other income:							
Milestone revenue	\$	_	\$ —	\$ 30,000,000	\$ 10,000,000	\$ 20,000,000	
Reimbursement of research and development costs		_	1,482,337	14,671,508	4,286,896	3,868,885	
Contract revenue		6,409	275,154	2,237,115	309,278	1,809,279	
Contract revenue — related parties	2,48	8,095	410,799	98,337	40,062	29,524	
Other income — gain on sale of patent to related party			497,000				
Total revenues and other income	4,12	4,504	2,665,290	47,006,960	14,636,236	25,707,688	
Operating expenses:							
Research and development	18,44		14,036,070	29,887,613	6,920,214	6,120,270	
Selling, general and administrative	7,44	6,777	8,226,730	8,116,163	1,485,488	3,769,787	
Milestone royalties — related parties				1,500,000	500,000	1,250,000	
Total operating expenses	25,89	1,211	22,262,800	39,503,776	8,905,702	11,140,057	
(Loss) income from operations	(21,76	6,707)	(19,597,510)	7,503,184	5,730,534	14,567,631	
Non-operating income (expense):							
Interest income		5,547	96,494	1,045,980	80,440	305,628	
Interest expense		1,813)	(173,519)	(310,771)	(84,300)	(20,248)	
Other (loss) income	(25	3,601)	20,861	254,560	(68,433)	139,672	
Total non-operating (expense) income, net	(24	9,867)	(56,164)	989,769	(72,293)	425,052	
(Loss) income before income taxes	(22,01	6,574)	(19,653,674)	8,492,953	5,658,241	14,992,683	
Income tax provision	·	_		(1,768,039)	(558,407)	(3,727,873)	
Net (loss) income	\$ (22,01	6,574)	\$ (19,653,674)	\$ 6,724,914	\$ 5,099,834	\$ 11,264,810	
Pro forma net (loss) income per share (Note 3) (unaudited):							
Basic pro forma net (loss) income per share	\$	(5.24)	\$ (4.66)	\$ 1.60	\$ 1.21	\$ 2.67	
Diluted pro forma net (loss) income per share	\$	(5.24)	\$ (4.66)	\$ 1.55	\$ 1.18	\$ 2.59	
Pro forma weighted average common shares outstanding — basic	4,20	5,188	4,213,257	4,213,378	4,214,065	4,213,862	
Pro forma weighted average common shares outstanding — diluted	4,20	5,188	4,213,257	4,331,479	4,317,015	4,342,524	
Comprehensive (loss) income:							
Net (loss) income	\$ (22,01	6,574)	\$ (19,653,674)	\$ 6,724,914	\$ 5,099,834	\$ 11,264,810	
Other comprehensive (loss) income:							
Foreign currency translation	(11	5,246)	(13,108)	32,688	(117,392)	(4,318)	
Comprehensive (loss) income	\$ (22,13	1,820)	\$ (19,666,782)	\$ 6,757,602	\$ 4,982,442	\$ 11,260,492	

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

# SUCAMPO PHARMACEUTICALS, INC. and AFFILIATED COMPANIES Combined Statements of Changes in Stockholders' (Deficit) Equity

		A Convertible erred Stock Amount	Clas Commo Shares	ss A on Stock Amount	Class Common Shares			SPL non Stock Amount	Comm	PE on Stock Amount	Additional Paid-In Capital	Deferred Compensation	Accumulated Other Comprehen- sive Loss		Stockholders' (Deficit) Equity
Balance at															
December 31, 2002 Amortization of		\$20,288,104	38,000	\$ 380	3,581,300	\$35,813	1,000	\$420,650	5,000	\$ 7,628	\$ 10,620,914	\$ (16,849)	\$ 715	\$ (3,365,566)	\$ 27,991,789
deferred compensation Foreign	_	_	_	_	_	_	_	_	_	_	_	15,653	_	_	15,653
currency translation Net loss										_ 			(115,246)	(22,016,574)	(115,246) (22,016,574)
Balance at December 31, 2003	3,780	20,288,104	38,000	380	3,581,300	35,813	1,000	420,650	5,000	7,628	10,620,914	(1,196)	(114,531)	(25,382,140)	5,875,622
Amortization of deferred compensation	_	_	_	_	_	_	_	_	_	_	_	68,418	_	_	68,418
Issuance of 5,000 shares of restricted class A common															
stock Foreign	_	_	5,000	50	_						129,000	(129,050)	_	_	_
currency translation Net loss	_=												(13,108) ———	(19,653,674)	(13,108) (19,653,674)
Balance at December 31, 2004 Amortization of	3,780	20,288,104	43,000	430	3,581,300	35,813	1,000	420,650	5,000	7,628	10,749,914	(61,828)	(127,639)	(45,035,814)	(13,722,742)
deferred compensation Conversion of		_		_	_							26,210	_	_	26,210
class B common stock to class A															
common stock Issuance of stock options	_	_	500,000	5,000	(500,000)	(5,000)	_	_	_	_	_	_	_	_	_
and vesting modifications (Notes 2 and 11)											2,334,709				2,334,709
Forfeitures of 3,750 shares of restricted class A	_	_	_	_	_	_	_	_	_	_	2,334,703	_	_	_	2,334,709
common stock Exercise of	_	_	(3,750)	(37)	_	_	_	_	_	_	(96,750)	35,618	_	_	(61,169)
1,000 options for 1,000 shares of class A common															
stock Foreign currency	_	_	1,000	10	_	_		_	_	_	1,850	_	_	_	1,860
translation Net income Balance at	_=												32,688 	6,724,914	32,688 6,724,914
December 31, 2005 Issuance of class A		20,288,104	540,250	5,403	3,081,300	30,813	1,000	420,650	5,000	7,628	12,989,723	_	(94,951)	(38,310,900)	(4,663,530)
common stock at \$85 per share, net of offering costs of \$51,045															
(unaudited) Foreign currency	_	_	229,412	2,294	_		_	_	_	_	19,446,681	_	_	_	19,448,975
translation (unaudited) Net income	_	_	_	_	_	_	_	_	_	_	_	_	(4,318)	_	(4,318)
(unaudited) Balance at March 31,														11,264,810	11,264,810
2006 (unaudited)	3,780	\$20,288,104	769,662	\$ 7,697	3,081,300	\$30,813	1,000	\$420,650	5,000	\$ 7,628	\$ 32,436,404	<u>\$</u>	\$ (99,269)	<u>\$(27,046,090</u> )	\$ 26,045,937

# **Combined Statements of Cash Flows**

Cash flows from operating activities		Year	Ended December	r 31,	Three Months Ended March, 31		
Cash flows from operating activities: Net (loss) income to net cash (used in) provided by Net (loss) income to net cash (used in) provided by Operating activities: Depreciation and amortization		2003	2004	2005	2005	2006	
Net (loss) income					(unaudited)	(unaudited)	
Net (loss) income	Cash flows from operating activities:						
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:  Depreciation and amortization  Befared tax (benefit) expense  Befared the tax (benefit) expense  Befared tax (benefit) e		\$ (22,016,574)	\$ (19,653,674)	\$ 6,724,914	\$ 5.099.834	\$ 11,264,810	
Depreciation and amortization   91,278   95,412   61,764   15,633   16,995   20,000   20,00		+ (==,===,=: -)	+ (==,===,==,=,=,	4 0,. = 1,0 = 1	4 0,000,000	4, ,,	
Depreciation and amortization   91,278   95,412   61,764   15,633   16,995   20,000   20,00	operating activities:						
Deferred tax (benefit) expense   15,633   68,418   2,299,750   295,876   295,876   Colorable   Color		91,278	95,412	61,764	15,633	16,995	
Stock-based compensation expense   15,653   68,418   2,997,50   8,737   — Changes in operating assets and liabilities:	Amortization of discount on note	86,877	63,558	´—	´—	´ —	
Stock-based compensation expense   15,653   68,418   2,997,50   8,737   — Changes in operating assets and liabilities:	Deferred tax (benefit) expense		(302,276)	295,876	295,876	_	
Accounts receivable (106,337) 13,353 (488,826) (9,960,069) 110,240 Deposits and other assets (15,329) 7,297 15,362 14,734 (15,631) Deferred licensing fees		15,653	68,418	2,299,750	8,737	_	
Deposits and other assets							
Deferred licensing fees	Accounts receivable	(106,337)	13,353	(488,826)	(9,960,069)	110,240	
Prepaid expenses and other current assets	Deposits and other assets	(15,329)	7,297	15,362	14,734	(156,531)	
Accounts payable		· —	(989,691)	61,859	15,464	15,465	
Accrued expenses (730,551) 1,134,442 354,637 55,638 (958,755) Income taxes payable and receivable, net 333,892 376,579 1,463,896 25,5641 581,892 Deferred revenue 4,598,364 21,532,743 13,561,362 2,991,281 (5,287,004) Other liabilities (15,104,104) 115,194 (1,520,174) Net cash (used in) provided by operating activities (15,104,104) 115,194 (1,520,174) Net cash (used in) provided by operating activities (15,104,104) 115,194 (1,520,174) Net cash (used in) provided by operating activities (15,104,104) 115,104 (1,102,174) Net cash (used in) provided by containing activities (15,104,104) 115,104 (1,102,174) Net cash (used in) provided by investing activities (16,104,104) 115,104 (1,102,174) Net cash (used in) provided by investing activities (16,104,104) 115,104 (1,102,1074) Net cash (used in) provided by investing activities (16,104,104) 115,104 (1,102,1074) 115,1		74,591	223,732	(103,357)		(120,645)	
Income taxes payable and receivable, net   335,892   376,579   1,463,896   255,641   581,895   256,004   21,532,743   13,561,362   2,991,281   (5,287,004)   2,544,578   (1,041,044)   115,194   (1,520,174)   2,544,578   (1,041,044)   115,194   (1,520,174)   3,210,392   23,815,487   1,413,957   6,526,695   3,236   3,245,358   3,245	Accounts payable	2,499,122	(1,904,079)	609,654	2,374,901	2,580,402	
Deferred revenue         4,598,364         21,532,743         13,561,362         2,991,281         (5,287,004)           Other liabilities         (15,167,014)         3,210,392         23,815,487         1,143,957         6,526,695           Cash flows from investing activities:         (15,167,014)         3,210,392         23,815,487         1,413,957         6,526,695           Cash flows from investing activities:         (3,000,000)         (28,435,058)         —         (102,268)           Proceeds from the sale of short-term investments         —         3,000,000         3,000,000         7,000           Purchases of property and equipment         (84,851)         (17,971)         (38,512)         (16,537)         (5,548)           Proceeds from disposal of property and equipment         —         2,202         —         —         -		(730,551)	1,134,442	354,637	55,638	(958,755)	
Other liabilities         2,544,578         (1,041,404)         115,194         (1,520,174)           Net cash (used in) provided by operating activities         (15,167,014)         3,210,392         23,815,487         1,413,957         6,526,695           Cash flows from investing activities:         —         (3,000,000)         (28,435,058)         —         (102,268)           Proceeds from the sale of short-term investments         —         3,000,000         3,000,000         3,000,000         —           Purchases of property and equipment         (84,851)         (17,971)         (38,512)         (16,537)         (5,548)           Proceeds from disposal of property and equipment         (84,851)         (30,15,769)         25,735,700         2,983,463         (107,816)           Proceeds from exercise of stock options         —         1,860         — <td></td> <td>335,892</td> <td>376,579</td> <td>1,463,896</td> <td>255,641</td> <td>581,892</td>		335,892	376,579	1,463,896	255,641	581,892	
Net cash (used in) provided by operating activities	Deferred revenue	4,598,364	21,532,743	13,561,362	2,991,281	(5,287,004)	
Cash flows from investing activities:   Purchases of short-term investments   —   (3,000,000)   (28,435,058)   — (102,268)     Proceeds from the sale of short-term investments   —   (3,000,000)   (3,000,000)   (1,537)     Purchases of property and equipment   (84,851)   (17,971)   (38,512)   (16,537)   (5,548)     Proceeds from disposal of property and equipment   —   (2,020)   —   —   —   (16,537)   (5,548)     Proceeds from disposal of property and equipment   —   (84,851)   (3,015,769)   (25,473,570)   (2,983,463)   (107,816)     Cash flows from disposal of property and equipment   —   —   —   —   —   —   —   —   —	Other liabilities		2,544,578	(1,041,404)	115,194	(1,520,174)	
Purchases of short-term investments         —         (3,000,000)         (28,435,058)         —         (102,268)           Proceeds from the sale of short-term investments         —         3,000,000         3,000,000         —           Purchases of property and equipment         (84,851)         (17,971)         (38,512)         (16,537)         (5,548)           Proceeds from disposal of property and equipment         —         2,202         —         —         —           Net cash (used in) provided by investing activities         (84,851)         (3,015,769)         (25,473,570)         2,983,463         (107,816)           Cash flows from financing activities         —	Net cash (used in) provided by operating activities	(15,167,014)	3,210,392	23,815,487	1,413,957	6,526,695	
Purchases of short-term investments         —         (3,000,000)         (28,435,058)         —         (102,268)           Proceeds from the sale of short-term investments         —         3,000,000         3,000,000         —           Purchases of property and equipment         (84,851)         (17,971)         (38,512)         (16,537)         (5,548)           Proceeds from disposal of property and equipment         —         2,202         —         —         —           Net cash (used in) provided by investing activities         (84,851)         (3,015,769)         (25,473,570)         2,983,463         (107,816)           Cash flows from financing activities         —	· /1 0 1						
Proceeds from the sale of short-term investments         —         3,000,000         3,000,000         —           Purchases of property and equipment         (84,851)         (17,971)         (38,512)         (16,537)         (5,548)           Proceeds from disposal of property and equipment         2,202         — <t< td=""><td></td><td>_</td><td>(3.000.000)</td><td>(28,435,058)</td><td>_</td><td>(102,268)</td></t<>		_	(3.000.000)	(28,435,058)	_	(102,268)	
Purchases of property and equipment         (84,851)         (17,971)         (38,512)         (16,537)         (5,548)           Proceeds from disposal of property and equipment         —         2,202         —         —         —         —           Net cash (used in) provided by investing activities         (84,851)         (3,015,769)         (25,473,570)         2,983,463         (107,816)           Cash flows from financing activities:         —         —         —         1,860         —         —           Proceeds from exercise of stock options         —         —         —         —         19,448,975           Issuance of common stock         —         —         —         —         —         19,448,975           Capitalized IPO costs         —         —         —         —         —         —         —         —         1,208,182           Payments on notes payable — related parties         (316,550)         (316,550)         (2,280,356)         — <td< td=""><td></td><td>_</td><td>(=,,,,,,,,,,,,,,</td><td></td><td>3.000.000</td><td>(==,===)</td></td<>		_	(=,,,,,,,,,,,,,,		3.000.000	(==,===)	
Proceeds from disposal of property and equipment         2,202         —		(84,851)	(17,971)		-,,	(5,548)	
Net cash (used in) provided by investing activities         (84,851)         (3,015,769)         (25,473,570)         2,983,463         (107,816)           Cash flows from financing activities:         —		(5 1,552)		(55,511)	(= 5,551)	(5,5 10)	
Cash flows from financing activities:       Proceeds from exercise of stock options       1,860       - 19,448,975         Issuance of common stock       — (156,084)         Capitalized IPO costs       — (156,084)         Issuance of notes payable — related parties       2,974,070       2,607,958       — 1,208,182         Payments on notes payable — related parties       (316,550)       (316,550)       (2,280,356)       — - 20,501,073         Net cash provided by (used in) financing activities       2,657,520       2,291,408       (2,278,496)       — 20,501,073         Effect of exchange rates on cash and cash equivalents       271,313       361,528       (544,989)       (265,069)       (4,318)         Net (decrease) increase in cash and cash equivalents       (12,323,032)       2,847,559       (4,481,568)       4,132,351       26,915,634         Cash and cash equivalents at beginning of period       31,393,166       19,070,134       21,917,693       21,917,693       17,436,125         Cash paid for interest       \$ 19,070,134       \$ 21,917,693       \$ 17,436,125       \$ 26,050,044       \$ 44,351,759         Tax refunds received       \$ 35,842       \$ 68,312       \$ 250,868       8 3,237       \$ 20,439         Tax payments made       \$ 84,460 <td></td> <td>(84 851)</td> <td></td> <td>(25.473.570)</td> <td>2 983 463</td> <td>(107.816)</td>		(84 851)		(25.473.570)	2 983 463	(107.816)	
Proceeds from exercise of stock options         —         —         1,860         —         —           Issuance of common stock         —         —         —         —         —         —         —         19,448,975           Capitalized IPO costs         —         —         —         —         —         1,208,182           Issuance of notes payable — related parties         2,974,070         2,607,958         —         —         1,208,182           Payments on notes payable — related parties         (316,550)         (316,550)         (2,280,356)         —         —         —           Net cash provided by (used in) financing activities         2,657,520         2,291,408         (2,278,496)         —         20,501,073           Effect of exchange rates on cash and cash equivalents         271,313         361,528         (544,989)         (265,069)         (4,318)           Net (decrease) increase in cash and cash equivalents         (12,323,032)         2,847,559         (4,481,568)         4,132,351         26,915,634           Cash and cash equivalents at beginning of period         31,393,166         19,070,134         21,917,693         21,917,693         17,436,125         26,050,044         \$44,351,759           Supplemental cash flow disclosures:         S         35,842	· , , , , , , , , , , , , , , , , , , ,	(0.,001)	(5,015,765)	(20, 170,070)	2,500,100	(107,010)	
Issuance of common stock				1.860			
Capitalized IPO costs         —         —         —         (156,084)           Issuance of notes payable — related parties         2,974,070         2,607,958         —         —         1,208,182           Payments on notes payable — related parties         (316,550)         (316,550)         (2,280,356)         —         —         —           Net cash provided by (used in) financing activities         2,657,520         2,291,408         (2,278,496)         —         20,501,073           Effect of exchange rates on cash and cash equivalents         271,313         361,528         (544,989)         (265,069)         (4,318)           Net (decrease) increase in cash and cash equivalents         (12,323,032)         2,847,559         (4,481,568)         4,132,351         26,915,634           Cash and cash equivalents at beginning of period         31,393,166         19,070,134         21,917,693         21,917,693         17,436,125           Cash and cash equivalents at end of period         \$19,070,134         \$21,917,693         \$17,436,125         \$26,050,044         \$44,351,759           Supplemental cash flow disclosures:         \$35,842         \$68,312         \$250,868         \$83,237         \$20,439           Tax refunds received         \$-         \$-         \$-         \$-         \$-				1,000		19 448 975	
Issuance of notes payable — related parties         2,974,070         2,607,958         —         —         1,208,182           Payments on notes payable — related parties         (316,550)         (316,550)         (2,280,356)         —         —           Net cash provided by (used in) financing activities         2,657,520         2,291,408         (2,278,496)         —         20,501,073           Effect of exchange rates on cash and cash equivalents         271,313         361,528         (54,989)         (265,069)         (4,318)           Net (decrease) increase in cash and cash equivalents         (12,323,032)         2,847,559         (4,481,568)         4,132,351         26,915,634           Cash and cash equivalents at beginning of period         31,393,166         19,070,134         21,917,693         21,917,693         17,436,125           Cash and cash equivalents at end of period         \$19,070,134         \$21,917,693         \$17,436,125         \$26,050,044         \$44,351,759           Supplemental cash flow disclosures:         S         \$68,312         \$250,868         83,237         \$20,439           Tax refunds received         \$         \$         \$         \$         \$         \$         \$         \$         \$         \$         \$         \$         \$         \$         \$			_				
Payments on notes payable — related parties         (316,550)         (316,550)         (2,280,356)         —         —           Net cash provided by (used in) financing activities         2,657,520         2,291,408         (2,278,496)         —         20,501,073           Effect of exchange rates on cash and cash equivalents         271,313         361,528         (544,989)         (265,069)         (4,318)           Net (decrease) increase in cash and cash equivalents         (12,323,032)         2,847,559         (4,481,568)         4,132,351         26,915,634           Cash and cash equivalents at beginning of period         31,393,166         19,070,134         21,917,693         21,917,693         17,436,125           Cash and cash equivalents at end of period         \$ 19,070,134         \$ 21,917,693         \$ 17,436,125         \$ 26,050,044         \$ 44,351,759           Supplemental cash flow disclosures:         ***         \$ 68,312         \$ 250,868         \$ 83,237         \$ 20,439           Tax refunds received         \$ 35,842         \$ 68,312         \$ 250,868         \$ 83,237         \$ 20,439           Tax payments made         \$ -         \$ 84,460         \$ -         \$ -         \$ -           Supplemental disclosure of non-cash investing and financing activities:         * * * * * * * * * * * * * * * * * * *		2 974 070	2 607 958				
Net cash provided by (used in) financing activities         2,657,520         2,291,408         (2,278,496)         —         20,501,073           Effect of exchange rates on cash and cash equivalents         271,313         361,528         (544,989)         (265,069)         (4,318)           Net (decrease) increase in cash and cash equivalents         (12,323,032)         2,847,559         (4,481,568)         4,132,351         26,915,634           Cash and cash equivalents at beginning of period         31,393,166         19,070,134         21,917,693         21,917,693         17,436,125           Cash and cash equivalents at end of period         \$ 19,070,134         \$ 21,917,693         \$ 17,436,125         \$ 26,050,044         \$ 44,351,759           Supplemental cash flow disclosures:         \$ 35,842         \$ 68,312         \$ 250,868         \$ 83,237         \$ 20,439           Tax refunds received         \$ -         \$ 84,460         \$ -         \$ -         \$ -           Tax payments made         \$ -         \$ -         \$ -         \$ -         \$ -         \$ -           Supplemental disclosure of non-cash investing and financing activities:         \$ -         \$ -         \$ -         \$ -         \$ -         \$ -         \$ -         \$ 3,145,453				(2.280.356)	_	1,200,102	
Effect of exchange rates on cash and cash equivalents         271,313         361,528         (544,989)         (265,069)         (4,318)           Net (decrease) increase in cash and cash equivalents         (12,323,032)         2,847,559         (4,481,568)         4,132,351         26,915,634           Cash and cash equivalents at beginning of period         31,393,166         19,070,134         21,917,693         21,917,693         17,436,125           Cash and cash equivalents at end of period         \$ 19,070,134         \$ 21,917,693         \$ 17,436,125         \$ 26,050,044         \$ 44,351,759           Supplemental cash flow disclosures:         \$ 35,842         \$ 68,312         \$ 250,868         \$ 83,237         \$ 20,439           Tax refunds received         \$ -         \$ 84,460         \$ -         \$ -         \$ -           Tax payments made         \$ -         \$ -         \$ -         \$ -         \$ 3,145,453   Supplemental disclosure of non-cash investing and financing activities:						20 501 072	
Net (decrease) increase in cash and cash equivalents         (12,323,032)         2,847,559         (4,481,568)         4,132,351         26,915,634           Cash and cash equivalents at beginning of period         31,393,166         19,070,134         21,917,693         21,917,693         17,436,125           Cash and cash equivalents at end of period         \$ 19,070,134         \$ 21,917,693         \$ 17,436,125         \$ 26,050,044         \$ 44,351,759           Supplemental cash flow disclosures:         \$ 35,842         \$ 68,312         \$ 250,868         \$ 83,237         \$ 20,439           Tax refunds received         \$ -         \$ 84,460         \$ -         \$ -         \$ -           Tax payments made         \$ -         \$ -         \$ -         \$ -         \$ 3,145,453   Supplemental disclosure of non-cash investing and financing activities:	1 1 7				(205,000)		
Cash and cash equivalents at beginning of period         31,393,166         19,070,134         21,917,693         21,917,693         17,436,125           Cash and cash equivalents at end of period         \$ 19,070,134         \$ 21,917,693         \$ 17,436,125         \$ 26,050,044         \$ 44,351,759           Supplemental cash flow disclosures:           Cash paid for interest         \$ 35,842         \$ 68,312         \$ 250,868         \$ 83,237         \$ 20,439           Tax refunds received         \$ —         \$ 84,460         \$ —         \$ —         \$ —           Tax payments made         \$ —         \$ —         \$ —         \$ 3,145,453   Supplemental disclosure of non-cash investing and financing activities:							
Cash and cash equivalents at end of period         \$ 19,070,134         \$ 21,917,693         \$ 17,436,125         \$ 26,050,044         \$ 44,351,759           Supplemental cash flow disclosures:           Cash paid for interest         \$ 35,842         \$ 68,312         \$ 250,868         \$ 83,237         \$ 20,439           Tax refunds received         \$ -         \$ 84,460         \$ -         \$ -         \$ -           Tax payments made         \$ -         \$ -         \$ -         \$ 3,145,453   Supplemental disclosure of non-cash investing and financing activities:	Net (decrease) increase in cash and cash equivalents	(12,323,032)	2,847,559	(4,481,568)	4,132,351	26,915,634	
Cash and cash equivalents at end of period         \$ 19,070,134         \$ 21,917,693         \$ 17,436,125         \$ 26,050,044         \$ 44,351,759           Supplemental cash flow disclosures:           Cash paid for interest         \$ 35,842         \$ 68,312         \$ 250,868         \$ 83,237         \$ 20,439           Tax refunds received         \$ -         \$ 84,460         \$ -         \$ -         \$ -           Tax payments made         \$ -         \$ -         \$ -         \$ 3,145,453   Supplemental disclosure of non-cash investing and financing activities:	Cash and each aguiralents at haginning of paried	21 202 166	10.070.124	21 017 602	21 017 602	17 426 125	
Supplemental cash flow disclosures:  Cash paid for interest \$ 35,842 \$ 68,312 \$ 250,868 \$ 83,237 \$ 20,439    Tax refunds received \$ - \$ 84,460 \$ - \$ - \$ - \$ - \$ - \$   Tax payments made \$ - \$ - \$ - \$ - \$ 3,145,453    Supplemental disclosure of non-cash investing and financing activities:							
Cash paid for interest         \$ 35,842         \$ 68,312         \$ 250,868         \$ 83,237         \$ 20,439           Tax refunds received         \$ -         \$ 84,460         \$ -         \$ -         \$ -           Tax payments made         \$ -         \$ -         \$ -         \$ 3,145,453   Supplemental disclosure of non-cash investing and financing activities:		\$ 19,070,134	\$ 21,917,693	\$ 17,436,125	\$ 26,050,044	\$44,351,759	
Tax refunds received \$ - \$84,460 \$ - \$ - \$ - \$ - Tax payments made \$ - \$ - \$ - \$ - \$ 3,145,453 \$ Supplemental disclosure of non-cash investing and financing activities:							
Tax payments made \$ - \$ - \$ - \$ 3,145,453  Supplemental disclosure of non-cash investing and financing activities:	Cash paid for interest	\$ 35,842	\$ 68,312	\$ 250,868	\$ 83,237	\$ 20,439	
Tax payments made \$ \$ \$ \$ \$ \$ 3,145,453  Supplemental disclosure of non-cash investing and financing activities:	Tax refunds received	\$ —	\$ 84,460	\$ —	\$ —	\$ —	
Supplemental disclosure of non-cash investing and financing activities:	Tay payments made	¢	¢	¢	¢		
	rax payments made	<b>Ф</b>	φ <u> </u>	Φ	Φ	φ 3,143,453	
Conversion of class B common stock to class A common stock \$ \$ \$ 5,000 \$ \$		•	•				
	Conversion of class B common stock to class A common stock	<u> </u>	<u> </u>	\$ 5,000	<u> </u>	<u> </u>	

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

### **Notes to Combined Financial Statements**

# 1. Business Organization and Presentation

### **Description of the Business**

Sucampo Pharmaceuticals, Inc. (SPI), was incorporated in the State of Delaware on December 5, 1996 and is headquartered in Bethesda, Maryland. On May 12, 2006, the Company entered into an acquisition agreement with one of its affiliates to purchase the outstanding shares of Sucampo Pharma Europe Ltd. (SPE) and Sucampo Pharma, Ltd. (SPL), both related parties and under common control. SPE operates in the United Kingdom and SPL operates in Japan. The acquisition is expected to occur prior to a proposed initial public offering for SPI (see Note 14). The acquisition will be accounted for as a merger of companies under common control, and accounted for at historical cost. Hereinafter, these affiliated companies shall be referred to collectively as the "Company." The financial information of these three entities under common control is being presented in these combined financial statements. The Company is an emerging pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostone technology.

The Company is a member of a group of affiliated companies (Affiliates) in which the Company's founders and controlling stockholders own directly or indirectly the majority holdings. Currently, one of the Company's founders is a member of some of the Affiliates' Boards and serves as the Chief Operating Officer and Chief Scientific Officer of the Company (see notes 7 and 8 for disclosures relating to transactions with Affiliates).

In January 2006, the Company received marketing approval from the U.S. Food and Drug Administration (FDA) for its first product, AMITIZA<sup>TM</sup> (lubiprostone), to treat chronic idiopathic constipation in adults. Commercialization of AMITIZA began in April 2006 throughout the United States.

# Basis of Presentation and Principles of Combination

The accompanying combined financial statements reflect the accounts of SPI, SPE and SPL. All inter-company accounts and transactions among these three entities have been eliminated for this combination. The combined financial statements have been prepared on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America.

### **Revisions to Combined Financial Statements**

The Company has revised the accompanying combined statements of cash flows for the years ended December 31, 2003 and 2004 to correct immaterial errors related to repayments on a related party note payable to R-Tech Ueno, Ltd. (Japan) (RTU) and the associated non-cash interest expense related to amortization of the discount. The Company also made immaterial revisions as a result of incorrect exchange rates used in translating certain foreign currency-denominated notes payable for the years ended December 31, 2003 and 2004 in the statements of cash flows and Note 7.

The net effect of these errors in 2003 was to overstate operating cash outflows by approximately \$87,000, understate financing cash outflows by approximately \$473,000 and misstate the effect of exchange rate changes on cash and cash equivalents by approximately \$386,000.

The net effect of these errors in 2004 was to understate operating cash inflows by approximately \$63,000, understate financing cash outflows by approximately \$453,000 and misstate the effect of exchange rate changes on cash and cash equivalents by approximately \$390,000.

# Notes to Combined Financial Statements — (Continued)

### Interim Financial Data

The unaudited interim condensed combined financial statements as of March 31, 2006 and for the three months ended March 31, 2005 and 2006 have been prepared in accordance with generally accepted accounting principles for interim information. Accordingly, they do not contain all of the information and footnotes required by generally accepted accounting principles for complete financial statements. However, in the opinion of management, all adjustments, consisting of normal recurring adjustments considered necessary for a fair statement of the results of the interim periods have been included. The results for the three months ended March 31, 2006 are not necessarily indicative of the results to be expected for the year ending December 31, 2006. Certain information in footnote disclosures normally included in annual financial statements has been condensed or omitted for the interim periods presented, in accordance with the rules and regulation of the Securities and Exchange Commission (SEC) for interim financial statements.

### **Capital Resources**

The Company has a limited operating history and its expected activities will necessitate significant uses of working capital throughout 2006 and beyond. The Company's capital requirements will depend on many factors, including the success of the Company's research and development efforts and successful development of new products, payments received under contractual agreements with other parties, the status of competitive products and market acceptance of the Company's new products by physicians and patients. The Company plans to continue financing operations in part with the cash received from the joint collaboration and license agreement with Takeda Pharmaceutical Company Limited (Takeda) (see Note 10).

# 2. Summary of Significant Accounting Policies

### Cash and Cash Equivalents

For the purpose of the combined balance sheets and statements of cash flows, cash equivalents include all highly liquid investments with an original maturity date or remaining maturity date at time of purchase of three months or less.

### **Short-term Investments**

Short-term investments consist entirely of auction rate securities. The Company's investments in these securities are classified as available-for-sale securities under Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities". Although these securities have variable interest rates which typically reset every 7 to 35 days, they have longer-term contractual maturities, spanning from September 1, 2024 to April 1, 2040, which is why they are not classified as cash equivalents. These investments are classified within current assets because the Company has the ability and the intent to liquidate these securities if needed within a short-term time period.

These available-for-sale securities are accounted for at fair market value and unrealized gains and losses on these securities, if any, are included in accumulated other comprehensive loss in stockholders' (deficit) equity. At December 31, 2004 and 2005, and March 31, 2006, the fair market value of these securities was equivalent to the cost and no unrealized gains and losses were recorded. Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts, if any, on short-term investments are amortized or accreted to maturity and included in interest income. During the years ended December 31, 2003, 2004 and 2005 and for the three months ended March 31, 2005 and 2006, there were no short-term investments that were purchased at a premium or discount. The Company uses the specific identification method in computing realized gains and losses on sale of short-term investments. During the

# Notes to Combined Financial Statements — (Continued)

years ended December 31, 2003, 2004 and 2005 and for the three months ended March 31, 2005 and 2006 (unaudited), there were no gains or losses realized on the sale of short-term investments.

### Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents and short-term investments. The Company places its cash and cash equivalents and short-term investments with highly rated financial institutions. At December 31, 2004 and 2005 and March 31, 2006 (unaudited), the Company had \$18,764,929, \$16,455,210 and \$41,709,269, respectively, of cash and cash equivalents and short-term investments in excess of federally insured limits. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

# Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued liabilities, approximate their fair values due to their short maturities. The fair value of the Company's long-term debt with its related parties (see Note 7) approximates the carrying value based on the variable nature of interest rates and current market rates available to the Company.

### Accounts Receivable

Accounts receivable represent amounts due from the FDA as a refund to the Company for fees previously paid, as well as amounts due under the joint collaboration and licensing agreement with Takeda (see Note 10). The Company did not record an allowance for doubtful accounts at December 31, 2004 and 2005 or March 31, 2006 (unaudited) because it does not have a history of credit losses and write-offs of accounts receivable.

# **Property and Equipment**

Property and equipment are recorded at cost and consist of computer and office machines, furniture and fixtures and leasehold improvements. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Computer and office machines are depreciated over four years and furniture and fixtures are depreciated over seven years. Leasehold improvements are amortized over the shorter of five years or the life of the lease. Significant additions and improvements are capitalized. Expenditures for maintenance and repairs are charged to earnings as incurred. When assets are sold or retired, the related cost and accumulated depreciation are removed from the respective accounts and any resulting gain or loss is included in earnings.

# **Deferred Licensing Fees**

Deferred licensing fees represent a royalty payment made to a related party licensor after the Company received an up-front cash payment upon entering into the joint collaboration and license agreement with Takeda (See Note 10). The royalty payment made to the related party was initially deferred and is being amortized to general and administrative expense as the Company recognizes the related revenue over the term of the agreement.

# Impairment of Long-lived Assets

When necessary, the Company assesses the recoverability of its long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to

# Notes to Combined Financial Statements — (Continued)

the carrying value. There have been no impairment charges recorded during the years ended December 31, 2003, 2004 or 2005 or during the three months ended March 31, 2005 or 2006 because there have been no indicators of impairment during those periods.

### Revenue Recognition

The Company generates revenue from the following primary sources: up-front payments under research and development arrangements, milestone payments and research and development cost sharing payments under the joint collaboration and license agreement with Takeda (see Note 10). The Company recognizes revenue from these sources in accordance with Staff Accounting Bulletin (SAB) 104, "Revenue Recognition" (SAB 104), Emerging Issues Task Force (EITF) Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables", and EITF No. 99-19, "Reporting Revenue Gross as a Principal Versus Net as an Agent".

Up-front licensing fees, which are recorded as contract revenue, are recognized as revenue on the straight-line basis over the estimated performance period under the related agreement because no separate earnings process has been completed when the up-front licensing fee is received.

Up-front option fees received by the Company related to potential joint collaboration and license agreements with Takeda are not recognized as revenue immediately since the transactions do not represent a separate earnings process. Since there are contingent performance obligations by the Company when and if the options are exercised, the Company's policy is to recognize revenue immediately upon expiration of the option or to commence revenue recognition upon exercise of the option and continue recognition over the estimated performance period. When recognized, option fees are recorded as contract revenues.

The Company follows the substantive milestone revenue recognition method for recognizing contingent payments. If a milestone is earned related to the Company's performance, it evaluates whether substantive effort was involved in achieving the milestone. Factors the Company considers in determining whether a milestone is substantive and can be accounted for separately from an up-front payment include assessing the level of risk and effort in achieving the milestone, the timing of its achievement relative to the up-front payments, and whether the amount of the payment was reasonable in relation to the Company's level of effort. If these criteria are met, the Company recognizes the milestone payment when it is earned.

Reimbursement of development cost under the joint collaboration and license agreement with Takeda is recognized as revenue using a proportional performance method in accordance with SAB 104. The Company provides multiple services under this agreement; however, there is insufficient evidence of the fair values of each of the individual services. Revenue is therefore recognized on a straight-line basis over the development activity period, estimated to be completed at the end of 2006. The Company believes a straight-line basis is representative of the pattern in which performance takes place. The revenue recognized is limited to the lesser of the cumulative straight-line basis amount or the cumulative reimbursable portion of the research and development costs incurred (see Note 10). The Company has determined, in accordance with EITF 99-19, that it is acting as a principal in this arrangement and, as such, it has recorded reimbursements of development costs as revenues.

Revenues from the performance of research and development cost reimbursement activities under a long-term strategic alliance agreement (see Note 9) are recorded over the period in which the actual research and development activities have occurred, which was equivalent to the term of the agreement, in accordance with SAB 104. This methodology has been utilized for all payments received in advance by the Company.

Contract revenue related to development and consulting activities with related parties is accounted for under the proportional performance method and as services are rendered, respectively. Cost sharing payments received in advance are recorded as deferred revenue and recognized as revenue over the applicable clinical

# Notes to Combined Financial Statements — (Continued)

trial period. The application of this revenue recognition method is based on the proportional clinical trial costs incurred against total expected costs relative to the respective cost sharing arrangement.

Beginning in the second quarter of 2006, the Company will receive royalty payments under its joint collaboration and license agreement with Takeda relating to net sales of AMITIZA by Takeda. Because of the lack of historical data regarding sales returns, royalty payments related to the portion of sales by Takeda that are subject to a right of return will not be reported as revenue until the right of return lapses.

Beginning in the second quarter of 2006, the Company will receive reimbursements of selling and marketing expenses under a Supplemental Agreement with Takeda. The Company has determined, in accordance with EITF 99-19, that it is acting as a principal in this arrangement and, as such, will record reimbursements of these amounts as revenues.

# **Deferred Revenue**

Consistent with the Company's policy on revenue recognition, deferred revenue represents cash received in advance for licensing fees, option fees, consulting, research and development contracts and related cost sharing and supply agreements. Such payments are reflected as deferred revenue until revenue can be recognized under the Company's revenue recognition policy. The classification of current deferred revenue is attributable to management's assumptions as to when the Company will complete the earnings process and be able to recognize the deferred amount as revenue. At December 31, 2004 and 2005 and March 31, 2006 (unaudited), total deferred revenue was \$28,315,684, \$41,933,046 and \$36,646,042, respectively.

### Other Liabilities

Other liabilities represents the portion of option payments received in advance that are refundable in the event that certain contractual contingencies are not met (see Note 10).

# Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the cost of salaries and expenses to third parties who conduct research and development activities pursuant to development and consulting agreements on behalf of the Company. Costs related to the acquisition of intellectual property are expensed as incurred since the underlying technology associated with such acquisitions were made in connection with the Company's research and development efforts and the technology is unproven and had not received regulatory approval at its early stage of development. Milestone payments due under agreements with third party contract research organizations (CROs) are accrued when it is deemed probable that the milestone event will be achieved.

# Selling, General and Administrative Expenses

Selling, general and administrative costs are expensed as incurred and consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, information technology and human resource functions, as well as costs associated with sales and marketing activities. Other costs include facility costs and professional fees for legal and accounting services.

# Milestone Royalties — Related Parties

Milestone royalties — related parties are expensed as incurred immediately when the related milestone revenue is recognized. The milestone royalty is 5% of milestone payments received under any sublicensing agreements for AMITIZA. In addition, for each indication for AMITIZA for which there is regulatory approval, the Company must pay a \$250,000 milestone. The milestone royalties are to be paid to Sucampo AG

# Notes to Combined Financial Statements — (Continued)

(SAG), (Switzerland), affiliated through common ownership (see Note 8 for additional information on the lubiprostone license agreement between SAG and the Company).

# Interest Income and Expense

Interest income consists of interest earned on the Company's cash and cash equivalents and short-term investments. Interest expense primarily consists of interest incurred on a related party notes payable.

### **Employee Stock-Based Compensation**

On January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) Statement No. 123R, "Share-Based Payment", (SFAS 123R), under the prospective method, which requires the measurement and recognition of compensation expense for all share-based payments made to employees and directors be based on estimated fair values. Through December 31, 2005, the Company has elected to account for stock-based compensation attributable to stock options awarded to employees, directors and officers using the intrinsic value method prescribed in Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25). Under APB 25 guidance, stock-based compensation cost is measured as the excess, if any, of the fair market value of the Company's common stock at the date of grant over the exercise price of the option granted. Compensation cost, if any, is recognized over the related vesting period, as appropriate.

SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure" (SFAS 148) amends the disclosure requirements of SFAS No. 123, "Accounting for Stock-Based Compensation" (SFAS 123) to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

Had stock-based employee compensation expense been recorded based on the fair value at the grant dates consistent with the recognition method prescribed by SFAS 123, the Company's net (loss) income for the years ended December 31, 2003, 2004 and 2005 would have been changed to the following pro forma amounts:

	Year	Year Ended December 31,				
	2003	2004	2005			
Net (loss) income	\$ (22,016,574)	\$ (19,653,674)	\$ 6,724,914			
Add: Stock-based employee compensation expense included in net (loss) income	_	_	136,561			
Less: Stock-based employee compensation expense determined under SFAS 123	(33,385)	(107,032)	(179,175)			
Pro forma net (loss) income	\$ (22,049,959)	\$ (19,760,706)	\$ 6,682,300			

The Company has elected to recognize stock-based employee compensation expense under SFAS 123 for its fixed awards with pro-rata vesting based on an accelerated vesting model in accordance with FASB Interpretation No. 28, "Accounting for Stock Appreciation Rights and Other Variable Stock Option Plan or Award Plans" (FIN 28), and affirmed in EITF 00-23, "Issues Related to the Accounting for Stock Compensation under APB Opinion No. 25 and FASB Interpretation No. 44." EITF 00-23 allows companies with fixed awards to amortize the stock-based employee compensation over the vesting periods of the individual stock awards.

There were no such options issued to employees for the years ended December 31, 2003 or 2005 or for the three months ended March 31, 2006 (unaudited). The weighted average fair value per share of options granted to employees during 2004 was \$1.70. The fair value for employee options was estimated at the date of

## Notes to Combined Financial Statements — (Continued)

grant using the Black-Scholes option pricing model with the following weighted average assumptions for 2004:

Expected term	1.8 years
Risk free interest rate	2.43%
Expected volatility	0%
Expected dividend rate	0%

Determining the fair value of the Company's common stock requires making complex and subjective judgments. Our approach to valuation is based on a discounted future cash flow approach that uses the Company's estimates of revenue, driven by assumed market growth rates and estimated costs as well as appropriate discount rates. These estimates are consistent with the plans and estimates that the Company uses to manage its business. There is inherent uncertainty in making these estimates. The Company elected to use the minimum-value method, as explained in SFAS 123, to determine the fair value for the employee options granted during 2004.

Adoption of SFAS 123R was implemented utilizing the prospective transition method. Under this method, stock-based compensation expense will be recognized for all share-based payment awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R.

The Company chose the following to use for recording its stock-based compensation expense under SFAS 123R:

- the straight-line method of allocating compensation cost under SFAS 123R,
- continue utilizing the Black-Scholes model as its chosen option-pricing model,
- utilize the "simplified" method to calculate the expected term for options as discussed under Staff Accounting Bulletin (SAB) No. 7, "Share-Based Payment" (SAB 107), and
- an estimate of expected volatility based on the historical volatility of similar entities whose share prices are publicly available.

The result of the adoption of SFAS 123R did not affect the combined financial statements for the periods presented because all outstanding stock options at January 1, 2006 were fully vested and there were no new stock options awarded to employees or modifications to outstanding stock options during the three months ended March 31, 2006 (unaudited). Also, prior periods do not need to be restated for this adoption because the prospective method was chosen by the Company.

# Non-employee Stock-Based Compensation

In August 2005, the Company awarded certain non-employees a total of 60,000 stock options with an exercise price of \$49.75 per share for research and development services. As a result, the Company immediately recognized \$2,163,189 in research and development expense during the year ended December 31, 2005 because the stock option awards were immediately exercisable upon grant. Under the guidance of EITF 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods, or Services", the stock-based compensation expense was calculated at the

## Notes to Combined Financial Statements — (Continued)

date of grant using the fair value method as calculated using the Black-Scholes option pricing model with the following assumptions:

Expected term	4 years
Risk free interest rate	2.67%
Expected volatility	53.9%
Expected dividend rate	0%

The weighted average fair value per share of options granted for the year ended December 31, 2005 was \$36.05. There were no options granted to non-employees during the years ended December 31, 2003 and 2004 or during the three months ended March 31, 2005 and 2006 (unaudited).

#### **Income Taxes**

The Company accounts for income taxes under SFAS No. 109, "Accounting for Income Taxes" (SFAS 109). Under the asset and liability method of SFAS 109, deferred income taxes are recognized for the expected future tax consequences of temporary differences by applying enacted statutory tax rates in effect for the year in which the differences are expected to reverse to differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities. Valuation allowances are provided if it is anticipated that some or all of a deferred tax asset may not be realized. The Company also follows SFAS 5, "Accounting for Contingencies," to assess potential income tax accruals from assessments that could be applied by the U.S. Internal Revenue Service or other foreign taxing authorities from existing tax exposures for taxes ultimately expected to be paid.

For all significant transactions between the Company and SPE and SPL, the Company's management has evaluated the terms of the transactions using significant estimates and judgments to ensure that each significant transaction would be similar if the Company completed the transaction with an unrelated party. Although the Company believes there will be no material tax liabilities to the Company as a result of multi-jurisdictional transactions, there can be no assurance that taxing authorities will not assert that transactions were entered into at monetary values other than fair values. If such assertions were made, the Company's intention would be to vigorously defend its positions; however, there can be no assurance that additional liabilities may not occur as a result of any such assertions.

#### Foreign Currency Translation

The Company translates the assets and liabilities of its foreign combined affiliates, SPE and SPL, into U.S. dollars at the current exchange rate in effect at the end of the year. The gains and losses that result from this process are included in other comprehensive income (loss) in the stockholders' equity section of the balance sheet. The revenue and expense accounts of the foreign subsidiaries are translated into U.S. dollars at the average rates that prevailed during the relevant period.

#### Foreign Currency Transaction

Realized and unrealized currency gains or losses on transactions are included in net income. Similarly, unrealized currency gains or losses on assets and liabilities denominated in a currency other than the functional currency are also included in net income.

#### Other Comprehensive (Loss) Income

SFAS No. 130, "Reporting Comprehensive Income (Loss)," requires that all components of comprehensive income (loss) be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is net income (loss) plus certain other items that are recorded directly to stockholders'

## Notes to Combined Financial Statements — (Continued)

(deficit) equity. The Company has reported the comprehensive income (loss) in the combined statements of operations.

#### Certain Risks, Concentrations and Uncertainties

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

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

Revenues from one unrelated party accounted for 39% of the Company's combined total revenues and other income for the year ended December 31, 2003. A second unrelated party, Takeda, accounted for 63%, 99%, 99% and 99% of the Company's combined total revenues and other income for the years ended December 31, 2004 and December 2005 and the three months ended March 31, 2005 and 2006 (unaudited), respectively.

#### **Segment Information**

Management has determined that the Company has three reportable segments, which are based on its method of internal reporting, which disaggregates its business by geographical location. The Company's reportable segments are the United States, Europe and Japan.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

#### **Recent Accounting Pronouncements**

In December 2004, the FASB issued SFAS No. 123R, "Share-Based Payment", (SFAS 123R) a revision of SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS 123R requires companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use APB 25's intrinsic method of accounting for share-based payments. In accordance with the new pronouncement, the Company has begun recognizing the expense associated with its share-based payments, as determined using a fair-value-based method, in its statements of operations beginning in 2006. The standard generally allows two alternative transition methods in the year of adoption — prospective application and retroactive application with restatement of prior financial statements to include the same amounts that were previously included in the pro forma disclosures. On January 1, 2006, the Company adopted SFAS 123R using the prospective method of implementation. According to the prospective method, the previously issued financial statements will not be adjusted. The adoption of this pronouncement will not have any financial impact on the Company's combined financial statements until new stock option awards are granted to employees because all outstanding stock

## Notes to Combined Financial Statements — (Continued)

options at January 1, 2006 were fully vested and no options were granted during the three months ended March 31, 2006 (see Note 11).

SFAS No. 154, "Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3" (SFAS 154), was issued by the FASB in May 2005. This Statement replaces APB Opinion No. 20, "Accounting Changes", and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements", and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS 154 applies to all voluntary changes in accounting principle and requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. This Statement also requires that a change in depreciation, amortization or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 as of January 1, 2006 did not have a material effect on the Company's combined financial statements.

In November 2005, the FASB Staff issued FASB Staff Position (FSP) FAS 115-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" (FSP FAS 115-1). FSP FAS 115-1 addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. This FSP also includes accounting considerations subsequent to the recognition of other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP amends FASB Statements No. 115, "Accounting for Certain Investments in Debt and Equity Securities", and No. 124, "Accounting for Certain Investments Held by Not-for-Profit Organizations", and APB Opinion No. 18, "The Equity Method of Accounting for Investments in Common Stock". The guidance in this FSP must be applied to reporting periods beginning after December 15, 2005. The adoption of FSP FAS 115-1 as of January 1, 2006 did not have a material effect on the Company's combined financial statements.

In June 2006, the FASB Staff issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" (FIN 48), which clarifies the accounting for uncertain tax positions. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that we recognize in the financial statements the impact of a tax position if that position is more likely than not to be sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on de-recognition, balance sheet classification, interest and penalties, accounting in interim periods and footnote disclosures. The Company will be required to adopt FIN 48 as of January 1, 2007 and is in the process of determining the impact, if any, of the adoption of FIN 48 on the combined financial statements.

#### 3. Pro Forma (unaudited)

## Pro Forma Net (Loss) Income Per Share

Historical net income (loss) per share information is not presented in the statement of operations and comprehensive (loss) income due to the multiple classes of stock from multiple issuers outstanding as a result of the combined nature of the financial statements. We have calculated pro forma net (loss) income per share to give effect to the exchange of 211,765 shares of SPI class A common stock for the acquisition of the common stock of SPE and SPL and the automatic conversion of series A preferred stock into class A common stock as a result of the Company's proposed initial public offering (see Note 14).

Basic pro forma net (loss) income per share is computed by dividing net (loss) income by the sum of the weighted average class A and B common shares outstanding, and shares of SPI class A common exchanged

# Notes to Combined Financial Statements — (Continued)

for SPE and SPL shares outstanding. Diluted pro forma net (loss) income per share is computed by dividing net (loss) income by weighted average common shares and potential common shares outstanding.

The computation of pro forma net (loss) income per share for the years ended December 31, 2003, 2004 and 2005 and for the three months ended March 31, 2005 and 2006 is shown below. The Company has used the negotiated exchange rate at which SPE and SPL shares will be converted into SPI shares in the reorganization (Note 14) in calculating the pro forma basic and diluted net (loss) income per share for all periods presented.

	Yea	r Ended December 31	Three Mor Marc	iths Ended ch 31,	
	2003 (unaudited)	2004 (unaudited)	2005 (unaudited)	2005 (unaudited)	2006 (unaudited)
Basic pro forma net (loss) income per share:					
Net (loss) income	\$ (22,016,574)	\$ (19,653,674)	\$ 6,724,914	\$ 5,099,834	\$ 11,264,810
Weighted average class A and B common shares outstanding for basic net (loss) income per share	3,615,423	3,623,492	3,623,613	3,624,300	3,624,097
Shares of SPI class A common exchanged for SPE and SPL shares outstanding	211,765	211,765	211,765	211,765	211,765
Automatic conversion of series A preferred stock into class A common stock	378,000	378,000	378,000	378,000	378,000
	4,205,188	4,213,257	4,213,378	4,214,065	4,213,862
Basic pro forma net (loss) income per share	\$ (5.24)	\$ (4.66)	\$ 1.60	\$ 1.21	\$ 2.67
Diluted pro forma net (loss) income per share:					
Net (loss) income	\$ (22,016,574)	\$ (19,653,674)	\$ 6,724,914	\$ 5,099,834	\$ 11,264,810
Weighted average class A and B common shares outstanding for diluted net (loss) income per share	3,615,423	3,623,492	3,623,613	3,624,300	3,624,097
Shares of SPI class A common stock exchanged for SPE and SPL shares outstanding	211,765	211,765	211,765	211,765	211,765
Automatic conversion of series A preferred stock into class A common stock	378,000	378,000	378,000	378,000	378,000
Assumed exercise of stock options under the treasury stock method			118,101	102,950	128,662
	4,205,188	4,213,257	4,331,479	4,317,015	4,342,524
Diluted pro forma net (loss) income per share	\$ (5.24)	\$ (4.66)	\$ 1.55	\$ 1.18	\$ 2.59
Potentially dilutive securities include the following:					
Series A preferred stock	3,780	3,780	3,780	3,780	3,780
Employee stock options*	_	_	111,000	111,000	111,000
Non-employee stock options*	_	_	60,000	60,000	60,000

<sup>\*</sup> Employee stock options of 122,500 and 208,375 for 2003 and 2004 are not included as they were considered to be anti-dilutive. The Company did not have any non-employee stock options for 2003 and 2004.

# Pro Forma Stockholders' (Deficit) Equity

In connection with the Company's proposed initial public offering described in Note 14, SPI will issue 211,765 shares of its class A common stock to acquire all the capital stock of its affiliates, SPE and SPL, in connection with the closing of an acquisition agreement dated May 12, 2006. Simultaneously, series A preferred stock will automatically convert into shares of class A common stock at a ratio of 100 shares of class A common stock for each share of preferred stock in accordance with the terms of the preferred stock. The pro forma balance sheet as of March 31, 2006 is presented to give effect to the above capital transactions.

# Notes to Combined Financial Statements — (Continued)

# 4. Property and Equipment

Property and equipment consists of the following as of:

		December 31,			March 31,	
		2004 2005			2006	
		<u></u>			(ur	audited)
Computer and office machines	\$	372,521	\$	390,058	\$	390,275
Furniture and fixtures		243,189		274,526		279,797
Leasehold improvements		52,375		48,776		48,835
Total cost		668,085		713,360	<u></u>	718,907
Less: accumulated depreciation and amortization	(	(467,373)		(535,900)		(552,894)
	\$	200,712	\$	177,460	\$	166,013

Depreciation and amortization expense for the years ended December 31, 2003, 2004 and 2005 was \$91,278, \$95,412 and \$61,764, respectively. Depreciation and amortization expense for the three months ended March 31, 2005 and 2006 (unaudited) was \$15,633 and \$16,995, respectively.

# 5. Accrued Expenses

Accrued expenses consist of the following as of:

		December 31,			N	Iarch 31,
		2004		2005		2006
					(u	naudited)
Research and development costs	\$	1,303,442	\$	1,406,893	\$	289,793
Commercialization costs		_		_		396,975
Employee compensation		379,641		487,240		242,699
Legal service fees		_		89,803		76,500
Other expenses		45,494		99,278		118,492
	\$	1,728,577	\$	2,083,214	\$	1,124,459

# 6. Commitments and Contingencies

# **Operating Leases**

The Company leases office spaces in the United States, United Kingdom and Japan under operating leases through 2010. The leases require the Company to make certain non-cancelable lease payments until expiration. Total future minimum lease payments under operating leases are as follows as of December 31, 2005:

2006	\$ 454,921
2007	448,477
2008	406,596
2009	372,669
2010	60,951
Total minimum lease payments	\$ 1,743,614

## Notes to Combined Financial Statements — (Continued)

Rent expense for all operating leases was \$449,603, \$490,241 and \$538,092 for the years ended December 31, 2003, 2004 and 2005, respectively. Rent expense for all operating leases was \$88,736 and \$132,209 for the three months ended March 31, 2005 and 2006 (unaudited).

#### Research and Development Costs

The Company routinely enters into several agreements with third party CROs to oversee clinical research and development studies provided on an outsourced basis. The Company is not contractually obligated to pay the CRO if the service or reports are not provided. Future estimated annual costs under these agreements as of December 31, 2005 are as follows:

2006	\$ 3,091,000
2007	 730,000
Total estimated annual costs	\$ 3,821,000

#### 7. Notes Payable — Related Parties

In October 2000, the Company entered into a note agreement with RTU, affiliated through common ownership, pursuant to which the Company borrowed \$1,266,192. The rate of interest charged on the loan was calculated on the basis of two percentage points per annum on the outstanding principal balance. Principal and interest payments were due in eight semi-annual installments of \$158,275, which commenced on April 1, 2001. The maturity date of the note was October 1, 2004. As a result of the borrowing rate of the note payable being below market rates at the date of issuance, the calculated discount of \$311,335 was based on an imputed interest rate of 9%. Discount amortization for the years ended December 31, 2003 and 2004 were \$86,877 and \$63,558, respectively. The effective interest rate on the debt for the years ended December 31, 2004 was approximately 9%. The note was completely paid as of December 31, 2004.

On August 1, 2003, SPL entered into a note agreement with Sucampo AG (SAG), affiliated through common ownership, pursuant to which SPL borrowed \$2,494,800. The rate of interest charged on the loan was calculated on an annual basis of 1% in excess of the 6-month Tokyo InterBank Offered Rate (TIBOR) per annum on the outstanding principal balance. Principal and interest payments were due and payable within six months from the date of the agreement, but could be automatically extended for six month periods not to exceed two years. On August 1, 2005, an addendum to the note was executed which extended the term to July 31, 2007. The rate of interest charged on the loan was also amended and is now equal to the minimum rate permitted by the Swiss Federal Tax Administration for obligations denominated in Japanese Yen, per annum (approximately 2.5% at December 31, 2005) on the outstanding principal balance, payable semi-annually. As of December 31, 2005 and March 31, 2006 (unaudited), the note had approximately \$2.5 million outstanding.

On February 20, 2004 and March 29, 2004, SPL issued 3-year bonds with an aggregate face value of \$1,025,970 to S&R Technology Holdings, LLC (affiliated through common ownership). Interest on the bonds was payable every six-months at a rate of 0.5% per annum, which represented a market rate of interest in Japan. The bonds were paid in full by December 31, 2005 and all conversion rights were cancelled.

On May 7, 2004, SPE entered into a three-year facility agreement with S&R Technology Holdings, LLC, affiliated through common ownership, pursuant to which SPE borrowed \$603,919 during May 2004 and \$613,925 during July of 2004. The rate of interest charged on the agreement was calculated on the basis of Euro LIBOR plus 0.5% per annum (approximately 2.9% at December 31, 2005). Principal and interest payments were repayable anytime during the three year term. The note was completely paid off by December 31, 2005.

#### Notes to Combined Financial Statements — (Continued)

On July 1, 2004, SPE formalized a note agreement with SAG, related to the following advances previously made to SPE by SAG for general working capital purposes: \$157,590 on March 20, 2003, \$321,680 on August 6, 2003 and \$364,144 on March 3, 2004. The rate of interest charged on the loan is equal to the minimum rate permitted by the Swiss Federal Tax Administration, per annum (approximately 5.0% at December 31, 2005) on the outstanding principal balance. Principal and interest payments were due and payable within six months from the date of the agreement, but could be automatically extended for six month periods not to exceed two years. If the note is extended, the interest must be paid on June 30th and December 31st of each year. As of December 31, 2005 and March 31, 2006, the note had been extended to July 1, 2006 and had approximately \$850,000 outstanding.

On February 27, 2006, SPE entered into a note agreement with SAG, pursuant to which SPE borrowed \$1,200,000. The rate of interest charged on the loan is equal to the minimum rate permitted by the Swiss Federal Tax Administration for obligations denominated in British Pounds, per annum (approximately 5.0% at December 31, 2005) on the outstanding principal balance. Principal and interest payments are due and payable within six months from the date of the agreement, but can be automatically extended for six month periods, not to exceed two years. If the note is extended, the interest must be paid on June 30th and December 31st of each year. As of March 31, 2006 (unaudited), the note had approximately \$1.2 million outstanding.

#### 8. Related Party Transactions

In October 2002, Sucampo Japan entered into a services agreement with R-Tech whereby Sucampo Japan agreed to perform marketing, regulatory and intellectual property support services for R-Tech relating to RESCULA for a specified monthly fee. The agreement was terminated in August 2003.

In January 2003, Sucampo Japan entered into a services agreement with Sucampo AG whereby Sucampo Japan agreed to perform patent and trademark maintenance services for Sucampo AG for a specified monthly fee. The agreement was terminated in August 2003.

On March 7, 2003, the Company entered into an exclusive supply agreement with RTU, affiliated through common ownership. The agreement grants RTU the exclusive right to manufacture and supply RUG-015, a prostone compound, and lubiprostone, and in consideration for such right RTU agreed to pay the Company as follows: \$1 million upon execution of the agreement, \$2 million upon commencement of a first Phase II lubiprostone trial, \$3 million upon commencement of a first Phase II RUG-015 trial and \$2 million upon commencement of the earlier of a second Phase II or a first Phase III RUG-015 trial. Upon execution of the agreement, the Company had already commenced Phase II clinical trials for RUG-015 and lubiprostone, which resulted in an immediate payment of \$6.0 million — \$1 million for the agreement execution, \$2 million for the commencement of the first Phase II lubiprostone trial, and \$3 million for the commencement of the first phase II RUG-015 trial. The Company evaluated the \$6.0 million in cash receipts from RTU and determined the payments were made for the exclusive right to supply inventory to the Company and determined that the amounts should be deferred until commercialization of the drugs begins since this is the point at which the underlying services would commence. Management also was unable to adequately assign value between the two compounds based on the information available to the Company and determined that the full \$6.0 million deferred amount would be amortized over the contractual life of the relationship which was equivalent to the estimated commercialization periods of both RUG-015 and lubiprostone (estimated to be through December 2020).

During the year ended December 31, 2005, the Company ceased the development of RUG-015 due to less than satisfactory Phase II results and the Company's Board of Directors approved the Company's decision to discontinue the development of RUG-015. In addition to the Company's Board of Directors, RTU also formally approved the abandonment of RUG-015, which was a requirement in the supply agreement terms. Because the

## Notes to Combined Financial Statements — (Continued)

Company was unable to assign value to the compounds at the time the agreement was executed and the \$6.0 million was received from RTU, the full \$6.0 million remained deferred at the abandonment of RUG-015.

On September 1, 2003, the Company entered into a one-year research agreement with SAG for research consulting services provided by the Company. Under the terms of the agreement, SAG was required to pay the Company approximately \$27,000 per month as services were rendered. For the years ended December 31, 2003 and 2004, the Company recognized approximately \$324,000 in contract revenue — related parties in conjunction with this agreement. This agreement was completed as of September 1, 2004 and was not extended by either party.

On August 17, 2004, the Company entered into a sales agreement with SAG for the Company to sell its patent for Rescula® for \$497,000. For the year ended December 31, 2004, the entire proceeds from the sale of the Rescula® patent were recorded as other income — gain on sale of patent to related party. The Company did not incur any expenses for work related to Rescula® during the year ended December 31, 2004.

On October 20, 2004, the Company and SAG amended the initial license agreement for lubiprostone to grant to the Company a royalty-bearing exclusive license, with right of sublicense. In consideration of the license, the Company is required to pay SAG 5% of any upfront and/or milestone payments the Company receives under any sublicensing agreements as well as \$250,000 upon the regulatory approval for each indication for the product. In addition, the Company is required to pay SAG a patent and know-how royalty equivalent of 2.2% and 1.0%, respectively, of net sales of the licensed product, determined on a country-by-country basis. On October 29, 2004, the Company sublicensed lubiprostone to Takeda (see Note 10) and received \$20.0 million of up-front payments during 2004. The Company paid SAG \$1.0 million during 2004 for the 5% royalty on the up-front payment. The Company accounted for the \$1.0 million prepayment to SAG as a deferred licensing fee and is amortizing the payment over the term of the contract on a straight-line basis. The Company expensed \$10,309 and \$61,859 of the deferred licensing fee for the years ended December 31, 2004 and 2005, respectively.

During the year ended December 31, 2005, the Company paid SAG \$1.5 million in royalty payments upon receiving \$30.0 million in milestone payments from Takeda for work surrounding lubiprostone. During the three month period ended March 31, 2005, the Company paid SAG a royalty payment of \$500,000 upon receiving a \$10.0 million milestone payment from Takeda for the NDA filing of lubiprostone. During the three month period ended March 31, 2006 (unaudited), the Company paid SAG royalty payments of \$1.0 million and \$250,000 upon receiving a \$20.0 million milestone payment from Takeda for the FDA approval of lubiprostone. The royalty payments of \$1.5 million, \$500,000 and \$1,250,000 to SAG during the year ended December 31, 2005 and three month periods ended March 31, 2005 and 2006 (unaudited), respectively, were expensed in the respective period as milestone royalties — related parties.

On April 4, 2005 the Company entered into a letter of intent to license SPI-017 from SAG allowing an eight month period to conduct due diligence before any final contract negotiations. Upon signing, the Company paid SAG a \$400,000 non-refundable up-front payment. This payment was recorded as research and development expenses for the year ended December 31, 2005. During February 2006, the Company and SAG executed an exclusive license for North, Central and South America to develop and commercialize SPI-017 under SAG's patent(s)/license(s) and the Company made an additional payment of \$1,100,000 to SAG upon final execution. Additionally, the Company will pay SAG milestone payments as follows: \$1,000,000 upon initiation of Phase II of the first indication, \$2,000,000 upon filing of each NDA (not to exceed \$6,000,000), \$2,000,000 upon approval of each NDA (not to exceed \$6,000,000) and 5% of any milestone payments paid to the Company by a third party if the Company sub-licenses rights to a third party. Finally, the Company will pay a patent royalty and know how royalty payment of 4.5% and 2%, respectively. The terms of the license require that SAG and the Company cooperate in conducting future experiments via a joint research committee. The board of directors of SPI approved the restatement of this license on June 15, 2006 (see Note 14).

## Notes to Combined Financial Statements — (Continued)

On June 24, 2005, SPE entered into a 20 year exclusive manufacturing and supply agreement with RTU, affiliated through common ownership. The agreement grants RTU the exclusive right to manufacture and supply lubiprostone for clinical and commercial supplies. In consideration of the exclusive rights, RTU paid SPE \$2.0 million prior to the execution of the agreement on March 31, 2005. Management has determined that the amount should be deferred until such time as the commercial benefit to RTU can be realized. The Company has recorded this amount as deferred revenue, net of current portion as of December 31, 2005 and March 31, 2006 (unaudited).

#### 9. Strategic Alliance Agreement

On February 1, 1999, the Company entered into a five-year strategic alliance agreement with a non-related party that established a long-term alliance for the development and commercialization of medical pharmaceutical products for the treatment of ophthalmic diseases. The Company agreed to conduct non-clinical tests, clinical tests and other research and development for designated compounds prior to the finalization and commercialization of the product. In turn, the Company received payments totaling \$8,000,000, which were amortized ratably over the agreement period. In the event of termination, no amounts were required to be repaid. The Company recognized revenue of approximately \$1,600,000 and \$67,000 for the years ended December 31, 2003 and 2004 under this agreement. All revenues related to this agreement were recognized by December 31, 2004.

## 10. Collaboration and License Agreements

On October 29, 2004, the Company entered into a sixteen-year joint collaboration and license agreement with Takeda to develop and commercialize lubiprostone for gastroenterology indications in the United States and Canada. Under the terms of the agreement, the Company received an upfront payment of \$20 million and, upon reaching future development and commercial milestones, could receive up to \$190 million in additional non-refundable payments. The Company has earned \$30 million and \$20 million in milestones for the year ended December 31, 2005 and the three months ended March 31, 2006 (unaudited), respectively, which is recorded in milestone revenue. The Company is amortizing the up-front payment over the terms of the agreement and has recognized \$206,186 and \$1,237,115 in contract revenue for the years ended December 31, 2004 and 2005, respectively. The Company has recognized \$309,278 in contract revenue for each of the three months ended March 31, 2005 and 2006 (unaudited), respectively.

The Company received \$5 million as an option payment in 2004 to continue negotiations for additional territories held by SPE and SPL. The agreement provided for a negotiation terms of 12 months for the SPL territory and until NDA approval of AMITIZA for the SPE territory. Of the \$5 million payment received, if negotiations did not succeed, a total \$2.5 million would be required to be returned to Takeda (\$1 million for the SPL territory and \$1.5 million for the SPE territory). The remaining \$2.5 million was retained by the Company. As to that portion of the option agreement relating to SPL (\$2 million), the Company recorded \$1 million as current deferred revenue and \$1 million as other liabilities — short term in 2004. As to the option payment relating to SPE (\$3 million), the Company recorded \$1.5 million as long term deferred revenue and \$1.5 million as other liabilities — long term in 2004. The option right expired for SPL during 2005 and \$1 million was returned to Takeda and the Company recorded the other non-refundable \$1 million in contract revenue for the year ended December 31, 2005. The option right expired for SPE during the first quarter of 2006 and \$1.5 million was returned to Takeda and the Company recorded the other non-refundable \$1.5 million in contract revenue for the three months ended March 31, 2006 (unaudited). See Note 2 for a discussion of the revenue recognition policy for option payments received by the Company.

The agreement provides for cost sharing arrangements, whereby Takeda will fund all development costs up to \$30 million for the development of constipation and C-IBS indications. The Company will fund all costs

## Notes to Combined Financial Statements — (Continued)

in excess of \$30 million up to \$50 million, and Takeda and the Company will equally share all remaining development expenditures. For the years ended December 31, 2004 and 2005, respectively, the Company has received and recognized revenue of \$1,482,337 and \$14,671,508 in reimbursement of research and development costs based on the proportional performance method in accordance with SAB 104. For the three months ended March 31, 2005 and 2006, the Company has recognized revenue of \$4,286,896 and \$3,868,885 in reimbursement of research and development costs. The Company has also incurred \$1,482,337 and \$25,867,306 in research and development expenses relating to the development of constipation and C-IBS indications for the years ended December 31, 2004 and 2005, respectively. The Company has also incurred \$5,689,590 and \$5,531,510 in related research and development expenditures for the three months ended March 31, 2005 and 2006 (unaudited), respectively.

Also, the Company and Takeda will share equally all external costs of regulatory-required studies up to \$20 million, whereas Takeda will fund all remaining costs in excess of \$20 million related to the studies. In addition, for new indications and formulations, Takeda will fund all development costs including regulatory-required studies, the maximum of \$50 million and \$20 million, respectively, for each new indication and formulation. The Company and Takeda will share equally all costs in excess of these amounts. There have not been any external costs of regulatory-required studies through March 31, 2006 (unaudited).

Upon commercialization, Takeda will pay on a quarterly basis royalties as a percentage of net revenues of the product. The Company has not recorded any royalty revenues as of March 31, 2006 (unaudited).

On February 1, 2006, the Company entered into a Supplemental Agreement with Takeda which specifies certain activities to be performed by the Company and Takeda pursuant to the October 29, 2004 agreement. Under the terms of the supplemental agreement, Takeda will reimburse the Company for its future costs incurred for safety monitoring, certain costs associated with the Company's medical and scientific affairs, medical marketing activities, and certain sales activities attributable to the Company's sales representatives.

#### 11. Stockholders' Equity

# **Capital Structure**

On July 7, 2003, the Company amended its certificate of incorporation to increase authorized shares of stock to 10,010,000 shares, \$0.01 par value per share, consisting of 5,000,000 shares designated as class A common stock, 5,000,000 shares designated as class B common stock and 10,000 shares designated as series A preferred stock, \$0.01 par value per share.

On July 7, 2003, the Company's Board of Directors approved a one hundred-for-one stock split for both the class A common stock and the class B common stock for stockholders of record as that date. Under such amendment, the Company converted 380 shares of outstanding class A common stock into 38,000 shares of class A common stock, \$0.01 par value, and 35,813 shares of outstanding class B common stock into 3,581,300 shares of outstanding class B common stock, \$0.01 par value. All outstanding shares, including stock options, have been retroactively reflected in the accompanying Combined Financial Statements and Notes to Combined Financial Statements for all periods presented to reflect the stock split.

The class A common stock is entitled to one vote per share and, with respect to the election of Directors, votes as a separate class and is entitled to elect that number of Directors which constitutes ten percent of the total membership of the Board of Directors. The class B common stock is entitled to 10 votes per share and votes as a separate class on the remaining percentage of Board of Directors not voted on by the class A common stockholders. Each holder of record of class B common stock may, in such holder's sole discretion and at such holder's option, convert any whole number or all of such holder's shares of class B common stock into fully paid and non-assessable shares of class A common stock for each share of class B common stock surrendered for conversion. The class B common stock is not transferable, except upon conversion.

## Notes to Combined Financial Statements — (Continued)

On March 18, 2005, R-Tech converted all shares of its class B common stock into 500,000 shares of class A common stock. As a result, the Company has 543,000 shares of class A common stock outstanding, \$0.01 par value, and 3,081,300 shares of outstanding class B common stock, \$0.01 par value, at December 31, 2005.

During March 2006, the Company sold 229,412 shares of class A common stock in a private transaction. As a result, the Company received approximately \$19.5 million in gross proceeds and incurred approximately \$51,000 in offering costs, which were netted against the proceeds.

Each share of series A convertible preferred stock is convertible at the option of the holder into one hundred shares of class A common stock and has no dividend rights. Holders of series A convertible preferred stock have the same voting rights as holders of class A common stock based on the number of shares of class A common stock into which their shares are convertible. If at any time the Company effects a firm commitment underwritten public offering of its stock, the series A convertible preferred stock will be automatically converted into shares of class A common stock.

SPE has only one class of stock. Under the terms of its articles of incorporation, SPE has 10,000 ordinary shares authorized at \$1.53 par value. Currently, there are 5,000 shares issued and outstanding.

SPL has only one class of stock. Under the terms of its articles of incorporation, SPL has 4,000 ordinary shares authorized at \$420.65 par value. Currently, there are 1,000 shares issued and outstanding.

## Stock Option Plan

On February 15, 2001, the Company adopted a stock option plan (Plan) in order to provide common stock incentives to certain eligible employees, officers and directors, consultants and advisors of the Company. The Board of Directors administers the Plan and has sole discretion to grant options. The exercise price of each option granted under the Plan is determined by the Board of Directors and is to be no less than 100% of the fair market value of the Company's common stock on the date of grant. Determinations of fair market value under the Plan will be made in accordance with methods and procedures established by the Board. On September 1, 2003, the Board of Directors amended the Plan to allow for a maximum of 1,000,000 shares of class A common stock to be issued under all awards, including incentive stock options under the Plan. At March 31, 2005, approximately 829,000 shares were available for future grants under the Plan.

# Notes to Combined Financial Statements — (Continued)

A summary of the activity of the Company's stock option plan is presented below for the three years ended December 31, 2005. All options relate to class A common stock:

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
	Shares	Exercise Price	value
Options outstanding, December 31, 2002	122,500	\$ 5.53	
Options granted	_	_	
Options forfeited	_	_	
Options outstanding, December 31, 2003	122,500	5.53	
Options granted	45,000	38.55	
Options forfeited	(4,125)	8.60	
Options outstanding, December 31, 2004	163,375	14.54	
Options exercised	(1,000)	1.86	
Options forfeited	(51,375)	34.26	
Options outstanding, December 31, 2005	111,000	5.53	
Options outstanding, March 31, 2006 (unaudited)	111,000	5.53	\$ 8,820,965
Options exercisable at December 31, 2005	111,000	5.53	
Options exercisable at March 31, 2006 (unaudited)	111,000	5.53	\$ 8,820,965

The following table summarizes information about employee stock options outstanding and exercisable at December 31, 2005 and March 31, 2006 (unaudited):

	Ou	utstandir	ng	Exercisable			
 Exercise Price	Number of Shares		Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Pi		
\$ 1.86	93,500	\$	1.86	93,500	\$	1.86	
25.15	17,500		25.15	17,500		25.15	
	111,000		5.53	111,000		5.53	

As of December 31, 2005, these employee stock options are all vested and have a maximum term of 10 years. The weighted average remaining contractual life of options outstanding as of December 31, 2005 is 4.34 years.

In May 2005, the Company approved a modification to two employees' stock option awards. The modification was to accelerate the remaining unvested stock options so the shares could be immediately exercisable. According to FASB Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation" (FIN 44), the result of such a modification is to remeasure the stock options that were modified. The remeasurement of the stock options resulted in an immediate charge of \$98,400, which was included in general and administrative expenses for the year ended December 31, 2005.

During the year ended December 31, 2004, SPI's Board of Directors approved a cash payment of \$120,000 to settle stock option awards. Also, during the year ended December 31, 2005, SPI's Board of Directors approved a cash payment of \$180,000 to settle options that were granted and fully vested during 2004. According to FIN 44, the result of such transactions is to record the total compensation charge as the

# Notes to Combined Financial Statements — (Continued)

sum of (i) the intrinsic value of the award at the original measurement date for each award and (ii) the amount of cash paid to the employees that exceeds the lesser of the intrinsic value (if any) of the award at (1) the original measurement date or (2) immediately prior to the cash settlement. Because the options were not initially granted below fair value and no intrinsic value existed for the awards, the Company recorded compensation expenses of \$120,000 and \$180,000, which was included in general and administrative expenses for the years ended December 31, 2004 and 2005, respectively.

The Company granted certain stock options to non-employees in August 2005 and recorded a charge of \$2.2 million in conjunction with the grant which was recorded as a component of research and development expenses. The following table summarizes information about the non-employee stock options that were immediately exercisable at the grant date during August 2005:

		Outstanding	(Non-employe	e)	Exercisable (Non-employee)		
			W	eighted	•	W	eighted
Exercise		Number of	Average		Number of	Average	
	Price	Shares	Exer	cise Price	Shares	Exer	cise Price
\$	49.75	60,000	\$	49.75	60,000	\$	49.75

These non-employee stock options vested immediately and have a maximum term of 10 years. The weighted average remaining contractual life of options outstanding as of December 31, 2005 was 9.25 years.

## 12. Income Taxes

The provision for income taxes consists of the following as of December 31:

	20	003	2004	2005
Current tax expense (benefit):				
Federal	\$	_	\$ —	\$ 1,504,922
State		_	_	261,250
Foreign		_	302,276	(294,009)
Total current expense			302,276	1,472,163
Deferred (benefit) expense:				
Federal		_	_	_
State		_	_	_
Foreign		_	(302,276)	295,876
Total deferred (benefit) expense			(302,276)	295,876
Total income tax expense	\$	_	\$	\$ 1,768,039

## Notes to Combined Financial Statements — (Continued)

Deferred tax assets, net, consist of the following as of December 31:

	 2004		2005
Deferred tax assets:			
Net operating loss carryforwards	\$ 13,927,587	\$	481,913
Deferred revenue	3,225,292		14,369,596
General business credit carryforwards	3,263,350		3,252,453
Accrued expenses	723,226		523,939
Tax benefits on stock options			847,883
Other	 17,721		<u> </u>
Gross deferred tax assets	 21,157,176	<u> </u>	19,475,784
Deferred tax liabilities:			
Property and equipment	(5,621)		(39,657)
Deferred licensing fee	_		(24,139)
Gross deferred tax liabilities	 (5,621)		(63,796)
Less: valuation allowance	(20,834,356)		(19,411,988)
Net deferred tax assets	\$ 317,199	\$	

As of December 31, 2004 and 2005, management did not believe it was more likely than not that the deferred tax assets would be realized due to the uncertainty of the Company's ability to generate a sufficient level and proper mix of taxable income in the near term. Consequently, a valuation allowance of \$20.8 million and \$19.4 million has been recorded as of December 31, 2004 and 2005, respectively.

The provision for income taxes varies from the income taxes provided based on the federal statutory rate of 34% as follows for the three years ended December 31:

	2003	2004	2005
Federal tax provision at statutory rate	34.0%	34.0%	34.0%
State taxes, net of federal tax benefit	_	5.0	2.0
General business credits	<del>-</del>	2.9	(20.1)
Changes in valuation allowance	(33.9)	(40.8)	(14.3)
Adjustment to net operating loss carryforward	_	_	13.8
Changes in other tax matters	(0.1)	(1.1)	5.4
Total	0.0%	0.0%	20.8%
General business credits Changes in valuation allowance Adjustment to net operating loss carryforward Changes in other tax matters	(0.1)	2.9 (40.8) — (1.1)	(20.1) (14.3)

The effective income tax rate on earnings from continuing operations was 20.8% in 2005 as compared to 0% in 2004 and 2003. The higher effective tax rate in 2005 is attributable to the Company's 2005 taxable income position in excess of net operating loss carryforwards and allowable tax credit offsets.

At December 31, 2004 and 2005, the Company had U.S. federal net operating loss carryforwards (NOLs) of \$32.8 million and \$0, respectively, and foreign NOLs of \$1.7 million and \$1.4 million, respectively. The U.S. NOLs were fully utilized as of December 31, 2005, and the foreign NOLs begin to expire in December 2010. At December 31, 2004 and 2005, the Company had general business credits of \$3.3 million, which also may be available to offset future income tax liabilities and will expire if not utilized at various dates beginning December 31, 2022. The realization of the benefits of the tax credits is dependent on sufficient taxable income in future years. Lack of earnings, a change in the ownership of the Company, or the application of the alternative minimum tax rules could adversely affect the Company's ability to utilize these tax credits.

# Notes to Combined Financial Statements — (Continued)

# 13. Segment Reporting

The Company has determined that it has three reportable geographic segments based on the Company's method of internal reporting, which disaggregates business by geographic location. These segments are the United States, Europe and Japan. The Company evaluates performance of these segments based on income from operations. 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 by the European and Japanese entities to the domestic entity. Following is a summary of financial information by reportable geographic segment.

	Uni	ted States	Eur	rope	 pan housan	Elim	company inations	Co	mbined
Three Months Ended									
March 31, 2006 (unaudited)									
Milestone revenue	\$	20,000	\$	_	\$ _	\$	_	\$	20,000
Reimbursement of research and development costs		3,869		_	_		_		3,869
Contract revenue		309	1	,500	_		_		1,809
Contract revenue — related parties		_			 30		<u> </u>		30
Total revenues		24,178	1	,500	30	·	_		25,708
Depreciation and amortization		14		_	2		_		16
Other operating expenses		10,922		155	48		<u> </u>		11,125
Income (loss) from operations		13,242	1	,345	(20)		_		14,567
Interest income		304		1	1				306
Interest expense		(4)		_	(16)				(20)
Other non-operating income, net		18		8	114		<u> </u>		140
Income before income taxes	\$	13,560	\$ 1	,354	\$ 79	\$		\$	14,993
Capital expenditures	\$	5	\$		\$	\$		\$	5

# Notes to Combined Financial Statements — (Continued)

	Uni	ted States	Europe		Japan (in thou		Intercompany Eliminations ands)		Со	mbined
Three Months Ended March 31, 2005 (unaudited)										
Milestone revenue	\$	10,000	\$	_	\$	_	\$	_	\$	10,000
Reimbursement of research and development costs		4,287		_		_		_		4,287
Contract revenue		309		_		_		_		309
Contract revenue — related parties		_		_		40		_		40
Total revenues		14,596				40				14,636
Depreciation and amortization		14		_		1		_		15
Other operating expenses		8,361		423		107		_		8,891
Income (loss) from operations		6,221		(423)		(68)		_		5,730
Interest income		79		1		34		(34)		80
Interest expense		(38)		(71)		(9)		34		(84)
Other non-operating (expenses) income, net		<u> </u>		(104)		36		<u> </u>		(68)
Income (loss) before income taxes	\$	6,262	\$	(597)	\$	(7)	\$	_	\$	5,658
Capital expenditures	\$	17	\$		\$		\$		\$	17
Year Ended December 31, 2005										
Milestone revenue	\$	30,000	\$	_	\$	_	\$	_	\$	30,000
Reimbursement of research and development costs		14,672		_		_		_		14,672
Contract revenue		1,237		_	1	,000		_		2,237
Contract revenue — related parties		<u> </u>				98		<u> </u>		98
Total revenues		45,909		_	1	,098		_		47,007
Depreciation and amortization		60		_		1		_		61
Other operating expenses		37,713		1,475		254		<u> </u>		39,443
Income (loss) from operations		8,136	(	1,475)		843		_		7,504
Interest income		940		3		136		(34)		1,045
Interest expense		(157)		(139)		(49)		34		(311)
Other non-operating income, net				174		81		_		255
Income (loss) before income taxes	\$	8,919	\$ (	1,439)	\$ 1	,011	\$		\$	8,493
Capital expenditures	\$	39	\$		\$		\$		\$	39
		F-29								

# Notes to Combined Financial Statements — (Continued)

	Un	ited States	Europe	<u>Japan</u> (in thousan	El	tercompany liminations	Co	ombined
Year Ended December 31, 2004								
Milestone revenue	\$	_	\$ —	\$ —	\$	_	\$	_
Reimbursement of research and development costs		1,482	_	_		_		1,482
Contract revenue		275		_		_		275
Contract revenue — related parties		1,239		82		(413)		908
Total revenues		2,996		82		(413)		2,665
Depreciation and amortization		83	2	11		_		96
Other operating expenses		18,655	2,422	1,503		(412)		22,168
Loss from operations	,	(15,742)	(2,424)	(1,432)		(1)		(19,599)
Interest income		93	3	162		(162)		96
Interest expense		(260)	(43)	(33)		162		(174)
Other non-operating (expenses) income, net		22	(164)	164		1		23
Loss before income taxes	\$	(15,887)	\$(2,628)	\$(1,139)	\$	_	\$	(19,654)
Capital expenditures	\$	14	\$ —	\$ 4	\$		\$	18
Year Ended December 31, 2003	,							
Milestone revenue	\$	_	\$ —	\$ —	\$	_	\$	_
Reimbursement of research and development costs		_	_	_		_		_
Contract revenue		1,637	_	_		_		1,637
Revenues — related parties		1,012		5,138		(3,662)	_	2,488
Total revenues		2,649	_	5,138		(3,662)		4,125
Depreciation and amortization		81	_	10		_		91
Other operating expenses		24,110	425	4,928		(3,662)		25,801
(Loss) income from operations		(21,542)	(425)	200		_		(21,767)
Interest income		145	1	104		(104)		146
Interest expense		(210)	(15)	(21)		104		(142)
Other non-operating (expenses) income, net		<u> </u>	4	(258)		<u> </u>		(254)
(Loss) income before income taxes	\$	(21,607)	\$ (435)	\$ 25	\$		\$	(22,017)
Capital expenditures	\$	66	<u> </u>	\$ 19	\$		\$	85
		F-30						

## Notes to Combined Financial Statements — (Continued)

							Inter	company		
	Uni	ited States	Ει	ırope	Jap	oan	Elim	inations	Co	mbined
					(in th	iousa	nds)			
March 31, 2006 (unaudited)										
Property, plant and equipment, net	\$	107	\$	3	\$	56	\$	<u> </u>	\$	166
Identifiable assets	\$	71,713	\$	893	\$ 2,	666	\$	(25)	\$	75,247
December 31, 2005										
Property, plant and equipment, net	\$	116	\$	3	\$	58	\$	<u> </u>	\$	177
Identifiable assets	\$	45,314	\$	1,363	\$ 2,	576	\$	(1,320)	\$	47,933
December 31, 2004										
Property, plant and equipment, net	\$	118	\$	5	\$	78	\$	<u> </u>	\$	201
Identifiable assets	\$	20,920	\$	2,481	\$ 5,	090	\$	(1,665)	\$	26,826

#### 14. Subsequent Events

In April 2006, the Company sold 52,795 shares of class A common stock in a private placement transaction, and received approximately \$4.5 million in net proceeds from that transaction.

On May 23, 2006, the Company's Board of Directors approved a transaction to have SPI acquire all the capital stock of its affiliated European and Asian operating companies, SPE and SPL, via a tax-free reorganization pursuant to Internal Revenue Code Section 368 (a)(1)(B). This transaction is anticipated to close prior to the Company's planned initial public offering. This reorganization is subject to the satisfaction of a number of conditions and may be terminated by the parties in specified circumstances. However, the proposed initial public offering will not be closed unless the reorganization has been consummated.

On June 5, 2006, the Company's Board of Directors approved a 2006 Stock Option Plan and reserved 1,000,000 shares of class A common stock for issuance under that plan. In addition, the Board approved the Employee Stock Purchase Plan and reserved 500,000 shares of class A common stock for issuance under that plan. The Board also authorized the Company to begin pursuing a process for an initial public offering of its class A common stock.

On June 8, 2006, the Company's Board of Directors approved a decision to repay all related party notes payable by June 30, 2006.

#### Restated Sucampo AG License

The Company's Board of Directors has approved a restated license agreement with SAG, which will become effective immediately prior to the closing of the Company's anticipated initial public offering. This agreement supersedes all previous license and data sharing arrangements between the parties and functions as a master license agreement with respect to Sucampo AG's prostone technology. Under the agreement, SAG has granted to SPI and its wholly owned subsidiaries a royalty-bearing, exclusive, worldwide license, with the right to sublicense, to develop and commercialize AMITIZA, SPI-8811, SPI-017 and all other prostone compounds covered by patents and patent applications held by SAG. In connection with this transaction certain personnel of SAG who perform research in the field of prostones will transfer to SPL and the filing and maintenance costs relating to the patent portfolio licensed from SAG will be assumed by the Company. This agreement was executed on June 30, 2006.



, 2006

# **Banc of America Securities LLC**

# **Deutsche Bank Securities**

# **Leerink Swann & Company**

, 2006, all dealers that buy, sell or trade the class A common stock may be required to deliver a prospectus, regardless of whether they are Until participating in this offering. This is in addition to the dealers' obligations to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

#### **PART II**

## INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the National Association of Securities Dealers Inc. filing fee and the NASDAQ listing fee.

	Ar	mount
Securities and Exchange Commission registration fee	\$	9,229
National Association of Securities Dealers Inc. fee		9,125
NASDAQ Stock Market listing fee		*
Accountants' fees and expenses		*
Legal fees and expenses		*
Blue Sky fees and expenses		*
Transfer agent's fees and expenses		*
Printing and engraving expenses		*
Miscellaneous		*
Total expenses	\$	*

<sup>\*</sup> To be filed by amendment.

#### Item 14. Indemnification of Directors and Officers.

Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as director, notwithstanding any provision of law imposing such liability, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnify for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or

other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses.

Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by

We maintain a general liability insurance policy which covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of class A common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us with the meaning of the Securities Act, as amended, against certain liabilities.

## Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of common stock issued, and options granted by us, within the past three years. Also included is the consideration, if any, received by us for such shares and options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

#### (a) Issuances of Capital Stock

From March 31, 2006 through April 12, 2006, we issued and sold 282,207 shares of our class A common stock at a purchase price per share of \$85.00 to nine accredited investors for an aggregate purchase price of \$24.0 million.

All of these issuances were made in reliance on the exemption provided by Section 4(2) of the Securities Act or Regulation D promulgated thereunder. The recipients of securities in each of the above-referenced transactions represented their intentions to acquire the securities for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and appropriate legends were affixed to the instruments representing such securities issued in such transactions. All recipients either received adequate information about us or had, through their relationship with us, adequate access to such information.

## (b) Certain Grants and Exercises of Stock Options

The sale and issuance of the securities described below were exempt from registration under the Securities Act in reliance on Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving a public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

Pursuant to our stock plans, as of May 31, 2006, we have issued options to purchase an aggregate of 338,100 shares of class A common stock. Of these options:

- options to purchase 83,500 shares of class A common stock have been canceled or lapsed without being exercised;
- options to purchase 1,000 shares of class A common stock have been exercised; and
- options to purchase a total of 253,600 shares of class A common stock are currently outstanding, at a weighted average exercise price of \$41.88 per share.

# Item 16. Exhibits and Financial Statement Schedules.

# (a) Exhibits

Exhibit Number	Description of Exhibit
1.1***	Form of Underwriting Agreement
3.1*	Certificate of Incorporation of the Registrant, as amended
3.2***	Form of Restated Certificate of Incorporation of the Registrant to be effective upon closing of the offering
3.3*	Bylaws of the Registrant, as amended
3.4***	Form of Restated Bylaws of the Registrant to be effective upon the closing of the offering
4.1***	Specimen Stock Certificate evidencing the shares of class A common stock
5.1***	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP
10.1*	Amended and Restated 2001 Stock Incentive Plan
10.2***	2006 Stock Incentive Plan
10.3***	2006 Employee Stock Purchase Plan
10.4***	Form of Incentive Stock Option Agreement for 2006 Stock Incentive Plan
10.5***	Form of Nonstatutory Stock Option Agreement for 2006 Stock Incentive Plan
10.6***	Form of Restricted Stock Agreement for 2006 Stock Incentive Plan
10.7	Non-employee Director Compensation Summary
10.8	Employment Agreement, dated June 16, 2006, between the Registrant and Dr. Sachiko Kuno
10.9	Employment Agreement, dated June 16, 2006, between the Registrant and Dr. Ryuji Ueno
10.10*	Form of Executive Employment Agreement
10.11*	Indemnification Agreement, dated May 26, 2004, between the Registrant and Dr. Sachiko Kuno
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10.13*	Indemnification Agreement, dated May 26, 2004, between the Registrant and Mr. Michael Jeffries
10.14*	Indemnification Agreement, dated May 26, 2004, between the Registrant and Mr. Hidetoshi Mine
10.15*	Indemnification Agreement, dated May 23, 2006, between the Registrant and Mr. Gregory D. Perry
10.16*	Form of Investor Rights Agreement
10.17*	Lease Agreement, dated September 16, 1998, between the Registrant and Plaza West Limited Partnership, successor in interest to Trizechahn Plaza West Limited Partnership, as amended
10.18*	Sublease Agreement, dated October 26, 2005, between the Registrant and First Potomac Realty Investment L.P.
10.19	Amended and Restated Patent Access Agreement, dated June 30, 2006, among the Registrant, Sucampo Pharma Europe Ltd., Sucampo Pharma, Ltd. and Sucampo AG

Exhibit Number	Description of Exhibit
10.20***	Exclusive Manufacturing and Supply Agreement, dated June 23, 2004, between the Registrant and R-Tech Ueno, Ltd., as amended on 2006
10.21**	Collaboration and License Agreement, dated October 29, 2004, between the Registrant and Takeda Pharmaceutical Company Limited
10.22**	Agreement, dated October 29, 2004, among the Registrant, Takeda Pharmaceutical Company Limited and Sucampo AG
10.23**	Supply Agreement, dated October 29, 2004, among the Registrant, Takeda Pharmaceutical Company Limited and R-Tech Ueno, Ltd.
10.24**	Supply and Purchase Agreement, dated January 25, 2006, among the Registrant, Takeda Pharmaceutical Company Limited and R-Tech Ueno, Ltd.
10.25**	Supplemental Agreement, dated February 1, 2006, between the Registrant and Takeda Pharmaceutical Company Limited
10.26**	Services Agreement, dated February 9, 2006, between the Registrant and Ventiv Commercial Services, LLC
21.1*	Subsidiaries of the Registrant
23.1	Consent of PricewaterhouseCoopers LLP
23.2***	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1)
24.1*	Powers of Attorney
24.2	Power of Attorney for Timothy Maudlin
24.3	Power of Attorney for V. Sue Molina
99.1*	Consent of Leerink Swann & Co., Inc.

Previously filed.

# (b) Financial Statement Schedules

None.

# Item 17. Undertakings

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions described under Item 14 above, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

<sup>\*\*</sup> Previously filed. Confidential treatment has been requested for portions of this exhibit.

<sup>\*\*\*</sup> To be filed by amendment.

The undersigned Registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

# **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has duly caused this amendment to registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bethesda, Maryland on the 11th day of August, 2006.

SUCAMPO PHARMACEUTICALS, INC.

By: /s/ Sachiko Kuno

Sachiko Kuno, Ph.D. President and Chief Executive Officer

II-6

Pursuant to the requirements of the Securities Act of 1933, this amendment to registration statement has been signed by the following persons in the capacities held on the dates indicated.

Signa	ture	<u>T</u> itle	Date
/s/ Sachiko Kuno,		Director, President and Chief Executive Officer (Principal Executive Officer)	August 11, 2006
* Ryuji Ueno, M.D., F	h.D., Ph.D.	Chief Scientific Officer, Chief Operating Officer and Chairman of the Board of Directors	August 11, 2006
/s/ Mariam E. l Mariam Mo		Chief Financial Officer (Principal Financial and Accounting Officer)	August 11, 2006
* Michael J. Je	ffries	Director	August 11, 2006
* Timothy I. Ma	udlin	Director Elect	August 11, 2006
* Hidetoshi M		Director	August 11, 2006
* V. Sue Mol		Director Elect	August 11, 2006
* Gregory D. F		Director	August 11, 2006
*By: /s/ Sac Sachiko I	erry HIKO KUNO Kuno, Ph.D. Py-in-Fact	_	
		II-7	

# **EXHIBIT INDEX**

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<sup>\*</sup> Previously filed.

<sup>\*\*</sup> Previously filed. Confidential treatment has been requested for portions of this exhibit.

<sup>\*\*\*</sup> To be filed by amendment.

# SUCAMPO PHARMACEUTICALS, INC.

# Non-Employee Director Compensation Program

Each director who is not an employee of, or a spouse of an employee of, Sucampo Pharmaceuticals, Inc. (the "Company") (a "Non-Employee Director") shall receive an annual retainer of \$60,000 for service as a director.

Each Non-Employee Director will also receive a fee of \$1,000 for each meeting of the full board or any committee of the board attended in person or by telephone.

The Company shall reimburse each Non-Employee Director for out-of-pocket expenses incurred in connection with attending any board and committee meetings in person.

#### EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), dated as of June 16, 2006 (the "Effective Date"), is hereby entered into in the State of Maryland by and between SUCAMPO PHARMACEUTICALS, INC., a Delaware corporation (the "Company."), and SACHIKO KUNO, Ph.D. ("Executive").

**WHEREAS**, Executive is one of the founders of the Company and has been employed by the Company for some time, most recently pursuant to the terms of an Amended and Restated Employment Agreement effective as of July 1, 2004;

**WHEREAS**, Executive and her spouse own a controlling interest in Sucampo AG, which will enter into an Amended and Restated Patent Access Agreement with Company to be executed on or about the date hereof (the "Patent Access Agreement") pursuant to which Sucampo AG has licensed certain of its patented technology and know-how to the Company on an exclusive basis in the Company's Territory;

WHEREAS, Executive possesses certain skills, experience or expertise which will be of continued value to the Company;

**WHEREAS**, the parties acknowledge that Executive's abilities and services are unique and will continue to significantly enhance the business prospects of the Company; and

**WHEREAS**, in light of the foregoing, the Company desires to continue to employ Executive as its Chief Executive Officer and President, and Executive desires to remain in such employment.

**NOW, THEREFORE**, in consideration of the promises and the mutual covenants and agreements herein contained, the Company and Executive hereby agree as follows:

## **Article 1. Employment Agreement**

## 1.1 Employment and Duties

The Company offers and Executive hereby accepts employment with the Company for the Term (as hereinafter defined) as its Chief Executive Officer and President, and in connection therewith, agrees to perform such duties as Executive shall reasonably be assigned by the Company's Board of Directors. Executive hereby warrants and represents that Executive has no contractual commitments or other obligations to third parties inconsistent with Executive's acceptance of this employment and performance of the obligations set forth in this Agreement. Executive shall perform such duties and carry out Executive's responsibilities hereunder faithfully and to the best of Executive's ability, and shall devote Executive's full business time and best efforts to the business and affairs of the Company during normal business hours (exclusive of periods of vacation, sickness, disability, or other leaves to which Executive is entitled). Notwithstanding the foregoing, it is understood and agreed that Executive may devote a reasonable amount of her business time to the affairs of the Sucampo Group Companies (i.e., Sucampo AG, S&R Technology Holdings LLC, S&R Foundation, R-Tech Ueno, Ltd., Sucampo Pharma, Ltd. and Sucampo Pharma Europe, Ltd.) in which she is currently engaged as a director, officer, manager, member or employee, as the case may be, and that such activities shall be permitted under this Agreement insofar as they do not materially interfere with Executive's performance of her responsibilities and duties under this Agreement. Executive will perform all of Executive's responsibilities in compliance with all applicable laws and will ensure that the operations that Executive manages are in compliance with all applicable laws.

## **Article 2. Employment Term**

# 2.1 <u>Term</u>

The term of Executive's employment hereunder (the "<u>Term</u>") shall be deemed to commence on the Effective Date and shall end on the third anniversary of the Effective Date, unless sooner terminated as hereinafter provided; <u>provided</u>, <u>however</u>, that the Term shall be automatically renewed and extended for an additional period of one (1) year on each anniversary thereafter unless either party gives a Notice of Termination (as defined below) to the other party at least sixty (60) days prior to such anniversary.

## 2.2 Survival on Merger or Acquisition

In the event the Company is acquired during the Term, or is the non-surviving party in a merger, or sells all or substantially all of its assets, this Agreement shall not automatically be terminated, and the Company agrees to use its best efforts to ensure that the transferee or surviving company shall assume and be bound by the provisions of this Agreement.

## **Article 3. Compensation and Benefits**

## 3.1 Compensation

(a) <u>Base Salary</u>. The Company shall pay Executive a salary at an annual rate that is not less than Three Hundred Eighty Thousand Dollars (\$380,000.00), to be paid in bi-weekly installments, in arrears (the "<u>Base Salary</u>"). Thereafter, the Base Salary will be reviewed by the Compensation Committee of the Board of Directors (the "Compensation

Committee") at least annually, and its recommendations shall be reviewed and approved by the independent members of the Board. Base Salary may, in the sole discretion of the independent Directors, be increased, but not decreased (unless mutually agreed by Executive and the Company).

- (b) <u>Stock Compensation</u>. Following the occurrence of the <u>Equity Eligibility Date</u>, Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the 2006 Stock Incentive Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discretionary, and shall be made by the Compensation Committee, subject to review and approval by the independent members of the Board. In the event that, during the Term (i) the Company is acquired or is the non-surviving party in a merger, or (ii) the Company sells all or substantially all of its assets, or (iii) in the event of the death of Executive, all unvested restricted stock awards and incentive stock options having previously been awarded to Executive shall immediately vest and may be exercised in accordance with the terms of the Plan and the Executive's grant award. For purposes of this Agreement, the "Equity Eligibility Date" shall be the date upon which the equity ownership in the Company of Executive, when combined with that of Dr. Ryuji Ueno, shall cease to represent at least fifty percent (50%) of the Company's total equity.
- (c) <u>Bonuses</u>. Executive shall be eligible to receive an annual bonus award in recognition of Executive's contributions to the success of the Company pursuant to the Company's management incentive bonus program as it may be amended or modified from time to time. The bonus award shall be based on an annual incentive target of fifty

percent (50%) of Executive's Base Salary, and determined by the Compensation Committee's assessment of Executive's achievement of annual objectives. The Compensation Committee's recommendation shall be reviewed and approved by the independent members of the Board. The decision to make an award and the amount of any award shall be determined by the independent Directors, in their sole discretion.

(d) <u>Withholding Taxes</u>. All compensation due to Executive shall be paid subject to withholding by the Company to ensure compliance with all applicable laws and regulations.

## 3.2 Participation in Benefit Plans

Executive shall be entitled to participate in all employee benefit plans or programs of the Company offered to other employees to the extent that Executive's position, tenure, salary, and other qualifications make Executive eligible to participate in accordance with the terms of such plans. The Company does not guarantee the continuance of any particular employee benefit plan or program during the Term, and Executive's participation in any such plan or program shall be subject to all terms, provisions, rules and regulations applicable thereto. Executive will be entitled to four (4) weeks of vacation per year, to be used and administered in accordance with the Company's vacation policy as it may change from time to time.

#### 3.3 Expenses

The Company will pay or reimburse Executive for all reasonable and necessary out-of-pocket expenses incurred by Executive in the performance of Executive's duties under this Agreement. Executive shall provide to the Company detailed and accurate records of such

expenses for which payment or reimbursement is sought, and Company payments shall be in accordance with the regular policies and procedures maintained by the Company from time to time.

# 3.4 Professional Organizations

During the Term, Executive shall be reimbursed by the Company for the annual dues payable for membership in professional societies associated with subject matter related to the Company's interests. New memberships for which reimbursement will be sought shall be approved by the Company in advance.

#### 3.5 Parking

During the Term, the Company shall either provide parking for Executive's automobile at the Company's expense or reimburse Executive for such expense.

## **Article 4. Termination of Employment**

## 4.1 Definitions

As used in Article 4 of this Agreement, the following terms shall have the meaning set forth for each below:

(a) "Benefit Period" shall mean the eighteen (18) month period commencing on the Date of Termination which occurs in connection with a termination of employment described in the first sentence of Section 4.4(a).

- (b) "Cause" shall mean any of the following:
  - (i) the gross neglect or willful failure or refusal of Executive to perform Executive's duties hereunder (other than as a result of Executive's death or Disability);
  - (ii) perpetration of an intentional and knowing fraud against or affecting the Company or any customer, supplier, client, agent or employee thereof;
- (iii) any willful or intentional act that could reasonably be expected to injure the reputation, financial condition, business or business relationships of the Company or Executive's reputation or business relationships;
  - (iv) conviction (including conviction on a nolo contendere plea) of a felony or any crime involving fraud, dishonesty or moral turpitude;
- (v) the material breach by Executive of this Agreement (including, without limitation, the Employment Covenants set forth in Article 5 of this Agreement); or
- (vi) the failure or continued refusal to carry out the directives of the Board of Directors that are consistent with Executive's duties and responsibilities under this Agreement which is not cured within thirty (30) days after receipt of written notice from the Company specifying the nature of such failure or refusal; <a href="mailto:provided">provided</a>, <a href="however">however</a>, that Cause shall not exist if such refusal arises from

Executive's reasonable, good faith belief that such failure or refusal is required by law.

- (c) "<u>Date of Termination</u>" shall mean the date specified in the Notice of Termination (as hereinafter defined) (except in the case of Executive's death, in which case the Date of Termination shall be the date of death); <u>provided</u>, <u>however</u>, that if Executive's employment is terminated by the Company other than for Cause, the date specified in the Notice of Termination shall be at least thirty (30) days from the date the Notice of Termination is given to Executive
- (d) "Notice of Termination" shall mean a written notice from the Company to Executive that indicates Section 2 or the specific provision of Section 4 of this Agreement relied upon as the reason for such termination or nonrenewal, the Date of Termination, and, in the case of termination or non-renewal by the Company for Cause, in reasonable detail, the facts and circumstances claimed to provide a basis for termination or nonrenewal.
  - (e) "Good Reason" shall mean:
    - (i) Company effects a material diminution of Executive's position, authority or duties;
    - (ii) any requirement that Executive, without her consent, move her regular office to a location more than fifty (50) miles from Company's executive offices;

- (iii) the material failure by Company, or its successor, if any, to pay compensation or provide benefits or perquisites to Executive as and when required by the terms of this Agreement; or
  - (iv) any material breach by Company of this Agreement.

The Executive shall have Good Reason to terminate Executive's employment if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within twenty-one (21) days. If either condition is not met, Executive shall not have a Good Reason to terminate Executive's employment.

# (f) "Change in Control" shall mean:

- (i) the acquisition by any person of beneficial ownership of fifty percent (50%) or more of the outstanding shares of the Company's voting securities; or
  - (ii) the Company is the non-surviving party in a merger; or
- (iii) the Company sells all or substantially all of its assets; provided, however, that no "Change in Control" shall be deemed to have occurred merely as the result of a refinancing by the Company or as a result of the Company's insolvency or the appointment of a conservator; or

(iv) the Compensation Committee of the Company, in its sole and absolute discretion determines that there has been a sufficient change in the share ownership or ownership of the voting power of the Company's voting securities to constitute a change of effective ownership or control of the Company.

### 4.2 Termination Upon Death or Disability

This Agreement, and Executive's employment hereunder, shall terminate automatically and without the necessity of any action on the part of the Company upon the death of Executive. In addition, if at any time during the Term, Executive shall become physically or mentally disabled (as determined by an independent physician competent to assess the condition at issue), whether totally or partially, so that Executive is unable substantially to perform Executive's duties and services hereunder, with or without reasonable accommodation, for either (i) a period of sixty (60) consecutive calendar days, or (ii) ninety (90) consecutive or non-consecutive calendar days during any consecutive five (5) month period (the "Disability Date"), the Company may terminate this Agreement and Executive's employment hereunder by written notice to Executive after the Disability Date (but before Executive has recovered from such disability).

### 4.3 Company's and Executive's Right to Terminate

This Agreement and Executive's employment hereunder may be terminated at any time by the Company for Cause or, if without Cause, upon thirty (30) days prior written notice to Executive. In the event the Company should give Executive notice of termination without Cause, the Company may, at its option, elect to provide Executive with thirty (30) days' salary in lieu of Executive's continued active employment during the notice period. This Agreement and

Executive's employment hereunder may be terminated by Executive at any time for Good Reason and, if without Good Reason, upon thirty (30) days prior written notice to the Company.

### 4.4 Compensation Upon Termination

(a) <u>Severance</u>. In the event the Company terminates (or elects not to renew) this Agreement without Cause or pursuant to Section 4.2 due to the disability of Executive, or in the event Executive terminates this Agreement for Good Reason, Executive shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement of any COBRA continuation premium payments made by Executive for the Benefit Period, and (iii) a lump sum severance payment equal to twenty-four (24) months of Executive's then current Base Salary to be made not later than ten (10) business days following the expiration of the revocation period in Executive's release (as provided in Section 4.4(c) below) without any revocation having occurred. Notwithstanding the foregoing, the Company shall, to the extent necessary and only to the extent necessary, modify the timing of delivery of severance benefits to Executive if the Company reasonably determines that the timing would subject the severance benefits to any additional tax or interest assessed under Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"). In such event, the payments will be made as soon as practicable without causing the severance benefits to trigger such additional tax or interest under Section 409A of the Code In the event this Agreement is terminated (or not renewed) for any reason other than by the Company without Cause or pursuant to Section 4.2 due to the disability of Executive or by Executive for Good Reason, Executive shall not be entitled to the continuation of any compensation, bonuses or

benefits provided hereunder, or any other payments following the Date of Termination, other than Base Salary earned through such Date of Termination.

- (b) <u>Change in Control</u>. In the event that Executive is terminated other than for "Cause" within eighteen (18) months following the occurrence of a "Change in Control" of the Company, then Executive shall be entitled to a severance payment in an amount that is two (2) times the amount specified in Section 4.4(a), clause (iii) above (the "Change in Control Severance Payment"). In the event that Executive shall become entitled to a Change in Control Severance Payment as provided herein, the Company shall cause its independent auditors promptly to review, at the Company's sole expense, the applicability to those payments of Sections 280G and 4999 of the Code. If the auditors determine that any payment of the Change in Control Severance Payment would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, then such payment owed to Executive shall be reduced by an amount calculated to provide to Executive the maximum Change in Control Severance Payment which will not trigger application of Sections 280G and 4999 of the Code.
- (c) <u>Release</u>. Anything to the contrary contained herein notwithstanding, as a condition to Executive receiving severance benefits to be paid pursuant to this Section 4.4, Executive shall execute and deliver to the Company a general release in the form attached hereto as Exhibit A. The Company shall have no obligation to provide any severance benefits to Executive until it has received the general release from Executive and any revocation or rescission period applicable to the Release shall have expired without revocation or rescission.

### **Article 5. Employment Covenants**

### 5.1 Definitions

As used in this Article 5 of the Agreement, the following terms shall have the meaning set forth for each below:

- (a) "Affiliate" shall mean a person or entity that directly, or indirectly through one or more intermediaries, controls or is controlled by, or under common control with another person or entity, including current and former directors and officers of such an entity.
- (b) "Confidential Information" shall mean all confidential and proprietary information of the Company, its Predecessors and Affiliates, whether in written, oral, electronic or other form, including but not limited to trade secrets; technical, scientific or business information; processes; works of authorship; Inventions; discoveries; developments; systems; chemical compounds; computer programs; code; algorithms; formulae; methods; ideas; test data; know how; functional and technical specifications; designs; drawings; passwords; analyses; business plans; information regarding actual or demonstrably anticipated business, research or development; marketing, sales and pricing strategies; and information regarding the Company's current and prospective consultants, customers, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii)

Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall (a) promptly, but in no event more than 72 hours after learning of such court order or other government process, notify, pursuant to Section 6.1 below, the Company; (b) at the Company's expense, take all reasonable necessary steps requested by the Company to defend against the enforcement of such court order or other government process, and permit the Company to intervene and participate with counsel of its choice in any proceeding relating to the enforcement thereof; and (c) if such compelled disclosure is required, Executive shall disclose only that portion of the Confidential Information that is necessary to meet the minimum legal requirement imposed on Executive.

(c) "Executive Work Product" shall mean all Confidential Information and Inventions conceived of, created, developed or prepared by Executive (whether individually or jointly with others) before or during Executive's entire course of employment with the Company, during or outside of working hours, which relate in any manner to the actual or demonstrably anticipated business, research or development of the Company, or result from or are suggested by any task assigned to Executive or any work performed by Executive for or on behalf of the Company or any of its Affiliates.

- (d) "Invention" shall mean any apparatus, biological processes, cell line, chemical compound, creation, data, development, design, discovery, formula, idea, improvement, innovation, know-how, laboratory notebook, manuscript, process or technique, whether or not patentable or protectable by copyright, or other intellectual property in any form.
- (e) "Predecessor" shall mean an entity, the major portion of the business and assets of which was acquired by another entity in a single transaction or in a series of related transactions.
  - (f) "Trade Secrets," as used in this Agreement, will be given its broadest possible interpretation under the law applicable to this Agreement.

### 5.2 Nondisclosure and Nonuse

Executive acknowledges that prior to and during Executive's entire course of employment with the Company, Executive has had and will have occasion to create, produce, obtain, gain access to or otherwise acquire, whether individually or jointly with others, Confidential Information. Accordingly, during the term of Executive's employment with the Company and at all times thereafter, Executive shall keep secret and shall not, except for the Company's benefit, disclose or otherwise make available to any person or entity or use, reproduce or commercialize, any Confidential Information, unless specifically authorized in advance by the Company in writing.

### 5.3 Other Confidentiality Obligations

Executive acknowledges that the Company may, from time to time, have agreements with other persons or entities or with the U.S. Government or governments of other countries, or

agencies thereof, which impose confidentiality obligations or other restrictions on the Company. Executive hereby agrees to be bound by all such obligations and restrictions and shall take all actions necessary to discharge the obligations of the Company thereunder, including, without limitation, signing any confidentiality or other agreements required by such third parties.

### 5.4 Return of Confidential Information

At any time during Executive's employment with the Company, upon the Company's request, and in the event of Executive's termination of employment with the Company for any reason whatsoever, Executive shall immediately surrender and deliver to the Company all records, materials, notes, equipment, drawings, documents and data of any nature or medium, and all copies thereof, relating to any Confidential Information (collectively the "the Company Materials") which is in Executive's possession or under Executive's control. Executive shall not remove any of the Company Materials from the Company's business premises or deliver any of the Company Materials to any person or entity outside of the Company, except as required in connection with Executive's duties of employment. In the event of the termination of Executive's employment for any reason whatsoever, Executive shall promptly sign and deliver to the Company a Termination Certificate in the form of Exhibit B attached hereto.

### 5.5 Confidential Information of Others

Executive represents that Executive's performance of all the terms of this Agreement and Executive's employment with the Company do not and will not breach any agreement to keep in confidence proprietary information, knowledge or data with regard to which Executive has obligations of confidentiality or nonuse, and Executive shall not disclose to the Company or cause the Company to use any such confidential proprietary information, knowledge or data

belonging to any previous employer of Executive or other person, except as such disclosure or use may be authorized in writing by the previous employer or other person. Executive represents that Executive has not brought and will not bring to the Company or use at the Company any confidential materials or documents of any former employer or other person that are not generally available to the public, unless express written authorization for their possession and use has been obtained from such former employer or other person. Executive agrees not to enter into any agreement, whether written or oral, that conflicts with these obligations.

### 5.6 Other Obligations

The terms of this Section 5 are in addition to, and not in lieu of, any statutory or other contractual or legal obligation to the Company to which Executive may be subject relating to the protection of Confidential Information.

### 5.7 <u>Assignment of Confidential Information and Inventions; Works Made for Hire</u>

Executive hereby assigns to the Company all right, title and interest in all intellectual property, including any patent applications, trade secrets, know how, copyrights, software, or trademarks associated with the Executive Work Product and Confidential Information. Executive hereby acknowledges and agrees that all Executive Work Product subject to copyright protection constitutes "work made for hire" under United States copyright laws (17 U.S.C. § 101) and is owned exclusively by the Company. To the extent that title to any Executive Work Product subject to copyright protection does not constitute a "work for hire," and to the extent title to any other Executive Work Product does not, by operation of law or otherwise, vest in the Company, all right, title, and interest therein, including, without limitation, all copyrights, patents and trade secrets, and all copyrightable or patentable subject matter, are

hereby irrevocably assigned to the Company. Executive shall promptly disclose to the Company in writing all Executive Work Product. Executive shall, without any additional compensation, execute and deliver all documents or instruments and give the Company all assistance it requires to transfer all right, title, and interest in any Executive Work Product to the Company; to vest in the Company good, valid and marketable title to such Executive Work Product; to perfect, by registration or otherwise, trademark, copyright and patent protection of the Company with respect to such Executive Work Product; and otherwise to protect the Company's trade secret and proprietary interest in such Executive Work Product. Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agents and attorneys-in-fact to act for and on Executive's behalf, and to execute and file any documents and to do all other lawfully permitted acts to further the purposes of this Section 5.7 with the same legal force and effect as if executed by Executive.

### 5.8 Representations

Executive represents that, to the best of her knowledge, none of the Inventions will violate or infringe upon any right, patent, copyright, trademark or right of privacy, or constitute libel or slander against or violate any other rights of any person, firm or corporation, and that Executive will not knowingly create any Invention which causes any such violation.

### 5.9 Inventions, Intellectual Property and Equipment Not Transferred

Executive has set forth on Exhibit C attached hereto a complete list and brief description of all Inventions, intellectual property and equipment located at the Company which is owned directly or indirectly by Executive and which shall not be transferred to the Company pursuant to this Agreement. Except as so listed, Executive agrees that she will not assert any rights under

any intellectual property as having been made or acquired by Executive prior to being employed by the Company. The Company may, at its discretion, require detailed disclosures and materials demonstrating ownership of the intellectual property so listed.

### 5.10 Effect of Patent Access Agreement

Pursuant to the Patent Access Agreement among Sucampo AG ("SAG"), Sucampo Pharmaceuticals, Inc. ("SPI"), Sucampo Pharma, Ltd. ("SPL"), and Sucampo Pharma Europe, Ltd. ("SPE"), SAG has licensed certain of its patented technology and know-how to SPI, SPL, and SPE on an exclusive basis in their respective Territories (as that term is defined in the Patent Access Agreement). The Patent Access Agreement contains provisions pursuant to which patented technology or know-how owned by SAG is either (i) not licensed to SPI, SPL, or SPE, or (ii) if licensed by SAG to SPI, SPL, or SPE, will be transferred back or revert to SAG under certain circumstances. In the event that the provisions of this Agreement and the Patent Access Agreement conflict with respect to the transfer of or right to use any patented technology or know-how covered by the Patent Access Agreement, the parties agree that the provisions of the Patent Access Agreement shall control.

# 5.11 Exclusivity of Employment

During the Term, and without prior approval of the Board of Directors, Executive shall not directly or indirectly engage in any activity competitive with or adverse to the Company's business or welfare or render a material level of services of a business, professional or commercial nature to any other person or firm, whether for compensation or otherwise; provided, however, that Executive may devote a reasonable amount of her business time to the affairs of Sucampo Group Companies in which she is currently engaged as a director, officer, manager,

member or employee, as the case may be, and may participate in charitable and civic undertakings, provided that such activities do not materially interfere with the performance of Executive's duties and responsibilities to the Company.

# 5.12 Covenant Not to Compete

Executive agrees to be bound and abide by the following covenant not to compete:

- (a) <u>Term and Scope</u>. During Executive's employment with the Company and for a period of twelve (12) months after Executive's separation from employment for any reason whatsoever, Executive will not render to any Conflicting Organization (as hereinafter defined), services, directly or indirectly, anywhere in the world in connection with any Conflicting Product (as hereunder defined), except that Executive may accept employment with a Conflicting Organization whose business is diversified (and which has separate and distinct divisions) if Executive first certifies to the Company in writing that such prospective employer is a separate and distinct division of the Conflicting Organization and that Executive will not render services directly or indirectly in respect of any Conflicting Product. Such twelve (12) month time period shall be tolled during any period that Executive is engaged in activity in violation of this covenant.
- (b) <u>Judicial Construction</u>. Executive and the Company agree that, if the period of time or the scope of this Covenant Not to Compete shall be adjudged unreasonably overbroad in any court proceeding, then the period of time and/or scope shall be modified accordingly, so that this covenant may be enforced with respect to such services or geographic areas and during such period of time as is judged by the court to be reasonable.

(c) Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

"Conflicting Product" means any product, method or process, system or service of any person or organization other than the Company that is the same as, similar to or interchangeable with any product, method or process, system or service involving prostones, prostone compounds or derivates, or any prostone-related technology.

"Conflicting Organization" means any person or organization which is engaged in research on or development, production, marketing, licensing, selling, servicing or other commercialization of any Conflicting Product.

### 5.13 Non-Solicitation

For twelve (12) months after termination of employment with the Company for any reason, Executive shall not directly or indirectly solicit or hire, or assist any other person in soliciting or hiring, any person employed by the Company (as of the date of Executive's termination) or any person who, as of the date of Executive's termination, was in the process of being recruited by the Company, or induce any such employee to terminate his or her employment with the Company.

### 5.14 Judicial Enforcement

In the event of a breach or violation of any provision of this Article 5 by Executive, the parties agree that, in addition to any other remedies it may have, the Company shall be entitled to equitable relief for specific performance, and Executive hereby agrees and acknowledges that the

Company has no adequate remedy at law for the breach of the employment covenants contained herein.

### **Article 6. Miscellaneous**

# 6.1 Notices

All notices or other communications which are required or permitted hereunder shall be deemed to be sufficient if contained in a written instrument given by personal delivery, air courier or registered or certified mail, postage prepaid, return receipt requested, addressed to such party at the address set forth below or such other address as may thereafter be designated in a written notice from such party to the other party:

To Company: Sucampo Pharmaceuticals, Inc.

4733 Bethesda Avenue, Suite 450 Bethesda, Maryland 20814

Attention: Chairperson, Board of Directors

To Executive: Sachiko Kuno, Ph.D.

24687 Yacht Club Road St. Michael, Maryland 21663

All such notices, advances and communications shall be deemed to have been delivered and received (i) in the case of personal delivery, on the date of such delivery, (ii) in the case of air courier, on the business day after the date when sent and (iii) in the case of mailing, on the third business day following such mailing.

# 6.2 Headings

The headings of the articles and sections of this Agreement are inserted for convenience only and shall not be deemed a part of or affect the construction or interpretation of any provision hereof.

### 6.3 Modifications; Waiver

No modification of any provision of this Agreement or waiver of any right or remedy herein provided shall be effective for any purpose unless specifically set forth in a writing signed by the party to be bound thereby. No waiver of any right or remedy in respect of any occurrence or event on one occasion shall be deemed a waiver of such right or remedy in respect of such occurrence or event on any other occasion.

# 6.4 Entire Agreement

This Agreement, together with the Exhibits hereto and Executive's Acknowledgement of Consideration, contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, that certain agreement between Executive and the Company dated and effective as of July 21, 2004.

### 6.5 Severability

Any provision of this Agreement that may be prohibited by, or unlawful or unenforceable under, any applicable law of any jurisdiction shall, as to such jurisdiction, be ineffective without affecting any other provision hereof. To the full extent, however, that the provisions of such

applicable law may be waived, they are hereby waived, to the end that this Agreement be deemed to be a valid and binding agreement enforceable in accordance with its terms.

# 6.6 Controlling Law

This Agreement has been entered into by the parties in the State of Maryland and shall be continued and enforced in accordance with the laws of Maryland.

### 6.7 Arbitration

Any controversy, claim, or breach arising out of or relating to this Agreement or the breach thereof shall be settled by arbitration in the State of Maryland in accordance with the rules of the American Arbitration Association for commercial disputes and the judgment upon the award rendered shall be entered by consent in any court having jurisdiction thereof; <u>provided</u>, <u>however</u>, that this provision shall not preclude the Company from seeking injunctive or similar relief from the courts to enforce its rights under the Employment Covenants set forth in Article 5 of this Agreement. It is understood and agreed that, in the event the Company gives notice to Executive of termination for Cause and it should be finally determined in a subsequent arbitration that Executive's termination was not for Cause as defined in this Agreement, then the remedy awarded to Executive shall be limited to such compensation and benefits as Executive would have received in the event of Executive's termination other than for Cause at the same time as the original termination.

# 6.8 Assignments

Subject to obtaining Executive's prior approval, which shall not be unreasonably withheld or delayed, the Company shall have the right to assign this Agreement and to delegate all rights,

duties and obligations hereunder to any entity that controls the Company, that the Company controls or that may be the result of the merger, consolidation, acquisition or reorganization of the Company and another entity. Executive agrees that this Agreement is personal to Executive and Executive's rights and interest hereunder may not be assigned, nor may Executive's obligations and duties hereunder be delegated (except as to delegation in the normal course of operation of the Company), and any attempted assignment or delegation in violation of this provision shall be void.

### 6.9 Read and Understood

Executive has read this Agreement carefully and understands each of its terms and conditions. Executive has sought independent legal counsel of Executive's choice to the extent Executive deemed such advice necessary in connection with the review and execution of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

### SUCAMPO PHARMACEUTICALS, INC.

By: /s/ Kei S. Tolliver

Kei S. Tolliver

Its: Secretary

/s/ Sachiko Kuno

SACHIKO KUNO, Ph.D.

# **GENERAL RELEASE**

This General Release is made and entered into as of theday of, 20 (the "Separation Date"), by and between
(hereinafter "Executive") and Sucampo Pharmaceuticals, Inc. ("SPI"), a corporation organized under the laws of the State of Delaware, and its affiliates
(hereinafter collectively referred to as the "Company").
WHEREAS, Executive and SPI are parties to an Employment Agreement dated
WHEREAS, Executive and Company intend to settle any and all claims that Executive may have against Company as a result of any act, occurrence,
decision, event or omission occurring at any time prior to the signing of this General Release, including, but not limited to, any matter or fact arising out of
Executive's employment with SPI, the termination of Executive's employment pursuant to Section of the Agreement [here specify the particular
section invoked for the termination], or the events giving rise to the Agreement or this General Release;
WHEREAS, under the terms of the Agreement, Executive promised to enter into this General Release as a condition precedent to the separation payments
and benefits to be provided under the Agreement;
<b>NOW, THEREFORE</b> , in consideration of the provisions and the mutual covenants contained herein, the parties agree as follows:

1. Release of Claims. Executive and the Company intend to settle any and all claims that Executive may have against the Company as a result of the
hiring of Executive, Executive's employment, Executive's compensation while employed, and the termination of Executive's employment. Executive agrees
that in exchange for SPI's promises in the Agreement and in exchange for the separation pay and benefits to be paid to Executive as described in the
Agreement, Executive, on behalf of Executive and Executive's heirs, successors and assigns, hereby releases and forever discharges the Company, its
predecessors, successors, and assigns, and their respective officers, directors, shareholders, agents, employees, and insurers (the "Released Parties"), from all
liability for damages and from all claims that Executive may have against the Released Parties arising from or relating to the hiring of Executive, Executive's
compensation while employed, Executive's employment, the termination of Executive's employment pursuant to Section of the Agreement [here specify
the particular section invoked for the termination], and any other actions, decisions, alleged omissions, or events occurring on or prior to the signing of
this General Release.

A. Executive understands and agrees that Executive's release of claims in this General Release includes, but is not limited to, any claims Executive may have under Title VII of the Federal Civil Rights Act of 1964, as amended; the Americans with Disabilities Act, the Equal Pay Act, the Fair Labor Standards Act, the Employee Retirement and Income Security Act, the Age Discrimination in Employment Act, the Family and Medical Leave Act, the Maryland Fair Employment Practices Act, or any other federal, state, or local statute, ordinance, or law.

B. Executive also understands that Executive is giving up all other claims, whether grounded in contract or tort theories, including, but not limited to, wrongful discharge, breach of contract, tortious interference with contractual relations, promissory estoppel,

detrimental reliance, breach of the implied covenant of good faith and fair dealing, breach of express or implied promise, breach of manuals or other policies, breach of fiduciary duty, assault, battery, fraud, invasion of privacy, intentional or negligent misrepresentation, defamation, including libel, slander, discharge defamation and self-publication defamation, discharge in violation of public policy, whistleblower, intentional or negligent infliction of emotional distress, or any other theory, whether legal or equitable.

- C. Executive will not institute any lawsuit against the Released Parties arising from or relating to the hiring of Executive, Executive's employment, Executive's compensation while employed, the termination of Executive's employment, or any other actions, decisions, alleged omissions, or events occurring prior to the signing of this General Release.
- D. To the extent required by law, nothing contained in this General Release will be interpreted to prevent Executive from filing a charge with a governmental agency or participating in or cooperating with an investigation conducted by a governmental agency. However, Executive agrees that Executive is waiving the right to any monetary damages or other individual legal or equitable relief awarded as a result of any such proceeding related to any claim against the Released Parties arising from or relating to the hiring of Executive, Executive's employment, Executive's compensation while employed, the termination of Executive's employment, or any other actions, decisions, alleged omissions, or events occurring on or prior to the signing of this General Release.

E. Notwithsta	anding any of the foregoing, this General Release shall not apply with respect to any rights or claims which Executive may have under the
terms of Section	_ of the Agreement itself <b>[same section as cited above]</b> or to any rights or benefits Executive may

have related to vested accrued benefits under the terms of the Company's benefit plans or to the Executive's right to be indemnified by the Company pursuant to the terms of its bylaws and the law of the State of Delaware.

- F. Executive may revoke this release of claims, insofar as it extends to potential claims under the Age Discrimination in Employment Act, by informing the Company of Executive's intent to revoke this release within seven (7) calendar days following the execution of this General Release. Executive understands that any such revocation must be stated in writing and delivered by hand or by certified mail-return receipt requested within the seven (7) day period to [INSERT name and mailing address]. If Executive exercises this right to revoke or rescind, the Company shall have no obligation to provide severance pay or benefits to Executive as provided by the Agreement.
- G. Executive acknowledges that the Company's obligation to provide any severance pay or benefits pursuant to the Agreement shall not become effective or enforceable until the revocation period identified above has expired without notice of revocation having been made.
- 2. This General Release shall be binding upon, and insure to the benefit of, Executive and the Company and their respective successors and permitted assigns.
- 3. Executive hereby acknowledges and states that Executive has read this General Release and has been advised to consult with an attorney prior to signing this General Release. Executive further represents that Executive has had adequate time to consider the terms of this General Release, that it is written in language which is understandable to Executive, that

Executive fully appreciates the meaning of the terms of this General Release, an	d that Executive enters into this General Release freely and voluntarily.			
<i>IN WITNESS WHEREOF</i> , Executive after due consideration and consultation, has authorized, executed, and delivered this General Release upon the date indicated below.				
DATE:				
	NAME			

# **TERMINATION CERTIFICATE**

I hereby certify that I do not have in my possession or under my control, nor have I failed to return, any "Company Materials" as defined in that certain Employment Agreement (the "Agreement") entered into between Sucampo Pharmaceuticals, Inc., a Delaware corporation, and me, dated				
I further certify that I have complied with and will continue to comply with all the terms of the Agreement.				
	Executive's Signature			
Print Name				
	Date			

EXHIBIT C
Inventions, Intellectual Property, and Equipment Not Transferred to Company

The inventions, intellectual property and/or equipment listed below are currently owned by Sucampo AG, and no rights with respect to the listed inventions, intellectual property and/or equipment are intended to be transferred or assigned to the Company by reason of the Employment Agreement.

Description	Patent No.	Application No.	Country	Status
METHOD FOR INHIBITING INFECTION OF HUMAN T-CELLS	4840941	144131	U.S.A.	Granted
			DIV2	
METHOD FOR TOPICALLY CLEANSING THE HUMAN BODY	5100879	398318	U.S.A.	Granted
			CIP	
CONDOM	4869270	196574	U.S.A.	Granted
TREATMENT OF SHOCK BY CYCLODEXTRINS AND THEIR	5071838	679864	U.S.A.	Granted
DERIVATIVES			CIP	
IMPROVEMENT IN DIURESIS BY CYCLODEXTRINS AND THEIR	5132298	599607	U.S.A.	Granted
DERIVATIVES				
COMPOSITION FOR TREATMENT OF LIGHT-INJURED RETINAL	6248759	09/408562	U.S.A.	Granted
DEGENERATION DISEASE				
COMPOSITION FOR TREATMENT OF LIGHT-INJURED RETINAL		2000-573361	JAPAN	pending
DEGENERATION DISEASE				
AGENT FOR TREATING VISUAL CELL FUNCTION DISORDER	6864232	09/869129	U.S.A.	Granted
AGENT FOR TREATING VISUAL CELL FUNCTION DISORDER		200-590655	JAPAN	pending
AGENT FOR TREATING VISUAL CELL FUNCTION DISORDER		99959930.1	EPC	pending
AGENT FOR TREATING DRY EYE		09/926411	U.S.A.	Allowed
AGENT FOR TREATING DRY EYE	6872383	10/354083	U.S.A.	Granted
			CA	
AGENT FOR TREATING DRY EYE		2001-615007	JAPAN	pending
AGENT FOR TREATING DRY EYE	1173177	00921047.7	EPC	Granted
COMPOSITION FOR TOPICAL ADMINISTRATION	7033604	10/187013	U.S.A.	Granted
COMPOSITION FOR TOPICAL ADMINISTRATION		11/258914	U.S.A.	pending
			DIV	
COMPOSITION FOR TOPICAL ADMINISTRATION		2003-510107	JAPAN	pending
COMPOSITION FOR TOPICAL ADMINISTRATION		02741390.5	EPC	pending
OPHTHALMIC COMPOSITION	6403598	09/485414	U.S.A.	Granted
OPHTHALMIC COMPOSITION	6476039	10/133450	U.S.A.	Granted
			DIV	
OPHTHALMIC COMPOSITION		11-22996	JAPAN	pending
COMPOSITION FOR TREATMENT OF EXTERNAL SECRETION	6339088	09/673563	U.S.A.	Granted
DISORDERS EXCEPT HYPOLACRIMATION				
COMPOSITION FOR TREATMENT OF EXTERNAL SECRETION		2000-599253	JAPAN	pending
DISORDERS EXCEPT HYPOLACRIMATION				
_ 1				

Description	Patent No.	Application No.	Country	Status
METHOD OF TREATING OCULAR ALLERGIES WITH A		10/523842	U.S.A.	pending
MACROLIDE COMPOUND				
METHOD OF TREATING OCULAR ALLERGIES WITH A		2004-527368	JAPAN	pending
MACROLIDE COMPOUND	40.400.44		** • •	
METHOD FOR INHIBITING INFECTION OF HUMAN T-CELLS	4840941	144131	U.S.A.	Granted
METHOD FOR TORICALLY CLEANISM THE HUMAN RODY	F100070	200210	DIV2	C
METHOD FOR TOPICALLY CLEANSING THE HUMAN BODY	5100879	398318	U.S.A. CIP	Granted
METHOD FOR DIAGNOSIS OR PREDICTING SUSCEPTIBILITY TO		11/043959	U.S.A.	pending
PSYCHIATRIC DISORDERS		11/043333	0.5.A.	pending
METHOD FOR DIAGNOSIS OR PREDICTING SUSCEPTIBILITY TO		2005-021515	JAPAN	pending
PSYCHIATRIC DISORDERS		2005 021515	0111111	penamg
METHOD FOR DIAGNOSIS OF OPTIC NEUROPATHY		PCT/JP05/005601	PCT	pending
METHOD FOR TREATING OCULAR HYPERTENSION AND		10/429677	U.S.A.	Allowed
GLAUCOMA				
METHOD FOR TREATING OCULAR HYPERTENSION AND			U.S.A.	pending
GLAUCOMA			CA	
METHOD AND COMPOSITION FOR TREATING OCULAR		2005-501572	JAPAN	pending
HYPERTENSION AND GLAUCOMA				
METHOD AND COMPOSITION FOR TREATING OCULAR		2502437	Canada	pending
HYPERTENSION AND GLAUCOMA			77.0	••
METHOD AND COMPOSITION FOR TREATING OCULAR		03758746.6	EPC	pending
HYPERTENSION AND GLAUCOMA	200240	000001 5	EDC	C
PROSTAGLANDINS OF THE F SERIES OCULAR HYPOTENSIVE AGENTS	289349 5001153	8830931.5	EPC U.S.A.	Granted Granted
OCULAR HYPOTENSIVE AGENTS OCULAR HYPOTENSIVE AGENTS	5001153	246059 584669	U.S.A. U.S.A.	Granted Granted
OCOLAR HIPOTENSIVE AGENTS	3131444	304009	CA	Giailled
OCULAR HYPOTENSIVE AGENTS	2209939	8821104.0	England	Granted
OCULAR HYPOTENSIVE AGENTS	308135	88308299.2	EPC	Granted
OCULAR HYPOTENSIVE AGENTS	455264	91108317.8	EPC DIV	Granted
OCULAR HYPOTENSIVE AGENTS	5194429	615515	U.S.A.	Granted
			DIV	
OCULAR HYPOTENSIVE AGENTS	5236907	774750	U.S.A.	Granted
			CA	
OCULAR HYPOTENSIVE AGENTS	2008226	63-248720	JAPAN	Granted
OCULAR HYPOTENSIVE AGENTS	2009965	63-248721	JAPAN	Granted
OCULAR HYPOTENSIVE AGENTS	366279	89310016.4	EPC	Granted
OCULAR HYPOTENSIVE AGENTS	580268	93202691.7	EPC DIV	Granted
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	458588	91304574.6	EPC	Granted
COMBINATION FOR OCULAR ADMINISTRATION				
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	5166175	704570	U.S.A.	Granted
COMBINATION THE ATMENT OF OCH AR INVESTMENT ON WHITH A CAVIER CICTURE	2514525	0.445500	T A TO A TO	6 1
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	2511585	3-147793	JAPAN	Granted
COMBINATION				

Description	Patent No.	Application No.	Country	Status
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	2042937	2042937-2	Canada	Granted
COMBINATION				
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	109862	8273/91	Korea	Granted
COMBINATION				
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	60036	80103866	TAIWAN	Granted
COMBINATION				
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	458590	91304576.1	EPC	Granted
COMBINATION  THE ATM CENT OF A CAMADA MADERITAN MADERITAN AND A CAMADA C	E4 EE 4 00	000450	TT C A C A	
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	5175189	899170	U.S.A. CA	Granted
COMBINATION FOR OPHTHALMIC USE	20.42026	20.42020 4	C1-	C
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	2042936	2042936-4	Canada	Granted
COMBINATION FOR OPHTHALMIC USE TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	59178	80103867	TAIWAN	Granted
COMBINATION FOR OPHTHALMIC USE	591/6	00103007	IAIWAN	Granted
TREATMENT OF OCULAR HYPERTENSION WITH AN OCULAR	5397797	08/031875	U.S.A. CA	Granted
SYNERGISTIC COMBINATION	3337737	00/031073	0.5.A. CA	Granted
TREATMENT OF OCULAR HYPERTENSION WITH AN OCULAR	2042934	2042934-8	Canada	Granted
SYNERGISTIC COMBINATION	20 1233 1	20123310	Cunada	Grantea
TREATMENT OF OCULAR HYPERTENSION WITH AN OCULAR	59100	80103868	TAIWAN	Granted
SYNERGISTIC COMBINATION		55-555		
PROCESS OF PREPARING PROSTAGLANDIN INTERMEDIATES	2119050	3-223415	JAPAN	Granted
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	5547968	8/487637	U.S.A.	Granted
COMBINATION			CA3	
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	2511611	4-43018	JAPAN	Granted
COMBINATION				
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	2061907	2061907-4	Canada	Granted
COMBINATION				
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	221369	3307/92	Korea	Granted
COMBINATION		0.4.00.000		
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC	63244	81100863	TAIWAN	Granted
COMBINATION THE ATMENT OF OCH AR INVESTMENT ON AUTH A SYMERCISTIC	E01670	02201412.0	EDC	C
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION	501678	92301412.0	EPC	Granted
INCREASING THE CHOROIDAL BLOOD FLOW	5221690	867359	U.S.A.	Granted
INCREASING THE CHOROIDAL BLOOD FLOW  INCREASING THE CHOROIDAL BLOOD FLOW	2592196	4-263463	JAPAN	Granted
INCREASING THE CHOROIDAL BLOOD FLOW  INCREASING THE CHOROIDAL BLOOD FLOW	2065889	2065889-4	Canada	Granted
TREATMENT OF OCULAR HYPERTENSION	5432174	8/162386	U.S.A. CA	Granted
TREATMENT OF OCULAR HYPERTENSION	5452174	5-56852	JAPAN	pending
TREATMENT OF OCULAR HYPERTENSION	0561073	92307700.2	EPC	Granted
PROCESS FOR PRODUCTION OF PROSTAGLANDIN INTERMEDIATES	5274130	07/937949	U.S.A.	Granted
PROCESS FOR PRODUCTION OF PROSTAGLANDIN INTERMEDIATES	2746800	4-233473	JAPAN	Granted
STABILIZATION OF A PROSTANOIC ACID COMPOUND	5523461	8/202132	U.S.A.	Granted
STABILIZATION OF A PROSTANOIC ACID COMPOUND	2839798	4-227047	JAPAN	Granted

Description	Patent No.	Application No.	Country	Status
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC	5773471	08/613048	U.S.A.	Granted
ACID COMPOUNDS				
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	3625946	8-53063	JAPAN	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS		2171226	Canada	pending
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	96107319.5	96107319.5	China	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	399795	6237/96	Korea	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	127611	85102651	TAIWAN	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	701620	48003/96	Australia	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	286141	286141	New Zealand	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	310178	19960974	Norway	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	730866	96301637.3	EPC	Granted
A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT	149214	86105124	TAIWAN	Granted
A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT	6043213	08/981229	U.S.A.	Granted
AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT	6159930	09/450008	U.S.A. DIV	Granted
A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT	3058920	9-537910	JAPAN	Granted
A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT		2225398	Canada	pending
A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT	97190706.4	97190706.4	China	Granted
A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT	0455475	709546/97	Korea	Granted
A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT	725508	25761/97	Australia	Granted
A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT	320601	19975962	Norway	Granted
A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN AS AN ACTIVE INGREDIENT	834320	97917418.2	EPC	Granted
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION	6329426	09/220847	U.S.A. CIP	Granted
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION		11-521457	JAPAN	pending
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION		2274708	Canada	pending
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION		98945530.8	EPC	pending
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION		00103455.2	Hong Kong	pending
DRUG COMPOSITIONS FOR THE TREATMENT OF OCULAR HYPERTENSION OR GLAUCOMA		2000-590641	JAPAN	pending
DRUG COMPOSITIONS FOR THE TREATMENT OF OCULAR HYPERTENSION OR GLAUCOMA		2356912	Canada	pending

Description	Patent No.	Application No.	Country	Status
COMPOSITION FOR APOPTOSIS INHIBITION		09/816655	U.S.A.	pending
COMPOSITION FOR APOPTOSIS INHIBITION		90107002	TAIWAN	pending
COMPOSITION FOR APOPTOSIS INHIBITION		2001-568431	JAPAN	pending
COMPOSITION FOR APOPTOSIS INHIBITION		2403086	Canada	pending
COMPOSITION FOR APOPTOSIS INHIBITION		01809737.5	China	pending
COMPOSITION FOR APOPTOSIS INHIBITION		2002-7012410	Korea	pending
COMPOSITION FOR APOPTOSIS INHIBITION	2001239551	2001239551	Australia	Granted
COMPOSITION FOR APOPTOSIS INHIBITION	521464	521464	New Zealand	Granted
COMPOSITION FOR APOPTOSIS INHIBITION		01914192.8	EPC	pending
TREATMENT OF OCULAR HYPERTENSION	6458836	09/900021	U.S.A. CIP3	Granted
TREATMENT OF OCULAR HYPERTENSION		P010101231	ARGENTINA	pending
TREATMENT OF OCULAR HYPERTENSION		90106162	TAIWAN	pending
TREATMENT OF OCULAR HYPERTENSION		2001-566636	JAPAN	pending
TREATMENT OF OCULAR HYPERTENSION		2402597	Canada	pending
TREATMENT OF OCULAR HYPERTENSION		01809339.6	China	pending
TREATMENT OF OCULAR HYPERTENSION		2002-7011970	Korea	pending
TREATMENT OF OCULAR HYPERTENSION	2001241143	2001241143	Australia	Granted
TREATMENT OF OCULAR HYPERTENSION	521325	521325	New Zealand	Granted
TREATMENT OF OCULAR HYPERTENSION	2002/7140	2002/7140	South Africa	Granted
TREATMENT OF OCULAR HYPERTENSION		PI 0109192	Brazil	pending
TREATMENT OF OCULAR HYPERTENSION	233584	PA/A/2002/008967	Mexico	pending
TREATMENT OF OCULAR HYPERTENSION		IN/PCT/2002/01464	India	pending
TREATMENT OF OCULAR HYPERTENSION		151683	Israel	pending
TREATMENT OF OCULAR HYPERTENSION		PV2002-3092	Czech	pending
TREATMENT OF OCULAR HYPERTENSION		P0300391	Hungary	pending
TREATMENT OF OCULAR HYPERTENSION		20024381	Norway	pending
TREATMENT OF OCULAR HYPERTENSION		01912374.4	EPC	pending
	_			

Description	Patent No.	Application No.	Country	Status
CONTROL OF INTRAOCULAR PRESSURE DURING SURGERY	6414021	09/645361	U.S.A.	Granted
CONTROL OF INTRAOCULAR PRESSURE DURING SURGERY		2001-250329	JAPAN	pending
EYE DROP COMPOSITION		11/110698	U.S.A.	pending
			CIP	
EYE DROP COMPOSITION		2005-513236	JAPAN	pending
EYE DROP COMPOSITION		2006-7003299	Korea	pending
EYE DROP COMPOSITION			Canada	pending
EYE DROP COMPOSITION		04720157.9	EPC	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		10/477359	U.S.A.	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		2002-589015	JAPAN	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		2003-7014707	Korea	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		2002255346	Australia	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		2444627	Canada	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		PI 0209601-3	Brazil	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		PA/A/2003/010363	Mexico	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		20035043	Norway	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		02724768.3	EPC	pending
METHOD FOR INHIBITING APOPTOSIS	6852687	10/132567	U.S.A.	Granted
METHOD FOR INHIBITING APOPTOSIS		2002-123755	JAPAN	pending
METHOD FOR INHIBITING APOPTOSIS		02009265.6	EPC	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		93124177	TAIWAN	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		10/567462	U.S.A.	pending
COMPOSITION FOR PROMOTING HAIR GROWTH			Canada	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		2006-7002643	Korea	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		200480029804.9	China	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		2006-519266	JAPAN	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		04771825.9	EPC	pending
COMPOSITION AND METHOD FOR SCARP AND HAIR		2005-034763	JAPAN	pending
TREATMENT				

Description	Patent No.	Application No.	Country	Status
COMPOSITION AND METHOD FOR SCARP AND HAIR		PCT/JP05/024276	PCT	pending
TREATMENT				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		10/550414	U.S.A.	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		2006-507702	JAPAN	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		2520957	Canada	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		10-2005-7018312	Korea	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		200480009070.8	China	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		04724735.8	EPC	pending
DISEASE				
ENDOTHELIN ANTAGONIST		8-155383	JAPAN	pending
HAIR GROWTH AGENT	3217293	9-100091	JAPAN	Granted

### EMPLOYMENT AGREEMENT

**THIS EMPLOYMENT AGREEMENT** (the "<u>Agreement</u>"), dated as of June 16, 2006 (the "<u>Effective Date</u>"), is hereby entered into in the State of Maryland by and between SUCAMPO PHARMACEUTICALS, INC., a Delaware corporation (the "<u>Company</u>"), and RYUJI UENO, M.D., Ph.D. ("<u>Executive</u>").

**WHEREAS**, Executive is one of the founders of the Company and has been employed by the Company for some time, most recently pursuant to the terms of a Second Amended and Restated Employment Agreement effective as of August 15, 2004;

**WHEREAS**, Executive and his spouse own a controlling interest in Sucampo AG, which will enter into an Amended and Restated Patent Access Agreement with Company to be executed on or about the date hereof (the "Patent Access Agreement") pursuant to which Sucampo AG has licensed certain of its patented technology and know-how to the Company on an exclusive basis in the Company's Territory;

WHEREAS, Executive possesses certain skills, experience or expertise which will be of continued value to the Company;

**WHEREAS**, the parties acknowledge that Executive's abilities and services are unique and will continue to significantly enhance the business prospects of the Company; and

**WHEREAS**, in light of the foregoing, the Company desires to continue to employ Executive as its Chief Operating Officer and Chief Scientific Officer, and Executive desires to remain in such employment.

**NOW, THEREFORE**, in consideration of the promises and the mutual covenants and agreements herein contained, the Company and Executive hereby agree as follows:

## **Article 1. Employment Agreement**

### 1.1 Employment and Duties

The Company offers and Executive hereby accepts employment with the Company for the Term (as hereinafter defined) as its Chief Operating Officer and Chief Scientific Officer, and in connection therewith, agrees to perform such duties as Executive shall reasonably be assigned by the Company's Board of Directors. Executive hereby warrants and represents that Executive has no contractual commitments or other obligations to third parties inconsistent with Executive's acceptance of this employment and performance of the obligations set forth in this Agreement. Executive shall perform such duties and carry out Executive's responsibilities hereunder faithfully and to the best of Executive's ability, and shall devote Executive's full business time and best efforts to the business and affairs of the Company during normal business hours (exclusive of periods of vacation, sickness, disability, or other leaves to which Executive is entitled). Notwithstanding the foregoing, it is understood and agreed that Executive may devote a reasonable amount of his business time to the affairs of the Sucampo Group Companies (i.e., Sucampo AG, S&R Technology Holdings LLC, S&R Foundation, R-Tech Ueno, Ltd., Sucampo Pharma, Ltd. and Sucampo Pharma Europe, Ltd.) in which he is currently engaged as a director, officer, manager, member or employee, as the case may be, and that such activities shall be permitted under this Agreement insofar as they do not materially interfere with Executive's performance of his responsibilities and duties under this Agreement. Executive will perform all of Executive's responsibilities in compliance with all applicable laws

and will ensure that the operations that Executive manages are in compliance with all applicable laws.

### **Article 2. Employment Term**

### 2.1 <u>Term</u>

The term of Executive's employment hereunder (the "Term") shall be deemed to commence on the Effective Date and shall end on the third anniversary of the Effective Date, unless sooner terminated as hereinafter provided; provided, however, that the Term shall be automatically renewed and extended for an additional period of one (1) year on each anniversary thereafter unless either party gives a Notice of Termination (as defined below) to the other party at least sixty (60) days prior to such anniversary.

### 2.2 Survival on Merger or Acquisition

In the event the Company is acquired during the Term, or is the non-surviving party in a merger, or sells all or substantially all of its assets, this Agreement shall not automatically be terminated, and the Company agrees to use its best efforts to ensure that the transferee or surviving company shall assume and be bound by the provisions of this Agreement.

# Article 3. Compensation and Benefits

### 3.1 Compensation

(a) <u>Base Salary</u>. The Company shall pay Executive a salary at an annual rate that is not less than Four Hundred Fifty Thousand Dollars (\$450,000.00), to be paid in bi-weekly installments, in arrears (the "<u>Base Salary</u>"). Thereafter, the Base Salary will be

reviewed by the Compensation Committee of the Board of Directors (the "Compensation Committee") at least annually, and its recommendations shall be reviewed and approved by the independent members of the Board. Base Salary may, in the sole discretion of the independent Directors, be increased, but not decreased (unless mutually agreed by Executive and the Company).

- (b) <u>Stock Compensation</u>. Following the occurrence of the <u>Equity Eligibility Date</u>, Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the 2006 Stock Incentive Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discretionary, and shall be made by the Compensation Committee, subject to review and approval by the independent members of the Board. In the event that, during the Term (i) the Company is acquired or is the non-surviving party in a merger, or (ii) the Company sells all or substantially all of its assets, or (iii) in the event of the death of Executive, all unvested restricted stock awards and incentive stock options having previously been awarded to Executive shall immediately vest and may be exercised in accordance with the terms of the Plan and the Executive's grant award. For purposes of this Agreement, the "Equity Eligibility Date" shall be the date upon which the equity ownership in the Company of Executive, when combined with that of Dr. Sachiko Kuno, shall cease to represent at least fifty percent (50%) of the Company's total equity.
- (c) <u>Bonuses</u>. Executive shall be eligible to receive an annual bonus award in recognition of Executive's contributions to the success of the Company pursuant to the Company's management incentive bonus program as it may be amended or modified

from time to time. The bonus award shall be based on an annual incentive target of fifty percent (50%) of Executive's Base Salary, and determined by the Compensation Committee's assessment of Executive's achievement of annual objectives. The Compensation Committee's recommendation shall be reviewed and approved by the independent members of the Board. The decision to make an award and the amount of any award shall be determined by the independent Directors, in their sole discretion.

(d) Withholding Taxes. All compensation due to Executive shall be paid subject to withholding by the Company to ensure compliance with all applicable laws and regulations.

# 3.2 Participation in Benefit Plans

Executive shall be entitled to participate in all employee benefit plans or programs of the Company offered to other employees to the extent that Executive's position, tenure, salary, and other qualifications make Executive eligible to participate in accordance with the terms of such plans. The Company does not guarantee the continuance of any particular employee benefit plan or program during the Term, and Executive's participation in any such plan or program shall be subject to all terms, provisions, rules and regulations applicable thereto. Executive will be entitled to four (4) weeks of vacation per year, to be used and administered in accordance with the Company's vacation policy as it may change from time to time.

## 3.3 Expenses

The Company will pay or reimburse Executive for all reasonable and necessary out-of-pocket expenses incurred by Executive in the performance of Executive's duties under this

Agreement. Executive shall provide to the Company detailed and accurate records of such expenses for which payment or reimbursement is sought, and Company payments shall be in accordance with the regular policies and procedures maintained by the Company from time to time.

# 3.4 Professional Organizations

During the Term, Executive shall be reimbursed by the Company for the annual dues payable for membership in professional societies associated with subject matter related to the Company's interests. New memberships for which reimbursement will be sought shall be approved by the Company in advance.

#### 3.5 Parking

During the Term, the Company shall either provide parking for Executive's automobile at the Company's expense or reimburse Executive for such expense.

## **Article 4. Termination of Employment**

## 4.1 Definitions

As used in Article 4 of this Agreement, the following terms shall have the meaning set forth for each below:

(a) "Benefit Period" shall mean the eighteen (18) month period commencing on the Date of Termination which occurs in connection with a termination of employment described in the first sentence of Section 4.4(a).

- (b) "Cause" shall mean any of the following:
  - (i) the gross neglect or willful failure or refusal of Executive to perform Executive's duties hereunder (other than as a result of Executive's death or Disability);
- (ii) perpetration of an intentional and knowing fraud against or affecting the Company or any customer, supplier, client, agent or employee thereof:
- (iii) any willful or intentional act that could reasonably be expected to injure the reputation, financial condition, business or business relationships of the Company or Executive's reputation or business relationships;
  - (iv) conviction (including conviction on a nolo contendere plea) of a felony or any crime involving fraud, dishonesty or moral turpitude;
- (v) the material breach by Executive of this Agreement (including, without limitation, the Employment Covenants set forth in Article 5 of this Agreement); or
- (vi) the failure or continued refusal to carry out the directives of the Board of Directors that are consistent with Executive's duties and responsibilities under this Agreement which is not cured within thirty (30) days after receipt of written notice from the Company specifying the nature of such failure or refusal; <a href="mailto:provided">provided</a>, <a href="however">however</a>, that Cause shall not exist if such refusal arises from

Executive's reasonable, good faith belief that such failure or refusal is required by law.

- (c) "<u>Date of Termination</u>" shall mean the date specified in the Notice of Termination (as hereinafter defined) (except in the case of Executive's death, in which case the Date of Termination shall be the date of death); <u>provided</u>, <u>however</u>, that if Executive's employment is terminated by the Company other than for Cause, the date specified in the Notice of Termination shall be at least thirty (30) days from the date the Notice of Termination is given to Executive.
- (d) "Notice of Termination" shall mean a written notice from the Company to Executive that indicates Section 2 or the specific provision of Section 4 of this Agreement relied upon as the reason for such termination or nonrenewal, the Date of Termination, and, in the case of termination or non-renewal by the Company for Cause, in reasonable detail, the facts and circumstances claimed to provide a basis for termination or nonrenewal.
  - (e) "Good Reason" shall mean:
    - (i) Company effects a material diminution of Executive's position, authority or duties;
    - (ii) any requirement that Executive, without his consent, move his regular office to a location more than fifty (50) miles from Company's executive offices;

- (iii) the material failure by Company, or its successor, if any, to pay compensation or provide benefits or perquisites to Executive as and when required by the terms of this Agreement; or
  - (iv) any material breach by Company of this Agreement.

The Executive shall have Good Reason to terminate Executive's employment if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within twenty-one (21) days. If either condition is not met, Executive shall not have a Good Reason to terminate Executive's employment.

# (f) "Change in Control" shall mean:

- (i) the acquisition by any person of beneficial ownership of fifty percent (50%) or more of the outstanding shares of the Company's voting securities; or
  - (ii) the Company is the non-surviving party in a merger; or
- (iii) the Company sells all or substantially all of its assets; provided, however, that no "Change in Control" shall be deemed to have occurred merely as the result of a refinancing by the Company or as a result of the Company's insolvency or the appointment of a conservator; or

(iv) the Compensation Committee of the Company, in its sole and absolute discretion determines that there has been a sufficient change in the share ownership or ownership of the voting power of the Company's voting securities to constitute a change of effective ownership or control of the Company.

## 4.2 Termination Upon Death or Disability

This Agreement, and Executive's employment hereunder, shall terminate automatically and without the necessity of any action on the part of the Company upon the death of Executive. In addition, if at any time during the Term, Executive shall become physically or mentally disabled (as determined by an independent physician competent to assess the condition at issue), whether totally or partially, so that Executive is unable substantially to perform Executive's duties and services hereunder, with or without reasonable accommodation, for either (i) a period of sixty (60) consecutive calendar days, or (ii) ninety (90) consecutive or non-consecutive calendar days during any consecutive five (5) month period (the "Disability Date"), the Company may terminate this Agreement and Executive's employment hereunder by written notice to Executive after the Disability Date (but before Executive has recovered from such disability).

#### 4.3 Company's and Executive's Right to Terminate

This Agreement and Executive's employment hereunder may be terminated at any time by the Company for Cause or, if without Cause, upon thirty (30) days prior written notice to Executive. In the event the Company should give Executive notice of termination without Cause, the Company may, at its option, elect to provide Executive with thirty (30) days' salary in lieu of Executive's continued active employment during the notice period. This Agreement and

Executive's employment hereunder may be terminated by Executive at any time for Good Reason and, if without Good Reason, upon thirty (30) days prior written notice to the Company.

## 4.4 <u>Compensation Upon Termination</u>

(a) <u>Severance</u>. In the event the Company terminates (or elects not to renew) this Agreement without Cause or pursuant to Section 4.2 due to the disability of Executive, or in the event Executive terminates this Agreement for Good Reason, Executive shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement of any COBRA continuation premium payments made by Executive for the Benefit Period, and (iii) a lump sum severance payment equal to twenty-four (24) months of Executive's then current Base Salary to be made not later than ten (10) business days following the expiration of the revocation period in Executive's release (as provided in Section 4.4(c) below) without any revocation having occurred. Notwithstanding the foregoing, the Company shall, to the extent necessary and only to the extent necessary, modify the timing of delivery of severance benefits to Executive if the Company reasonably determines that the timing would subject the severance benefits to any additional tax or interest assessed under Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"). In such event, the payments will be made as soon as practicable without causing the severance benefits to trigger such additional tax or interest under Section 409A of the Code In the event this Agreement is terminated (or not renewed) for any reason other than by the Company without Cause or pursuant to Section 4.2 due to the disability of Executive or by Executive for Good Reason, Executive shall not be entitled to the continuation of any compensation, bonuses or

benefits provided hereunder, or any other payments following the Date of Termination, other than Base Salary earned through such Date of Termination.

- (b) <u>Change in Control</u>. In the event that Executive is terminated other than for "Cause" within eighteen (18) months following the occurrence of a "Change in Control" of the Company, then Executive shall be entitled to a severance payment in an amount that is two (2) times the amount specified in Section 4.4(a), clause (iii) above (the "Change in Control Severance Payment"). In the event that Executive shall become entitled to a Change in Control Severance Payment as provided herein, the Company shall cause its independent auditors promptly to review, at the Company's sole expense, the applicability to those payments of Sections 280G and 4999 of the Code. If the auditors determine that any payment of the Change in Control Severance Payment would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, then such payment owed to Executive shall be reduced by an amount calculated to provide to Executive the maximum Change in Control Severance Payment which will not trigger application of Sections 280G and 4999 of the Code.
- (c) <u>Release</u>. Anything to the contrary contained herein notwithstanding, as a condition to Executive receiving severance benefits to be paid pursuant to this Section 4.4, Executive shall execute and deliver to the Company a general release in the form attached hereto as Exhibit A. The Company shall have no obligation to provide any severance benefits to Executive until it has received the general release from Executive and any revocation or rescission period applicable to the Release shall have expired without revocation or rescission.

#### **Article 5. Employment Covenants**

## 5.1 Definitions

As used in this Article 5 of the Agreement, the following terms shall have the meaning set forth for each below:

- (a) "Affiliate" shall mean a person or entity that directly, or indirectly through one or more intermediaries, controls or is controlled by, or under common control with another person or entity, including current and former directors and officers of such an entity.
- (b) "Confidential Information" shall mean all confidential and proprietary information of the Company, its Predecessors and Affiliates, whether in written, oral, electronic or other form, including but not limited to trade secrets; technical, scientific or business information; processes; works of authorship; Inventions; discoveries; developments; systems; chemical compounds; computer programs; code; algorithms; formulae; methods; ideas; test data; know how; functional and technical specifications; designs; drawings; passwords; analyses; business plans; information regarding actual or demonstrably anticipated business, research or development; marketing, sales and pricing strategies; and information regarding the Company's current and prospective consultants, customers, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii)

Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall (a) promptly, but in no event more than 72 hours after learning of such court order or other government process, notify, pursuant to Section 6.1 below, the Company; (b) at the Company's expense, take all reasonable necessary steps requested by the Company to defend against the enforcement of such court order or other government process, and permit the Company to intervene and participate with counsel of its choice in any proceeding relating to the enforcement thereof; and (c) if such compelled disclosure is required, Executive shall disclose only that portion of the Confidential Information that is necessary to meet the minimum legal requirement imposed on Executive.

(c) "Executive Work Product" shall mean all Confidential Information and Inventions conceived of, created, developed or prepared by Executive (whether individually or jointly with others) before or during Executive's entire course of employment with the Company, during or outside of working hours, which relate in any manner to the actual or demonstrably anticipated business, research or development of the Company, or result from or are suggested by any task assigned to Executive or any work performed by Executive for or on behalf of the Company or any of its Affiliates.

- (d) "Invention" shall mean any apparatus, biological processes, cell line, chemical compound, creation, data, development, design, discovery, formula, idea, improvement, innovation, know-how, laboratory notebook, manuscript, process or technique, whether or not patentable or protectable by copyright, or other intellectual property in any form.
- (e) "Predecessor" shall mean an entity, the major portion of the business and assets of which was acquired by another entity in a single transaction or in a series of related transactions.
  - (f) "Trade Secrets," as used in this Agreement, will be given its broadest possible interpretation under the law applicable to this Agreement.

#### 5.2 Nondisclosure and Nonuse

Executive acknowledges that prior to and during Executive's entire course of employment with the Company, Executive has had and will have occasion to create, produce, obtain, gain access to or otherwise acquire, whether individually or jointly with others, Confidential Information. Accordingly, during the term of Executive's employment with the Company and at all times thereafter, Executive shall keep secret and shall not, except for the Company's benefit, disclose or otherwise make available to any person or entity or use, reproduce or commercialize, any Confidential Information, unless specifically authorized in advance by the Company in writing.

# 5.3 Other Confidentiality Obligations

Executive acknowledges that the Company may, from time to time, have agreements with other persons or entities or with the U.S. Government or governments of other countries, or

agencies thereof, which impose confidentiality obligations or other restrictions on the Company. Executive hereby agrees to be bound by all such obligations and restrictions and shall take all actions necessary to discharge the obligations of the Company thereunder, including, without limitation, signing any confidentiality or other agreements required by such third parties.

#### 5.4 Return of Confidential Information

At any time during Executive's employment with the Company, upon the Company's request, and in the event of Executive's termination of employment with the Company for any reason whatsoever, Executive shall immediately surrender and deliver to the Company all records, materials, notes, equipment, drawings, documents and data of any nature or medium, and all copies thereof, relating to any Confidential Information (collectively the "the Company Materials") which is in Executive's possession or under Executive's control. Executive shall not remove any of the Company Materials from the Company's business premises or deliver any of the Company Materials to any person or entity outside of the Company, except as required in connection with Executive's duties of employment. In the event of the termination of Executive's employment for any reason whatsoever, Executive shall promptly sign and deliver to the Company a Termination Certificate in the form of Exhibit B attached hereto.

#### 5.5 Confidential Information of Others

Executive represents that Executive's performance of all the terms of this Agreement and Executive's employment with the Company do not and will not breach any agreement to keep in confidence proprietary information, knowledge or data with regard to which Executive has obligations of confidentiality or nonuse, and Executive shall not disclose to the Company or cause the Company to use any such confidential proprietary information, knowledge or data

belonging to any previous employer of Executive or other person, except as such disclosure or use may be authorized in writing by the previous employer or other person. Executive represents that Executive has not brought and will not bring to the Company or use at the Company any confidential materials or documents of any former employer or other person that are not generally available to the public, unless express written authorization for their possession and use has been obtained from such former employer or other person. Executive agrees not to enter into any agreement, whether written or oral, that conflicts with these obligations.

#### 5.6 Other Obligations

The terms of this Section 5 are in addition to, and not in lieu of, any statutory or other contractual or legal obligation to the Company to which Executive may be subject relating to the protection of Confidential Information.

## 5.7 <u>Assignment of Confidential Information and Inventions; Works Made for Hire</u>

Executive hereby assigns to the Company all right, title and interest in all intellectual property, including any patent applications, trade secrets, know how, copyrights, software, or trademarks associated with the Executive Work Product and Confidential Information. Executive hereby acknowledges and agrees that all Executive Work Product subject to copyright protection constitutes "work made for hire" under United States copyright laws (17 U.S.C. § 101) and is owned exclusively by the Company. To the extent that title to any Executive Work Product subject to copyright protection does not constitute a "work for hire," and to the extent title to any other Executive Work Product does not, by operation of law or otherwise, vest in the Company, all right, title, and interest therein, including, without limitation, all copyrights, patents and trade secrets, and all copyrightable or patentable subject matter, are

hereby irrevocably assigned to the Company. Executive shall promptly disclose to the Company in writing all Executive Work Product. Executive shall, without any additional compensation, execute and deliver all documents or instruments and give the Company all assistance it requires to transfer all right, title, and interest in any Executive Work Product to the Company; to vest in the Company good, valid and marketable title to such Executive Work Product; to perfect, by registration or otherwise, trademark, copyright and patent protection of the Company with respect to such Executive Work Product; and otherwise to protect the Company's trade secret and proprietary interest in such Executive Work Product. Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agents and attorneys-in-fact to act for and on Executive's behalf, and to execute and file any documents and to do all other lawfully permitted acts to further the purposes of this Section 5.7 with the same legal force and effect as if executed by Executive.

## 5.8 Representations

Executive represents that, to the best of his knowledge, none of the Inventions will violate or infringe upon any right, patent, copyright, trademark or right of privacy, or constitute libel or slander against or violate any other rights of any person, firm or corporation, and that Executive will not knowingly create any Invention which causes any such violation.

#### 5.9 Inventions, Intellectual Property and Equipment Not Transferred

Executive has set forth on Exhibit C attached hereto a complete list and brief description of all Inventions, intellectual property and equipment located at the Company which is owned directly or indirectly by Executive and which shall not be transferred to the Company pursuant to this Agreement. Except as so listed, Executive agrees that he will not assert any rights under any

intellectual property as having been made or acquired by Executive prior to being employed by the Company. The Company may, at its discretion, require detailed disclosures and materials demonstrating ownership of the intellectual property so listed.

#### 5.10 Effect of Patent Access Agreement

Pursuant to the Patent Access Agreement among Sucampo AG ("SAG"), Sucampo Pharmaceuticals, Inc. ("SPI"), Sucampo Pharma, Ltd. ("SPL"), and Sucampo Pharma Europe, Ltd. ("SPE"), SAG has licensed certain of its patented technology and know-how to SPI, SPL, and SPE on an exclusive basis in their respective Territories (as that term is defined in the Patent Access Agreement). The Patent Access Agreement contains provisions pursuant to which patented technology or know-how owned by SAG is either (i) not licensed to SPI, SPL, or SPE, or (ii) if licensed by SAG to SPI, SPL, or SPE, will be transferred back or revert to SAG under certain circumstances. In the event that the provisions of this Agreement and the Patent Access Agreement conflict with respect to the transfer of or right to use any patented technology or know-how covered by the Patent Access Agreement, the parties agree that the provisions of the Patent Access Agreement shall control.

# 5.11 Exclusivity of Employment

During the Term, and without prior approval of the Board of Directors, Executive shall not directly or indirectly engage in any activity competitive with or adverse to the Company's business or welfare or render a material level of services of a business, professional or commercial nature to any other person or firm, whether for compensation or otherwise; provided, however, that Executive may devote a reasonable amount of his business time to the affairs of Sucampo Group Companies in which he is currently engaged as a director, officer, manager,

member or employee, as the case may be, and may participate in charitable and civic undertakings, provided that such activities do not materially interfere with the performance of Executive's duties and responsibilities to the Company.

# 5.12 Covenant Not to Compete

Executive agrees to be bound and abide by the following covenant not to compete:

- (a) <u>Term and Scope</u>. During Executive's employment with the Company and for a period of twelve (12) months after Executive's separation from employment for any reason whatsoever, Executive will not render to any Conflicting Organization (as hereinafter defined), services, directly or indirectly, anywhere in the world in connection with any Conflicting Product (as hereunder defined), except that Executive may accept employment with a Conflicting Organization whose business is diversified (and which has separate and distinct divisions) if Executive first certifies to the Company in writing that such prospective employer is a separate and distinct division of the Conflicting Organization and that Executive will not render services directly or indirectly in respect of any Conflicting Product. Such twelve (12) month time period shall be tolled during any period that Executive is engaged in activity in violation of this covenant.
- (b) <u>Judicial Construction</u>. Executive and the Company agree that, if the period of time or the scope of this Covenant Not to Compete shall be adjudged unreasonably overbroad in any court proceeding, then the period of time and/or scope shall be modified accordingly, so that this covenant may be enforced with respect to such services or geographic areas and during such period of time as is judged by the court to be reasonable.

(c) Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

"Conflicting Product" means any product, method or process, system or service of any person or organization other than the Company that is the same as, similar to or interchangeable with any product, method or process, system or service involving prostones, prostone compounds or derivates, or any prostone-related technology.

"Conflicting Organization" means any person or organization which is engaged in research on or development, production, marketing, licensing, selling, servicing or other commercialization of any Conflicting Product.

#### 5.13 Non-Solicitation

For twelve (12) months after termination of employment with the Company for any reason, Executive shall not directly or indirectly solicit or hire, or assist any other person in soliciting or hiring, any person employed by the Company (as of the date of Executive's termination) or any person who, as of the date of Executive's termination, was in the process of being recruited by the Company, or induce any such employee to terminate his or her employment with the Company.

## 5.14 Judicial Enforcement

In the event of a breach or violation of any provision of this Article 5 by Executive, the parties agree that, in addition to any other remedies it may have, the Company shall be entitled to equitable relief for specific performance, and Executive hereby agrees and acknowledges that the

Company has no adequate remedy at law for the breach of the employment covenants contained herein.

## Article 6. Miscellaneous

# 6.1 Notices

All notices or other communications which are required or permitted hereunder shall be deemed to be sufficient if contained in a written instrument given by personal delivery, air courier or registered or certified mail, postage prepaid, return receipt requested, addressed to such party at the address set forth below or such other address as may thereafter be designated in a written notice from such party to the other party:

To Company: Sucampo Pharmaceuticals, Inc.

4733 Bethesda Avenue, Suite 450 Bethesda, Maryland 20814

Attention: Chairperson, Board of Directors

To Executive: Ryuji Ueno, M.D., Ph.D.

24687 Yacht Club Road St. Michael, Maryland 21663

All such notices, advances and communications shall be deemed to have been delivered and received (i) in the case of personal delivery, on the date of such delivery, (ii) in the case of air courier, on the business day after the date when sent and (iii) in the case of mailing, on the third business day following such mailing.

# 6.2 Headings

The headings of the articles and sections of this Agreement are inserted for convenience only and shall not be deemed a part of or affect the construction or interpretation of any provision hereof.

## 6.3 Modifications; Waiver

No modification of any provision of this Agreement or waiver of any right or remedy herein provided shall be effective for any purpose unless specifically set forth in a writing signed by the party to be bound thereby. No waiver of any right or remedy in respect of any occurrence or event on one occasion shall be deemed a waiver of such right or remedy in respect of such occurrence or event on any other occasion.

# 6.4 Entire Agreement

This Agreement, together with the Exhibits hereto and Executive's Acknowledgement of Consideration, contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, that certain agreement between Executive and the Company dated and effective as of August 15, 2004.

## 6.5 Severability

Any provision of this Agreement that may be prohibited by, or unlawful or unenforceable under, any applicable law of any jurisdiction shall, as to such jurisdiction, be ineffective without affecting any other provision hereof. To the full extent, however, that the provisions of such

applicable law may be waived, they are hereby waived, to the end that this Agreement be deemed to be a valid and binding agreement enforceable in accordance with its terms.

# 6.6 Controlling Law

This Agreement has been entered into by the parties in the State of Maryland and shall be continued and enforced in accordance with the laws of Maryland.

#### 6.7 Arbitration

Any controversy, claim, or breach arising out of or relating to this Agreement or the breach thereof shall be settled by arbitration in the State of Maryland in accordance with the rules of the American Arbitration Association for commercial disputes and the judgment upon the award rendered shall be entered by consent in any court having jurisdiction thereof; <u>provided</u>, <u>however</u>, that this provision shall not preclude the Company from seeking injunctive or similar relief from the courts to enforce its rights under the Employment Covenants set forth in Article 5 of this Agreement. It is understood and agreed that, in the event the Company gives notice to Executive of termination for Cause and it should be finally determined in a subsequent arbitration that Executive's termination was not for Cause as defined in this Agreement, then the remedy awarded to Executive shall be limited to such compensation and benefits as Executive would have received in the event of Executive's termination other than for Cause at the same time as the original termination.

# 6.8 Assignments

Subject to obtaining Executive's prior approval, which shall not be unreasonably withheld or delayed, the Company shall have the right to assign this Agreement and to delegate all rights,

duties and obligations hereunder to any entity that controls the Company, that the Company controls or that may be the result of the merger, consolidation, acquisition or reorganization of the Company and another entity. Executive agrees that this Agreement is personal to Executive and Executive's rights and interest hereunder may not be assigned, nor may Executive's obligations and duties hereunder be delegated (except as to delegation in the normal course of operation of the Company), and any attempted assignment or delegation in violation of this provision shall be void.

## 6.9 Read and Understood

Executive has read this Agreement carefully and understands each of its terms and conditions. Executive has sought independent legal counsel of Executive's choice to the extent Executive deemed such advice necessary in connection with the review and execution of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

# SUCAMPO PHARMACEUTICALS, INC.

By: /s/ Kei S. Tolliver

Kei S. Tolliver

Its: Secretary

/s/ Ryuji Ueno

RYUJI UENO, M.D., Ph.D.

#### **GENERAL RELEASE**

	) and
Sucampo Pharmaceuticals, Inc. ("SPI"), a corporation organized under the laws of the State of Delaware, and its affiliates (hereinafter collectively referre	ed to
as the "Company").	

WHEREAS, Executive and SPI are parties to an Employment Agreement dated \_\_\_\_, 20\_\_\_ (hereinafter, the "Agreement");

**WHEREAS**, Executive and Company intend to settle any and all claims that Executive may have against Company as a result of any act, occurrence, decision, event or omission occurring at any time prior to the signing of this General Release, including, but not limited to, any matter or fact arising out of Executive's employment with SPI, the termination of Executive's employment pursuant to Section \_\_\_\_ of the Agreement [here specify the particular section invoked for the termination], or the events giving rise to the Agreement or this General Release;

**WHEREAS**, under the terms of the Agreement, Executive promised to enter into this General Release as a condition precedent to the separation payments and benefits to be provided under the Agreement;

NOW, THEREFORE, in consideration of the provisions and the mutual covenants contained herein, the parties agree as follows:

1. Release of Claims. Executive and the Company intend to settle any and all claims that Executive may have against the Company as a result of the
hiring of Executive, Executive's employment, Executive's compensation while employed, and the termination of Executive's employment. Executive agrees
that in exchange for SPI's promises in the Agreement and in exchange for the separation pay and benefits to be paid to Executive as described in the
Agreement, Executive, on behalf of Executive and Executive's heirs, successors and assigns, hereby releases and forever discharges the Company, its
predecessors, successors, and assigns, and their respective officers, directors, shareholders, agents, employees, and insurers (the "Released Parties"), from all
liability for damages and from all claims that Executive may have against the Released Parties arising from or relating to the hiring of Executive, Executive's
compensation while employed, Executive's employment, the termination of Executive's employment pursuant to Section of the Agreement [here specify
the particular section invoked for the termination], and any other actions, decisions, alleged omissions, or events occurring on or prior to the signing of
this General Release.

A. Executive understands and agrees that Executive's release of claims in this General Release includes, but is not limited to, any claims Executive may have under Title VII of the Federal Civil Rights Act of 1964, as amended; the Americans with Disabilities Act, the Equal Pay Act, the Fair Labor Standards Act, the Employee Retirement and Income Security Act, the Age Discrimination in Employment Act, the Family and Medical Leave Act, the Maryland Fair Employment Practices Act, or any other federal, state, or local statute, ordinance, or law.

B. Executive also understands that Executive is giving up all other claims, whether grounded in contract or tort theories, including, but not limited to, wrongful discharge, breach of contract, tortious interference with contractual relations, promissory estoppel,

detrimental reliance, breach of the implied covenant of good faith and fair dealing, breach of express or implied promise, breach of manuals or other policies, breach of fiduciary duty, assault, battery, fraud, invasion of privacy, intentional or negligent misrepresentation, defamation, including libel, slander, discharge defamation and self-publication defamation, discharge in violation of public policy, whistleblower, intentional or negligent infliction of emotional distress, or any other theory, whether legal or equitable.

- C. Executive will not institute any lawsuit against the Released Parties arising from or relating to the hiring of Executive, Executive's employment, Executive's compensation while employed, the termination of Executive's employment, or any other actions, decisions, alleged omissions, or events occurring prior to the signing of this General Release.
- D. To the extent required by law, nothing contained in this General Release will be interpreted to prevent Executive from filing a charge with a governmental agency or participating in or cooperating with an investigation conducted by a governmental agency. However, Executive agrees that Executive is waiving the right to any monetary damages or other individual legal or equitable relief awarded as a result of any such proceeding related to any claim against the Released Parties arising from or relating to the hiring of Executive, Executive's employment, Executive's compensation while employed, the termination of Executive's employment, or any other actions, decisions, alleged omissions, or events occurring on or prior to the signing of this General Release.

E. Notwithsta	anding any of the foregoing, this General Release shall not apply with respect to any rights or claims which Executive may have under the
terms of Section	_ of the Agreement itself [same section as cited above] or to any rights or benefits Executive may

have related to vested accrued benefits under the terms of the Company's benefit plans or to the Executive's right to be indemnified by the Company pursuant to the terms of its bylaws and the law of the State of Delaware.

- F. Executive may revoke this release of claims, insofar as it extends to potential claims under the Age Discrimination in Employment Act, by informing the Company of Executive's intent to revoke this release within seven (7) calendar days following the execution of this General Release. Executive understands that any such revocation must be stated in writing and delivered by hand or by certified mail-return receipt requested within the seven (7) day period to [INSERT name and mailing address]. If Executive exercises this right to revoke or rescind, the Company shall have no obligation to provide severance pay or benefits to Executive as provided by the Agreement.
- G. Executive acknowledges that the Company's obligation to provide any severance pay or benefits pursuant to the Agreement shall not become effective or enforceable until the revocation period identified above has expired without notice of revocation having been made.
- 2. This General Release shall be binding upon, and insure to the benefit of, Executive and the Company and their respective successors and permitted assigns.
- 3. Executive hereby acknowledges and states that Executive has read this General Release and has been advised to consult with an attorney prior to signing this General Release. Executive further represents that Executive has had adequate time to consider the terms of this General Release, that it is written in language which is understandable to Executive, that

Executive fully appreciates the meaning of the terms of this General Release, and ${\bf t}$	hat Executive enters into this General Release freely and voluntarily.
$\it IN~WITNESS~WHEREOF$ , Executive after due consideration and consultation, date indicated below.	has authorized, executed, and delivered this General Release upon the
DATE:	
	NAME

# **TERMINATION CERTIFICATE**

I hereby certify that I do not have in my possession or under my control, nor have I fai Employment Agreement (the "Agreement") entered into between Sucampo Pharmaceutic	. 3 1 3
I further certify that I have complied with and will continue to comply with all the term	ns of the Agreement.
	Executive's Signature
	Print Name
	Date

# EXHIBIT C

# **Inventions, Intellectual Property, and Equipment Not Transferred to Company**

The inventions, intellectual property and/or equipment listed below are currently owned by Sucampo AG, and no rights with respect to the listed inventions, intellectual property and/or equipment are intended to be transferred or assigned to the Company by reason of the Employment Agreement.

Description	Patent No.	Application No.	Country	Status
METHOD FOR INHIBITING INFECTION OF HUMAN T-CELLS	4840941	144131	U.S.A. DIV2	Granted
METHOD FOR TOPICALLY CLEANSING THE HUMAN BODY	5100879	398318	U.S.A. CIP	Granted
CONDOM	4869270	196574	U.S.A.	Granted
TREATMENT OF SHOCK BY CYCLODEXTRINS AND THEIR DERIVATIVES	5071838	679864	U.S.A. CIP	Granted
IMPROVEMENT IN DIURESIS BY CYCLODEXTRINS AND THEIR DERIVATIVES	5132298	599607	U.S.A.	Granted
COMPOSITION FOR TREATMENT OF LIGHT-INJURED RETINAL DEGENERATION DISEASE	6248759	09/408562	U.S.A.	Granted
COMPOSITION FOR TREATMENT OF LIGHT-INJURED RETINAL DEGENERATION DISEASE		2000-573361	JAPAN	pending
AGENT FOR TREATING VISUAL CELL FUNCTION DISORDER	6864232	09/869129	U.S.A.	Granted
AGENT FOR TREATING VISUAL CELL FUNCTION DISORDER		200-590655	JAPAN	pending
AGENT FOR TREATING VISUAL CELL FUNCTION DISORDER		99959930.1	EPC	pending
AGENT FOR TREATING DRY EYE		09/926411	U.S.A.	Allowed
AGENT FOR TREATING DRY EYE	6872383	10/354083	U.S.A. CA	Granted
AGENT FOR TREATING DRY EYE		2001-615007	JAPAN	pending
AGENT FOR TREATING DRY EYE	1173177	00921047.7	EPC	Granted
COMPOSITION FOR TOPICAL ADMINISTRATION	7033604	10/187013	U.S.A.	Granted
COMPOSITION FOR TOPICAL ADMINISTRATION		11/258914	U.S.A. DIV	pending
COMPOSITION FOR TOPICAL ADMINISTRATION		2003-510107	JAPAN	pending
COMPOSITION FOR TOPICAL ADMINISTRATION		02741390.5	EPC	pending
OPHTHALMIC COMPOSITION	6403598	09/485414	U.S.A.	Granted
OPHTHALMIC COMPOSITION	6476039	10/133450	U.S.A. DIV	Granted
OPHTHALMIC COMPOSITION		11-22996	JAPAN	pending
COMPOSITION FOR TREATMENT OF EXTERNAL SECRETION	6339088	09/673563	U.S.A.	Granted
DISORDERS EXCEPT HYPOLACRIMATION				
COMPOSITION FOR TREATMENT OF EXTERNAL SECRETION DISORDERS EXCEPT HYPOLACRIMATION		2000-599253	JAPAN	pending

Description	Patent No.	Application No.	Country	Status
METHOD OF TREATING OCULAR ALLERGIES WITH A		10/523842	U.S.A.	pending
MACROLIDE COMPOUND				
METHOD OF TREATING OCULAR ALLERGIES WITH A		2004-527368	JAPAN	pending
MACROLIDE COMPOUND				
METHOD FOR INHIBITING INFECTION OF HUMAN T-CELLS	4840941	144131	U.S.A. DIV2	Granted
METHOD FOR TOPICALLY CLEANSING THE HUMAN BODY	5100879	398318	U.S.A. CIP	Granted
METHOD FOR DIAGNOSIS OR PREDICTING SUSCEPTIBILITY		11/043959	U.S.A.	pending
TO PSYCHIATRIC DISORDERS				
METHOD FOR DIAGNOSIS OR PREDICTING SUSCEPTIBILITY		2005-021515	JAPAN	pending
TO PSYCHIATRIC DISORDERS				
METHOD FOR DIAGNOSIS OF OPTIC NEUROPATHY		PCT/JP05/005601	PCT	pending
METHOD FOR TREATING OCULAR HYPERTENSION AND		10/429677	U.S.A.	Allowed
GLAUCOMA				
METHOD FOR TREATING OCULAR HYPERTENSION AND			U.S.A. CA	pending
GLAUCOMA				
METHOD AND COMPOSITION FOR TREATING OCULAR		2005-501572	JAPAN	pending
HYPERTENSION AND GLAUCOMA				
METHOD AND COMPOSITION FOR TREATING OCULAR		2502437	Canada	pending
HYPERTENSION AND GLAUCOMA				
METHOD AND COMPOSITION FOR TREATING OCULAR		03758746.6	EPC	pending
HYPERTENSION AND GLAUCOMA				
PROSTAGLANDINS OF THE F SERIES	289349	8830931.5	EPC	Granted
OCULAR HYPOTENSIVE AGENTS	5001153	246059	U.S.A.	Granted
OCULAR HYPOTENSIVE AGENTS	5151444	584669	U.S.A. CA	Granted
OCULAR HYPOTENSIVE AGENTS	2209939	8821104.0	England	Granted
OCULAR HYPOTENSIVE AGENTS	308135	88308299.2	EPC	Granted
OCULAR HYPOTENSIVE AGENTS	455264	91108317.8	EPC DIV	Granted
OCULAR HYPOTENSIVE AGENTS	5194429	615515	U.S.A. DIV	Granted
OCULAR HYPOTENSIVE AGENTS	5236907	774750	U.S.A. CA	Granted
OCULAR HYPOTENSIVE AGENTS	2008226	63-248720	JAPAN	Granted
OCULAR HYPOTENSIVE AGENTS	2009965	63-248721	JAPAN	Granted
OCULAR HYPOTENSIVE AGENTS	366279	89310016.4	EPC	Granted
OCULAR HYPOTENSIVE AGENTS	580268	93202691.7	EPC DIV	Granted
TREATMENT OF OCULAR HYPERTENSION WITH A	458588	91304574.6	EPC	Granted
SYNERGISTIC COMBINATION FOR OCULAR				
ADMINISTRATION				
TREATMENT OF OCULAR HYPERTENSION WITH A	5166175	704570	U.S.A.	Granted
SYNERGISTIC COMBINATION				
TREATMENT OF OCULAR HYPERTENSION WITH A	2511585	3-147793	JAPAN	Granted
SYNERGISTIC COMBINATION				

TREATMENT OF OCULAR HYPERTENSION WITH A 2042937 2042937-2 Canada Granted SYNERGISTIC COMBINATION  TREATMENT OF OCULAR HYPERTENSION WITH A 109862 8273/91 Korea Granted SYNERGISTIC COMBINATION  TREATMENT OF OCULAR HYPERTENSION WITH A 60036 80103866 TAIWAN Granted SYNERGISTIC COMBINATION  TREATMENT OF OCULAR HYPERTENSION WITH A 458590 91304576.1 EPC Granted SYNERGISTIC COMBINATION  TREATMENT OF OCULAR HYPERTENSION WITH A 5175189 899170 U.S.A. CA Granted SYNERGISTIC COMBINATION FOR OPHTHALMIC USE  TREATMENT OF OCULAR HYPERTENSION WITH A 2042936 2042936-4 Canada Granted SYNERGISTIC COMBINATION FOR OPHTHALMIC USE  TREATMENT OF OCULAR HYPERTENSION WITH A 59178 80103867 TAIWAN Granted SYNERGISTIC COMBINATION FOR OPHTHALMIC USE
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SYNERGISTIC COMBINATION FOR OPHTHALMIC USE
TREATMENT OF OCULAR HYPERTENSION WITH AN OCULAR 5397797 08/031875 U.S.A. CA Granted
SYNERGISTIC COMBINATION
TREATMENT OF OCULAR HYPERTENSION WITH AN OCULAR 2042934 2042934-8 Canada Granted
SYNERGISTIC COMBINATION
TREATMENT OF OCULAR HYPERTENSION WITH AN OCULAR 59100 80103868 TAIWAN Granted
SYNERGISTIC COMBINATION
PROCESS OF PREPARING PROSTAGLANDIN INTERMEDIATES 2119050 3-223415 JAPAN Granted
TREATMENT OF OCULAR HYPERTENSION WITH A 5547968 8/487637 U.S.A. CA3 Granted
SYNERGISTIC COMBINATION  TREATMENT OF OCH AR INVESTMENT OF OCH AR INVEST
TREATMENT OF OCULAR HYPERTENSION WITH A 2511611 4-43018 JAPAN Granted
SYNERGISTIC COMBINATION TREATMENT OF OCULAR HYPERTENSION WITH A 2061907 2061907-4 Canada Granted
SYNERGISTIC COMBINATION TREATMENT OF OCULAR HYPERTENSION WITH A 221369 3307/92 Korea Granted
SYNERGISTIC COMBINATION TREATMENT OF OCULAR HYPERTENSION WITH A 63244 81100863 TAIWAN Granted
SYNERGISTIC COMBINATION STATEMENT OF OCCULAR HYPERTENSION WITH A 63244 61100005 TATWAIN GIAILLEG
TREATMENT OF OCULAR HYPERTENSION WITH A 501678 92301412.0 EPC Granted
SYNERGISTIC COMBINATION
INCREASING THE CHOROIDAL BLOOD FLOW 5221690 867359 U.S.A. Granted
INCREASING THE CHOROIDAL BLOOD FLOW 5221090 607359 0.5.A. Granted
INCREASING THE CHOROIDAL BLOOD FLOW 2065889 2065889-4 Canada Granted
TREATMENT OF OCULAR HYPERTENSION 5432174 8/162386 U.S.A. CA Granted
TREATMENT OF OCULAR HYPERTENSION 5432174 6/102300 0.5.A. CA Granted TREATMENT OF OCULAR HYPERTENSION 5-56852 JAPAN pending
TREATMENT OF OCCULAR HYPERTENSION 0561073 92307700.2 EPC Granted
PROCESS FOR PRODUCTION OF PROSTAGLANDIN 5274130 07/937949 U.S.A. Granted
INTERMEDIATES  PROCESS FOR PRODUCTION OF PROSTACI ANDIN 2746900 4 222472 IADAN Crapted
PROCESS FOR PRODUCTION OF PROSTAGLANDIN 2746800 4-233473 JAPAN Granted INTERMEDIATES
STABILIZATION OF A PROSTANOIC ACID COMPOUND 5523461 8/202132 U.S.A. Granted
STABILIZATION OF A PROSTANOIC ACID COMPOUND 5523461 8/202132 0.5.A. Granted STABILIZATION OF A PROSTANOIC ACID COMPOUND 2839798 4-227047 JAPAN Granted
STADILIZATION OF A FROSTANOIC ACID COMPOUND 2005/30 4-22/04/ JAPAN GIBILEU

Description	Patent No.	Application No.	Country	Status
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC	5773471	08/613048	U.S.A.	Granted
ACID COMPOUNDS				
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	3625946	8-53063	JAPAN	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS		2171226	Canada	pending
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC	96107319.5	96107319.5	China	Granted
ACID COMPOUNDS TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	399795	6237/96	Korea	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC ACID COMPOUNDS	127611	85102651	TAIWAN	Granted
TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC	701620	48003/96	Australia	Granted
ACID COMPOUNDS TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC	286141	286141	New Zealand	Granted
ACID COMPOUNDS TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC	310178	19960974	Norway	Granted
ACID COMPOUNDS TREATMENT OF OPTIC NERVE DISORDER WITH PROSTANOIC	730866	96301637.3	EPC	Granted
ACID COMPOUNDS A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN	149214	86105124	TAIWAN	Granted
AS AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN	6043213	08/981229	U.S.A.	Granted
AS AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN	6159930	09/450008	U.S.A. DIV	Granted
AS AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN	3058920	9-537910	JAPAN	Granted
AS AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN		2225398	Canada	pending
AS AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN	97190706.4	97190706.4	China	Granted
AS AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN	0455475	709546/97	Korea	Granted
AS AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN	725508	25761/97	Australia	Granted
AS AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN	320601	19975962	Norway	Granted
AS AN ACTIVE INGREDIENT A PHARMACEUTICAL COMPOSITION CONTAINING ALBUMIN	834320	97917418.2	EPC	Granted
AS AN ACTIVE INGREDIENT TREATMENT OF OCULAR HYPERTENSION WITH A	6329426	09/220847	U.S.A. CIP	Granted
SYNERGISTIC COMBINATION TREATMENT OF OCULAR HYPERTENSION WITH A		11-521457	JAPAN	pending
SYNERGISTIC COMBINATION TREATMENT OF OCULAR HYPERTENSION WITH A		2274708	Canada	pending
SYNERGISTIC COMBINATION TREATMENT OF OCULAR HYPERTENSION WITH A		98945530.8	EPC	pending
SYNERGISTIC COMBINATION TREATMENT OF OCULAR HYPERTENSION WITH A		00103455.2	Hong Kong	pending
SYNERGISTIC COMBINATION DRUG COMPOSITIONS FOR THE TREATMENT OF OCULAR		2000-590641	JAPAN	pending
HYPERTENSION OR GLAUCOMA DRUG COMPOSITIONS FOR THE TREATMENT OF OCULAR HYPERTENSION OR GLAUCOMA		2356912	Canada	pending
II I FERTENSION OR GLAUCOWA				

Description	Patent No.	Application No.	Country	Status
COMPOSITION FOR APOPTOSIS INHIBITION		09/816655	U.S.A.	pending
COMPOSITION FOR APOPTOSIS INHIBITION		90107002	TAIWAN	pending
COMPOSITION FOR APOPTOSIS INHIBITION		2001-568431	JAPAN	pending
COMPOSITION FOR APOPTOSIS INHIBITION		2403086	Canada	pending
COMPOSITION FOR APOPTOSIS INHIBITION		01809737.5	China	pending
COMPOSITION FOR APOPTOSIS INHIBITION		2002-7012410	Korea	pending
COMPOSITION FOR APOPTOSIS INHIBITION	2001239551	2001239551	Australia	Granted
COMPOSITION FOR APOPTOSIS INHIBITION	521464	521464	New Zealand	Granted
COMPOSITION FOR APOPTOSIS INHIBITION		01914192.8	EPC	pending
TREATMENT OF OCULAR HYPERTENSION	6458836	09/900021	U.S.A. CIP3	Granted
TREATMENT OF OCULAR HYPERTENSION		P010101231	ARGENTINA	pending
TREATMENT OF OCULAR HYPERTENSION		90106162	TAIWAN	pending
TREATMENT OF OCULAR HYPERTENSION		2001-566636	JAPAN	pending
TREATMENT OF OCULAR HYPERTENSION		2402597	Canada	pending
TREATMENT OF OCULAR HYPERTENSION		01809339.6	China	pending
TREATMENT OF OCULAR HYPERTENSION		2002-7011970	Korea	pending
TREATMENT OF OCULAR HYPERTENSION	2001241143	2001241143	Australia	Granted
TREATMENT OF OCULAR HYPERTENSION	521325	521325	New Zealand	Granted
TREATMENT OF OCULAR HYPERTENSION	2002/7140	2002/7140	South Africa	Granted
TREATMENT OF OCULAR HYPERTENSION		PI 0109192	Brazil	pending
TREATMENT OF OCULAR HYPERTENSION	233584	PA/A/2002/008967	Mexico	pending
TREATMENT OF OCULAR HYPERTENSION		IN/PCT/2002/01464	India	pending
TREATMENT OF OCULAR HYPERTENSION		151683	Israel	pending
TREATMENT OF OCULAR HYPERTENSION		PV2002-3092	Czech	pending
TREATMENT OF OCULAR HYPERTENSION		P0300391	Hungary	pending
TREATMENT OF OCULAR HYPERTENSION		20024381	Norway	pending
TREATMENT OF OCULAR HYPERTENSION		01912374.4	EPC	pending
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Description	Patent No.	Application No.	Country	Status
CONTROL OF INTRAOCULAR PRESSURE DURING SURGERY	6414021	09/645361	U.S.A.	Granted
CONTROL OF INTRAOCULAR PRESSURE DURING SURGERY		2001-250329	JAPAN	pending
EYE DROP COMPOSITION		11/110698	U.S.A. CIP	pending
EYE DROP COMPOSITION		2005-513236	JAPAN	pending
EYE DROP COMPOSITION		2006-7003299	Korea	pending
EYE DROP COMPOSITION			Canada	pending
EYE DROP COMPOSITION		04720157.9	EPC	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		10/477359	U.S.A.	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		2002-589015	JAPAN	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		2003-7014707	Korea	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		2002255346	Australia	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		2444627	Canada	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		PI 0209601-3	Brazil	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		PA/A/2003/010363	Mexico	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		20035043	Norway	pending
TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA		02724768.3	EPC	pending
METHOD FOR INHIBITING APOPTOSIS	6852687	10/132567	U.S.A.	Granted
METHOD FOR INHIBITING APOPTOSIS		2002-123755	JAPAN	pending
METHOD FOR INHIBITING APOPTOSIS		02009265.6	EPC	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		93124177	TAIWAN	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		10/567462	U.S.A.	pending
COMPOSITION FOR PROMOTING HAIR GROWTH			Canada	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		2006-7002643	Korea	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		200480029804.9	China	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		2006-519266	JAPAN	pending
COMPOSITION FOR PROMOTING HAIR GROWTH		04771825.9	EPC	pending
COMPOSITION AND METHOD FOR SCARP AND HAIR		2005-034763	JAPAN	pending
TREATMENT				

Description	Patent No.	Application No.	Country	Status
COMPOSITION AND METHOD FOR SCARP AND HAIR		PCT/JP05/024276	PCT	pending
TREATMENT				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		10/550414	U.S.A.	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		2006-507702	JAPAN	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		2520957	Canada	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		10-2005-7018312	Korea	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		200480009070.8	China	pending
DISEASE				
METHOD FOR TREATING VASCULAR HYPERPERMEABLE		04724735.8	EPC	pending
DISEASE				
ENDOTHELIN ANTAGONIST		8-155383	JAPAN	pending
HAIR GROWTH AGENT	3217293	9-100091	JAPAN	Granted

# Amended and Restated Patent Access Agreement among

Sucampo AG,

Sucampo Pharmaceuticals, Inc., Sucampo Pharma Europe, Ltd. and Sucampo Pharma, Ltd. June 30, 2006

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Schedule 3.1

**Pre-Paid Milestone Payments** 

#### AMENDED AND RESTATED

#### PATENT ACCESS AGREEMENT

THIS AMENDED AND RESTATED PATENT ACCESS AGREEMENT ("Agreement") is made as of June 30, 2006 by and among (1) Sucampo AG, a corporation organized and existing under the laws of Switzerland and having its principal office at Graben 5, CH-6300 Zug, Switzerland ("SAG"), (2) Sucampo Pharmaceuticals, Inc., a corporation organized and existing under the laws of the state of Delaware, U.S.A. and having its principal office at 4733 Bethesda Avenue, Suite 450, Bethesda, Maryland 20814, U.S.A., ("SPI"), (3) Sucampo Pharma, Ltd., a corporation organized and existing under the laws of Japan and having its principal office at 2-2-16 Sonezakishinchi, Kita-Ku, Osaka, Japan 530-0002 ("SPL"), and (4) Sucampo Pharma Europe, Ltd., a corporation organized and existing under the laws of the United Kingdom and having its principal office 78 Cannon Street, London, EC4N6NQ, U.K. ("SPE") (each referred to herein as a "party" and collectively as the "parties").

#### **RECITALS:**

- A. SAG owns all right, title and interest in and to certain patent rights, know-how, and trade secrets related to certain pharmaceutical compounds, and desires to license to SPI, SPE and SPL (each, an "Operating Company") the exclusive rights under patented technology and know-how, to develop and commercialize such compounds in such parties' respective territories.
  - B. SPI is an Affiliate of SAG, and as of the Effective Time (as defined below) each of SPE and SPL will be wholly owned subsidiaries of SPI.
- C. The parties on July 30, 2002 entered in to a certain Patent Access and Data Sharing Agreement, amended by Addenda dated December 12, 2002, December 18, 2002, March 5, 2003 and August 31, 2003, amended and restated on February 9, 2004 and further amended on April 27, 2005 (the "Original Patent Access Agreement"), whereby SAG licensed certain of its patented technology and know-how to each of the Operating Companies on an exclusive basis in their respective Territories.
- D. On November 30, 2000, SPI and SAG entered into a certain License Agreement, amended June 1, 2001 (the "8811 License Agreement"), whereby SAG licensed its patented technology and know-how related to certain compounds, including the 8811compound, to SPI on an exclusive basis in North and South America.
- E. On October 20, 2004, SPI and SAG entered into a certain License Agreement (the "0211 License Agreement") whereby SAG licensed its patented technology and know-how related to the 0211 compound to SPI on an exclusive basis in its Territory.
- F. On February 21, 2006, SPI and SAG entered into a certain License Agreement (the "017 License Agreement") whereby SAG licensed its patented technology and know-how related to the 017 compound to SPI on an exclusive basis in its Territory.
- G. The parties now wish to further amend and restate the Original Patent Access Agreement and additionally to supercede thereby the 8811 License Agreement, the 0211 License

Agreement and the 017 License Agreement (such agreements, together with the Original Patent Access Agreement, the "Original Agreements").

NOW, THEREFORE, the parties hereto agree as follows:

#### ARTICLE 1 — DEFINITIONS

As used herein, the following definitions and terms shall have the designated meanings:

- Section 1.1 "Affiliate" means, with respect to a party, any Person which directly or indirectly controls, is controlled by, or is under common control with such Party. For purposes of this definition only, a Person shall be deemed to "control" another Person if (i) it owns, directly or indirectly, at least fifty percent (50%) of the issued and outstanding voting securities, capital stock, or other comparable equity or ownership interest of such other Person, or (ii) it has the de facto ability to control or direct the management of such other Person. If the laws of the jurisdiction in which such Person operates prohibit ownership by a Person of fifty percent (50%) or more, "control" shall be deemed to exist at the maximum level of ownership allowed by such jurisdiction, provided, however, that there is a de facto ability to direct or control its management.
- **Section 1.2** "**Bankruptcy**" means, with respect to SAG, a bankruptcy, composition ("Nachlassverfahren") or any other enforcement action in accordance with the Swiss Federal Code on Debt Collection and Bankruptcy of April 11, 1889, as amended from time to time.
- **Section 1.3** "**Commercially Reasonable Efforts**" means, with respect to a Selection Pool Compound, the carrying out of development activities in a diligent and expeditious manner using efforts and resources that pharmaceutical companies of similar market position typically devote to their own compounds or products of similar market potential.
- **Section 1.4 "Competing Product"** means any pharmaceutical product (i) any mode of action of which is substantially the same as the primary mode of action of any Original Compound or Selection Pool Compound or (ii) that is approved for (or under pre-clinical or clinical development for) an indication which is the same as (or a subset of) an indication for which a Licensed Product is approved or under pre-clinical or clinical development.
- **Section 1.5** "**Confidential Information**" means all information (including, without limitation, Regulatory Data and Information, as defined below) provided to a party by another party, whether oral, in writing or otherwise, including, without limitation, any information on the research, development, markets, customers, suppliers, patent applications, inventions, products, procedures, designs, formulas, business plans, financial projections, organizations, employees, consultants or any other similar aspects of a party's present or future business.
- Section 1.6 "Development Affiliate" means an Affiliate of SAG, other than an Operating Company, engaged in the discovery and/or development of prostone compounds.
- **Section 1.7 "Development Cost"** means the out-of-pocket costs and internal costs incurred in connection with non-clinical and clinical development of a compound. Internal costs shall be determined by the FTE Rate multiplied by the number of FTEs. Out-of-pocket costs

shall mean external third party costs incurred by a party (or for its account by a contract research organization ("CRO")), including, without limitation, clinical trial expenses such as investigator payments, CRO management fees, registration fees, third party monitoring costs and comparator drugs.

**Section 1.8** "Effective Time" means the closing of the initial public offering of common stock of SPI pursuant to an effective registration statement under the Securities Act of 1933, as amended.

**Section 1.9** "Expiration" or "Expired" means with respect to a particular patent, the patent's expiration, abandonment; cancellation, disclaimer, award to another party other than SAG in an interference proceeding, or declaration of invalidity or unenforceability of all claims thereof by a court or other authority of competent jurisdiction (including a re-examination or reissue proceeding) from which no further appeal has or can be taken. References to an "Unexpired" patent shall mean a patent that has not Expired.

Section 1.10 "Founders" and "Founder" mean Dr. Ryuji Ueno and Dr. Sachiko Kuno, together and separately, as the case may be.

**Section 1.11** "FTE" means a full time equivalent person year of professional scientific and/or technical work or managerial work to the extent working on or directly involved in the development of a compound.

Section 1.12 "FTE Rate" means (i) with respect to activities of FTEs based in the SPL Territory, Thirty Four Million Five Hundred Thousand Yen (¥34,500,000) for the first full calendar year of the Agreement, subject to an annual increase at the beginning of each calendar year thereafter by the percentage increase, if any, in the Japanese Consumer Price Index, using index base 2000=100 ("JCPI"), as published by the Statistics Bureau of the Ministry of Internal Affairs and Communications for the calendar month most recently preceding such calendar year over the JCPI for the same calendar month in the immediately preceding calendar year, (ii) with respect to activities of FTEs based in the SPE Territory, Two Hundred Fifty Thousand Euros (€250,000) for the first full calendar year of the Agreement, subject to an annual increase at the beginning of each calendar year thereafter by the percentage increase, if any, in the European Index of Consumer Prices for All Items, using index base 2005=100 ("EICP"), as published by the European Commission for the calendar month most recently preceding such calendar year over the EICP for the same calendar month in the immediately preceding calendar year and (iii) with respect to activities of FTEs based in the SPI Territory, Three Hundred Thousand Dollars for the first full calendar year of the Agreement, subject to an annual increase at the beginning of each calendar year thereafter by the percentage increase, if any, in the Consumer Price Index for all Urban Consumers for all Items, using index base 1982-84=100 ("CPIU"), as published by the Bureau of Labor Statistics of the United States Department of Labor for the calendar month most recently preceding such calendar year over the CPIU for the same calendar month in the immediately preceding calendar year.

**Section 1.13 "Health Authority"** means the United States Food & Drug Administration, the European Medicines Evaluation Agency, the Japanese Kouseiroudosho and any corresponding counterparts, as well as any successor entities thereto.

Section 1.14 "Licensed Know-How" means the Original Know-How and the Selection Pool Know-How.

**Section 1.15** "Licensed Patents" means the Original Patents and the Selection Pool Patents, including without limitation, the issued patents, and patents arising out of the patent applications, listed on Exhibit A hereto.

**Section 1.16** "Licensed Product" means any human or veterinary pharmaceutical product (whether prescription or over-the-counter), the manufacture, use or sale of which is covered by a Licensed Patent or which uses or incorporates any of the Licensed Know-How that is substantial and confidential.

Section 1.17 "Loss of Control Date" means the first date upon which (i) the Founders together beneficially own less than a majority of the voting power represented by SPI's voting stock and (ii) neither Founder is a member of the Board of Directors of SPI. For purposes of this definition, "beneficial ownership" shall have the meaning given to that term in Section 13(d) of the Securities Exchange Act of 1934, as amended, and shares beneficially owned by either of the Founders individually shall be aggregated with shares beneficially owned by them together.

Section 1.18 "Lubiprostone Product" means a pharmaceutical preparation for human use that contains the compound SPI-0211 as an active ingredient.

**Section 1.19 "Marketing Authorization Application"** means a New Drug Application ("NDA"), as defined in the United States Food, Drug and Cosmetic Act and applicable regulations promulgated there under, a Marketing Authorization Application, as issued by the European Medicines Evaluation Agency, any counterpart authorization as issued by the Japanese Kouseiroudosho and any counterpart in any other country.

Section 1.20 "Net Sales" of Licensed Products for a particular period by a particular Operating Company means the amount billed by an Operating Company and its Affiliates and their sublicensees to distributors and other third parties for the sale of Licensed Products in such Operating Company's Territory (but not including sales between an Operating Company and its Affiliates), less cash discounts and/or quantity discounts allowed, credits for customers; returns and allowances; taxes, tariffs or duties levied, absorbed or directly imposed and properly allocable to sales of such products; shipping and insurance costs and other outbound transportation charges prepaid or allowed; uncollectible amounts; and amounts allowed or credited for chargebacks, retroactive price reductions or rebates; all as determined by the standard accounting practices of the Operating Company (or its Affiliate or Sublicensee, as applicable), which must be in conformity with Generally Accepted Accounting Principles, International Accounting Standards or any other standard accepted by the resident jurisdiction of the Operating Company (or its Affiliate or Sublicensee, as applicable) sells at a single price or rate a packaged combination of products, not all of which if sold individually would be Licensed Products, then "Net Sales" of Licensed Products with respect to such sales of packaged products shall equal the total sales price of the packaged combination multiplied by the ratio of the individual retail list price of the Licensed Products contained in the packaged combination to the sum of all individual retail list prices of every item in the packaged combination (if all of such items were

sold separately). If all such items are not sold separately, any item not sold separately shall have a price attributed to it by the Operating Company for purposes of this definition consistent with pricing of similar products or their functional equivalents by such Operating Company. Notwithstanding the foregoing, with respect to sales of Licensed Products by Takeda Pharmaceutical Company Limited ("Takeda") as SPI's Sublicensee, "Net Sales" shall mean Net Sales Revenue, as such term is defined in the Collaboration and License Agreement between SPI and Takeda dated as of October 29, 2004 ("Takeda Agreement"), for so long as the Takeda Agreement remains in effect.

**Section 1.21 "Operating Company"** refers individually to SPL, SPE and SPI.

Section 1.22 "Original Compound" means any of (i) SPI-0211, (ii) SPI-8811 or (iii) SPI-017, or any isomer, ester, salt, hydrate, solvate, homolog, conjugate or polymorph thereof.

Section 1.23 "Original Know-How" means all technical information, data, trade secrets and know-how owned by or licensed (with the right of sublicense) to SAG on or before the Effective Time, or acquired, made, created, developed, conceived or reduced to practice by SAG (or a Development Affiliate of SAG) or any Operating Company during the term of this Agreement, relating to an Original Compound (including, without limitation, composition of matter, formulations, dosing regimens, synthesis and utility of an Original Compound) or necessary, used or useful for the development, manufacture or commercialization of an Original Compound.

Section 1.24 "Original Patents" means all patents and patent applications or relevant portions thereof owned by or licensed (with a right of sublicense) to SAG on or before the Effective Time, or which derive from inventions that are acquired, made, created, developed, conceived or reduced to practice by SAG (or a Development Affiliate of SAG) or any Operating Company during the term of this Agreement, relating to an Original Compound (including, without limitation, composition of matter, formulations, dosing regimens, synthesis and utility of an Original Compound) or necessary, used or useful for the development, manufacture or commercialization of an Original Compound, and all reissues, continuations, continuations-in-part, extensions, reexaminations, and foreign counterparts thereof.

Section 1.25 "Person" means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization.

Section 1.26 "Selection Pool Compound" means any prostone compound (or analog, prodrug, precursor or metabolite thereof) (i) derived, discovered or acquired by SAG on or before the Effective Time (other than the Original Compounds) or (ii) derived or discovered by any Operating Company during the Specified Period.

**Section 1.27 "Selection Pool Know-How**" means all technical information, data, trade secrets and know-how (i) owned by or licensed (with the right of sublicense) to SAG on or before the Effective Time or (ii) acquired, made, created, developed, conceived or reduced to practice by SAG (or a Development Affiliate of SAG) during the term of this Agreement.

Section 1.28 "Selection Pool Patents" means all patents and patent applications or relevant portions thereof (i) that are owned by or licensed (with the right of sublicense) to SAG on or before the Effective Time or (ii) which derive from inventions that are acquired, made, created, developed, conceived or reduced to practice by SAG (or a Development Affiliate of SAG) during the term of this Agreement, in each case relating to a Selection Pool Compound (including, without limitation, composition of matter, method of use, formulations, dosing regimens, synthesis and utility of a Selection Pool Compound) or necessary, used or useful for the development, manufacture or commercialization of a Selection Pool Compound, or (iii) which derive from an invention that is made, created, developed, conceived or reduced to practice by any Operating Company during the Specified Period the practice of which would, in the absence of a license, infringe on a claim of any unexpired patent described in (i) or (ii), and which has been assigned to SAG in accordance with Section 2.4. Selection Pool Patents include all reissues, continuations, continuations-in-part, extensions, reexaminations, and foreign counterparts of any of the foregoing.

Section 1.29 "Specified Period" means that period beginning the day after the Effective Time and ending on the later of (i) June 30, 2011 or (ii) the Loss of Control Date.

**Section 1.30 "Sublicense Income"** means all signing fees and/or milestones due and payable to an Operating Company from a third party in consideration of the sublicensing or assignment by such Operating Company to such third party of rights under this Agreement. For the avoidance of doubt, Sublicense Income shall not include (a) amounts due and payable from such third parties as the purchase price for securities (whether equity, debt or otherwise), (b) research and development funding from such third parties or (c) royalties on sales of Licensed Products by such third parties.

Section 1.31 "Territory" means (a) with respect to SPL, the following countries located in Asia: Australia; Bhutan; Brunei; Cambodia; China (including Hong Kong); India; Indonesia; Japan; Korea; Laos; Malaysia; Mongolia; Myanmar; Nepal; New Zealand; Pakistan; Philippines; Singapore; Sri Lanka; Taiwan; Thailand; and Viet Nam (the "SPL Territory"); (b) with respect to SPI, all of the countries located in North, Central and South America, including the Caribbean, and their territories and possessions, and including for avoidance of doubt the United States of America and all of its territories and possessions and any other location where the FDA has jurisdiction over pharmaceutical products intended for human use (the "SPI Territory"), and (c) with respect to SPE, all the remaining countries in the world (the "SPE Territory").

## ARTICLE 2 — PATENT AND KNOW-HOW ACCESS

Section 2.1 Patent Licenses. Subject to the terms and provisions of this Agreement, SAG hereby grants the following licenses:

(a) SAG hereby grants to SPI a royalty-bearing and exclusive license, with right of sublicense as provided in Section 2.3, under the Licensed Patents to develop, import, use, make, have made, export, offer for sale and sell Licensed Products throughout the SPI Territory;

- (b) SAG hereby grants to SPL a royalty-bearing and exclusive license, with right of sublicense as provided in Section 2.3, under the Licensed Patents to develop, import, use, make, have made, export, offer for sale and sell Licensed Products throughout the SPL Territory;
- (c) SAG hereby grants to SPE a royalty-bearing and exclusive license, with right of sublicense as provided in Section 2.3, under the Licensed Patents to develop, import, use, make, have made, export, offer for sale and sell Licensed Products throughout the SPE Territory;

PROVIDED, HOWEVER, that each Operating Company shall have the limited right to make or have made a Licensed Product in the Territory of any other Operating Company solely for the purpose of developing, making, having made, using, offering for sale, selling or importing such Licensed Product in that Operating Company's own Territory.

Section 2.2 License to Know-How. Subject to the terms and conditions of this Agreement, SAG hereby grants the following licenses:

- (a) SAG hereby grants to SPI a royalty-bearing and exclusive license, with right of sublicense as provided in Section 2.3, under the Licensed Know-How to develop, import, use, make, have made, export, offer for sale and sell Licensed Products throughout the SPI Territory;
- (b) SAG hereby grants to SPL a royalty-bearing and exclusive license, with right of sublicense as provided in Section 2.3, under the Licensed Know-How to develop, import, use, make, have made, export, offer for sale and sell Licensed Products throughout the SPL Territory; and
- (c) SAG hereby grants to SPE a royalty-bearing and exclusive license, with right of sublicense as provided in Section 2.3, under the Licensed Know-How to develop, import, use, make, have made, export, offer for sale and sell Licensed Products throughout the SPE Territory;

PROVIDED, HOWEVER, that each Operating Company shall have the limited right to make or have made a Licensed Product in the Territory of any other Operating Company solely for the purpose of developing, making, having made, using, offering for sale, selling or importing such Licensed Product in that Operating Company's own Territory.

**Section 2.3 Sublicensing.** Each Operating Company shall have the right to sublicense its rights under Section 2.1 and Section 2.2 to third parties (including, without limitation, the other Operating Companies), provided that the agreement in which such sublicense is granted shall conform with the terms of this Agreement as may be necessary for the Operating Company to abide by all duties, obligations and restrictions provided under this Agreement. In no event may an Operating Company grant a sublicense that diminishes the rights or increases the obligations of any other party under this Agreement without the prior written consent of that party. With reasonable promptness following execution, the Operating Company shall provide a copy of any sublicense to SAG provided that the financial terms of such sublicense agreement may be redacted.

Section 2.4 Improvement Patents. Each Operating Company hereby assigns to SAG all right, title and interest in and to any patentable invention made, created, developed, conceived or reduced to practice by it during the Specified Period, the practice of which would, in the absence of a license, infringe on a claim of any of the unexpired Selection Pool Patents. Further, each Operating Company hereby assigns to SAG all right, title and interest in and to any patentable invention made, created, developed, conceived or reduced to practice by it during the term of this Agreement, the practice of which would, in the absence of a license, infringe on a claim of any of the unexpired Original Patents. Each Operating Company agrees that upon request it will furnish all necessary documentation relating to or supporting chain of title, sign all papers, take all rightful oaths, and do all acts which may be reasonably necessary for vesting title to such inventions in SAG, its successors, assigns and legal representatives or nominees. For the avoidance of doubt, such inventions shall be included in the licenses granted in Section 2.1 and Section 2.2 in accordance with their terms.

**Section 2.5 Development Affiliate Intellectual Property.** SAG shall ensure that any Development Affiliate promptly assigns to SAG all right, title and interest in and to any prostone-related technical information, data, trade secrets, know-how and inventions made, created, developed, conceived or reduced to practice by such Development Affiliate during the term of this Agreement. For the avoidance of doubt, such technical information, data, trade secrets, know-how and inventions shall be included in the licenses granted in Section 2.1 and Section 2.2 in accordance with their terms.

**Section 2.6 SAG Know-How Transfer**. Upon request, SAG shall provide to each Operating Company copies of all tangible Licensed Know-How not previously disclosed to such Operating Company. From time to time during the term of this Agreement, SAG shall reasonably inform each Operating Company of the existence of any updated or new Licensed Know-How.

### ARTICLE 3 — MILESTONE PAYMENTS, ROYALTIES AND REPORTS

## Section 3.1 Milestone Payments and Sublicense Income.

(a) In consideration of the licenses granted in Section 2.1 and Section 2.2, each Operating Company shall pay to SAG milestones with respect to each Licensed Product of (i) \$500,000 upon treatment of the first patient in the first Phase II Clinical Trial for such Licensed Product designed for use (or actually used) in such Operating Company's Territory and (ii) \$1,000,000 upon the filing of the first Marketing Authorization Application for such Licensed Product in the applicable Operating Company's Territory. The milestone payments payable under this Section 3.1(a) by each Operating Company with respect to a Licensed Product shall be payable only once, regardless of dosage form, dosage amount, indication, or delivery method. The parties acknowledge that the Operating Companies have made, prior to the Effective Time, those milestone payments set forth on Schedule 3.1 hereto in consideration of licenses to Original Patents and Original Know-How granted pursuant to the Original Agreements.

- (b) In addition to the milestone payments set forth in Section 3.1(a) above, in the event that an Operating Company should receive any Sublicense Income, such Operating Company shall pay to SAG five percent (5%) of such Sublicense Income.
- **Section 3.2 Patent Royalty**. In consideration of the licenses granted in Section 2.1, each Operating Company shall pay to SAG, on a country-by-country basis, the following royalties on Net Sales of Licensed Products in such Operating Company's respective Territory:
  - (a) With respect to Net Sales of Licensed Products for which the manufacture, use or sale of such Licensed Products is covered by an Unexpired patent that is included in the Original Patents:
    - (i) During the period from the first commercial sale of such Licensed Product until such time as all of the Pre-IPO Patents (as defined below) that would be infringed by the sale of such Licensed Product have Expired in the country of sale, four and one-half percent (4.5%); (provided that, with respect to Net Sales of Lubiprostone Product by SPI, its Affiliates and sublicensees in the SPI Territory, such rate shall be two and two-tenths percent (2.2%)); and
    - (ii) If applicable, thereafter until such time as all of the remaining Licensed Patents that would be infringed by the sale of such Licensed Product have Expired in the country of sale, two and one-quarter percent (2.25%) (provided that, with respect to Net Sales of Lubiprostone Product by SPI, its Affiliates and sublicensees in the SPI Territory, such rate shall be one and one-tenth percent (1.1%)).
  - (b) With respect to Net Sales of Licensed Products for which the manufacture, use or sale of such Licensed Products is covered by an Unexpired patent that is included in the Selection Pool Patents but was not covered at any time by a Pre-IPO Patent, during the period from the first commercial sale of such Licensed Product until such time as all of the Licensed Patents that would be infringed by the sale of such Licensed Product have Expired in the country of sale, two and one-quarter percent (2.25%).

For purposes of this Section 3.2, a "Pre-IPO Patent" means a Licensed Patent which was owned by or licensed (with right of sublicense) to SAG on or before the Effective Time, and all reissues, continuations, continuations-in-part, extensions, reexaminations, and foreign counterparts thereof. Upon expiration of the royalty obligation set forth in this Section 3.2, such Operating Company's license under Section 2.1 shall continue on a fully-paid and royalty-free basis.

# Section 3.3 SAG Know-How Royalty.

(a) In consideration of the licenses granted in Section 2.2, each Operating Company shall pay to SAG, on a country-by-country basis, a royalty of two percent (2%) of Net Sales of Licensed Products in such Operating Company's respective Territory

(provided that, with respect to Net Sales of Lubiprostone Product by SPI, its Affiliates and sublicensees in the SPI Territory, such rate shall be one percent (1%)).

(b) The royalty obligation set forth in Section 3.3(a) shall continue, on a country-by-country basis, until the fifteenth anniversary of the first commercial sale of the Licensed Products. Upon expiration of such royalty obligation, such Operating Company's license under Section 2.2 shall continue on a fully-paid and royalty-free basis.

### Section 3.4 Reports and Payments.

- (a) Within ten (10) days upon (i) the occurrence of a milestone event described in Section 3.1(a) or (ii) upon payment of any Sublicense Income to an Operating Company, such Operating Company shall inform SAG accordingly. SAG shall thereupon issue an invoice to such Operating Company for the applicable milestone payment due in accordance with Section 3.1 payable within thirty (30) days from the date of the invoice.
- (b) Within sixty (60) days after the end of each calendar quarter, each Operating Company shall provide SAG with a written report indicating (i) the amount of Net Sales of Licensed Products by such Operating Company and by any sublicensee during such quarter, and (ii) the amount of the royalties due for such quarter. SAG shall thereupon issue an invoice to such Operating Company for such royalties payable within thirty (30) days from the date of the invoice. With respect to Net Sales of an Operating Company made by such Operating Company's sublicensees, in the event an Operating Company has entered into a sublicensing agreement with a sublicensee and such sublicensee has not submitted payments and/or reports on Net Sales to such Operating Company in a timely manner in accordance with the terms thereof, such Operating Company shall not be deemed in breach of its obligations under this Section 3.4(a) so long as such Operating Company is diligently pursuing its remedies against such sublicensee, and provided that such Operating Company provides the applicable report and payment due under this Section 3.4(a) promptly upon receipt of the corresponding report and payment from its sublicensee.
- (c) All payments may be made in the local currency of the party making the payment, except that milestone payments made pursuant to Section 3.1 shall be made in U.S. Dollars. With respect to Net Sales of SPL, such Net Sales shall be converted into Yen using the applicable average exchange rate for converting the applicable currency to the Yen as published by Bloomberg on the last business day of each month during the reporting calendar quarter. With respect to Net Sales of SPE, such Net Sales shall be converted into Euros using the applicable average exchange rate for converting the applicable currency to the Euro as published by Bloomberg on the last business day of each month during the reporting calendar quarter. With respect to Net Sales of SPI, such Net Sales shall be converted into U.S. Dollars using the applicable average exchange rate for converting the applicable currency to the U.S. Dollar as published by Bloomberg on the last business day of each month during the reporting calendar quarter.

**Section 3.5 Records**. Each Operating Company agrees to keep and cause its sublicensees to keep accurate written records sufficient in detail to enable SAG to verify the information contained in the reports described in Section 3.4. Each Operating Company and such sublicensees shall retain such records for a particular quarter for a period of not less than ten years after the end of such quarter.

Section 3.6 Audit of Records. Upon reasonable notice and during regular business hours, each Operating Company shall from time to time (but no more frequently than once annually) make available the records referred to in Section 3.5 for audit by an independent nationally recognized accounting firm selected by SAG and reasonably acceptable to the Operating Company to verify the accuracy of the reports provided to SAG. Such representatives shall execute a suitable confidentiality agreement reasonably acceptable to the parties prior to conducting such audit. Such representatives may disclose to the auditing party only their conclusions regarding the accuracy and completeness of the reports described in Section 3.4 and the records related thereto, and shall not disclose confidential business information of the audited party to SAG without the prior written consent of the audited party. Such audits shall be at the SAG's cost and expense; provided that if any such audit reveals underpayment of royalties by five percent (5%) or more for any quarter, then the audited party shall reimburse SAG for the fees and expenses of the independent auditors incurred by SAG in connection with such audit. If SAG conducts an audit of any Operating Company pursuant to this Section 3.6, then any audit during that year of any other Operating Company(ies) must be conducted simultaneously.

## Section 3.7 Withholding Taxes.

- (a) Each Operating Company will make all payments to SAG under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment. Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by the applicable Operating Company on behalf of SAG to the appropriate governmental authority, and such Operating Company will furnish SAG with proof of payment of such tax. Any such tax required to be withheld will be borne by SAG.
- (b) Each Operating Company and SAG will cooperate with respect to all documentation required by any taxing authority or reasonably requested by an Operating Company to secure a reduction in the rate of applicable withholding taxes and/or to receive a credit for any withheld taxes paid.
- (c) If an Operating Company had a duty to withhold taxes in connection with any payment it made to SAG under this Agreement but such Operating Company failed to withhold, and such taxes were assessed against and paid by such Operating Company, then SAG will indemnify and hold harmless such Operating Company from and against such taxes (excluding interest, penalties, and any other additions to tax, which shall be borne by such Operating Company).

#### ARTICLE 4 — DEVELOPMENT

Section 4.1 Commercially Reasonable Efforts. Each Operating Company shall use Commercially Reasonable Efforts to develop the Selection Pool Compounds during the Specified Period, which Commercially Reasonable Efforts shall include incurrence of at least \$333,333 in Development Costs annually on development projects involving at least one Selection Pool Compound (or, so long as Operating Companies are Affiliates of one another, incurrence in the aggregate by such Operating Companies of at least \$1,000,000 in Development Costs annually on development projects involving at least one Selection Pool Compound). An Operating Company will be deemed to have met its obligations under this Section 4.1 with respect to any given Selection Pool Compound: (i) pharmacological animal in vivo results to support the indication for which the Selection Pool Compound is being developed and (ii) genotoxicity data including an AMES test, a chromosome aberration test and a micronucleus test. Further, for so long as Operating Companies are Affiliates of one another, then such Operating Companies will be deemed to have met their obligations under this Section 4.1 with respect to a Selection Pool Compound if one Operating Company collects Minimum Data with respect to such Selection Pool Compound. For the avoidance of doubt, it is understood and agreed that the Operating Companies fulfilled their diligence obligations with respect to Original Patents and Original Know-How prior to the Effective Time and no further development activity with respect to the Original Compounds shall be necessary for the Operating Companies to retain their licenses under the Original Patents and Original Know-How for Licensed Products comprising Original Compounds.

#### Section 4.2 Reporting.

- (a) Within three (3) months after the end of the Specified Period, each Operating Company shall provide SAG with a reasonably detailed written summary of its development activities with respect to the Selection Pool Compounds, including Development Costs incurred with respect thereto, during the Specified Period. Such written report shall identify (i) those Selection Pool Compounds with respect to which the Operating Company has collected Minimum Data (the "Development Compounds") and (ii) those Selection Pool Compounds with respect to which the Operating Company intends in good faith to collect Minimum Data during the immediately following twelve (12) month period ("Election Compounds"). The Operating Company shall deliver to SAG, with respect to each Development Compound, such Minimum Data as SAG may reasonably request.
- (b) Within thirty (30) days following the end of the twelve (12) month period for which an Operating Company has indicated its intention to develop an Election Compound, such Operating Company shall provide SAG with a reasonably detailed written summary of its development activities with respect to the Election Compounds during such twelve (12) month period. Such written report shall identify those Election Compounds with respect to which the Operating Company has collected Minimum Data. The Operating Company shall deliver to SAG, with respect to each Election Compound, such Minimum Data as SAG may reasonably request.

(c) For so long as Operating Companies are Affiliates of one another, such Operating Companies may satisfy their reporting obligations under this Section 4.2 by providing a consolidated report.

**Section 4.3 Remedy.** The Operating Companies' sole and exclusive liability and SAG's sole and exclusive remedy for any breach of Section 4.1 shall be as follows:

- (a) After delivery of the report and the Minimum Data described in Section 4.2(a), SAG may terminate the Operating Companies' license rights under Section 2.1 and Section 2.2 only with respect to those Selection Pool Compounds that are neither Development Compounds nor Election Compounds upon notice to SPI. Upon such written notice by SAG, the Operating Companies shall disclose to SAG preclinical data obtained by the Operating Companies during the Specified Period to the extent relating to Selection Pool Compounds as to which the licenses have been terminated in accordance with the preceding sentence. Further, the Operating Companies hereby grant to SAG a royalty-free and exclusive license, with right of sublicense, to use such preclinical data for all purposes, subject to the Operating Companies' retained rights to use such preclinical data in connection with Original Compounds and Selection Pool Compounds as to which the Operating Companies have retained their license rights hereunder to develop, import, use, make, have made, export, offer for sale and sell Licensed Products.
- (b) After delivery of the report described in Section 4.2(b), SAG may terminate the Operating Companies' license rights under Section 2.1 and Section 2.2 upon written notice to SPI with respect to any Election Compounds for which such Operating Companies failed to deliver Minimum Data. Upon such written notice by SAG, the Operating Companies shall disclose to SAG preclinical data obtained by the Operating Companies during the twelve (12) month period described in Section 4.2(b) to the extent relating to Election Compounds as to which the licenses have been terminated in accordance with the preceding sentence. Further, the Operating Companies hereby grant to SAG a royalty-free and exclusive license, with right of sublicense, to use such preclinical data for all purposes, subject to the Operating Companies' retained rights to use such preclinical data in connection with Original Compounds and Selection Pool Compounds as to which the Operating Companies have retained their license rights hereunder to develop, import, use, make, have made, export, offer for sale and sell Licensed Products.

Section 4.4 Noncompete. During the Specified Period, neither SAG nor any of its Affiliates (including Development Affiliates but excluding Operating Companies) shall, directly or indirectly, develop, manufacture, market, sell, detail or promote any Competing Product in the Territory of any Operating Company. Further, for a period of two (2) years after the end of the Specified Period, neither SAG nor any of its Affiliates (including Development Affiliates but excluding Operating Companies) shall, directly or indirectly, manufacture (other than the manufacture of clinical product in furtherance of development activities), market, sell, detail or promote any Competing Product (including, for the avoidance of doubt, any Selection Pool Compound reacquired by SAG pursuant to Section 4.3 that meets the definition of Competing Product) in the Territory of any Operating Company.

#### ARTICLE 5 — CONFIDENTIALITY

Section 5.1 Confidentiality. Each party agrees not to disclose or use any of the other party's Confidential Information except as expressly permitted in connection with the exercise of its rights hereunder. Each party shall not disclose the other party's Confidential Information to any employee or consultant unless such employee or consultant is obligated under a confidentiality agreement to maintain such other party's Confidential Information in strict confidence, and not to use such information other than, in accordance with the terms of this Agreement. Each party agrees to hold the other party's Confidential Information in strict confidence and treat it with not less than the same degree of care to avoid disclosure as such party employs with respect to its own information of like importance.

Section 5.2 Exclusions. The parties' obligations under this ARTICLE 5 shall exclude any information which:

- (a) is or becomes publicly available through no fault of the receiving party; or
- (b) can be reasonably demonstrated to have been known to the receiving party independently of any disclosure of "Confidential Information" by the disclosing party or its employees, agents or consultants; or
- (c) is disclosed to the receiving party by a third party who, to the best of the receiving party's knowledge, is lawfully in possession of the same and has the right to make such disclosure; or
- (d) has been independently developed by the receiving party without reference to the information disclosed to the receiving party by the disclosing party or its employees, agents or consultants.
- **Section 5.3 Permitted Disclosures**. Notwithstanding anything else to the contrary, the parties may disclose Confidential Information as may be required by applicable law or court order. In addition, upon consent of the party providing the information, which consent shall not be unreasonably withheld, each Operating Company shall have the right to disclose Confidential Information to its sublicensees, professional advisors, and *bona fide* potential investors and business partners, who are bound by obligations of confidentiality.
- **Section 5.4 Delivery and Return of Confidential Information**. Upon termination of this Agreement or the licenses granted hereunder as provided herein, each party shall within 30 days of such termination return to the other party all of the other party's Confidential Information. Notwithstanding the foregoing, each party shall have the right to retain one copy of such other party's Confidential Information in its corporate files for archival purposes only.

#### ARTICLE 6 — INTELLECTUAL PROPERTY

**Section 6.1 Ownership of Intellectual Property**. Subject to the rights granted in Section 2.1 and Section 2.2, and to the assignment obligation in Section 2.4, each party shall own all right, title and interest in and to any inventions, whether or not patentable, that may be conceived or developed by it, its employees or its agents during the term of this Agreement.

#### Section 6.2 Patent Prosecution and Maintenance.

- (a) SAG hereby grants to SPI an irrevocable power of attorney during the term of this Agreement to undertake the preparation, filing, prosecution, amendment, maintenance and reissue of the Licensed Patents in each Operating Company's Territory in accordance with this Section 6.2, including without limitation a power of attorney to execute patent application forms on behalf of and in the name of SAG. SPI shall have the sole and exclusive right and option to apply for, prosecute, or cause the issuance, amendment, maintenance, abandonment, re-examination or reissue of any patents included within the Licensed Patents, any patent applications listed in Exhibit A hereto, or any other patent applications related to trade secrets or know-how included within the Licensed Patents, in each Operating Company's Territory, all in SAG's name. Further, SPI shall have the sole and exclusive right and option in each Operating Company's Territory to (i) obtain patent term extensions (including without limitation, any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to the Licensed Patents, (ii) with respect to data exclusivity periods (such as those periods listed in the FDA's Orange Book (including without limitation any available pediatric extensions) or periods under national implementations of Article 10.1(a)(iii) of EU Directive 2001/EC/83, and all international equivalents), seek, maintain and enforce all such data exclusivity periods available for Licensed Products and (iii) with respect to filings in the FDA Orange Book (and foreign equivalents) for issued Licensed Patents for a Licensed Product, list and maintain all applicable Licensed Patents required to be filed by it, or that it is permitted to file, under applicable law in connection with such Licensed Product.
- (b) SAG hereby grants to SPI and, upon SPI's request, to each of the Operating Companies an irrevocable power of attorney during the term of this Agreement to have the exclusive rights licensed under this Agreement registered (either by filing this Agreement in whole or in part or by filing a written declaration confirming the existence and effectiveness of the rights licensed under this Agreement) with any national patent register within the Territory. In particular, upon the execution of this Agreement, SAG will sign and deliver to SPI the "Declaration of Licensed Rights" as attached in Exhibit B hereto.
- (c) SAG shall cooperate reasonably and in good faith with SPI to enable SPI to exercise its rights under this Section 7.2, including, without limitation, providing SPI or, upon SPI's request, any of the Operating Companies with written authorizations as may be required for SPI to exercise its rights under this Section 7.2. SAG shall furnish to SPI copies of all communications from patent offices regarding patents or patent applications concerning the Licensed Patents to permit SPI to respond to such communications in SAG's name. SPI shall supply each other Operating Company with a copy of each application filed in its Territory, together with notice of its filing date and serial number. SPI shall bear all costs and expenses incurred in connection with the preparation, filing, prosecution, amendment, maintenance and reissue of Licensed Patents pursuant to this Section 6.2.

#### **Section 6.3 Infringement by Third Parties.**

- (a) Each party shall promptly notify the other parties in writing if such party knows or has reason to believe that the rights of any of the parties relating to the Licensed Patents are being infringed by a third party.
- (b) In the event a third party is developing, marketing, selling or promoting a Competing Product, then SPI shall have the first right, but not the obligation, to prosecute at its expense any alleged infringement, misappropriation or misuse of the Licensed Patents by such third party. In all other cases, SAG shall have the first right, but not the obligation, to prosecute at its expense any alleged infringement, misappropriation or misuse of the Licensed Patents. If SPI decides at any time not to commence or continue to prosecute any alleged infringement, misappropriation or misuse of the Licensed Patents, it shall so notify SAG in writing within thirty (30) days or any shorter time limit necessary to preserve SAG's rights, and SAG shall have the right, in its absolute discretion and sole expense, to commence or continue such prosecution of such action. In any such legal action, the other party shall cooperate with and at the request of the party prosecuting the suit. The proceeds of any such legal action shall be allocated first, to cover the expenses of prosecution and investigation incurred by the party bringing the legal action; and second, to cover the expenses incurred by the other party participating in such legal action. Any remaining amounts shall be allocated seventy-five percent (75%) to the party initiating the action and twenty-five percent (25%) to SAG (if SPI is the initiating party, otherwise to SPI).

#### Section 6.4 Third Party Claims.

- (a) If any party shall become aware of any action or suit, or threat of action or suit, by a third party alleging that the manufacture, use or sale of any Licensed Product or the practice of know-how infringes a patent, or violates any other proprietary rights of any third party, the party aware shall promptly notify the other parties of the same and fully disclose the basis therefor.
- (b) A party defending such third party action shall not have the right to settle such claim in a manner that would impair the other parties' rights under this Agreement or require the other parties to make any monetary payments or be subject of an injunction, without the prior written consent of the non-defending party or parties, such consent however not being unreasonably withheld. If, however, by the terms of any settlement or if by a judgment, decree or decision of a court, tribunal or other authority of competent jurisdiction, an Operating Company or their licensee is required to obtain a license from a third party in order to make, have made, use, sell or import a Licensed Product in an Operating Company's Territory (hereinafter "Third Party License") fifty percent (50%) of payments under such Third Party License, including any upfront payments, shall be deducted from any royalties payable under Section 3.2 by such Operating Company on future sales.
  - (c) Reasonable attorneys' fees and legal costs shall be borne by the party defending the action.

Section 6.5 Non-Suit Covenant. In the event (i) SAG obtains rights to a Selection Pool Compound pursuant to Section 4.3 and (ii) SAG determines that it (through an Affiliate or permitted sublicensee) cannot reasonably develop, manufacture, market, sell, detail or promote such Selection Pool Compound without infringing a claim of a Licensed Patent which is exclusively licensed under Section 2.1, then SAG shall so notify the applicable Operating Compan(ies). Upon request by SAG, the applicable Operating Compan(ies) shall meet with SAG and discuss in good faith reasonable terms for an appropriate covenant not to sue with respect to such Selection Pool Compound. The applicable Operating Compan(ies) shall enter into a covenant not to sue SAG (or its Affiliates or permitted sublicensees) under their rights to Licensed Patents to the extent reasonably necessary to permit SAG (through its Affiliate or permitted sublicensee) to develop, manufacture, market, sell, detail or promote such Selection Pool Compound; provided, however, that the applicable Operating Compan(ies) shall not be obligated to grant any covenant not to sue with respect to any patent or patent application which derives from inventions that are acquired, made, created, developed, conceived or reduced to practice by the applicable Operating Compan(ies) after the Specified Period.

### ARTICLE 7 — REGULATORY MATTERS

Section 7.1 Regulatory Filings. Each Operating Company (or its designee) shall have the sole right to file for and to hold title to all regulatory approvals for the Licensed Products in its Territory at its expense. Each Operating Company shall notify SAG in writing within thirty (30) days of receipt of any regulatory approval for the sale of the Licensed Products in its Territory. SAG shall provide the Operating Companies reasonable assistance, at the request and expense of the applicable Operating Company, in obtaining such regulatory approvals for the Licensed Products in its Territory.

**Section 7.2 Audits by Tax Authorities.** Each party agrees to provide reasonable assistance to another party under audit by a tax authority. As part of this assistance, each assisting party shall make available to the party under audit, any agreement the assisting party may have with a tax authority concerning the arm-length nature of charges made under this Agreement.

## **ARTICLE 8 — REPRESENTATIONS & WARRANTIES**

**Section 8.1 Organization**. Each party represents and warrants to the other parties that such party is a corporation duly organized, validly existing, and, where applicable, in good standing under the laws of the jurisdiction of its incorporation.

Section 8.2 Authorization of Transaction. Each party represents and warrants to the other parties that it has full power and authority (including full corporate power and authority) to execute and deliver this Agreement and to perform its obligations hereunder. All necessary corporate proceedings (including any necessary approval by the board of directors) have been taken by such party to duly authorize the execution, delivery, and performance of this Agreement by such party. This Agreement constitutes the valid and legally binding obligation of such party, enforceable against such party in accordance with the terms and conditions hereof.

**Section 8.3 No Conflicts.** SAG represents and warrants to the Operating Companies that it has not entered into any inconsistent prior obligations concerning the Licensed Patents or Licensed Know-How that would prevent the Operating Companies from exercising the rights being licensed to them hereunder.

**Section 8.4 Right to License.** SAG represents and warrants to the Operating Companies that, as of the Effective Time, it owns or has the right to license or sublicense all the rights granted to the Operating Companies herein with respect to the Licensed Patents and Licensed Know-How. SAG further represents and warrants to the Operating Companies that SAG owns, as of the Effective Time, all of the technology related to prostones (including without limitation patents, patent applications, technical information, data, trade secrets and know-how) acquired, made, created, developed, conceived or reduced to practice by SAG or any of its Affiliates on or before the Effective Time.

**Section 8.5 No Claims**. SAG represents and warrants to the Operating Companies that, as of the execution date of this Agreement, it has not received written notification from a third party that the manufacture, use, importation or sale of the Licensed Products under the license granted herein under the Licensed Patents and Licensed Know-How will infringe any patents, copyrights, trade secrets or any other intellectual property rights of any third parties.

#### **ARTICLE 9 — TERM AND TERMINATION**

**Section 9.1 Term**. This Agreement shall be effective as of July 30, 2002, may be terminated as set forth in this ARTICLE 9, and shall otherwise remain in effect until the later of (i) the expiration of all Licensed Patents and (ii) the expiration of all royalty obligations for all Licensed Products in all countries.

#### Section 9.2 Termination.

(a) Subject to Section 4.3, if an Operating Company materially breaches any of the material terms, conditions or agreements of this Agreement, SAG may terminate this Agreement with respect to such Operating Company only, by giving the breaching party sixty (60) days notice in writing, particularly specifying the breach. Such notice of termination shall not be effective unless the breach is established through arbitration, as set out in Section 10.2, and the breaching party fails to cure the specified breach within sixty (60) days of such breach being established. In the event of any dispute, and during such 60-day period, one or more executive officers of each such party (meaning for purposes hereunder any vice president or higher level officer) shall meet or correspond to discuss such alleged breach and/or attempted cure thereof, and attempt in good faith to resolve any dispute between the parties with respect thereto. Any termination for material breach, to the extent that it relates to a Licensed Product or Products, shall be on a Licensed Product-by-Licensed Product basis and the license as to all other Licensed Products shall survive. If this Agreement is terminated with respect to one or two of the Operating Companies, it shall remain in full force and effect with the remaining Operating Company or Companies.

- (b) If SAG breaches any of the material terms, conditions or agreements of this Agreement with respect to one or more of the Operating Companies, such Operating Company or Companies may terminate this Agreement by giving SAG sixty (60) days notice in writing, particularly specifying the breach. Such notice of termination shall not be effective if SAG cures the specified breach within such 60-day period. During such 60-day period, one or more executive officers of each such party (meaning for purposes hereunder any vice president or higher level officer) shall meet or correspond to discuss such alleged breach and/or attempted cure thereof, and attempt in good faith to resolve any dispute between the parties with respect thereto. If this Agreement is terminated with respect to one or two of the Operating Companies, it shall remain in full force and effect with the remaining Operating Company or Companies.
- (c) A party may, by written notice to another party (which notice shall be effective upon receipt), terminate this Agreement in the event that such other party makes an assignment for the benefit of creditors, goes into liquidation or receivership or otherwise loses legal control of its business. If this Agreement is terminated with respect to one or two of the Operating Companies, it shall remain in full force and effect with the remaining Operating Company or Companies.

Section 9.3 Effect of Termination. Upon the termination of any rights granted hereunder, each Operating Company shall have the right to dispose of all Licensed Products then on hand to which such termination applies, and the royalties shall be paid to SAG or an Operating Company, if applicable, with respect to such Licensed Product as though such rights had not terminated. Termination of this Agreement shall not affect any of the parties' respective rights and obligations accruing prior to such termination. Section 4.4 (Noncompete), ARTICLE 5 (Confidentiality), ARTICLE 10 (Dispute Resolution) and ARTICLE 11 (Miscellaneous) shall survive termination of this Agreement for any reason and continue thereafter in full force and effect.

### Section 9.4 Rights under Bankruptcy.

- (a) In the event of Bankruptcy by SAG, to the extent possible under the applicable law, the intellectual property licenses granted by SAG hereunder and the reciprocal obligations of the Operating Companies to make royalty and milestone payments shall remain in full force and effect and shall be binding on the administrator and SAG's estate and shall vest in any assignee or successor in interest of SAG and its business or of SAG's rights and obligations under this Agreement.
- (b) In the event that any Licensed Patent will be realized in the Bankruptcy by SAG, irrespective of whether by a public auction or by private sale, each Operating Company shall have a preemption right to acquire such Licensed Patent for its respective Territory and on such terms and conditions, including the purchase price, as may be offered by a third party through such public auction or private sale.

#### ARTICLE 10 — DISPUTE RESOLUTION AND CHOICE OF LAW

**Section 10.1 Negotiation**. The parties agree to consult and negotiate in good faith to try to resolve any dispute, controversy or claim 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.

Section 10.2 Arbitration. Any dispute, controversy or claim that arises out of or relates to this Agreement that is not resolved under Section 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 Time, as modified by Section 10.3 below. Judgment upon the award rendered by the arbitrators may be entered in any court of competent jurisdiction. The place of arbitration shall be London, England. 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 knowledge of and experience in the ethical pharmaceutical industry, and at least one (1) arbitrator shall have knowledge of and experience in international law and technology licensing.

**Section 10.3 Special Rules**. Notwithstanding any provision to the contrary in the ICC's Rules of Arbitration, the parties hereby stipulate that any arbitration hereunder shall be subject to the following special rules:

- (a) The arbitrators may not award or assess punitive damages against either party; and
- (b) Each party shall bear its own costs and expenses of the arbitration and shall share equally the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees to the prevailing party.

Section 10.4 Governing Law. This Agreement shall be construed in accordance with the laws of the State of New York (without reference to its choice of law or conflicts of law rules).

#### ARTICLE 11 — RIGHT OF FIRST REFUSAL

**Section 11.1 Right of First Refusal**. SAG shall not, during the term of this Agreement, sell all or any part of its business, whether through an asset sale, stock sale, merger, consolidation, or any other form of similar business transaction, unless it complies with the provisions of this Section 11.1.

(a) If, during the term of this Agreement, SAG wishes to sell all or any part of its business, whether through an asset sale, stock sale, merger, consolidation, or any other form of similar business transaction, SAG shall first provide written notice to SPI (an "Offer Notice") setting forth (i) the name and address of the party to which SAG proposes to make such sale (the "Offeror"), (ii) the portion of its business SAG proposes

to sell, if less than the entire business, (iii) the consideration to be delivered to SAG for the proposed sale and (iv) all other material terms and conditions of the proposed transaction. SPI shall then have sixty (60) days following its receipt of the Offer Notice within which to give notice to SAG (the "Acceptance Notice") that it wishes to acquire the business, or applicable portion thereof, on terms corresponding to those set forth in the Offer Notice, in which case the closing of such acquisition shall be closed at a time mutually agreeable to SAG and SPI, but not more than thirty (30) days after delivery by SPI of the Acceptance Notice. To the extent that the consideration proposed to be paid by the Offeror for consists of property other than cash or a promissory note, the consideration required to be paid by SPI may consist of cash equal to the value of such property, as determined in good faith by agreement of the SPI and SAG.

(b) If SPI does not deliver an Acceptance Notice within the 60-day period described above, then SAG shall have the right within the ninety (90) days following the expiration of the 60-day period described in Section 11.1(a) to sell its business, or the applicable portion thereof, at a price and on terms and conditions no less favorable to SAG than those contained in the Offer Notice. If SAG wishes to sell the applicable portion of its business at a price or on terms that are less favorable to it than those set forth in the Offer Notice, or if it wishes to sell all or any portion of its business more than ninety (90) days after the expiration of the 60-day period described in Section 11.1(a) above, then, as a condition precedent to such transaction, SAG must again comply with the terms of this Section 11.1.

#### **ARTICLE 12 — MISCELLANEOUS**

**Section 12.1 Assignment**. Upon written approval of the other parties, which approval shall not unreasonably be withheld and shall be timely given, a party may assign or otherwise transfer its rights and obligations under this Agreement to any successor in interest (by merger, share exchange, combination or consolidation of any type, operation of law, purchase or otherwise), provided that such assignee or successor agrees to be bound by the terms hereof.

**Section 12.2 Entire Agreement.** This Agreement, together with the Exhibits and Schedules hereto, constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes all previous proposals or agreements, oral or written, and all negotiations, conversations or discussions heretofore had between the parties related to the subject matter of this Agreement. Without limiting the foregoing, this Agreement shall supercede in their entirety the Original Agreements.

**Section 12.3 Waiver, Discharge, etc.** This Agreement may not be released, discharged, abandoned, changed or modified in any manner, except by an instrument in writing signed on behalf of each of the parties to this Agreement by their duly authorized representatives. The failure of either party to enforce at any time any of the provisions of this Agreement shall in no way be construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part of it or the right of either party after any such failure to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach.

**Section 12.4 Execution in Counterparts**. This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same agreement, and shall become a binding agreement when one or more counterparts have been signed by each party and delivered to the other party.

**Section 12.5 Titles and Headings; Construction**. The titles and headings to Sections herein are inserted for the convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. This Agreement shall be construed without regard to any presumption or other rule requiring construction hereof against the party causing this Agreement to be drafted.

**Section 12.6 Benefit.** Nothing in this Agreement, expressed or implied, is intended to confer on any person other than the parties to this Agreement or their respective permitted successors or assigns; any rights, remedies, obligations or liabilities under or by reason of this Agreement.

**Section 12.7 Force Majeure**. If the performance of this Agreement or any obligation hereunder (other than the payment of monies due owing hereunder) is prevented, restricted or interfered with by reason of any event or condition beyond the reasonable control of such party (including without limitation acts of State or governmental action, riots, disturbance, war, strikes, lockouts, slowdowns, prolonged shortage of energy or other supplies, epidemics, fire, flood, hurricane, typhoon, earthquake, lightning and explosion, or any refusal or failure of any governmental authority to grant any export license legally required), the party so affected shall be excused from such performance, only for so long as and to the extent that such a force prevents, restricts or interferes with the party's performance and provided that the party affected gives notice thereof to the other parties and uses diligent efforts to remedy such event or conditions.

**Section 12.8 Notices**. All notices or other communications to a party required or permitted hereunder shall be in writing and shall be delivered personally or by telecopy (receipt confirmed) to such party (or, in the case of an entity, to an executive officer of such party) or shall be given by registered mail, addressed as follows:

If to SAG, to: Sucampo AG

Graben 5

CH-6300 Zug, Switzerland

Attention: Eric Buis

Facsimile number: +41-41-729-8893

if to SPI, to: Sucampo Pharmaceuticals, Inc.

4733 Bethesda Avenue, Suite 450 Bethesda, Maryland 20814, U.S.A.

Attention: Sachiko Kuno

Facsimile number: +1-301-961-3440

with copy to: Wilmer Cutler Pickering Hale and Dorr LLP

1875 Pennsylvania Avenue, NW

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Facsimile number: +1-202-663-6363

if to SPL, to: 2-2-16 Sonezakishinchi,

Kita-Ku, Osaka Japan 530-0002

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If to SPE, to: Sucampo Pharma Europe, Ltd.

78 Cannon Street

London EC4N 6NQ U.K. Attention: Kei Tolliver

Facsimile number: +44-207-618-8661

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A party may change its above-specified recipient and/or mailing address by notice to the other parties given in the manner herein prescribed. All notices shall be deemed given on the day when actually delivered as provided above (if delivered personally or by telecopy) or on the day shown on the return receipt (if delivered by mail).

**Section 12.9 Severability.** If a court or tribunal of competent jurisdiction holds any provision of this Agreement invalid, the remaining provisions shall nonetheless be enforceable according to their terms. Further, if any provision is held to be overbroad as written, such provision shall be deemed amended to narrow its application to the extent necessary to make the provision enforceable according to applicable law and shall be enforced as amended.

Section 12.10 Limitation of Liability. IN NO EVENT SHALL A PARTY BE LIABLE TO THE OTHER PARTIES OR ANY OTHER PERSON FOR ANY SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY ARISING OUT OF THIS AGREEMENT, AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN.

Section 12.11 Unaffiliated Operating Company. In the event one Operating Company ceases to be an Affiliate of the other Operating Companies, this Agreement shall be amended to remove such Operating Company as a party and novated with respect to such Operating Company. Simultaneously with such amendment and novation, (i) SAG and such Operating Company will enter into an agreement covering the subject matter hereof so as to preserve the arrangement which previously existed between SAG and such Operating Company under this Agreement and (ii) SPI shall grant such Operating Company (if such Operating Company is SPE or SPL) an irrevocable power of attorney to undertake the preparation, filing, prosecution, amendment, maintenance and reissue of the Licensed Patents in such Operating Company's Territory.

IN WITNESS WHEREOF, each of the parties has caused this Amended and Restated Patent Access and Data Sharing Agreement to be executed in the manner appropriate to each, effective as of the date first above written.

SUCAMPO AG	SUCAMPO PHARMACEUTICALS, INC.
By: /s/ Eric Buis Dr. Eric Buis Director	By: /s/ Sachiko Kuno Dr. Sachiko Kuno President, Chief Executive Officer
SUCAMPO AG	SUCAMPO PHARMA, LTD.
By: /s/ Urs Burgherr Dr. Urs. Burgherr Director	By: /s/ Misako Nakata  Ms. Misako Nakata  Representative Director
SUCAMPO PHARMA EUROPE, LTD.	
By: /s/ Kei Tolliver  Ms. Kei Tolliver  Director	

Exhibit A
Licensed Patents

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-11	PROSTAGLANDINS OF THE D SERIES, AND TRANQUILIZERS AND SOPORIFICS CONTAINING THE SAME	U.S.A. CIP	403774	1989/9/6	5073569	1991/12/17	
A-11	PROSTAGLANDINS OF THE D SERIES, AND TRANQUILIZERS AND SOPORIFICS CONTAINING THE SAME	U.S.A. DIV	715151	1991/6/13	5137915	1992/8/11	
A-11	PROSTAGLANDINS OF THE D SERIES, AND TRANQUILIZERS AND SOPORIFICS CONTAINING THE SAME	U.S.A. CA3	8/310109	1994/9/23	5534547	1996/7/9	
A-11	PROSTAGLANDINS OF THE D SERIES, AND TRANQUILIZERS AND SOPORIFICS CONTAINING THE SAME	JAPAN	63-18327	1988/1/28	2071783	1996/7/25	
A-11	PROSTAGLANDINS OF THE D SERIES, AND TRANQUILIZERS AND SOPORIFICS CONTAINING THE SAME	Canada	557480	1988/1/27	1322749	1993/10/5	
A-11	PROSTAGLANDINS OF THE D SERIES, AND TRANQUILIZERS AND SOPORIFICS CONTAINING THE SAME	EPC	88300710.6	1988/1/28	281239	1992/3/25	GB,FR,DE
A-12	PROSTAGLANDINS E AND ANTI ULCERS CONTAINING SAME	U.S.A. CA	681031	1991/4/5	5225439	1993/7/6	
A-12	PROSTAGLANDINS E AND ANTI ULCERS CONTAINING SAME	U.S.A. CA	700895	1991/5/13	5166174	1992/11/24	
A-12	PROSTAGLANDINS E AND ANTI ULCERS CONTAINING SAME	U.S.A. DIV	925220	1992/8/6	5284858	1994/2/8	
A-12	PROSTAGLANDINS E AND ANTI ULCERS CONTAINING SAME	U.S.A. DIV	08/53487	1993/4/28	5428062	1995/6/27	
A-12	PROSTAGLANDINS E AND ANTI ULCERS CONTAINING SAME	U.S.A. CA	08/53561	1993/4/28	5380709	1995/1/10	

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-12	PROSTAGLANDINS E AND	U.S.A. DIV2	08/401675	1995/3/10	5886034	1999/3/23	Er Designated Country
11 1 <b>-</b>	ANTI ULCERS CONTAINING	0.0.11. 0112	00/1010/5	1555/5/10	5000051	1000/0/20	
	SAME						
A-12	PROSTAGLANDINS E AND	U.S.A. DIV3	09/073253	1998/5/6	6265440	2001/7/24	
	ANTI ULCERS CONTAINING						
	SAME						
A-12	PROSTAGLANDINS E AND	JAPAN	63-18326	1988/1/28	1961313	1995/8/10	
	ANTI ULCERS CONTAINING						
	SAME						
A-12	PROSTAGLANDINS E AND	Canada	557407	1988/1/26	1323364	1993/10/19	
	ANTI ULCERS CONTAINING						
	SAME						
A-12	PROSTAGLANDINS E AND	Korea	0702/88	1988/1/28	68912	1993/12/20	
	ANTI ULCERS CONTAINING SAME						
A-12	PROSTAGLANDINS E AND	TAIWAN	77100543	1988/1/28	36059	1990/5/1	
A-12	ANTI ULCERS CONTAINING	IAIWAN	//100343	1900/1/20	30039	1990/3/1	
	SAME						
A-12	PROSTAGLANDINS E AND	EPC	88300709.8	1988/1/28	284180	1992/8/19	GB,FR,DE,IT,NL,CH,BE,AT,
	ANTI ULCERS CONTAINING	21 0	0000070010	1500/1/20	20.100	1002/0/10	LU,SE, ES,GR
	SAME						, , ,
A-15	FERVESCENCE COMPOSITION	U.S.A. CIP	440449	1989/11/22	5001154	1991/3/19	
A-15	FERVESCENCE COMPOSITION	JAPAN	63-117192	1988/5/13	1963660	1995/8/25	
A-15	FERVESCENCE COMPOSITION	Canada	566799	1988/5/13	1306699	1992/8/25	
A-15	FERVESCENCE COMPOSITION	New Zealand	226198	1988/9/15	226198	1991/9/18	
A-15	FERVESCENCE COMPOSITION	EPC	88304206.1	1988/5/10	292177	1992/3/25	GB,FR,DE
A-17	CATHARTICS	U.S.A. CA2	996495	1992/12/30	5317032	1994/5/31	
A-17	CATHARTICS	JAPAN	63-245737	1988/9/29	1954133	1995/7/28	
A-17	CATHARTICS	Canada	578500	1988/9/27	1312014	1992/12/29	
			2				
			2				

FILE							
No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-17	CATHARTICS	Korea	12841/88	1988/9/30	64454	1993/8/17	
A-17	CATHARTICS	TAIWAN	77106582	1988/9/23	36138	1990/5/2	
A-17	CATHARTICS	Australia	22920/88	1988/9/29	609883	1991/9/2	
A-17	CATHARTICS	New Zealand	226362	1988/9/28	226362	1991/11/22	
A-17	CATHARTICS	EPC	88308842.9	1988/9/23	310305	1992/7/22	GB,FR,DE,IT,NL,CH,BE,AT, LU,SE, ES,GR
A-20	STABILIZATION OF 13,14- DIHYDRO-15-KETO- PROSTAGLANDINS	JAPAN	63-45622	1988/2/26	2597629	1997/1/9	
A-20	STABILIZATION OF 13,14- DIHYDRO-15-KETO- PROSTAGLANDINS	New Zealand	228111	1989/2/23	228111	1991/6/21	
A-20	STABILIZATION OF 13,14- DIHYDRO-15-KETO- PROSTAGLANDINS	EPC	89301888.7	1989/2/24	330511	1992/8/12	GB,FR,DE
A-22	TRACHEOBRONCHODILATOR	U.S.A. CA2	8/77495	1993/6/17	5362751	1994/11/8	<del>-</del>
A-22	TRACHEOBRONCHODILATOR	JAPAN	63-115409	1988/5/11	2597649	1997/1/9	
A-22	TRACHEOBRONCHODILATOR	Australia	34578/89	1989/5/9	625718	1992/11/10	
A-22	TRACHEOBRONCHODILATOR	EPC	89304723.3	1989/5/10	345951	1993/3/10	GB,FR,DE
A-23	USE OF 15-KETO- PROSTAGLANDIN E OR F COMPOUNDS FOR UTERINE CONTRACTION	U.S.A. CA	687790	1991/4/22	5185374	1993/2/9	
A-23	USE OF 15-KETO- PROSTAGLANDIN E OR F COMPOUNDS FOR UTERINE CONTRACTION	JAPAN	1-118026	1989/5/11	2032807	1996/3/19	
A-23	USE OF 15-KETO- PROSTAGLANDIN E OR F COMPOUNDS FOR UTERINE CONTRACTION	JAPAN DIV	6-283283	1994/11/17	2529095	1996/6/14	
			3				

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-23	USE OF 15-KETO-	Canada	599424	1989/5/11	1330796	1994/7/19	
	PROSTAGLANDIN E OR F						
	COMPOUNDS FOR UTERINE						
	CONTRACTION						
A-23	USE OF 15-KETO-	Australia	34579/89	1989/5/9	619543	1992/5/25	
	PROSTAGLANDIN E OR F						
	COMPOUNDS FOR UTERINE						
	CONTRACTION		0000.480.4.4		5.45.65	1000/0/0	CD
A-23	USE OF 15-KETO-	EPC	89304724.1	1989/5/10	342003	1993/9/8	GB,FR,DE
	PROSTAGLANDIN E OR F						
	COMPOUNDS FOR UTERINE						
A 24	CONTRACTION	II.C.A. C.A	CEDEEO	1001/2/22	E4.00000	1000/10/0	
A-24	HYPERSPHYXIA-CAUSING COMPOSITION	U.S.A. CA	672758	1991/3/22	5169863	1992/12/8	
A-24	HYPERSPHYXIA-CAUSING	JAPAN	63-125303	1988/5/23	2106314	1996/11/6	
A-24	COMPOSITION	JAPAN	03-123303	1900/3/23	2100314	1990/11/0	
A-24	HYPERSPHYXIA-CAUSING	JAPAN	63-182281	1988/7/20	2760514	1998/3/20	
11 27	COMPOSITION	32117111	05 102201	1500/7/20	2700514	1330/3/20	
A-24	HYPERSPHYXIA-CAUSING	JAPAN DIV	7-30674	1995/2/20	2633495	1997/4/25	
	COMPOSITION						
A-24	HYPERSPHYXIA-CAUSING	EPC	89305163.1	1989/5/22	343904	1993/4/28	GB,FR,DE,IT
	COMPOSITION						
A-26	PRECURSOR OF	U.S.A.	386074	1989/7/28	4918202	1990/4/17	
	PROSTAGLANDIN AND						
	PRODUCTION THEREOF						
A-26	PRECURSOR OF	U.S.A. DIV	467455	1990/1/19	4994584	1991/2/19	
	PROSTAGLANDIN AND						
A 20	PRODUCTION THEREOF	TADANI	C2 101100	1000/7/20	2015206	1006/2/2	
A-26	PRECURSOR OF PROSTAGLANDIN AND	JAPAN	63-191190	1988/7/29	2015306	1996/2/2	
	PRODUCTION THEREOF						
A-28	PROSTAGLANDIN I ANALOGUE	U.S.A.	521621	1990/5/10	5107014	1992/4/21	
A-28 A-28	PROSTAGLANDIN I ANALOGUE PROSTAGLANDIN I ANALOGUE	JAPAN	63-286274	1988/11/10	2059804	1992/4/21	
A-28	PROSTAGLANDIN I ANALOGUE	JAPAN	63-332219	1988/12/27	2059804	1996/6/10	
A-28	PROSTAGLANDIN I ANALOGUE	Canada	2016300-3	1900/12/27	2039808	2001/12/11	
11-20	1 ROOM GEMENT THE MECOUL	Canada	2010300-3	1330/3/0	2010300	2001/12/11	
			4				

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-28	PROSTAGLANDIN I ANALOGUE	Korea	6557/90	1990/5/9	89549	1995/9/25	21 Designated Country
A-28	PROSTAGLANDIN I ANALOGUE	TAIWAN	79103767	1990/5/10	52296	1992/3/6	
A-28	PROSTAGLANDIN I ANALOGUE	EPC	90305046.6	1990/5/10	455899	2000/2/16	GB,FR,DE
A-29	TREATMENT OF HYPERLIPIDEMIA	U.S.A. CA	899171	1992/6/15	5234954	1993/8/10	
	WITH 15-KETO-PROSTAGLANDIN						
	COMPOUNDS						
A-29	TREATMENT OF HYPERLIPIDEMIA	JAPAN	2-196742	1990/7/24	2137963	1998/8/21	
	WITH 15-KETO-PROSTAGLANDIN						
	COMPOUNDS						
A-29	TREATMENT OF HYPERLIPIDEMIA	Canada	2022081-3	1990/7/26	2022081	1996/1/9	
	WITH 15-KETO-PROSTAGLANDIN						
4 20	COMPOUNDS	EDC	00005005 4	1000/7/10	44.00.40	100 4/2/2	CD ED DE
A-29	TREATMENT OF HYPERLIPIDEMIA	EPC	90307895.4	1990/7/19	410646	1994/3/2	GB,FR,DE
	WITH 15-KETO-PROSTAGLANDIN COMPOUNDS						
A-30	IMPROVEMENT OF EXCRETION OF	U.S.A. REISSUE	953786	1992/9/30	RE 34756	1994/10/11	
A-30	POTASSIUM ION BY PROSTANOIC ACID	0.3.A. KEI330E	933700	1332/3/30	KE 54750	1334/10/11	
	DERIVATIVES						
A-30	IMPROVEMENT OF EXCRETION OF	JAPAN	2-196743	1990/7/24	2609479	1997/2/13	
	POTASSIUM ION BY PROSTANOIC ACID						
	DERIVATIVES						
A-30	IMPROVEMENT OF EXCRETION OF	Canada	2022323-5	1990/7/25	2022323	1995/7/25	
	POTASSIUM ION BY PROSTANOIC ACID						
	DERIVATIVES						
A-30	IMPROVEMENT OF EXCRETION OF	EPC	90307944.0	1990/7/20	410652	1995/5/17	GB,FR,DE
	POTASSIUM ION BY PROSTANOIC ACID						
	DERIVATIVES	***		1000/0/0		10001010	
A-31	IMPROVEMENT OF EXCRETION OF	U.S.A.	564489	1990/8/8	5126372	1992/6/30	
	NONPROTEIN NITROGEN INTO THE INTESTINE BY PROSTANOIC ACID						
	DERIVATIVES						
A-31	IMPROVEMENT OF EXCRETION OF	JAPAN	2-210882	1990/8/8	2138075	1998/8/28	
11 51	NONPROTEIN NITROGEN INTO THE	37117111	2 210002	1330/0/0	2130073	1550/0/20	
	INTESTINE BY PROSTANOIC ACID						
	DERIVATIVES						
A-31	IMPROVEMENT OF EXCRETION OF	Canada	2022372-3	1990/7/31	2022372	2000/5/2	
	NONPROTEIN NITROGEN INTO THE						
	INTESTINE BY PROSTANOIC ACID						
	DERIVATIVES						
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			J				

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-31	IMPROVEMENT OF EXCRETION OF NONPROTEIN NITROGEN INTO THE INTESTINE BY PROSTANOIC ACID DERIVATIVES	EPC	90308385.5	1990/7/31	415564	1995/4/26	GB,FR,DE
A-35	TREATMENT OF HEPATOBILIARY DISEASE WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	U.S.A.	600048	1990/10/19	5096927	1992/3/17	
A-35	TREATMENT OF HEPATOBILIARY DISEASE WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	JAPAN	2-282420	1990/10/19	1879002	1994/10/7	
A-35	TREATMENT OF HEPATOBILIARY DISEASE WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	Canada	2027814-5	1990/10/17	2027814	1996/7/30	
A-35	TREATMENT OF HEPATOBILIARY DISEASE WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	Korea	16811/90	1990/10/20	127297	1997/10/21	
A-35	TREATMENT OF HEPATOBILIARY DISEASE WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	TAIWAN	79108801	1990/10/18	53077	1992/4/7	
A-35	TREATMENT OF HEPATOBILIARY DISEASE WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	EPC	90311457.7	1990/10/18	424156	1996/1/10	GB,FR,DE,IT,NL,CH,BE,AT, LU,SE, ES,GR,DK
A-36	TREATMENT OF PULMONARY DYSFUNCTION WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	U.S.A. CA	892642	1992/6/2	5254588	1993/10/19	
A-36	TREATMENT OF PULMONARY DYSFUNCTION WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	JAPAN	2-319575	1990/11/21	2059846	1996/6/10	
A-36	TREATMENT OF PULMONARY DYSFUNCTION WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	Canada	2030344-1	1990/11/20	2030344	2000/4/18	
A-36	TREATMENT OF PULMONARY DYSFUNCTION WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	Korea	18961/90	1990/11/22	153779	1998/7/7	
A-36	TREATMENT OF PULMONARY DYSFUNCTION WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	TAIWAN	79109730	1990/11/19	51233	1992/1/14	
A-36	TREATMENT OF PULMONARY DYSFUNCTION WITH 15-KETO- PROSTAGLANDIN COMPOUNDS	EPC	90312641.5	1990/11/21	430552	1995/11/8	GB,FR,DE,IT,NL,CH,SE
A-37	USE OF 15-KETO-PROSTAGLANDIN COMPOUND FOR IMPROVEMENT OF ENCEPHALIC FUNCTION	U.S.A.	616960	1990/11/21	5117042	1992/5/26	
			6				

FILE							
No. A-37	Title USE OF 15-KETO-	Country U.S.A. DIV	Application No. 777595	Filing Date 1991/10/16	Patent No. 5290811	Issue Date 1994/3/1	EP Designated Country
	PROSTAGLANDIN						
	COMPOUND FOR						
	IMPROVEMENT OF ENCEPHALIC FUNCTION						
A-37	USE OF 15-KETO-	U.S.A. DIV2	8/142968	1993/10/29	5426115	1995/6/20	
	PROSTAGLANDIN						
	COMPOUND FOR IMPROVEMENT OF						
	ENCEPHALIC FUNCTION						
A-37	USE OF 15-KETO-	JAPAN	2-85439	1990/3/30	2081225	1996/8/9	
	PROSTAGLANDIN COMPOUND FOR						
	IMPROVEMENT OF						
	ENCEPHALIC FUNCTION						
A-37	USE OF 15-KETO- PROSTAGLANDIN	JAPAN	2-319573	1990/11/21	2032829	1996/3/19	
	COMPOUND FOR						
	IMPROVEMENT OF						
A 27	ENCEPHALIC FUNCTION USE OF 15-KETO-	IADAN DIV	6 200402	1004/12/2	2022050	2000/1/14	
A-37	PROSTAGLANDIN	JAPAN DIV	6-299402	1994/12/2	3023059	2000/1/14	
	COMPOUND FOR						
	IMPROVEMENT OF ENCEPHALIC FUNCTION						
A-37	USE OF 15-KETO-	Canada	2030345-0	1990/11/20	2030345	1998/12/8	
	PROSTAGLANDIN						
	COMPOUND FOR IMPROVEMENT OF						
	ENCEPHALIC FUNCTION						
A-37	USE OF 15-KETO-	Korea	18959/90	1990/11/22	147057	1998/5/14	
	PROSTAGLANDIN COMPOUND FOR						
	IMPROVEMENT OF						
	ENCEPHALIC FUNCTION						
A-37	USE OF 15-KETO- PROSTAGLANDIN	Korea DIV	5506/98	1998/2/21	167745	1998/9/29	
	COMPOUND FOR						
	IMPROVEMENT OF						
A-37	ENCEPHALIC FUNCTION USE OF 15-KETO-	TAIWAN	79109727	1990/11/19	58906	1993/2/9	
11 37	PROSTAGLANDIN	2122 / / / 22 /	75105727	1000, 11, 10	30300	1000/10	
	COMPOUND FOR						
	IMPROVEMENT OF ENCEPHALIC FUNCTION						
A-37	USE OF 15-KETO-	TAIWAN DIV	81104516	1992/6/10	63282	1993/12/9	
	PROSTAGLANDIN						
	COMPOUND FOR IMPROVEMENT OF						
	ENCEPHALIC FUNCTION						
A-37	USE OF 15-KETO-	EPC	90312642.3	1990/11/21	435443	1996/8/28	GB,FR,DE,IT,NL,CH,BE,AT,
	PROSTAGLANDIN COMPOUND FOR						LU,SE, ES,GR,DK
	IMPROVEMENT OF						
A 20	ENCEPHALIC FUNCTION	IICA CA	000040	1002/0/2	F2FCC0C	1002/10/20	
A-38	TREATMENT OF CARDIAC DYSFUNCTION WITH 15-	U.S.A. CA	892640	1992/6/2	5256696	1993/10/26	
	KETO-PROSTAGLANDIN						
A-38	COMPOUNDS TREATMENT OF CARDIAC	JAPAN	2-319574	1990/11/21	2059845	1996/6/10	
A-30	DYSFUNCTION WITH 15-	JALAIN	<b>2-</b> 31 <i>3</i> 3/4	1330/11/41	20J30 <del>4</del> J	1330/0/10	
	KETO-PROSTAGLANDIN						
A-38	COMPOUNDS TREATMENT OF CARDIAC	Canada	2030346-8	1990/11/20	2030346	2000/4/11	
11 00	DYSFUNCTION WITH 15-	Canada	2000-10-0	1000/11/20	200070	=300/ <del>-1</del> /11	
	KETO-PROSTAGLANDIN						
A-38	COMPOUNDS TREATMENT OF CARDIAC	Korea	18960/90	1990/11/22	167557	1998/9/29	
_ 30	DYSFUNCTION WITH 15-	- 3 <del>-</del>			2.33,	22.0,20	

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-38	TREATMENT OF CARDIAC	TAIWAN	79109728	1990/11/19	51647	1992/2/1	Dr Designated Country
	DYSFUNCTION WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
A-38	TREATMENT OF CARDIAC	EPC	90312640.7	1990/11/21	430551	1998/1/28	GB,FR,DE,IT,NL,CH,BE,AT,
	DYSFUNCTION WITH 15-KETO-						SE,ES, DK
	PROSTAGLANDIN COMPOUNDS						
A-39	NEW 15-DEHYDROXY-16-	U.S.A. CIP	921719	1992/7/30	5221799	1993/6/22	
	OXOPROSTAGLANDINS						
A-39	NEW 15-DEHYDROXY-16-	JAPAN	3-55930	1991/2/26	2511579	1996/4/16	
	OXOPROSTAGLANDINS						
A-39	NEW 15-DEHYDROXY-16-	Canada	2037009-2	1991/2/25	2037009	1998/1/27	
	OXOPROSTAGLANDINS						
A-39	NEW 15-DEHYDROXY-16-	Korea	3104/91	1991/2/26	109016	1996/12/10	
	OXOPROSTAGLANDINS						
A-39	NEW 15-DEHYDROXY-16-	TAIWAN	80101480	1991/2/26	61507	1993/7/21	
	OXOPROSTAGLANDINS						
A-39	NEW 15-DEHYDROXY-16-	Australia	71397/91	1991/2/26	633697	1993/5/28	
	OXOPROSTAGLANDINS						
A-39	NEW 15-DEHYDROXY-16-	EPC	91301480.9	1991/2/25	444844	1995/1/18	GB,FR,DE,IT,NL,CH,BE,AT,
	OXOPROSTAGLANDINS						LU,SE, ES,GR,DK
A-40	TREATMENT OF CATARACT	U.S.A.	07/680187	1991/4/3	5212324	1993/5/18	
	WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
A-40	TREATMENT OF CATARACT	U.S.A. CA	08/300541	1994/9/6	5686487	1997/11/11	
	WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
A-40	TREATMENT OF CATARACT	JAPAN	3-98202	1991/4/2	2073408	1996/7/25	
	WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
A-40	TREATMENT OF CATARACT	JAPAN	4-12795	1992/1/28	2125242	1997/1/13	
	WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
A-40	TREATMENT OF CATARACT	Canada	2039420-0	1991/3/28	2039420	1996/12/10	
	WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
A-40	TREATMENT OF CATARACT	Korea	5502/91	1991/4/4	123341	1997/9/12	
	WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
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FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-40	TREATMENT OF CATARACT	TAIWAN	80102419	1991/3/28	66662	1994/10/24	Dr Designated dodning
	WITH 15-KETO-						
	PROSTAGLANDIN						
	COMPOUNDS						
A-40	TREATMENT OF CATARACT	TAIWAN DIV	80106617	1992/8/21	71793	1995/10/5	
	WITH 15-KETO-						
	PROSTAGLANDIN						
4 40	COMPOUNDS	Δ . 1'	E 40 4E /04	1001/4/0	644440	1004/6/0	
A-40	TREATMENT OF CATARACT WITH 15-KETO-	Australia	74047/91	1991/4/3	644148	1994/6/2	
	PROSTAGLANDIN						
	COMPOUNDS						
A-40	TREATMENT OF CATARACT	EPC	91302925.2	1991/4/3	453127	1998/8/5	GB,FR,DE,IT,NL,CH,BE,ES
11 40	WITH 15-KETO-	Li C	31302323.2	1331/4/3	433127	1550/0/5	GD,11,,DE,11,11,E,G11,DE,E0
	PROSTAGLANDIN						
	COMPOUNDS						
A-42	BIOCHEMICAL TREATMENT	U.S.A. CIP	932690	1992/8/20	5302617	1994/4/12	
	WITH 15-DEHYDROXY-16-						
	OXOPROSTAGLANDIN						
	COMPOUNDS			10011100			
A-42	BIOCHEMICAL TREATMENT	JAPAN	3-125235	1991/4/26	2073410	1996/7/25	
	WITH 15-DEHYDROXY-16- OXOPROSTAGLANDIN						
	COMPOUNDS						
A-42	BIOCHEMICAL TREATMENT	Canada	2041240-2	1991/4/25	2041240	2001/7/31	
11-42	WITH 15-DEHYDROXY-16-	Canada	2041240-2	1331/4/23	2041240	2001/7/31	
	OXOPROSTAGLANDIN						
	COMPOUNDS						
A-42	BIOCHEMICAL TREATMENT	TAIWAN	80103238	1991/4/25	51651	1992/2/1	
	WITH 15-DEHYDROXY-16-						
	OXOPROSTAGLANDIN						
	COMPOUNDS						
A-42	BIOCHEMICAL TREATMENT	EPC	91303667.9	1991/4/24	454429	1997/1/29	GB,FR,DE
	WITH 15-DEHYDROXY-16-						
	OXOPROSTAGLANDIN						
A-43	COMPOUNDS TREATMENT OF PANCREATIC	U.S.A.	602210	1991/4/30	5164415	1992/11/17	
A-43	DISEASE WITH 15-KETO-	U.S.A.	693219	1991/4/30	5104415	1992/11/17	
	PROSTAGLANDIN						
	COMPOUNDS						
A-43	TREATMENT OF PANCREATIC	JAPAN	3-98617	1991/4/30	2515442	1996/4/30	
	DISEASE WITH 15-KETO-						
	PROSTAGLANDIN						
	COMPOUNDS						
A-43	TREATMENT OF PANCREATIC	Canada	2041417-1	1991/4/29	2041417	2002/5/21	
	DISEASE WITH 15-KETO-						
	PROSTAGLANDIN						
A-43	COMPOUNDS TREATMENT OF PANCREATIC	Korea	7058/91	1991/5/1	123343	1997/9/12	
A-43	DISEASE WITH 15-KETO-	Korea	/030/31	1991/3/1	123343	1337/3/12	
	PROSTAGLANDIN						
	COMPOUNDS						
A-43	TREATMENT OF PANCREATIC	TAIWAN	80103357	1991/4/30	62896	1993/11/10	
	DISEASE WITH 15-KETO-						
	PROSTAGLANDIN						
	COMPOUNDS						
A-43	TREATMENT OF PANCREATIC	EPC	91303856.8	1991/4/29	455448	1998/12/9	GB,FR,DE,IT,CH
	DISEASE WITH 15-KETO-						
	PROSTAGLANDIN						
	COMPOUNDS						

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A-48	TREATMENT OF	U.S.A. CA	972092	1992/11/5	5346921	1994/9/13	
	INFLAMMATORY DISEASES						
	WITH 15-KETO-						
	PROSTAGLANDIN						
	COMPOUNDS						
A-48	TREATMENT OF	JAPAN	3-169731	1991/7/10	2562239	1996/9/19	
	INFLAMMATORY DISEASES						
	WITH 15-KETO-						
	PROSTAGLANDIN						
A-48	COMPOUNDS TREATMENT OF	Canada	2046069-5	1991/7/2	2046069	2002/4/9	
Λ-40	INFLAMMATORY DISEASES	Callada	2040009-5	1991///2	2040009	2002/4/9	
	WITH 15-KETO-						
	PROSTAGLANDIN						
	COMPOUNDS						
A-48	TREATMENT OF	Korea	11731/91	1991/7/10	195430	1999/2/11	
	INFLAMMATORY DISEASES						
	WITH 15-KETO-						
	PROSTAGLANDIN						
	COMPOUNDS						
A-48	TREATMENT OF	TAIWAN	80105091	1991/7/1	59104	1993/2/15	
	INFLAMMATORY DISEASES						
	WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
A-48	TREATMENT OF	EPC	91306069.5	1991/7/3	467564	1996/4/24	GB,FR,DE,IT,NL,CH,BE,AT
A-40	INFLAMMATORY DISEASES	LIC	31300003.3	1331///3	407304	1330/4/24	LU,SE, ES,GR,DK
	WITH 15-KETO-						20,02, 20,01,21
	PROSTAGLANDIN						
	COMPOUNDS						
A-50	TREATMENT OF CATARACT	U.S.A.	739069	1991/8/1	5162370	1992/11/10	
	WITH PROSTACYCLIN						
	COMPOUNDS						
A-50	TREATMENT OF CATARACT	JAPAN	3-192947	1991/8/1	2134907	1998/2/13	
	WITH PROSTACYCLIN						
4 50	COMPOUNDS	TEA IX. 7A DI	00405604	1001/5/02	CD1.C1	1002/0/12	
A-50	TREATMENT OF CATARACT WITH PROSTACYCLIN	TAIWAN	80105691	1991/7/23	62164	1993/9/13	
	COMPOUNDS						
A-54	PROMOTION OF WOUND-	U.S.A.	851283	1992/3/12	5252605	1993/10/12	
A-34	HEALING WITH 15-KETO-	0.5.A.	031203	1332/3/12	3232003	1333/10/12	
	PROSTAGLANDIN						
	COMPOUNDS						
A-54	PROMOTION OF WOUND-	JAPAN	4-55100	1992/3/13	2515458	1996/4/30	
	HEALING WITH 15-KETO-						
	PROSTAGLANDIN						
	COMPOUNDS						
A-54	PROMOTION OF WOUND-	Canada	2062653-4	1992/3/11	2062653	2002/8/20	
	HEALING WITH 15-KETO-						
	PROSTAGLANDIN						
A-54	COMPOUNDS PROMOTION OF WOUND-	Korea	4144/92	1992/3/13	221370	1999/6/28	
A-54	HEALING WITH 15-KETO-	Korea	4144/92	1992/3/13	2213/0	1999/0/20	
	PROSTAGLANDIN						
	COMPOUNDS						
A-54	PROMOTION OF WOUND-	TAIWAN	81101756	1992/3/7	59447	1993/3/5	
-	HEALING WITH 15-KETO-				-	· · - · -	
	PROSTAGLANDIN						
	COMPOUNDS						
A-54	PROMOTION OF WOUND-	Australia	12861/92	1992/3/13	648877	1994/8/23	
	HEALING WITH 15-KETO-						
	PROSTAGLANDIN						
	COMPOUNDS						

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A-54	PROMOTION OF WOUND-	New Zealand	241940	1992/3/12	241940	1997/11/7	
	HEALING WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
A-54	PROMOTION OF WOUND-	EPC	92302016.8	1992/3/10	503887	1996/8/28	GB,FR,DE,ES
	HEALING WITH 15-KETO-						
	PROSTAGLANDIN COMPOUNDS						
A-55	METHOD OF PRODUCING a,b-	U.S.A.	861518	1992/4/1	5229529	1993/7/20	
	UNSATURATED						
	KETOLACTONES						
A-55	METHOD OF PRODUCING a,b-	JAPAN	4-73782	1992/3/30	2109156	1996/11/21	
	UNSATURATED						
	KETOLACTONES						
A-55	METHOD OF PRODUCING a,b-	TAIWAN	81102387	1992/3/28	60251	1993/4/30	
	UNSATURATED						
	KETOLACTONES						
A-61	PROCESS FOR PRODUCING a,b-	U.S.A.	8/244566	1993/9/29	5468880	1995/11/21	
	UNSATURATED KETONE						
A-61	PROCESS FOR PRODUCING a,b-	JAPAN	6-508895	1993/9/29	3207203	2001/7/6	
	UNSATURATED KETONE						
A-63	AGENT FOR TREATING	U.S.A. CA	08/797940	1997/2/12	5739161	1998/4/14	
	HEPATO-BILIARY DISEASES						
A-63	AGENT FOR TREATING	JAPAN	7-136579	1995/6/2	3183615	2001/4/27	
	HEPATO-BILIARY DISEASES						
A-63	AGENT FOR TREATING	JAPAN DIV	11-125756	1999/5/6	3183650	2001/4/27	
	HEPATO-BILIARY DISEASES						
A-63	AGENT FOR TREATING	Canada	2150287	1995/5/26	2150287	2004/8/10	
	HEPATO-BILIARY DISEASES						
A-63	AGENT FOR TREATING	Korea	1475/95	1995/6/3	260573	2000/4/10	
4 65	HEPATO-BILIARY DISEASES		05405222	100=1015	05405333	0004/10/07	
A-63	AGENT FOR TREATING	China	95107393.1	1995/6/2	95107393.1	2001/12/26	
A 60	HEPATO-BILIARY DISEASES	A	20.442./25	1005/0/4	6000.44	1000/0/6	
A-63	AGENT FOR TREATING	Australia	20412/95	1995/6/1	690241	1998/8/6	
A C2	HEPATO-BILIARY DISEASES	NI. 7	272224	1005 /5 /50	272224	1000/0/4	
A-63	AGENT FOR TREATING	New Zealand	272234	1995/5/29	272234	1996/6/14	
	HEPATO-BILIARY DISEASES						
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No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country			
A-63	AGENT FOR TREATING	EPC	95303718.1	1995/5/31	690049	1999/8/4	GB,FR,DE,IT,NL,CH,BE,AT,			
	HEPATO-BILIARY DISEASES						SE,ES,DK,PT			
A-70	ENDOTHELIN ANTAGONIST	TAIWAN	86107892	1997/6/7	126463	2001/5/25	_			
A-70	ENDOTHELIN ANTAGONIST	U.S.A.	09/011218	1997/6/4	6242485	2001/6/5				
A-70	ENDOTHELIN ANTAGONIST	U.S.A. DIV	09/475285	1999/12/30	6452039	2002/9/17				
A-70	ENDOTHELIN ANTAGONIST	JAPAN	10-501431	1997/6/4	3187438	2001/5/11				
A-70	ENDOTHELIN ANTAGONIST	Canada	2229183	1997/6/4						
A-70	ENDOTHELIN ANTAGONIST	China	97191058.8	1997/6/4						
A-70	ENDOTHELIN ANTAGONIST	Korea	700990/98	1997/6/4						
A-70	ENDOTHELIN ANTAGONIST	Australia	30478/97	1997/6/4	716176	2000/6/1				
A-70	ENDOTHELIN ANTAGONIST	EPC	97925279.8	1997/6/4	0857718	2002/8/14	AT,BE,CH,DE,DK,ES,FR,			
							GB,IT,NL, PT,SE			
A-80	TREATMENT OF PORTAL	TAIWAN	87116487	1998/10/3	146511	2002/4/8				
	HYPERTENSION									
A-80	TREATMENT OF PORTAL	U.S.A.	09/319868	1998/9/30	6291521	2001/9/18				
	HYPERTENSION									
A-80	TREATMENT OF PORTAL	JAPAN	11-521456	1998/9/30						
	HYPERTENSION									
A-80	TREATMENT OF PORTAL	Canada	2274670	1998/9/30						
	HYPERTENSION									
A-80	TREATMENT OF PORTAL	China	98802447.0	1998/9/30						
	HYPERTENSION									
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No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-80	TREATMENT OF PORTAL	Korea	10-1999-7005260	1998/9/30			
	HYPERTENSION						
A-80	TREATMENT OF PORTAL	Australia	92799/98	1998/9/30	740819	2002/2/28	
	HYPERTENSION						
A-80	TREATMENT OF PORTAL	New Zealand	336362	1998/9/30	336362	2001/5/10	
	HYPERTENSION						
A-80	TREATMENT OF PORTAL	Norway	19992858	1998/9/30			
	HYPERTENSION	,					
A-80	TREATMENT OF PORTAL	EPC	98945529.0	1998/9/30			
	HYPERTENSION						
A-80	TREATMENT OF PORTAL	Hong Kong	00105084.6	2000/8/15			
	HYPERTENSION						
A-83	ENDOTHELIN ANTAGONIST	TAIWAN	87118975	1998/11/17	205504	2004/10/26	
A-83	ENDOTHELIN ANTAGONIST	U.S.A.	09/355270	1998/11/16	6197821	2001/3/6	
A-83	ENDOTHELIN ANTAGONIST	JAPAN	11-530560	1998/11/16			
A-83	ENDOTHELIN ANTAGONIST	Canada	2279267	1998/11/16			
A-83	ENDOTHELIN ANTAGONIST	China	98803586.3	1998/11/16	98803586.3	2005/6/22	
A-83	ENDOTHELIN ANTAGONIST	Korea	10-1999-7006752	1998/11/16			
A-83	ENDOTHELIN ANTAGONIST	Australia	10537/99	1998/11/16	739343	2002/1/24	
A-83	ENDOTHELIN ANTAGONIST	New Zealand	336960	1998/11/16	336960	2001/6/6	
A-83	ENDOTHELIN ANTAGONIST	Norway	19993647	1998/11/16			
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No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
A-83	ENDOTHELIN ANTAGONIST	EPC	98953058.9	1998/11/16			
A-83	ENDOTHELIN ANTAGONIST	Hong Kong	00104940.3	2000/8/8			
A-88	DRUGS FOR TREATING	U.S.A.	09/615703	2000/7/13	6566398	2003/5/20	
	EXOCRINE GLAND						
	DISORDERS						
A-88	DRUGS FOR TREATING	U.S.A. DIV2	10/994364	2004/11/23			
	EXOCRINE GLAND						
	DISORDERS						
A-88	DRUGS FOR TREATING	TAIWAN	89113876	2000/7/12	225398	2004/12/21	
	EXOCRINE GLAND						
	DISORDERS						
A-88	DRUGS FOR TREATING	ARGENTINA	P000103635	2000/7/14			
	EXOCRINE GLAND						
	DISORDERS						
A-88	DRUGS FOR TREATING	JAPAN	2001-510445	2000/7/13			
	EXOCRINE GLAND						
4 00	DISORDERS	0 1	225564	2000/5/42			
A-88	DRUGS FOR TREATING	Canada	2377661	2000/7/13			
	EXOCRINE GLAND						
4 00	DISORDERS	CI.:	00010000 4	2000/5/42			
A-88	DRUGS FOR TREATING	China	00810238.4	2000/7/13			
	EXOCRINE GLAND						
A-88	DISORDERS  DRUGS FOR TREATING	Vovos	2002 7000471	2000/7/12			
A-00	DRUGS FOR TREATING EXOCRINE GLAND	Korea	2002-7000471	2000/7/13			
	DISORDERS						
A-88	DRUGS FOR TREATING	Australia	58533/00	2000/7/13	779936	2005/6/30	
A-00	EXOCRINE GLAND	Australia	30333/00	2000/7/13	779930	2003/0/30	
	DISORDERS						
A-88	USE OF PROSTAGLANDIN	New Zealand	516104	2000/7/13	516104	2004/3/29	
11 00	LIKE COMPOUND FOR THE	riew Zeululia	510104	2000/7/15	510104	200-1/3/23	
	TREATMENT OF EXTERNAL						
	SECRETION DISORDERS						
A-88	DRUGS FOR TREATING	South Africa	2001/9726	2000/7/13	2001/9726	2002/11/27	
11 00	EXOCRINE GLAND	Journ 1 IIII cu	2001/07/20	2000///15	2001/0/20	2002/11/2/	
	DISORDERS						
A-88	DRUGS FOR TREATING	Brazil	PI 0012387	2000/7/13			
	EXOCRINE GLAND						
	DISORDERS						
A-88	DRUGS FOR TREATING	Mexico	PA/A/2002/000437	2000/7/13			
-	EXOCRINE GLAND						
	DISORDERS						
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A-88	DRUGS FOR TREATING	India	IN/PCT/2002/00049	2000/7/13	i atciit 110.	155tic Date	2. Designated Country
	EXOCRINE GLAND						
	DISORDERS						
A-88	DRUGS FOR TREATING	Israel	147440	2000/7/13			
	EXOCRINE GLAND						
	DISORDERS						
A-88	DRUGS FOR TREATING	Turkey	2002/00065	2000/7/13			
	EXOCRINE GLAND						
1 00	DISORDERS	ъ.	2002402505	5000/5/45	226.404.6	2005/44/25	
A-88	DRUGS FOR TREATING	Russia	2002103597	2000/7/13	2264816	2005/11/27	
	EXOCRINE GLAND						
A-88	DISORDERS DRUGS FOR TREATING	Czech	PV2002-133	2000/7/13			
A-00	EXOCRINE GLAND	Czecii	F V 2002-133	2000///13			
	DISORDERS						
A-88	DRUGS FOR TREATING	Hungary	P 0202400	2000/7/13			
	EXOCRINE GLAND	- 8- 5					
	DISORDERS						
A-88	DRUGS FOR TREATING	Norway	20020133	2000/7/13			
	EXOCRINE GLAND						
	DISORDERS						
A-88	DRUGS FOR TREATING	EPC	00944426.6	2000/7/13			
	EXOCRINE GLAND						
A 00	DISORDERS  DRUGS FOR TREATING	Hans Vans	02100510.0	2000/7/12			
A-88	DRUGS FOR TREATING EXOCRINE GLAND	Hong Kong	03100518.0	2000/7/13			
	DISORDERS						
A-93	BICYCLIC COMPOUNDS	U.S.A.	09/688351	2000/10/16	6583174	2003/6/24	
11 55	COMPOSITION AND	0.5.21.	03/000331	2000/10/10	0505174	2005/0/24	
	METHOD FOR STABILIZING						
	THE SAME						
A-93	BICYCLIC COMPOUNDS	U.S.A. DIV	10/383581	2003/3/10			
	COMPOSITION AND						
	METHOD FOR STABILIZING						
	THE SAME						
A-93	BICYCLIC COMPOUNDS	TAIWAN	89121423	2000/10/13			
	COMPOSITION AND						
	METHOD FOR STABILIZING THE SAME						
Δ_93	BICYCLIC COMPOUNDS	ARGENTINA	P000105407	2000/10/13			
11-33	COMPOSITION AND	modimi	1000105407	2000/10/13			
	METHOD FOR STABILIZING						
	THE SAME						
A-93	BICYCLIC COMPOUNDS	JAPAN	2001-530318	2000/10/13			
	COMPOSITION AND						
	METHOD FOR STABILIZING						
	THE SAME	_					
A-93	BICYCLIC COMPOUNDS	Canada	2385732	2000/10/13			
	COMPOSITION AND						
	METHOD FOR STABILIZING						
	THE SAME						
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A-93	BICYCLIC COMPOUNDS	China	00814313.7	2000/10/13			
	COMPOSITION AND METHOD						
4 02	FOR STABILIZING THE SAME	17	2002 700 4700	2000/10/12			
A-93	BICYCLIC COMPOUNDS COMPOSITION AND METHOD	Korea	2002-7004709	2000/10/13			
	FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	Australia	76856/00	2000/10/13	780342	2005/7/7	
	COMPOSITION AND METHOD						
	FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	Australia DIV	2004242503	2004/12/24			
	COMPOSITION AND METHOD						
A 02	FOR STABILIZING THE SAME	Novy Zoaland	E10000	2000/10/12	E10020	2004/6/9	
A-93	BICYCLIC COMPOUNDS COMPOSITION AND METHOD	New Zealand	518020	2000/10/13	518020	2004/6/8	
	FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	South Africa	2002/2312	2000/10/13	2002/2312	2002/12/24	
	COMPOSITION AND METHOD						
	FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	Brazil	PI 0014869	2000/10/13			
	COMPOSITION AND METHOD FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	Mexico	PA/A/2002/003756	2000/10/13			
11 55	COMPOSITION AND METHOD	WICKICO	1111112002/005/50	2000/10/15			
	FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	India	IN/PCT/2002/00516	2000/10/13			
	COMPOSITION AND METHOD						
4 02	FOR STABILIZING THE SAME	T1	1 40000	2000/10/12			
A-93	BICYCLIC COMPOUNDS COMPOSITION AND METHOD	Israel	148803	2000/10/13			
	FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	Turkey	2002/01032	2000/10/13	2002/01032	2005/10/21	
	COMPOSITION AND METHOD	J					
	FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	Russia	2002112984	2000/10/13			
	COMPOSITION AND METHOD FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	Czech	PV2002-1037	2000/10/13			
11 55	COMPOSITION AND METHOD	GZCCII	1 72002 1007	2000/10/15			
	FOR STABILIZING THE SAME						
A-93	BICYCLIC COMPOUNDS	Hungary	P 0203746	2000/10/13			
	COMPOSITION AND METHOD						
A 02	FOR STABILIZING THE SAME	Now.zo	20021720	2000/10/12			
A-93	BICYCLIC COMPOUNDS COMPOSITION AND METHOD	Norway	20021736	2000/10/13			
	FOR STABILIZING THE SAME						
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FILE No. A-93	Title BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE	Country EPC	Application No. 00966462.4	Filing Date 2000/10/13	Patent No. 1220849	Issue Date 2004/5/19	EP Designated Country GB,FR,DE,IT,NL,CH,BE,AT, SE,ES, PT,DK,IE`
A-93	SAME BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	EPC DIV	04005836.4	2004/3/11			
A-93	BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE	Hong Kong	02107337.5	2002/10/7	1045693	2005/1/21	
A-93	SAME BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Hong Kong DIV	04109640.1	2004/12/6			
A-98	CHOLAGOGIC	U.S.A.	09/827375	2001/4/6	6469062	2002/10/22	
A-98	COMPOSITION CHOLAGOGIC	ARGENTINA	P010101663	2001/4/6			
A-98	COMPOSITION CHOLAGOGIC COMPOSITION	TAIWAN	90108254	2001/4/6	I 232750	2005/5/21	
A-98	CHOLAGOGIC	JAPAN	2001-574111	2001/4/5			
A-98	COMPOSITION CHOLAGOGIC COMPOSITION	China	01810583.1	2001/4/5	01810583.1	2006/2/15	
A-98	CHOLAGOGIC	Korea	2002-7013275	2001/4/5			
A-98	COMPOSITION CHOLAGOGIC COMPOSITION	Australia	2001244727	2001/4/5			
A-98	CHOLAGOGIC	New Zealand	521784	2001/4/5	521784	2005/8/11	
A-98	COMPOSITION CHOLAGOGIC COMPOSITION	Canada	2404767	2001/4/5			
A-98	CHOLAGOGIC	Brazil	PI 0107544	2001/4/5			
A-98	COMPOSITION CHOLAGOGIC COMPOSITION	Mexico	PA/A/2002/009915	2001/4/5	230686	2005/9/19	
			17				

FILE	Tr.1	6	A 1' NI	ET D	D. C.N.	I D.	EP Designated Country
No. A-98	CHOLAGOGIC	Country EPC	Application No. 01917828.4	Filing Date 2001/4/5	Patent No.	Issue Date	EP Designated Country
A-30	COMPOSITION	EIC	01317020.4	2001/4/5			
AR-1	TREATMENT OF OCULAR	U.S.A. CIP2	09/851111	2001/5/9	6596765	2003/7/22	
	HYPERTENSION	0.0.1.1.01.2	00/001111	2001/3/3	0000700		
AR-1	TREATMENT OF OCULAR	U.S.A. DIV	10/385621	2003/3/12			
	HYPERTENSION	0.0					
AR-1	TREATMENT OF OCULAR	JAPAN	2002-513466	2001/7/18			
	HYPERTENSION						
AR-3	ANTI-CONSTIPATION	U.S.A.	09/655760	2000/9/5	6414016	2002/7/2	
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	U.S.A. DIV	10/138650	2000/9/5	6610732	2003/8/26	
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	U.S.A. DIV2	10/443046	2003/5/22			
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	U.S.A. DIV3	11/142251	2005/6/2			
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	ARGENTINA	P010104216	2001/9/5			
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	TAIWAN	90121835	2001/9/4			
45.5	COMPOSITION	TABAN	2002 524402	2004/2/4			
AR-3	ANTI-CONSTIPATION	JAPAN	2002-524492	2001/9/4			
AD 2	COMPOSITION	Const	2410741	2001/0/4			
AR-3	ANTI-CONSTIPATION	Canada	2419741	2001/9/4			
AR-3	COMPOSITION ANTI-CONSTIPATION	China	01818323.9	2001/9/4			
AK-3	COMPOSITION	Cillia	01010323.9	2001/9/4			
AR-3	ANTI-CONSTIPATION	Korea	2003-7003261	2001/9/4			
AIX-J	COMPOSITION	Rolea	2003-7003201	2001/3/4			
AR-3	ANTI-CONSTIPATION	Australia	2001282615	2001/9/4			
7110 5	COMPOSITION	2 tustrana	2001202015	2001/3/4			
	33111 33111311						
			18				

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
AR-3	ANTI-CONSTIPATION	New Zealand	524401	2001/9/4	524401	2004/12/9	<u></u>
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	South Africa	2003/1673	2001/9/4	2003/1673	2003/11/26	
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	Brazil	PI 0114042	2001/9/4			
	COMPOSITION		T. 1. 10000 100 1000				
AR-3	ANTI-CONSTIPATION	Mexico	PA/A/2003/001959	2001/9/4	231553	2005/10/24	
AR-3	COMPOSITION ANTI-CONSTIPATION	India	00460/CHENP/2003	2001/0/4			
AK-3	COMPOSITION	IIIuia	00460/CHENP/2003	2001/9/4			
AR-3	ANTI-CONSTIPATION	Israel	154534	2001/9/4			
AIX-3	COMPOSITION	131001	154554	2001/3/4			
AR-3	ANTI-CONSTIPATION	Russia	2003109622	2001/9/4			
1111 5	COMPOSITION	russia	2003103022	2001/3/1			
AR-3	ANTI-CONSTIPATION	Czech	PV2003-787	2001/9/4			
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	Hungary	P0302422	2001/9/4			
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	Norway	20030996	2001/9/4			
	COMPOSITION						
AR-3	ANTI-CONSTIPATION	EPC	01961333.0	2001/9/4			
AD 7	COMPOSITION	TI C A	40/425205	2002/5/4	6000000	2006/4/2	
AR-7	COMPOSITION FOR TREATING	U.S.A.	10/135397	2002/5/1	6982283	2006/1/3	
	DRUG-INDUCED						
	CONSTIPATION						
AR-7	COMPOSITION FOR	ARGENTINA	P020101560	2002/4/29			
711( /	TREATING	INGLIVIIVI	1020101300	2002/4/23			
	DRUG-INDUCED						
	CONSTIPATION						
AR-7	COMPOSITION FOR	TAIWAN	91108513	2002/4/25			
	TREATING						
	DRUG-INDUCED						
	CONSTIPATION						
AR-7	COMPOSITION FOR	JAPAN	2002-586947	2002/4/26			
	TREATING						
	DRUG-INDUCED						
	CONSTIPATION						
			19				

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No. AR-7	Title COMPOSITION FOR	Country China	Application No. 02813389.7	Filing Date 2002/4/26	Patent No.	Issue Date	EP Designated Country
1111	TREATING	Ciliid	02013000.7	2002/ 1/20			
	DRUG-INDUCED						
	CONSTIPATION						
AR-7	COMPOSITION FOR	Korea	2003-7014221	2002/4/26			
	TREATING						
	DRUG-INDUCED CONSTIPATION						
AR-7	COMPOSITION FOR	Australia	2002251554	2002/4/26			
7111-7	TREATING	rustiana	2002231334	2002/4/20			
	DRUG-INDUCED						
	CONSTIPATION						
AR-7	COMPOSITION FOR	New Zealand	529187	2002/4/26	529187	2006/2/9	
	TREATING						
	DRUG-INDUCED						
AR-7	CONSTIPATION COMPOSITION FOR	Canada	2444103	2002/4/26			
AIX-/	TREATING	Callada	2444103	2002/4/20			
	DRUG-INDUCED						
	CONSTIPATION						
AR-7	COMPOSITION FOR	Brazil	PI 0209327	2002/4/26			
	TREATING						
	DRUG-INDUCED CONSTIPATION						
AR-7	COMPOSITION FOR	Mexico	PA/A/2003/010019	2002/4/26			
1111	TREATING	WEMEG	111/11/2005/010015	2002/ 1/20			
	DRUG-INDUCED						
	CONSTIPATION						
AR-7	COMPOSITION FOR	Norway	20034864	2002/4/26			
	TREATING						
	DRUG-INDUCED CONSTIPATION						
AR-7	COMPOSITION FOR	EPC	02720623.4	2002/4/26			
	TREATING						
	DRUG-INDUCED						
	CONSTIPATION						
AR-10	METHOD AND	U.S.A.	10/485370	2002/7/30			
	COMPOSITION FOR TREATMENT OF OCULAR						
	HYPERTENSION						
	AND GLUCOMA						
AR-10	METHOD AND	JAPAN	2003-516529	2002/7/30			
	COMPOSITION FOR						
	TREATMENT OF OCULAR						
	HYPERTENSION AND GLUCOMA						
AR-14	PHARMACEUTICAL	U.S.A.	10/298062	2002/11/18			
	COMPOSITION						
	COMPRISING A ClC-2						
AD 44	CHANNEL OPENER	A D CENTEIN A	D000104425	2002/44/40			
AR-14	PHARMACEUTICAL COMPOSITION	ARGENTINA	P020104435	2002/11/19			
	COMPOSITION COMPRISING A CIC-2						
	CHANNEL OPENER						
AR-14	PHARMACEUTICAL	TAIWAN	91133604	2002/11/18			
	COMPOSITION						
	COMPRISING A CIC-2						
AR-1/	CHANNEL OPENER PHARMACEUTICAL	JAPAN	2003-545320	2002/11/19			
1111.14	COMPOSITION	2111111	2000-0-0020	2002/11/13			
	COMPRISING A CIC-2						
	CHANNEL OPENER						
			20				

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
AR-14	PHARMACEUTICAL COMPOSITION	Canada	2466906	2002/11/19	Fatelit No.	Issue Date	Er Designated Country
	COMPRISING A CIC-2 CHANNEL	Currada		2002/11/15			
	OPENER						
AR-14	PHARMACEUTICAL COMPOSITION	EPC	02781814.5	2002/11/19			
	COMPRISING A CIC-2 CHANNEL						
	OPENER						
AR-15	PROSTAGLANDIN ANALOGS FOR	U.S.A.	10/293516	2002/11/14			
	TREATING CONSTIPATION						
AR-15	PROSTAGLANDIN ANALOGS FOR	ARGENTINA	P020104349	2002/11/13			
	TREATING CONSTIPATION						
AR-15	PROSTAGLANDIN ANALOGS FOR	TAIWAN	91133227	2002/11/13			
	TREATING CONSTIPATION						
AR-15	PROSTAGLANDIN ANALOGS FOR	JAPAN	2003-543603	2002/11/14			
	TREATING CONSTIPATION						
AR-15	PROSTAGLANDIN ANALOGS FOR	Canada	2464420	2002/11/14			
	TREATING CONSTIPATION						
AR-15	PROSTAGLANDIN ANALOGS FOR	Brazil	PI 0214075	2002/11/14			
AD 45	TREATING CONSTIPATION	EDC	007000000	2002/44/44			
AR-15	PROSTAGLANDIN ANALOGS FOR	EPC	02780083.8	2002/11/14			
AD 10	TREATING CONSTIPATION	II C A	10/147000	2002/5/20	COECOEC	2005/10/10	
AR-18 AR-18	CATHARTIC COMPOSITION CATHARTIC COMPOSITION	U.S.A. U.S.A. DIV	10/147980 11/190842	2002/5/20 2005/7/28	6956056	2005/10/18	
AR-18 AR-18	CATHARTIC COMPOSITION  CATHARTIC COMPOSITION	ARGENTINA	P020101832	2005/7/28			
AR-16 AR-18	CATHARTIC COMPOSITION  CATHARTIC COMPOSITION	TAIWAN	91110333	2002/5/17			
AR-18	CATHARTIC COMPOSITION  CATHARTIC COMPOSITION	JAPAN	2002-590991	2002/5/17			
AR-18	CATHARTIC COMPOSITION	China	02810184.7	2002/5/17			
1111-10	CALLE IN THE COMM CONTROL	Cimia	02010104./	2002/3/1/			
			21				

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
AR-18	CATHARTIC	Korea	2003-7014860	2002/5/17	r atent 140.	135ue Date	Er Designated Country
1111 10	COMPOSITION	110104	2003 701 1000	2002/0/1/			
AR-18	CATHARTIC	Australia	2002307725	2002/5/17			
	COMPOSITION						
AR-18	CATHARTIC	New Zealand	529406	2002/5/17	529406	2006/1/12	
	COMPOSITION						
AR-18	CATHARTIC	Canada	2445651	2002/5/17			
	COMPOSITION						
AR-18	CATHARTIC	Brazil	PI 0209863-6	2002/5/17			
	COMPOSITION						
AR-18	CATHARTIC	Mexico	PA/A/2003/010510	2002/5/17			
	COMPOSITION						
AR-18	CATHARTIC	EPC	02771715.6	2002/5/17			
	COMPOSITION						
AR-20	CHLORIDE CHANNEL	U.S.A.	10/231341	2002/8/30	7064148	2006/6/20	
	OPENER						
AR-20	CHLORIDE CHANNEL	U.S.A. DIV	11/333511	2006/1/18			
	OPENER						
AR-20	CHLORIDE CHANNEL	ARGENTINA	P020103284	2002/8/30			
	OPENER						
AR-20	CHLORIDE CHANNEL	TAIWAN	91119830	2002/8/30			
	OPENER						
AR-20	CHLORIDE CHANNEL	JAPAN	2003-533944	2002/8/29			
4 D 00	OPENER CHANNEL	6 1	2.450.454	2002/2/20			
AR-20	CHLORIDE CHANNEL	Canada	2458471	2002/8/29			
A.D. 20	OPENER	D "	DI 0010000	2002/0/20			
AR-20	CHLORIDE CHANNEL	Brazil	PI 0212233	2002/8/29			
AD 20	OPENER	Maria	DA /A /2004/00200C	2002/0/20			
AR-20	CHLORIDE CHANNEL OPENER	Mexico	PA/A/2004/002006	2002/8/29			
	OPENER						
			22				
			22				

FILE							
No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
AR-20	CHLORIDE CHANNEL OPENER	Australia	2002330747	2002/8/29			
AR-20	CHLORIDE CHANNEL OPENER	New Zealand	531503	2002/8/29	531503	2006/5/11	
AR-20	CHLORIDE CHANNEL OPENER	EPC	02767866.3	2002/8/29			
AR-21	METHOD AND COMPOSITION FOR	U.S.A.	10/531874	2003/10/22			
	TREATING OBESITY						
AR-21	METHOD AND COMPOSITION FOR	JAPAN	2004-546433	2003/10/22			
	TREATING OBESITY						
AR-21	METHOD AND COMPOSITION FOR	Canada	2502439	2003/10/22			
	TREATING OBESITY						
AR-21	METHOD AND COMPOSITION FOR	Australia	2003274735	2003/10/22			
	TREATING OBESITY						
AR-21	METHOD AND COMPOSITION FOR	New Zealand	539582	2003/10/22			
	TREATING OBESITY						
AR-21	METHOD AND COMPOSITION FOR	EPC	03758747.4	2003/10/22			
	TREATING OBESITY						
AR-29	ENTERIC COATED COMPOSITION	U.S.A.		2004/7/5			
AR-29	ENTERIC COATED COMPOSITION	JAPAN	2006-516862	2004/7/5			
AR-29	ENTERIC COATED COMPOSITION	EPC	0477747335.0	2004/7/5			
AR-32	METHOD FOR TREATING	U.S.A.	10/745689	2003/12/29			
	ABDOMINAL DISCOMFORT						
AR-32	METHOD FOR TREATING	TAIWAN	92136988	2003/12/26			
	ABDOMINAL DISCOMFORT						
AR-32	METHOD FOR TREATING	ARGENTINA	P030104848	2003/12/29			
	ABDOMINAL DISCOMFORT						
			23				

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
AR-32	METHOD FOR	JAPAN	2004-564537	2003/12/26			
	TREATING ABDOMINAL						
	DISCOMFORT						
AR-32	METHOD FOR	Canada	2510051	2003/12/26			
	TREATING ABDOMINAL						
	DISCOMFORT						
AR-32	METHOD FOR	Brazil	PI 0317740-8	2003/12/26			
	TREATING ABDOMINAL						
AD 22	DISCOMFORT METHOD FOR	Marria	DA /A /2005/00001	2002/42/20			
AR-32	METHOD FOR	Mexico	PA/A/2005/006981	2003/12/26			
	TREATING ABDOMINAL DISCOMFORT						
AR-32	METHOD FOR	China	200380109901.4	2003/12/26			
AK-32	TREATING ABDOMINAL	Cillia	200380109901.4	2003/12/20			
	DISCOMFORT						
AR-32	METHOD FOR	Korea	2005-7012162	2003/12/26			
1111 02	TREATING ABDOMINAL	110104	2003 / 012102	2000/12/20			
	DISCOMFORT						
AR-32	METHOD FOR	Australia	2003292556	2003/12/26			
	TREATING ABDOMINAL						
	DISCOMFORT						
AR-32	METHOD FOR	New Zealand	541110	2003/12/26			
	TREATING ABDOMINAL						
	DISCOMFORT						
AR-32	METHOD FOR	Norway	20053623	2003/12/26			
	TREATING ABDOMINAL						
	DISCOMFORT						
AR-32	METHOD FOR	EPC	03768289.5	2003/12/26			
	TREATING ABDOMINAL						
AD 40	DISCOMFORT METHOD AND	II C A	11/220405	2006/4/26			
AR-42	METHOD AND	U.S.A.	11/339495	2006/1/26			
	COMPOSITION FOR TREATING CENTRAL						
	NERVOUS SYSTEM						
	DISORDERS						
AR-42	METHOD AND	TAIWAN	95103028	2006/1/26			
T	COMPOSITION FOR		35105020	_000/1/20			
	TREATING CENTRAL						
	NERVOUS SYSTEM						
	DISORDERS						
AR-42	METHOD AND	ARGENTINA	P060100290	2006/1/26			
	COMPOSITION FOR						
	TREATING CENTRAL						
	NERVOUS SYSTEM						
	DISORDERS						
AR-42	METHOD AND	PCT	PCT/JP2006/301704	2006/1/26			
	COMPOSITION FOR						
	TREATING CENTRAL						
	NERVOUS SYSTEM						
AD 42	DISORDERS	II C A		2000/2/2			
AR-43	METHOD FOR	U.S.A.		2006/3/3			
	TREATING PERIPHERAL VASCULAR DISEASES						
	VASCULAR DISEASES						
			24				

FILE No.	Title	Country	Application No.	Filing Date	Patent No.	Issue Date	EP Designated Country
AR-43	METHOD FOR TREATING	TAIWAN	95107144	2006/3/3			<u> </u>
	PERIPHERAL VASCULAR DISEASES						
AR-43	METHOD FOR TREATING	ARGENTINA	P060100815	2006/3/3			
1110 10	PERIPHERAL	THOEITH	1000100015	2000/3/3			
	VASCULAR DISEASES						
AR-43	METHOD FOR TREATING	PCT	PCT/JP2006/304667	2006/3/3			
	PERIPHERAL VASCULAR DISEASES						
AR-46	PHARMACEUTICAL	U.S.A.	11/401382	2006/4/11			
	COMBINATION AND						
	METHOD FOR TREATING						
	GASTROINTESTINAL DISORDERS USING						
	THEREOF						
AR-46	PHARMACEUTICAL	PCT	PCT/JP2006/308001	2006/4/11			
	COMBINATION AND						
	METHOD FOR TREATING GASTROINTESTINAL						
	DISORDERS USING						
	THEREOF						
AR-48	METHOD FOR TREATING	U.S.A.	11/216012	2005/9/1			
	GASTROINTESTINAL DISORDER						
AR-48	METHOD FOR TREATING	TAIWAN	94129818	2005/8/31			
	GASTROINTESTINAL						
AR-48	DISORDER METHOD FOR TREATING	ARGENTINA	P050103687	2005/9/2			
AIX-40	GASTROINTESTINAL	ARGENTINA	F030103007	2003/3/2			
	DISORDER						
AR-48	METHOD FOR TREATING	PCT	PCT/JP05/016464	2005/9/1			
	GASTROINTESTINAL DISORDER						
AR-50	METHOD FOR TREATING	U.S.A.	11/384491	2006/3/21			
	GASTROINTESTINAL						
AD 50	MUCOSAL DISORDERS	DCT	DCT/ID200C/20C200	2006/2/22			
AR-50	METHOD FOR TREATING GASTROINTESTINAL	PCT	PCT/JP2006/306380	2006/3/22			
	MUCOSAL DISORDERS						
AR-51	METHOD FOR TREATING	U.S.A. (Pro.)		2006/2/28			
	CHRONIC						
	OBSTRUCTIVE PULMONARY DISEASE						
1100	15-KETO-17-HALO-	JAPAN	2-186285	1990/7/13	2081229	1996/8/9	
	PROSTAGLANDIN E						
	SERIES						

#### Exhibit B

#### **Declaration of Licensed Rights**

(Übersetzung der englischen Originalversion)

**Declaration** 

by

Sucampo AG, Graben 5, CH-6300 Zug ("SAG")

concerning

# **Grant of Licensed Rights**

- 1. On the basis of the Amended and Restated Patent Access Agreement dated June 30, 2006, (the "**Agreement**") SAG herewith declares to have granted to each of;
  - Sucampo Pharmaceuticals Incorporation, 4733 Bethesda Avenue, Suite 450, Bethesda, Maryland 20814, USA ("SPI") in the territory defined in <u>Annex 1a</u>);
  - Sucampo Pharma Limited, 2-2-16 Sonezakishinchi, Kita-Ku, Osaka, Japan 530-0002 ("**SPL**") in the territory defined in <u>Annex 1b</u>), and
  - Sucampo Pharma Europe Limited, 78 Cannon Street, London, EC4N6NQ, UK ("SPE") in the territory defined in <u>Annex 1c</u>),

Lizenzerklärung

von

Sucampo AG, Graben 5, CH-6300 Zug ("SAG")

betreffend

# Erteilung von Lizenzen

- Basierend auf der revidierten Patentzugangs Vereinbarung vom 30.Juni 2006 (Amended and Restated Patent Access Agreement) ("Vereinbarung") erklärt SAG hiermit, der
  - Sucampo Pharmaceuticals Incorporation, 4733 Bethesda Avenue, Suite 450, Bethesda, Maryland 20814, USA ("**SPI**") für das in <u>Anlage 1a</u>) definierte Territorium,
  - Sucampo Pharma Limited, 2-2-16 Sonezakishinchi, Kita-Ku, Osaka, Japan 530-0002 ("SPL") für das in <u>Anlage 1b</u>) definierte Territorium, und der
  - Sucampo Pharma Europe Limited, 78 Cannon Street, London, EC4N6NQ, UK ("SPE") für das in <u>Anlage 1c</u>) definierte Territorium,

an exclusive license to develop, import, use, make, have made, export, offer for sale and sell licensed products ("Licensed Products") throughout their allocated territories.

- 2. License Products pursuant to Section 1 shall mean any product for applications as human or veterinary pharmaceuticals covered by:
  - a) any patent or patent application owned by SAG as of the date of this Declaration, including, without limitation, the patents and patent applications listed in <u>Annex 2</u>, which relate to the prostone compound;
  - any license right SAG has acquired (with right of sublicense) as of the date of this Declaration which relate to the prostone compound;
  - any future patent or patent application derived from inventions that are acquired, made, created, developed, conceived or reduced to practice by SAG and which are relating to the prostone compound and/or the patents and patent applications as referred to in Sections 2a) und 2b) hereof;

je bezogen auf das ihr zugeteilte Territorium eine exklusive Lizenz für die Entwicklung, die Einfuhr, die Verwendung, die Herstellung, das Herstellenlassen, die Ausfuhr, das Angebot zum Verkauf und den Verkauf von lizenzierten Produkten ("Lizenzierte Produkte") eingeräumt zu haben.

- Als Lizenzierte Produkte im Sinne von Ziffer 1 gelten alle Produkte für die Anwendung als human- oder veterinärmedizinische, und die erfasst sind von:
  - a) sämtlichen Patenten oder Patentanmeldungen, die im Zeitpunkt dieser Lizenzerklärung im Eigentum der SAG stehen, darin insbesondere eingeschlossen die Patente und Patentanmeldungen gemäss Anlage 2, die sich auf die Substanz "Prostone" beziehen;
  - b) sämtlichen Lizenzrechten (inkl. Rechte zur Unterlizenzierung), die SAG bis zum Datum dieser Lizenzerklärung erworben hat und die sich auf die Substanz "Prostone" beziehen;
  - sämtlichen zukünftigen Patenten oder Patentanmeldungen aus Erfindungen, die durch SAG erworben, gemacht, entwickelt, weiterentwickelt, erdacht oder in die Praxis umgesetzt werden, und die sich auf die Substanz "Prostone" und/oder die in Ziffern 2a) und 2b) genannten Patente, Patentanmeldungen oder Lizenzrechte beziehen, und

- any technical information, data, trade secrets and know-how acquired, made, created, developed, conceived or reduced to practice by SAG which relate to the patents, patent applications, or licensed rights referred to in Sections 2a), 2b) and 2c) hereof.
- 3. The exclusive rights granted in Sections 1 and 2 comprise the right to grant sublicenses, for each of SPI, SPL, and SPE within their allocated territories.
- 4. SAG agreed with SPI, SPL, and SPE that, in the event of bankruptcy by SAG, to the extent possible under the applicable law, the exclusive rights in accordance with Sections 1 to 3 and the reciprocal obligations of SPI, SPL, and SPE to make royalty and milestone payments shall remain in full force and effect and shall be binding on the administrator and SAG's estate and shall vest in any assignee or successor in interest of SAG and its business or of SAG's rights and obligations under the Agreement. For the purpose of this Declaration, bankruptcy means, with respect to SAG, a bankruptcy, a composition or any other enforcement action in accordance with the Swiss Federal Code on Debt Collection and Bankruptcy of April 11, 1889, as amended from time to time.
- 5. In the event that any patent or patent application referred to in Sections 1 to 3 will be realized in SAG's bankruptcy, irrespective of whether by a public

- d) sämtlichen technischen Informationen, Daten,
   Geschäftsgeheimnissen und Erfahrungswissen (Know-how), die durch SAG erworben, gemacht, entwickelt, weiterentwickelt, erdacht oder in die Praxis umgesetzt werden, und die sich auf die in den Ziffern 2a), 2b) und 2c) genannten Patente,
   Patentanmeldungen und Lizenzrechte beziehen.
- 3. Die hiervor unter den Ziffern 1 und 2 eingeräumten Exklusivrechte umfassen auch das Recht der SPI, SPL und SPE, innerhalb des ihnen jeweils zugeteilten Territoriums Unterlizenzen zu erteilen.
- 4. SAG hat mit SPI, SPL und SPE verbindlich vereinbart, dass die in den Ziffern 1 3 beschriebenen Rechte auch im Konkursfall der SAG uneingeschränkt weiter bestehen sollen. Die diesbezüglichen Verpflichtungen und Rechte von SAG bzw. ihren Exklusivlizenznehmerinnen SPI, SPL und SPE sollen im Konkursfall uneingeschränkt auf die Konkursmasse der SAG und/oder auf jeden Abtretungsgläubiger und/oder Rechtsnachfolger von SAG übergehen. Als Konkursfall im Sinne dieser Lizenzerklärung gelten ein Konkurs, Nachlass oder jedes andere gegen SAG gerichtete Vollstreckungsverfahren gemäss den Bestimmungen des schweizerischen Bundesgesetzes vom 11. April 1889 über Schuldbetreibung und Konkurs (SchKG).
- 5. SAG hat SPI, SPL und SPE für die gewerblichen Schutzrechte, die die Basis der in den Ziffern 1 - 3 jeweils zugeteilten Rechte bilden, ein

auction or by private sale, each of SPI, SPL, and SPE shall have a preemption right to acquire such patent or patent application for its respective Territory and on such terms and conditions, including the purchase price, as may be offered by any third party bidder.

- 6. This Declaration forms an integral part of the Agreement and shall not constitute any rights or obligations other than provided in the Agreement. In the case of a discrepancy between any provision of this Declaration and any provision of the Agreement, the provisions of the Agreement shall prevail.
- 7. <u>Annexes 1 and 2</u> to this Declaration form an integral part of this Declaration.
- 8. In the case of a discrepancy between the German version and the English version of this Declaration, the English version shall prevail.

Vorkaufsrecht bezogen auf die jeweils zugeteilten Territorien eingeräumt. Falls im Konkursfall ein lizenziertes Patent oder eine Patentanmeldung verwertet wird, unabhängig davon, ob durch eine öffentliche Auktion oder durch freihändigen Verkauf, ist SPI, SPL und/oder SPE dieses Vorkaufsrecht einzuräumen, und zwar zu den gleichen Bedingungen (einschliesslich Kaufpreis), die ein Dritter zu erfüllen bereit ist.

- 6. Diese Lizenzerklärung bildet einen integrierenden Bestandteil der Vereinbarung und soll keine Rechte oder Pflichten begründen, die nicht auch in der Vereinbarung vorgesehenen sind. Bei Abweichungen oder Widersprüchen der Bestimmungen dieser Lizenzerklärung von Bestimmungen der Vereinbarung, gehen die Bestimmungen der Vereinbarung vor.
- 7. Die <u>Anlagen 1 und 2</u> zu dieser Lizenzerklärung bilden integrierende Bestandteile dieser Lizenzerklärung.
- Bei Divergenzen zwischen der deutschen Fassung dieser Lizenzerklärung und der englischen Fassung geht die englische Fassung vor.

9.	SAG hereby authorizes SPI to file this Declaration with the Swiss Federal Institute of Intellectual Property to have this Declaration registered and/or recorded in the Swiss patent register.	9.	SAG bevollmächtigt SPI hiermit, diese Lizenzerklärung beim Eidgenössischen Institut für Geistiges Eigentum einzureichen, damit sie im schweizerischen Patentregister eingetragen und/oder registriert wird.
	In addition, SAG hereby authorizes each of SPI, SPL, and SPE to file this Declaration with any national patent office within their allocated territories (according to <u>Annex 1</u> ) to have this Declaration registered and/or recorded in the respective patent register.		Zudem bevollmächtigt SAG die SPI, die SPL sowie die SPE, diese Lizenzerklärung bei jedem nationalen Patentamt in dem ihnen jeweils zugeteilten Territorium (gemäss <u>Anlage 1</u> ) einzureichen, damit diese Lizenzerklärung im entsprechenden Patentregister eingetragen und/oder registriert wird.
Pla	ce and Date: Zurich July 4, 2006		Ort und Datum: Zûrich, 4. Juli 2006
Suc	campo AG:		Sucampo AG:
/s/	Urs Burgherr		
Urs	Burgherr		
		5	
_			

# ANNEX 1 Territories allocated to SPE, SPI, and SPL

#### Annex 1a): Territory of SPI

All of the countries located in North, Central and South America, including the Caribbean, and their territories and possessions, and including for avoidance of doubt the United States of America and all of its territories and possessions, including but not limited to Puerto Rico, and any other location where the FDA has jurisdiction over pharmaceutical products intended for human use.

#### Annex 1b): Territory of SPL

The following countries located in Asia: Australia; Bhutan; Brunei; Cambodia; China (including Hong Kong); India; Indonesia; Japan; Korea; Laos; Malaysia; Mongolia; Myanmar; Nepal; New Zealand; Pakistan; Philippines; Singapore; Sri Lanka; Taiwan; Thailand; and Viet Nam.

### Annex 1c): Territory of SPE

All the remaining countries in the world (including, without limitation Switzerland)

#### ANLAGE 1 An SPE, SPI und SPL zugeteilte Territorien

#### Anlage 1a): Territorium von SPI

Alle Länder in Nord-, Zentral- und Südamerika, einschliesslich der Karibik, und ihre Territorien und Besitztümer, und zur Vermeidung von Missverständnissen einschliesslich der Vereinigten Staaten von Amerika und aller ihrer Territorien und Besitztümer, und insbesondere einschliesslich Puerto Rico, und aller anderer Orte, in welchen die US-FDA (U.S. Food and Drug Administration) zuständig für Humanpharmazeutika ist.

#### Anlage 1b): Territorium von SPL

Die folgenden asiatischen Länder:

Australien; Bhutan; Brunei; Kambodscha; China (inklusive Hong Kong); Indien; Indonesien; Japan; Korea; Laos; Malaysia; Mongolei; Myanmar; Nepal; Neuseeland; Pakistan; Philippinen; Singapur; Sri Lanka; Taiwan; Thailand und Vietnam.

#### Anlage 1c): Territorium von SPE

Alle übrigen Länder der Erde insbesondere auch die Schweiz.

# Annex 2 Patents or Patent Applications owned by SAG

Anlage 2 Im Eigentum der SAG stehende Patente oder Patentanmeldungen

# Schedule 3.1

# **Pre-Paid Milestone Payments**

Date of Payment SPI	Description of Milestone	Payment Amount
1/3/2001	Payment for Initiation of Phase II Clinical Trial — 8811 Compound	250,000
1/3/2001	Payment for 2711 Compound	150,000
1/3/2001	Payment for 10-110 Compound	150,000
1/3/2001	Payment for Initiation of Phase II Clinical Trial — 0211 Compound	250,000
9/17/2001	Payment for 015 Compound	100,000
9/17/2001	Payment for 016 Compound	100,000
9/17/2001	Payment for Rescula Combination	100,000
12/21/2004	5% of Upfront \$20M Payment for 0211 Compound	1,000,000
4/20/2005	5% of \$10M Payment for CIC NDA Filing for 0211 Compound	500,000
5/24/2005	5% of \$20M Payment for Initiation of c-IBS for 0211 Compound	1,000,000
3/10/2006	Payment for First NDA Approval of 0211 Compound	250,000
3/10/2006	5% of \$20M Payment for CIC NDA Approval for 0211 Compound	1,000,000
6/30/2005	Option Payment for 017 Compound	400,000
3/24/2006	Upfront Payment for 017 Compound	1,100,000
SPE None		
SPL		
4/1/2004	Payment for 015 Compound	250,000

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 1 to the Registration Statement on Form S-1 of our report dated August 11, 2006 relating to the combined financial statements of Sucampo Pharmaceuticals, Inc. and its affiliated companies (Sucampo Pharma Europe, Ltd. and Sucampo Pharma, Ltd.), which appears in such Registration Statement. We also consent to the references to us under the headings "Experts" and "Selected Combined Financial Data" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland August 11, 2006

#### POWER OF ATTORNEY

I hereby severally constitute and appoint Sachiko Kuno, Kei S. Tolliver and Brent B. Siler, and each of them singly, my true and lawful attorneys with full power to them, and each of them singly, with full powers of substitution and resubstitution, to sign for me and in my name in the capacity indicated below, the Registration Statement on Form S-1 filed herewith and any and all pre-effective and post-effective amendments to said Registration Statement, and any subsequent Registration Statement for the same offering which may be filed under Rule 462(b), and generally to do all such things in my name and on my behalf in my capacity as director to enable Sucampo Pharmaceuticals, Inc. to comply with the provisions of the Securities Act of 1933, as amended, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming my signature as it may be signed by my said attorneys, or any of them, or their substitute or substitutes, to said Registration Statement and any and all amendments thereto or to any subsequent Registration Statement for the same offering which may be filed under Rule 462(b).

/s/ Timothy I. Maudlin	_	
Timothy Maudlin	Director	August 5, 2006

#### POWER OF ATTORNEY

I hereby severally constitute and appoint Sachiko Kuno, Kei S. Tolliver and Brent B. Siler, and each of them singly, my true and lawful attorneys with full power to them, and each of them singly, with full powers of substitution and resubstitution, to sign for me and in my name in the capacity indicated below, the Registration Statement on Form S-1 filed herewith and any and all pre-effective and post-effective amendments to said Registration Statement, and any subsequent Registration Statement for the same offering which may be filed under Rule 462(b), and generally to do all such things in my name and on my behalf in my capacity as director to enable Sucampo Pharmaceuticals, Inc. to comply with the provisions of the Securities Act of 1933, as amended, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming my signature as it may be signed by my said attorneys, or any of them, or their substitute or substitutes, to said Registration Statement and any and all amendments thereto or to any subsequent Registration Statement for the same offering which may be filed under Rule 462(b).

August 9, 2006

/s/ V. Sue Molina

V. Sue Molina Director

Brent B. Siler

+1 202 663 6224 (t) +1 202 663 6363 (f) brent.siler@wilmerhale.com

#### BY EDGAR AND HAND DELIVERY

Jeffrey P. Riedler Assistant Director Securities and Exchange Commission 100 F Street N.E. Washington, D.C. 20549

Re: Sucampo Pharmaceuticals, Inc.

Amendment No. 1 to Registration Statement on Form S-l, filed August 11, 2006

File No. 333-135133

#### Dear Mr. Riedler:

On behalf of Sucampo Pharmaceuticals, Inc. ("Sucampo" or the "Company"), this letter responds to the comments in your letter dated July 14, 2006 to Sachiko Kuno, the President and Chief Executive Officer of Sucampo, regarding the initial filing of the Registration Statement on Form S-1 (the "Registration Statement"). Sucampo is filing Amendment No. 1 to the Registration Statement ("Amendment No. 1") today.

# <u>General</u>

1. Please note that our reply to your request for confidential treatment for portions of certain exhibits will be provided under separate cover.

#### **RESPONSE:**

The Company understands that your reply to the request for confidential treatment will be provided under separate cover.

2. Please note that when you file a pre-effective amendment containing pricing-related information, we may have additional comments. As you are likely aware, you must file this amendment prior to circulating the prospectus.

#### **RESPONSE:**

Wilmer Cutler Pickering Hale and Dorr LLP, 1875 Pennsylvania Avenue NW, Washington, DC 20006

Baltimore Beijing Berlin Boston Brussels London Munich New York Northern Virginia Oxford Palo Alto Waltham Washington



The Company understands that you may have additional comments when it files an amendment containing pricing information, and acknowledges that it must file this amendment prior to circulating the prospectus.

3. Please note that when you file a pre-effective amendment that includes your price range, it must be bone fide. We interpret this to mean that your range may not exceed \$2 if you price below \$20 and 10% if you price above \$20.

#### **RESPONSE:**

The Company understands that when it files a pre-effective amendment that includes a price range, the range must be bona fide.

4. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not complete lists. If our comments are applicable to portions of the filing that we have not cited as examples, please make the appropriate changes in accordance with our comments.

#### **RESPONSE:**

The Company acknowledges that where you provide examples to illustrate your comments, they are examples and not complete lists.

5. Please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus prior to its use.

#### **RESPONSE:**

The Company will provide proofs of all graphic, visual or photographic information it will provide in the printed prospectus prior to its use. We advise you that the Company does not currently intend to include graphical, visual or photographic information in the prospectus other than what was included in the initial filing.

6. Please revise your disclosure to identify your basis or the source for the following statements and provide us with third party support for these statements. The supporting documentation should be marked to indicate the text supporting the statements.



- AMITIZA is the only prescription product for the treatment of chronic idiopathic constipation that has been approved by the FDA for
  use by adults of all ages, including those over 65 years of age, and that has demonstrated effectiveness for use beyond 12 weeks.
- We estimate that approximately 12 million people can be characterized as suffering from chronic idiopathic constipation.

#### **RESPONSE:**

The Company advises you that its statement about AMITIZA is based upon general knowledge in the industry that only one prescription product besides AMITIZA has been approved by the FDA for treatment of chronic idiopathic constipation. As described in more detail on page 69 of the prospectus, that product, Zelnorm, has not been approved by the FDA for administration to patients over 65 years of age. In addition, the effectiveness of Zelnorm for the treatment of chronic idiopathic constipation has not been studied beyond 12 weeks. We are including supplementally with the hard copy of this letter, as <a href="https://doi.org/10.1007/nc.1007/

The Company advises you that its estimate that approximately 12 million people can be characterized as suffering from chronic idiopathic constipation is based on two studies from *The American Journal of Gastroenterology*. These studies are referred to in the sentence immediately prior to this statement in the Prospectus. The Company elected to begin this statement with the clause "Based on these studies, ..." in order to avoid repeating the entire reference in the prior sentence. We are including supplementally with the hard copy of this letter, as <a href="https://xitachment.2">Attachment.2</a>, a copy of the two studies from *The American Journal of Gastroenterology* marked to indicate the relevant sections that support this estimate. These studies, and the methodology used by the Company in arriving at the 12 million estimate, are summarized below:

• According to an epidemiological study by Higgins and Johanson published in *The American Journal of Gastroenterology* in 2004 (the "2004 study"), 14.7% of the U.S. population, or approximately 42 million people, suffer from chronic constipation as defined by the Rome II international diagnostic criteria. (This study is the basis of the statement in the Prospectus that 42 million people suffer from constipation.) This figure assumes an implied overall U.S. population of approximately 286 million people. The 2004 study, however, focuses on chronic constipation, without breaking out the subset of people who suffer from chronic constipation that is also "idiopathic", meaning that it is not caused by other diseases or by the use of medications.



• To derive the number of those sufferers whose chronic constipation is also idiopathic, the Company relied upon an earlier epidemiological study by Stewart et al. published in *The American Journal of Gastroenterology* in 1999 (the "1999 study"). The 1999 study estimated that, based on an overall prevalence rate for chronic constipation of 14.7% (we note that this rate is consistent with the rate estimated by the 2004 study), 4.6% of the U.S. population can be characterized as suffering from "functional constipation", which they define as a subset of chronic constipation that excludes incidences of constipation related to irritable bowel syndrome, outlet obstruction or some combination of the two. The 1999 study then indicates that approximately 8.3% of functional constipation sufferers reported a medical condition or treatment thought to be related to constipation, such as paralysis or use of narcotic medication. Because these 8.3% of functional constipation sufferers would not be characterized as idiopathic, the Company excluded them in deriving the prevalence rate for chronic idiopathic constipation in the United States. To make its estimate, the Company began with the 4.6% rate, representing those who sufferer from chronic constipation that is not attributable to irritable bowel syndrome or outlet obstruction, and then multiplied that rate by 91.7% in order to eliminate the 8.3% of cases that are not idiopathic. This yielded an overall prevalence rate of 4.2%. When applied to an assumed U.S. population of 286 million people, the population number implicit in the 2004 study, this resulted in the Company's estimate that 12 million people can be characterized as suffering from chronic idiopathic constipation.

Because the Company's 12 million estimate is derived from the statistics included in these studies, rather than quoting a number specifically set forth in the studies, the Company elected to characterize the statistic as its own "estimate" that was "based on" the studies. The Company believes that its estimate, and the process it used to derive that estimate from the statistics in the studies, are reasonable and well-founded.

7. We note your reference to a "Phase II/III" trial for AMITIZA for the treatment of irritable bowel syndrome and to a "Phase I/II" study of SPI-8811 in patients with portal hypertension. FDA trials are generally conducted sequentially. Please provide us your analysis of why these trials or studies should be referred to as "Phase II/III" and "Phase I/II" instead of just Phase I, Phase II or Phase III.

#### **RESPONSE:**

The Company expects that the Phase II/III clinical trial for opioid-induced bowel dysfunction (not irritable bowel syndrome with constipation) planned for early 2007 will be a Phase II study,



in that it will test multiple doses to determine the optimal dosage, and will also be designed to be a pivotal Phase III trial to determine the ultimate efficacy of the drug. In the case of AMITIZA to treat opioid-induced bowel dysfunction, this is possible because multiple clinical trials have already been completed on AMITIZA for the treatment of constipation, of which opioid-induced bowel dysfunction is a subset, and there is considerable data supporting its efficacy. Thus, it is possible to design a study with a sufficient number of patients such that it can satisfy the need for a traditional Phase II dosing trial and can also qualify as a pivotal Phase III trial.

Likewise, the Phase I/II trial of SPI-8811 in patients with portal hypertension planned for 2007 will combine elements of both a Phase I and a Phase II trial, in that it will focus both on safety and on gathering preliminary data on efficacy. In this case, the Company expects the trial will evaluate the drug's metabolism and will preliminarily explore its effect on the disease process.

8. We note that your collaboration with Takeda can be terminated if you fail to receive marketing approval from the FDA for AMITIZA for the treatment of irritable bowel syndrome. Please revise your disclosure in the third paragraph under AMITIZA on page 1 to discuss this Takeda termination right. Consider adding a separate risk factor that discusses your dependence on the future approval of AMITIZA for the treatment of irritable bowel syndrome. Why does Takeda have this termination right? Is your success substantially dependent on the future approval of AMITIZA for the treatment of irritable bowel syndrome?

#### RESPONSE:

The Company has revised its disclosure on page 3 of the prospectus in response to this comment. The Company believes that the additional disclosure, because it is in the nature of risk factor disclosure, is most appropriate in the "Risks Associated With Our Business" section of the Summary. We note that the Company previously included a description of the risks associated with this termination right under the risk factor titled "We depend significantly upon our collaboration with Takeda …" on page 20 of the prospectus. The Company believes this existing disclosure fairly and appropriately presents the risk, and does not believe that a separate risk factor is warranted. The Company does not believe that its success is substantially dependent on the approval of AMITIZA for the treatment of irritable bowel syndrome.

9. On page 51 you explain that you sold your rights in the patents relating to RESCULA as a result of the declining royalty revenues associated with these patents. On page 65, however, you state that RESCULA is currently marketed in more than 40 countries worldwide. If RESCULA is so widely marketed why is it that you were experiencing declining royalty revenues with your patents relating to RESCULA? Please explain.



#### **RESPONSE:**

The Company advises you that the patents relating to RESCULA that it purchased in 2000 and then resold in August 2004 were U.S. patents and thus the Company was only entitled to license those patents, and collect royalties, with respect to sales of RESCULA in the United States. Although RESCULA is approved by the FDA for sale within the United States, those sales have not been significant due to the availability of competitive products. As noted on page 111 of the prospectus, the Company's royalties from sales of RESCULA in 2003 and 2004 together totaled about \$36,000. In markets outside the United States, however, sales of RESCULA are significant. The Company believes that sales of RESCULA outside the United States are approximately \$60 million annually. The Company has modified its disclosure on pages 51 and 111 in response to this comment to clarify that the patents it purchased and then resold were U.S. patents.

#### Summary, pages 1-7

10. We refer to your statement on page 1 that you have completed a Phase IIa trial for non-alcoholic fatty liver disease and a Phase IIa trial for cystic fibrosis. This statement may suggest that you will now pursue advanced clinical trials, i.e. Phase III trials, for these indications. We note, however, that the results of these Phase IIa trials were inconclusive and as a result, you will not be pursuing further advanced clinical trials. Please revise your disclosure to clarify this fact.

#### **RESPONSE:**

The Company has modified the disclosure on pages 1 and 2 in response to this comment to delete the reference to the trials for non-alcoholic fatty liver disease, to clarify that it intends to pursue a Phase IIb trial for cystic fibrosis and to add disclosure about its other planned trials for SPI-8811.

11. We note your statement on page 105 that this offering will not be closed unless the Sucampo Group reorganization has been consummated. Please revise your summary to describe this material condition to the offering and to briefly explain the terms of the reorganization, its purpose, who proposed it and why it is a condition to the consummation of the firm commitment offering.

#### RESPONSE:

The Company believes that the key information about the timing of the reorganization that is material to investors is that the reorganization will be closed prior to the closing of this offering. The reorganization has been approved by the boards of directors and, to the extent required, the



stockholders of each of the constituent corporations. Although the reorganization is subject to customary closing conditions, principally the conditions that the registration statement for this offering be declared effective and that no material changes have occurred to the respective businesses of the constituent corporations, the key factor for investors in this offering is that this offering will not be completed, and they will not make an investment, if for some reason the reorganization is not closed. For that reason, and as disclosed in the Summary section on page 5 of the prospectus, the Company has elected to present all information throughout the prospectus as if the reorganization were completed. The Company has added disclosure on page 3 to make clear that the reorganization will occur prior to the closing of the offering. The Company has also deleted the reference to the closing conditions to the reorganization on page 107 reflecting its view that those conditions are not material to investors in this offering.

12. In the first paragraph under "Related Party Agreements" on page 2, you refer to "committed specific development efforts" and "planned for development within that year." Please revise your disclosure here to briefly explain what types of actions or developments satisfy these requirements so as to prevent a reversion to Sucampo AG or accomplish a one year extension, respectively.

#### **RESPONSE:**

The Company has expanded the disclosure on page 2 of the prospectus in response to this comment.

#### Risk Factors, pages 8-29

#### We have historically incurred significant losses and we might not achieve or maintain operating profitability. Page 8

13. Please consider revising this risk factor to briefly discuss how you are responsible for the next \$20 million in expenses related to AMITIZA as you discuss on page 40. It appears that this obligation could result in a significant increase in your expenses in the near future.

#### **RESPONSE:**

The Company has expanded the disclosure on page 8 in response to this comment.

If we are unable to retain our president and chief executive officer and chief scientific and operating officer and other key executives . . . ., page 9



14. Please revise this risk factor to provide the names and positions of all of your key executives.

#### **RESPONSE:**

The Company has expanded the disclosure on page 9 in response to this comment.

Please briefly describe the material term and termination provisions of your employment contracts with key executives.

#### **RESPONSE:**

The Company has expanded the disclosure on page 9 in response to this comment.

16. To the extent that you have experienced problems attracting and retaining key executives in the recent past, please revise to describe these problems. Additionally, if any key employee has plans to retire or leave your company in the near future, please revise the discussion to disclose this information.

#### **RESPONSE:**

The Company advises you that it does not believe that it has had any unusual difficulty in attracting or retaining key executives in the recent past. The Company nonetheless continues to believe this risk remains sufficiently material, as a future possibility, to merit inclusion in the prospectus. The Company also advises you that it is not aware of any key executives or key employees who plan to retire or leave the Company in the near future.

#### If we fail to attract retain and motivate qualified personnel . . . pages 9-10

17. To the extent known, please disclose the projected time frame and expected cost to hire the personnel you need to execute your current business plan.

#### **RESPONSE:**

The Company advises you that it does not have a specific plan, timeline or budget for hiring additional personnel. Although the Company believes it will generally require additional personnel in the future, the Company does not currently plan to add a material number of employees to its staff in the near future.



# We have identified material weaknesses in our internal control over financial reporting and those of Sucampo Europe and Sucampo Japan . . ., pages 10-11

18. We note your reference to the potential delisting of your class A common stock from the NASDAQ National Market. Your reference to the delisting implies that your class A common stock has already been or will be listed. It is inappropriate to refer to your possible listing on NASDAQ in this manner. Please revise your disclosure in this risk factor and elsewhere in the prospectus where applicable to clarify that you currently have only applied for the listing.

#### **RESPONSE:**

The Company has modified the disclosure on pages 10 and 11 of the prospectus in response to this comment.

19. If addition, if there a risk that you may actually not be listed on the NASDAQ National Market because of your internal control problems, please consider disclosing this risk and discussing how it would affect the offering. Would you still consummate the offering without a NASDAQ listing?

#### **RESPONSE:**

The Company does not believe that its internal control problems will prevent it from being listed on the NASDAQ National Market (now referred to as the NASDAQ Global Market), and therefore does not believe that a separate risk factor to this effect is warranted. If for some reason the Company were not to succeed in being listed on the NASDAQ Global Market, it might seek an alternative listing, but it would inform investors of that development before they made their investment decision.

## Commercial rights to some prostone compounds will revert back to Sucampo AG in the future. . . . ., pages 11-12

20. We note your disclosure here that Dr. Ueno will be primarily responsible for selecting the compounds the company chooses to develop so that they do not revert back to Sucampo AG at the end of the specified period. Please revise this risk factor to discuss the fact that Dr. Ueno together with his wife Dr. Kuno owns all of the stock of Sucampo AG.

#### RESPONSE:



The Company has modified the disclosure on page 12 of the prospectus in response to this comment.

## Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States..., page 16

21. Please revise your disclosure to name the "recent proposed legislation."

## RESPONSE:

The Company advises you that numerous drug re-importation bills have been introduced over the years. For example, in February 2005, bills were introduced in both the Senate (S.334) and the House of Representatives (H.R. 700) relating to drug re-importation. Hearings were heard on these bills, but they were not passed. In July 2006, both the Senate and the House passed versions of H.R. 5441, the appropriations act for the Department of Homeland Security, which permits limited re-importation of pharmaceutical products into the United States. Both versions would allow re-importation only by individuals, and not wholesalers, and the Senate-passed version would allow re-importation only from Canada. It has been reported that some sponsors of the re-importation provision may press for debate on separate stand-alone re-importation bills if, as some expect, the current re-importation language is eliminated from the legislation during the House-Senate conference committee to reconcile the Senate- and House-passed versions of the bill. The Company has modified the disclosure on page 16 of the prospectus in response to this comment to clarify that numerous legislative proposals have been introduced from time to time.

# We have no manufacturing capabilities and are dependent upon R-Tech to manufacture and supply. ..., pages 18-19

22. Please revise your disclosure to name the supplier upon whom R-Tech is dependent and consider whether you should add a risk factor regarding R-Tech's dependence on this supplier.

## **RESPONSE:**

The Company advises you that the primary ingredient used in the manufacture of prostones could be manufactured and supplied by a number of other companies, including R-Tech itself. While a disruption in the supply of this ingredient could result in a temporary suspension of production of prostones while an alternative supplier was engaged or while R-Tech prepared to manufacture the ingredient itself, the Company does not believe the identity of the existing supplier of this ingredient is material in the way it might be if the manufacturing process were so



unique or highly specialized that only one or a limited number of companies could supply it. The Company has revised the disclosure on page 19 of the prospectus to clarify the nature of the risk in response to this comment.

## We and R-Tech are dependent upon a single contract manufacturer. . . ., page 19

23. Please revise your disclosure to name the single contract manufacturer upon whom R-Tech is dependent.

## **RESPONSE:**

The Company advises you that several competing companies have the capability in FDA-approved facilities to produce gelatin capsules and to package those capsules for distribution. The current contract manufacturer itself has multiple facilities capable of performing these services. Accordingly, the Company does not believe the identity of the contract manufacturer is material. The Company nonetheless believes the existing risk factor accurately describes the risk, which is principally the delay that could be involved with replacing this manufacturer, and that the risk is sufficient to merit inclusion of the risk factor in the prospectus.

## We rely on third parties to conduct our clinical trials . . ., page 21

24. Please identify the third parties that you substantially rely on for conducting your clinical trials. Also, to the extent you have any agreements with such parties, please so indicate and describe in your Business section the material terms of the agreements. You should also file the agreements as exhibits to the registration statement. If you have determined that you are not substantially dependent on these parties, please provide us with an analysis supporting this determination and disclose the number of parties that you engage to conduct your clinical trials.

#### RESPONSE:

The Company advises you that it relies upon a large number of field investigators to conduct its clinical trials. Currently, for example, approximately 130 separate investigators are participating in the Company's ongoing trials for irritable bowel syndrome with constipation. The Company does not believe that it is substantially dependent upon any one of these parties. The Company also uses multiple contract research organization to coordinate the efforts of these field investigators and to accumulate the results of those trials. The Company believes that any of these parties could be easily replaced with minimal disruption. The contracts with these contract research organizations are generally terminable by the Company on short notice without penalty. Accordingly, the Company does not believe that it is substantially dependent upon any third party in connection with its clinical trials. The Company also believes that the terms of its



arrangements with its clinical investigators and its agreement with its contract research organization are ordinary-course and of the type that ordinarily accompany the kind of business conducted by the Company. For this reason, the Company does not believe the agreements with these parties are required to be filed as exhibits to the Registration Statement.

## Risks Related to Our Intellectual Property, pages 22-23

25. Please update to disclose whether there have been threats of litigation or negotiations regarding patent issues or other intellectual property, court challenges, legal actions, etc.

#### RESPONSE:

The Company advises you that there have not been any threats of litigation, court challenges, legal actions or negotiations regarding patent issues or other intellectual property.

## Our business activities involve the use of hazardous materials..., page 26

26. Please disclose whether you maintain insurance for the use of hazardous materials and, if so, the level of coverage. Please also disclose the cost to you of such coverage, if material.

# **RESPONSE:**

Upon reconsideration, the Company has concluded that it does not face material risks of the type described in the risk factor. Accordingly, the Company has deleted this risk factor from the prospectus.

## Use of Proceeds, page 31

27. Please clarify what stage of development you expect to achieve for each indication for your product candidates using the proceeds from the offering. For example, do you also expect to complete the pivotal Phase II/III clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction, additional clinical trials for SPI-8811 for cystic fibrosis and Phase I clinical trials for SPI-017?

## **RESPONSE:**



The Company has modified the disclosure on page 31 of the prospectus in response to this comment. We note that Takeda is responsible for the first \$50.0 million of costs associated with the development of each gastrointestinal indication for AMITIZA other than chronic idiopathic constipation and irritable bowel syndrome with constipation, including opioid-induced bowel dysfunction. The Company does not expect that the total costs to complete the pivotal clinical trials for this indication will exceed \$50.0 million and, therefore, does not expect to bear any of the costs of this trial. Accordingly, the Company has not allocated any of the proceeds of this offering to that trial.

## Dilution, page 34

28. Please revise to present a line item for historical tangible book value per share and the amounts attributable to pro forma adjustments to arrive at pro forma tangible book value per share.

## **RESPONSE:**

As discussed telephonically with Mr. Woody on July 24, 2006, the Company has not shown a line for historical tangible book value per share because the Company does not believe this is a meaningful metric given the various classes of common stock outstanding for the combined entities. For this reason, the Company has used pro forma tangible book value per share as its baseline for the dilution presentation. We note that this presentation is consistent with the manner in which the Company presents its historic earnings per share, which are shown only on a pro forma basis.

## Selected Combined Financial Data, page 36

29. Please disclose separately long term obligations and redeemable preferred stocks within your selected combined financial data as required by Item 301 of Regulation S-K.

## **RESPONSE:**

The Company has revised the disclosure on page 37 of the prospectus in response to this comment. The Company notes that its preferred stock is not redeemable and, thus, not presented separately in the "Selected Combined Financial Data" section.

30. We acknowledge your disclosure of management's basis for not presenting basic and diluted net income (loss) per share on page 6 and your current disclosures



within note 3 to the combined financial statements. Please provide to us additional information justifying exclusion from this table. Additionally, please give us management's justification for only presenting the pro forma net income per share for only the most recent physical year and interim period within the notes to the financial statements on a pro forma unaudited basis. Please cite within your response, the appropriate literature relied upon to form management's conclusion.

#### RESPONSE:

The Company has revised the presentation on pages 6, 36, F-4 and F-17 to include a presentation of pro forma net (loss) income for all historical periods presented. As discussed telephonically with Mr. Woody on July 24, 2006, the Company has used the negotiated exchange rate at which SPE shares and SPL shares will be converted into Company shares in the combination in calculating the pro forma weighted average shares outstanding for all periods.

## Management's Discussion and Analysis of Financial Condition and Results of Operations, pages 38-61

# Overview, pages 38-39

31. Your MD&A overview as currently written merely describes key aspects of your business that are summarized elsewhere in your prospectus. In our MD&A Interpretive Release No. 34-48960 (December 2003), we explained that an MD&A overview should include "the most important matters on which a company's executives focus in evaluating financial condition and operating performance and provide the context for the discussion and analysis of the financial statements" and that the overview should not be "a duplicative layer of disclosure." Please review and revise this section to remove any duplicative disclosure and summarize the most important matters regarding the company's financial condition and operating performance that provide the context for the rest of the MD&A.

## **RESPONSE:**

The Company has shortened the disclosure in the Overview section of the MD&A on pages 38 and 39 in response to this comment. The Company has focused on retaining only that information that will help the reader understand the remainder of the discussion in the MD&A.

## **Critical Accounting, page 43**



32. Considering you recently initiated commercial sales, please expand your revenue recognition policy to include how you will recognize revenue from product sales including revenue dilution items such as product returns, chargebacks, customer rebates and other discounts and allowances. Please address how you anticipate compensating for the lack of historical information when estimating your revenue dilution items.

## **RESPONSE:**

The Company advises you that it will receive royalty payments from the license of AMITIZA to Takeda based on the terms of the joint collaboration and license agreement. Takeda, and not the Company, will be responsible for commercial sales of AMITZA. Given that the royalties are based on net revenues earned by Takeda, substantially all of the revenue dilution items you refer to will be accounted for by Takeda. As such, the Company's revenue recognition policy will be based on third party sales and collectibility information obtained from Takeda and reviewed by the Company. The only dilution item the Company will account for is the right of return provision included in Takeda's sales to third parties. The Company will account for the right of return in accordance with FAS 48, *Right of Return*, as if the Company was selling AMITIZA directly to its customers. Because of the lack of historical data regarding sales returns, royalty receipts on the portion of sales by Takeda which are subject to a right of return will not be reported as revenue until the right of return labses.

The Company has expanded the disclosure on pages 44 and F-11 in response to this comment to discuss the accounting treatment for the Company's royalty revenue from the sale of AMITIZA.

## Stock-Based Compensation, page 44

- 33. We note your disclosures regarding how the board of directors determined the fair value of your common stock. In order or us to fully understand the fair values reflected in your financial statements, please provide an itemized chronological schedule covering all equity instruments issued since January 1, 2005 through the date of your response. Please provide the following information separately for each equity issuance:
  - a. The date of the transaction;
  - b. The number of shares/options issued/granted;
  - c. The exercise price or per share amount paid;
  - d. Management's fair market value per share estimate and how the estimate was made;
  - e. An explanation of how the fair value of the convertible preferred stock and common stock relate, given the applicable conversion ratios;



Page 16

- f. The identity of the recipient, indicating if the recipient was a related party;
- g. Nature and terms of concurrent transactions; and
- h. The amount of any compensation or interest expense element.

Progressively bridge management's fair market value determinations to the current estimated IPO price range. Please reconcile and explain the differences between the midpoint of your estimated offering price range and the fair values included in your analysis.

## **RESPONSE:**

The Company is providing the following itemized chronological schedule covering all equity instruments issued since January 1, 2005 through the date of this letter:

Date of Issuance	Type of Equity Issuance (c)	Number of Shares Issued/Options Granted	Exercise Price or Per Share Amount Paid	Fair Market Value Estimate (Per Common Share)	Expense or Charge
8/8/05	Non-employee stock				
	options	60,000	\$49.75	\$68.03	\$1,318,602 (a)
3/31/06	Class A common stock	229,412	\$85.00	\$85.00	_
4/10/06	Class A common stock	52,795	\$85.00	\$85.00	_
5/1/06	Employee stock options	82,600	\$85.00	\$85.00	TBD (b)

- (a) The non-employee stock options were fully vested and exercisable upon the grant date and the total expense of \$1,318,602 was recorded as stock-based compensation expense during the year ended December 31, 2005.
- (b) The stock-based compensation expense for the employee stock options granted on May 1, 2006 is in the process of being calculated by management as it prepares its financial statements for the quarter ended June 30, 2006.
- (c) All types of equity securities issued since January 1, 2005, besides the employee stock options, were granted or sold to third parties.



## Fair market value estimate — 2005

During the year ended December 31, 2005, the Company's management hired a third party valuation firm (the "Valuation Firm") to perform a retrospective valuation analysis to determine the indicated fair market value (the "Enterprise Value") range of the Company as of March 31, 2005. In performing the valuation analysis, the Valuation Firm considered management's assumptions and projections for the Company's two significant compounds — SPI-0211 (all indications) and SPI-8811 (cystic fibrosis and portal hypertension indications).

The Company received a valuation report as of March 31, 2005 from the Valuation Firm using the income method, an approved valuation method under the AICPA Practice Guide, *AICPA Audit and Accounting Practice Aid Series* — *Valuation of Privately-held-Company Equity Securities Issued as Compensation*. Management and the Valuation Firm determined that this method, compared to the market method, was the most appropriate method to use based on the Company's stage at the time of the retrospective valuation. The Valuation Firm estimated the enterprise value to be \$260 million to \$300 million based on a controlling basis with a 15% marketability discount. The discount rate was necessary due to the fact that the Company is a privately held company and the issued common shares are not traded on a public exchange. Therefore, a potential investor in the Company's equity would not have ready access to liquid secondary markets.

In determining the equity allocation of the Enterprise Value among the different shares of stock (preferred and Class A and B common stock) as of March 31, 2005, management determined that all classes of equity were considered equal due to there being no superior rights of any class of stock, including the outstanding preferred stock. Specifically, the Series A preferred stock has no redemption features, mandatory dividend rights or liquidation preferences.

On a fully-diluted basis, the fair market value estimate (per common share) at March 31, 2005 was as follows:

Median of enterprise value range:	\$ 280,000,000
Cash received from exercise of options <sup>1</sup> :	1,211,103
Company fair market value:	\$ 281,211,103
Shares outstanding <sup>2</sup> :	4,133,550
Fair market value estimate:	\$68.03 / common share



- 1 Management determined that the cash received from the exercise of outstanding stock options added to the median of the enterprise value range is appropriate because the calculation is on a fully-diluted basis, which would include the assumption that all outstanding stock options would be exercised.
- <sup>2</sup> Management included the conversion of preferred shares into common shares on a 100-for-one basis in calculating the shares outstanding.

Management and the Company's Board of Directors determined that the estimated fair market value of common stock at March 31, 2005 was equivalent to that as of August 8, 2005, the date in which the non-employee stock options were granted. The estimated fair market value per share did not change from March 31, 2005 to August 8, 2005 because there were no significant post-valuation events that occurred, such as regulatory approval of a product, additional indications in the pipeline, additions of key management personnel, achievement of milestones or a financing event.

## Fair market value estimate — 2006

The Board of Directors approved an exercise price for stock options granted in May 2006 equivalent to the price of Class A common stock sold to outside investors in March and April 2006. The Board determined that the sales price of common stock to an unrelated party is the best evidence of the fair market value of common stock of a privately held company. Also, it was determined that there was no change in the enterprise value from April 2006 to May 2006 because the Company encountered no valuation events (described above) during that period.

In the beginning of March 2006, the Company's Board of Directors received estimates of enterprise value from its investment bankers, Bank of America Securities LLC and Deutsche Bank. The estimated enterprise value was \$375 million to \$425 million, which is \$97.06 per average share on a fully-diluted basis (using the same allocation method described above). When the second round of Class A common shares was sold in March and April 2006 for \$85.00, the additional shares of 282,207 diluted the estimated fair market value per common share of the Company to \$90.86 per share on a fully-diluted basis.

Management subsequently assessed the fair market value per common share of the Company on a fully-diluted basis based on the arm's-length transaction of \$85.00 per common share compared to the estimated \$90.86 per common share and determined that the \$85.00 was the more appropriate fair value per common share for the exercise price of the employee stock options granted in May 2006.



## Research and Development Expenses, page 48

34. We acknowledge the uncertainties inherent in the clinical trial process and that it may be difficult to determine the precise duration and completion costs of your research and development projects. However, please revise your disclosure to provide the amount or range of estimated costs and timing to complete the phase in process and planned future phases. In your revised disclosure, please compare and contrast the estimated costs to your use of proceeds disclosure regarding research and development project expenditures on page 31. Additionally, please expand your disclosure of the research and development expenses to include the costs incurred during each period presented and to date on each project under development.

#### RESPONSE:

The Company has added disclosure on page 58 of the prospectus, under the caption "Funding Requirements", summarizing the estimated future costs to complete its planned development projects, and the timing of those projects, in response to this comment.

The Company advises you that it is impractical for it to break out historical research and development expenses by project for several reasons. First, clinical trials conducted with respect to a single compound, such as AMITIZA, typically produce data and information that is applicable to more than one indication. Second, clinical trials on one compound may produce data and information that is applicable to other compounds, particularly given the relatively similar nature of several of the Company's prostone compound candidates. Finally, the Company's European and Japanese affiliates, Sucampo Pharma Europe Ltd. ("SPE") and Sucampo Pharma, Ltd. ("SPL"), whose historic financial results are being presented on a combined basis with those of the Company, have not maintained records that allocate research and development costs among different compounds, indications or projects. For all these reasons, the Company respectfully submits that it would not be practicable for it to allocate historic expenses by project.

## Commitments and Contingencies, page 57

35. Please quantify your contingent milestone and royalty obligations consistent with your disclosures of the amounts you may receive in conjunction with the Takeda Pharmaceuticals agreements.

#### RESPONSE:



The Company has revised the disclosure on page 57 of the prospectus in response to this comment to quantify the milestone and royalty obligations.

## Liquidity and Capital Resources, pages 55-58

36. Please revise your disclosure to discuss your expected expenditures for the physical expansion of your operations as you discuss on pages 9 and 10 of the prospectus. To the extent practicable, please quantify any known expenditures.

## **RESPONSE:**

The Company has added disclosure on page 58 of the prospectus, under the caption "Funding Requirements", summarizing the estimated costs in connection with the expansion of its business in response to this comment.

## **Internal Control Over Financial Reporting, pages 60-61**

37. In this section and in the related risk factor on pages 10 and 11, please revise your disclosure to quantify the adjustments that resulted from the internal control deficiencies.

## **RESPONSE:**

The Company believes it would not be useful or relevant to an investor, and could be misleading, to disclose the specific dollar amount of each audit adjustment. While the Company recognizes that the occurrence of an audit adjustment is an indication of an internal control deficiency, the significance of a deficiency depends on the potential for a misstatement, not on whether a misstatement actually occurred. AS2, paragraph 131, requires that when evaluating the significance of a deficiency, one must determine:

- 1. the likelihood (remote or more than remote) that the deficiency, individually or in combination with other deficiencies, could result in a misstatement of an account balance or disclosure, and
- 2. the magnitude (inconsequential, more than inconsequential but less than material, or material) of the potential misstatement resulting from the deficiency.

Disclosure of the specific dollar amount of an audit adjustment could be misleading, as the reader might infer that all adjustments of a similar magnitude are considered to be a material weakness. An actual adjustment may not be material quantitatively, but based on other



considerations (qualitative and quantitative), one may conclude that the underlying control deficiency is nonetheless a material weakness. Additionally, an actual adjustment could be material quantitatively, and one could still conclude that the underlying control deficiency was not a material weakness. Consequently, a reader may inappropriately conclude that there is a direct relationship between the dollar amount of the actual adjustment and the fact of a material weakness. The reader might also incorrectly conclude that the potential for misstatement is limited to the amount of the audit adjustment. For these reasons, the Company has not disclosed the specific dollar amount of each audit adjustment.

## Business, pages 62-91

## **General**

38. We note that you have determined you have three reportable geographic segments, United States, Europe and Japan. Please consider revising your business description to provide any material disclosure with respect to the reportable segments. See Item 101(c) of Regulation S-K.

## RESPONSE:

The Company believes that it has adequately described the various geographic elements of its business throughout the prospectus to the degree material to an understanding of its business, operations and future plans.

## **Products and Product Candidates, pages 67-77**

39. We note your statement that "AMITIZA met all but one of the secondary efficacy endpoints with statistical significance." Please revise to disclose which secondary efficacy endpoint was not met.

## **RESPONSE:**

The Company has revised the disclosure on page 70 of the prospectus in response to this comment.

40. We refer to your disclosure regarding the long-term safety trials for AMITIZA for chronic idiopathic constipation. Please also disclose the results of the statistical analysis performed.

## **RESPONSE:**



The Company has revised the disclosure on page 71 of the prospectus in response to this comment.

41. We refer to your disclosure regarding the Phase II trial for AMITIZA for irritable bowel syndrome. Please revise your disclosure to explain what you mean by "improvement in mean change from baseline." Please consider quantifying your explanation.

## RESPONSE:

The Company has revised the disclosure on page 73 of the prospectus in response to this comment.

42. We refer to your discussion of the market for opioid-induced bowel dysfunction. Your discussion of the number of patients who suffer from chronic pain and acute pain is inappropriate as the number of patients who actually develop opioid-induced bowel dysfunction is likely to be a much smaller number. Please revise your disclosure to delete your references to the number of patients who suffer from chronic pain and acute pain.

## RESPONSE:

The Company has added disclosure on page 74 of the prospectus to clarify that it believes that over three million people in the United States currently suffer from opioid-induced bowel dysfunction. The basis for the Company's belief is a marketing study performed by Dynamic Research & Solutions, Inc., which the Company commissioned. Dynamic Research & Solutions, Inc. has not consented to the use of its name in the registration statement; however, the Company believes that this study is reliable and that its belief about the prevalence of opioid-induced bowel dysfunction is reasonable.

## Marketing and Sales, page 78

43. With respect to your agreement with Ventiv, please revise your disclosure to disclose any material amounts payable to Ventiv and the term and termination provisions of the agreement.

## RESPONSE:



The Company has expanded the disclosure on page 80 of the prospectus in response to this comment to describe in more detail the term and termination provisions of the agreement with Ventiv. With respect to pricing terms under this agreement, the Company notes that it has described generically the types of payments due to Ventiv on page 79 of the prospectus ("a flat monthly fee as well as periodic incentive fees upon the recruitment and maintenance of specified numbers of sales representatives") and that it has applied for confidential treatment of the specific pricing terms. The Company believes that these pricing terms constitute sensitive competitive information and that, accordingly, they should be treated confidentially.

## Certain Relationships and Related Party Transactions, pages 104-109

44. Please revise your disclosure to describe the conditions to the completion of the Sucampo Group reorganization and the circumstances under which it may be terminated.

## **RESPONSE:**

Please see the response to comment number 11.

## Principal Stockholders, pages 110-111

45. For each principal stockholder that is a nonpublic entity, please revise to identify the person or persons with investment and voting control over the shares.

#### **RESPONSE:**

The Company has expanded the disclosure in the footnotes on pages 113 and 114 of the prospectus in response to this comment. The Company advises you that Astellas Pharma, Inc. is a public company and that Tokio Marine and Nichido Fire Insurance Co., Ltd. is a subsidiary of Millea Holdings, Inc., a public insurance holding company.

## Shares Eligible for Future Sales, pages 117-118

46. Please disclose what factors Banc of America Securities LLC would consider in determining whether to grant a release from lock-ups.

## **RESPONSE:**

The Company has revised the disclosure on pages 121 and 124 of the prospectus in response to this comment to include factors Banc of America Securities LLC may consider in deciding whether to consent to an early release of shares subject to a lock-up agreement. Banc of America



Securities LLC has advised the Company that it does not have any current intent or arrangement to release shares subject to a lock-up.

## **Underwriting, pages 119-123**

47. Please revise your statement that you "expect" your class A common stock to be approved for quotation on the NASDAQ National Market to state that you have applied to have it approved for quotation.

## **RESPONSE:**

The Company has revised the disclosure on page 122 of the prospectus in response to this comment.

48. Please disclose the timing and amount of fees previously paid to Leerink Swann & Co. for their market research services. Please also disclose if any of the other underwriters have performed services for you in the past.

## RESPONSE:

The Company's payments to Leerink Swann & Co., Inc. ("Leerink") for research services relating to markets for the Company's products were in an amount that the Company believes is not material to the Company or an investor's investment decision. Leerink has advised us that the fees they have received for these services are in line with work they have done for other companies and competitive with other consulting firms. Leerink has not provided other services to the Company. Leerink has advised the Company that it considers the amount of fees paid for its market research services to be confidential information that, if disclosed, would harm its competitive position. It is willing to disclose this information to the SEC on a confidential basis, if required.

Banc of America Securities LLC ("BoA") has provided cash management and leasing services to the Company in the past. BoA has advised us that they regard the fees they have received for these fees to be customary in the industry. Accordingly, the Company believes these services are covered by the existing disclosure on page 125 of the prospectus, which states that the "underwriters and their affiliates have provided, and may in the future provide, investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees."

We have been advised that Deutsche Bank Securities Inc. has not performed services for the Company in the past.



## **Financial Statements**

## Note 2. Summary of Significant Accounting Policies

## Revenue Recognition, page F-9

49. Please tell us your basis for deferring option fee revenue until expiration of the option term. Based upon the terms disclosed, it would appear that you have earned the fee ratably over the option term. Please cite accounting literature relied upon.

#### RESPONSE:

During the year ended December 31, 2004, SPE and SPL entered into separate option agreements with Takeda whereby Takeda paid option fees to these entities, 50% of which were non-refundable, for the exclusive right to enter into joint collaboration and license agreements with these entities. The option agreements did not define the ultimate terms of the potential joint collaboration and license agreements, but did state that the option fees would be applied to any cash payments contractually due to SPE and SPL under the terms of the agreements, once defined. Future performance obligations by SPE and SPL would ultimately be included in the joint collaboration and license agreements should the options be exercised. There were no performance obligations on the part of SPE and SPL during the period that the options were outstanding.

The Company accounted for the non-refundable option fees in a manner that is similar to the accounting for non-refundable up-front licensing fees. Up-front licensing fees, as discussed under the revenue recognition policy in Note 2 of the combined financial statements on page F-10 of the prospectus, are recognized as revenue on a straight-line basis over the estimated performance period under the related agreement because no separate earnings process has been completed when the up-front licensing fee is received.

When SPE and SPL entered into the option agreements, they believed there were contingent and unspecified performance obligations that they would be required to fulfill if the options were exercised. The exercise of either option would have resulted in a joint collaboration and license agreement with Takeda, which would have included specified services to be performed by the Company over a period of time. Accordingly, the Company deferred the non-refundable option fee amount until the option was either exercised or expired. If the options had been exercised and a joint collaboration and license agreement entered into, SPE and SPL would then have recognized the deferred option fee over the estimated period in which the performance obligation



would have been performed, consistent with the recognition of an up-front payment of a licensing fee.

Because the option agreement ultimately expired unexercised and there were no performance obligations for SPE and SPL to meet at that time, the deferred non-refundable option fee was immediately recognized in full as contract revenue upon the option expiration.

In accordance with SAB 104, Revenue Recognition, and EITF Issue 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, the Company determined that the up-front option fee and future cash payments to SPE and SPL due as part of a joint collaboration and license agreement (pending the exercise of the option agreement) should be accounted for as a single unit of accounting. The option fee upon the execution of the option agreement was not considered a discrete earnings event because there was no exchange for products delivered or services performed by SPE and SPL. The Company believes that, if SPE and SPL had recognized the non-refundable option fees as revenue ratably over the option terms, whether estimated or defined, and the options were ultimately exercised, the Company would have prematurely recognized revenue prior to a discrete earnings event.

In response to this comment, the Company has expanded its disclosure of its revenue recognition policy in Note 2 of the combined financial statements on page F-10 of the prospectus to clarify its accounting treatment for option fees.

50. Please tell us your basis for determining that the reimbursement of development cost under the joint collaboration and license agreement with Takeda is revenue as opposed to a reimbursement of expense. Please address the factors described in EITF 99-19. Additionally, please tell us your basis for deferring recognition of the \$30 million as it appears that Takeda does not have any continuing obligation with regards to this amount.

## **RESPONSE:**

The Company's business strategy includes entering into collaborative development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company's drug candidates. As explained in Notes 2 and 10 of the combined financial statements on pages F-8 and F-22 of the prospectus, the Company and Takeda are involved in a joint collaboration and license agreement that includes, among other significant features, cost sharing arrangements for the development of AMITIZA for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation. Takeda funded the initial \$30 million in costs, the Company is required to fund the next \$20.0 million and Takeda will share equally with the Company any costs exceeding \$50 million. The initial funding of \$30 million from Takeda was received by the Company in quarterly installments based on estimates of the



development costs the Company was to incur for each upcoming three-month period until the full \$30 million was received. The Company received such quarterly funding from Takeda commencing in December 2004 and ending in September 2005.

The Company's accounting policy is to report the reimbursement of development costs as gross revenue as opposed to a reduction of expenses incurred. The Company assessed EITF 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, in arriving at this conclusion. Specifically, the Company has performed the following assessment of EITF 99-19, which indicated the Company is the principal in this arrangement:

- Indicators of gross revenue reporting:
  - *The company is the primary obligor in the arrangement* The Company is fully responsible for the development of the drug candidates, including developing and managing the development program. This indicates the Company is acting as the principal in this arrangement.
  - *The company has latitude in establishing price* The Company negotiated the reimbursement amount when the agreement was executed. This indicates the Company is acting as a principal in the arrangement.
  - The company changes the product or performs part of the service The Company is performing the majority of the service for this arrangement and is responsible for overseeing the development of drug candidates. This indicates the Company is acting as a principal in the arrangement.
  - *The company has discretion in supplier selection* The Company has the discretion to use its employees for its portion of the research and development or to use outside service providers. This indicates the Company is acting as a principal in the arrangement.
  - *The company is involved in the determination of product or service specifications* The Company is responsible for developing the drug candidates in the way management feels is most effective. This indicates the Company is acting as a principal in the arrangement.
  - The company has credit risk The Company received the initial reimbursement of development costs through a \$30 million non-refundable up-front payment. The Company was exposed to the credit risk associated with Takeda's ability to continue to fund the quarterly installments and for any future funding beyond the \$30.0 million. The inability to fund on the part of Takeda would have no legal bearing on the obligations the Company had for development costs incurred to date. This indicates the Company is acting as a principal in this arrangement.
- Indicators within the guidance that are not deemed applicable:
  - *The company has general inventory risk* This indicator is not applicable as no product is sold under the joint collaboration and license agreement.



• *The company has physical loss inventory risk* — This indicator is not applicable as no product is sold under the joint collaboration and license agreement.

The Company also assessed the guidance in EITF 01-14, *Income Statement Characterization of Reimbursements Received for 'Out-of-Pocket' Expenses Incurred*, and determined that this assessment did not change the above conclusions.

Other than the EITF topics discussed above, there is no specific authoritative accounting literature that specifically addresses the reimbursement of development costs received by biotechnology and pharmaceutical companies. The assessment of the guidance listed above was the Company's best effort to properly account for these transactions. The Company is aware that the EITF has a project on its agenda to provide additional guidance for these types of transactions. The income statement classification used by the Company is consistent with one of the views being discussed by the EITF.

The Company's accounting policy for the \$30 million received from Takeda in 2004 and 2005 for the development of AMITIZA for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation is to recognize the revenue over the period of the estimated developmental activities (through December 31, 2006). The revenue was amortized over this estimated period of development given that the Company and Takeda were expected to be directly involved in the development of the drug candidates and potential indications during this period. Once the Company received the \$30 million, management determined that it had a constructive obligation to continue the studies and clinical trials while funding the subsequent \$20 million in costs itself. This is consistent with the fact that the Company agreed to fund the \$20 million and share in any costs exceeding \$50 million. Management believed that it was appropriate to amortize the \$30 million over the life of the estimated development term because the payments were directly related to research and development costs and the Company's obligations to continue to fund the studies beyond the initial \$30.0 million.

In response to this comment, the Company has expanded its revenue recognition policy in Note 2 of the combined financial statements on page F-10 of the prospectus to clarify its accounting treatment for the reimbursement of development costs under the joint collaboration and license agreement with Takeda.

51. As you have commenced promotional activities in April 2006, please disclose how you propose to account for the reimbursement of these expenses by Takeda. Please specifically address whether you will be presenting the reimbursement gross versus net on your statement of operations and the justification for doing so given the factors described in EITF 99-19.

## **RESPONSE:**



In January 2006, the Company and Takeda entered into a supplemental agreement to the joint collaboration and license agreement whereby Takeda agreed to reimburse the Company for specified selling and marketing expenses. The Company's accounting policy is to report the reimbursement of these selling and marketing costs as gross revenue as opposed to a reduction of expenses incurred. The Company assessed EITF 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, in arriving at this conclusion. Specifically, the Company performed the following assessment of EITF 99-19, which indicated the Company is the principal in this arrangement:

- Indicators of gross revenue reporting:
  - The company is the primary obligor in the arrangement The Company is responsible for providing the sales and marketing activities. The Company has the ability to use internal or external sales representatives, determine the compensation structure for those sales representatives, and manage the day-to-day operations in order to ensure the sales and marketing activities are successful. This indicates the Company is acting as the principal in this arrangement.
  - *The company has latitude in establishing price* The Company negotiated the reimbursement amount when the supplemental agreement was executed. This indicates the Company is acting as a principal in the arrangement.
  - *The company changes the product or performs part of the service* The Company is performing all of the service for this arrangement. This indicates the Company is acting as a principal in the arrangement.
  - *The company has discretion in supplier selection* The Company, at its sole discretion, decided to use a third-party contract sales organization to assist in the creation of its sales force. This indicates the Company is acting as a principal in the arrangement.
  - The company is involved in the determination of product or service specifications The Company is responsible for managing sales staff in any manner it feels is appropriate. This indicates the Company is acting as a principal in the arrangement.
  - *The company has credit risk* The Company carries the credit risk for receivables related to the reimbursement of selling and marketing expenses. The Company's obligations to fund the sales and marketing activities incurred to date would be unaffected by non-payment of the Takeda receivables. This indicates the Company is acting as a principal in the arrangement.
- Indicators within the guidance that are not deemed applicable:
  - The company has general inventory risk This indicator is not applicable as no product is sold under the supplemental agreement.
  - The company has physical loss inventory risk This indicator is not applicable as no product is sold under the supplemental agreement.



The Company also assessed the guidance in EITF 01-14, *Income Statement Characterization of Reimbursements Received for 'Out-of-Pocket' Expenses Incurred*, and determined that this assessment did not change the above conclusions.

In response to this comment, the Company has expanded its revenue recognition policy in Note 2 of the combined financial statements on page F-11 of the prospectus to explain how the Company will account for the reimbursement of the sales and marketing expenses from Takeda.

## Note 7. Notes Payable — Related Parties, page F-18

52. Please reconcile for us the amounts presented under "issuance of notes payables — related parties" and "payments on notes payables — related parties" in the Combined Statements of Cash Flows to the amounts disclosed within note 7.

## **RESPONSE:**

The Company advises you that it has identified immaterial errors in the combined statements of cash flows and certain disclosures in Note 7 for the years ended December 31, 2003 and 2004. The Company inadvertently misclassified, for cash flow purposes only, repayments on a related party note payable to R-Tech and the associated non-cash interest expense related to amortization of the discount in the "effect of exchange rate changes on cash and cash equivalents" line item. The Company also applied incorrect exchange rates for issuances of selected foreign currency-denominated notes payable in the statements of cash flows for the years ended December 31, 2003 and 2004 and in certain of the disclosures in Note 7 (related solely to the U.S. dollar amounts disclosed for issuances of notes).

The Company was aware of the application of incorrect exchange rates in the statements of cash flows for 2003 and 2004 prior to the filing of the initial Form S-1 and decided not to record such adjustments after concluding with its Audit Committee that such amounts were not material. Such adjustments were maintained as unrecorded adjustments in an amount of \$125,000 to \$150,000 for both years and related solely to the statements of cash flows for these years.

The Company was not aware of the errors related to the note payable to R-Tech and certain disclosures in Note 7 at the time of the S-1 filing.

Although the Company believes that the above errors are not quantitatively or qualitatively material, the Company believes it is prudent to correct the combined statements of cash flows for the years ended December 31, 2003 and 2004. In addition to the revised combined statements of cash flows, the Company has added disclosure to Note 1 on page F-7



("Revisions to Combined Financial Statements") to describe the background of the errors and the impact of the corrections to the statements of cash flows. The Company does not believe that the errors are material so as to require a restatement. The Company further notes that the errors did not impact cash balances, the combined balance sheets, statements of operations and comprehensive (loss) income or statements of changes in stockholders' (deficit) equity for any period presented.

The net effect of these errors in 2003 was to overstate operating cash outflows by approximately \$87,000, understate financing cash outflows by approximately \$473,000 and misstate the effect of exchange rate changes on cash and cash equivalents by approximately \$386,000. The net effect of these errors in 2004 was to understate operating cash inflows by approximately \$64,000, understate financing cash outflows by approximately \$453,000 and misstate the effect of exchange rate changes on cash and cash equivalents by approximately \$389,000.

The Company has evaluated the materiality of these errors based on the criteria in Staff Accounting Bulletin No. 99 ("SAB 99"), *Materiality*. Based on this analysis, the Company has determined that the above errors are not quantitatively or qualitatively material to the combined financial statements for the years ended December 31, 2003 and 2004. The Company does not believe that the absolute dollar values of these errors are quantitatively material when viewed in light of traditional "rule-of-thumb" materiality measures. From a qualitative perspective, the Company believes that shareholders, creditors, potential investors and other interested parties generally focus on the Company's revenue growth, product development, research and development "pipeline", acceptance of its initial product, market potential for its product(s) and cash balances. The Company evaluated all qualitative factors outlined in SAB 99 and determined that the errors were not qualitatively material.

The Company further notes that its research and development efforts have primarily been funded by Takeda through a joint collaboration and license agreement, in which the Company has received over \$100 million to date for up-front licensing, research and development reimbursement and various milestone payments. The Company does not believe that a reasonable investor would be misled by the errors related to the note payable in the financing and operating sections of the combined statements of cash flows for the years ended December 31, 2003 and 2004, respectively. Further, the Company does not believe that the corresponding errors in the "effect of exchange rates on cash and cash equivalents" line would change the investment decisions of a reasonable investor.

After revising the statements of cash flows for 2003 and 2004 and revising certain of the U.S. dollar amounts of notes payable in Note 7, the Company presents below a reconciliation of "issuance of notes payables — related parties" in the combined statements of cash flows to the amounts disclosed in Note 7.

		Year Ended ember 31, 2003	Year Ended December 31, 2004		Year Ended December 31, 200		Three Months ended March 31, 2006	
Issuance of note payable to Sucampo AG (August 2003)		2,494,800	\$		\$		\$	
Issuance of note payable to S&R Technology Holdings, LLC								
(February and March 2004)		_		1,025,970		_		_
Issuance of note payable to S&R Technology Holdings, LLC								
(May and July 2004)		_		1,217,844		_		_
Issuance of note payable to Sucampo AG (March 2004)		479,270		364,144		_		_
Issuance of note payable to Sucampo AG (February 2006)		_				_		1,200,000
Total disclosed in Note 7		2,974,070		2,607,958		_		1,200,000
Difference		0		0		_		8,182*
Total disclosed in statements of cash flows	\$	2,974,070	\$	2,607,958	\$	_	\$	1,208,182



\* Determined by Company to be de minimis.

It is not possible to reconcile the payments on "notes payable — related parties" information in the statements of cash flows to Note 7, as the U.S. dollar equivalents of the repayments are not disclosed in Note 7 (all notes, with the exception of one, are denominated in foreign currencies). The repayment terms were disclosed, but not the U.S. dollar equivalents of the repayments.

53. Please reconcile your current disclosures of the minimum rate permitted by the Swiss Federal Tax Administration as of December 31, 2005. You disclose this rate to be 2.5% in regards to the August 1, 2003 Sucampo Pharma Ltd. agreement with Sucampo AG (SAG) and 5.0% in regards to the May 7, 2004 Sucampo Pharma Europe (SPE) agreement with SAG and the February 27, 2006 SPE agreement with SAG.

#### **RESPONSE:**

The Company advises you that the rules of the Swiss Federal Tax Administration provide different minimum interest rates depending upon the currency in which the underlying obligation is denominated. In this case, the minimum rate of 2.5% applied to the note from SPL to SAG that was denominated in Japanese Yen, while the minimum rate of 5.0% applied to the note from SPE to SAG that was denominated in British Pounds. The Company has revised the disclosure on pages F-19 and F-20 of the prospectus in response to this comment.

## Note 8. Related Party Transactions, page F-19

54. Please tell us why management deferred commencement of revenue recognition until commercialization of the drug begins for each of the exclusive manufacturing and supply agreements. Please cite appropriate accounting literature relied upon. Additionally, please disclose the estimated contractual life of the relationship.

## **RESPONSE:**

The Company entered into an agreement with R-Tech, a related party, in 2003 providing for R-Tech to have the exclusive right to manufacture and supply AMITIZA during its commercialization period. This agreement included a \$1.0 million non-refundable up-front payment and \$5.0 million in milestone payments, all of which R-Tech paid to the Company in 2003. Also, the Company's affiliate, SPE, entered into a similar agreement with R-Tech in 2005 for a non-refundable up-front payment of \$2.0 million.



The Company assessed SAB 104 in determining the appropriate accounting policy for the nonrefundable up-front payments received from R-Tech. SAB 104 (Section f, nonrefundable up-front fees, Question 1) states that specific facts and circumstances should be considered to determine the appropriate accounting for such up-front payments. If such fees are not in exchange for products delivered or services performed, the fees do not represent a discrete earnings event and deferral of the revenue is appropriate.

The overall purpose of the separate agreements between the Company and SPE with R-Tech was for R-Tech to be the sole supplier of AMITIZA. The nonrefundable up-front and milestone payments were made by R-Tech in consideration for being granted the exclusive right to manufacture and sell the drug to the Company. The Company determined that the cash payments from R-Tech were not in exchange for any products or services at that time and deferred the amount until the underlying earnings event occurred, which was the requirement to begin manufacturing the drug upon approval by the FDA.

The Company will begin to recognize this deferred amount as revenues upon commercialization of the products in the respective jurisdictions and will amortize the amount to revenue over the estimated term of the arrangements. There is no term specified in the arrangement. The Company estimates the term of these arrangements will continue through December 2020. This accounting treatment is also consistent with SAB 104 (Section f, nonrefundable up-front fees, Question 1), as the guidance provides that up-front fees are to be earned as the products and/or services are delivered and/or performed over the term of the arrangement or the expected period of performance.

In response to this comment, the Company has expanded its disclosure in Note 8 to the combined financial statements on page F-20 of the prospectus to clarify why the Company deferred commencement of revenue recognition until commercialization of the drug began and to specify the estimated commercialization period.

# Item 16. Exhibits and Financial Statement Schedules, pages II-3 to II-4

55. Please file your remaining exhibits, including the legal opinion with your next amendment or as soon as it becomes available as we will need time to review it prior to granting effectiveness of the registration statement.

## **RESPONSE:**

The Company understands that you will need time to review all the exhibits prior to granting effectiveness of the registration statement, and will file the remaining exhibits as soon as they become available.



\* \* \* \* \*

As noted above, the Company's responses to the staff's comments are reflected in Pre-Effective Amendment No. 1 to the Registration Statement, which is being filed concurrently herewith.

As requested by the staff, the Company acknowledges that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the Company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the Company may not assert this action as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

\* \* \* \* \*

If you have any questions or comments on the application, please contact either me at (202) 663-6224 or Bryant Morris at (202) 663-6058.

Respectfully,

/s/ Brent B. Siler

Brent B. Siler

cc: Ms. Sonia Barros
Ms. Christine Allen
Mr. Kevin Woody
Securities and Exchange Commission
Sachiko Kuno, Ph.D
Ms. Mariam Morris
Jeffrey D. Karpf, Esq.