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

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**Amendment No. 7**  
**to**  
**Form S-1**  
**REGISTRATION STATEMENT**  
**UNDER**  
**THE SECURITIES ACT OF 1933**

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**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)*

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**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)*

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**Ryuji Ueno, M.D., Ph.D., Ph.D.**  
**Chief Executive Officer**  
**Sucampo Pharmaceuticals, Inc.**  
**4733 Bethesda Avenue, Suite 450**  
**Bethesda, Maryland 20814**  
**(301) 961-3400**  
*(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)*

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**Copies to:**

**Brent B. Siler, Esq.**  
**Wilmer Cutler Pickering Hale and Dorr LLP**  
**1875 Pennsylvania Ave., NW**  
**Washington, District of Columbia 20006**  
**(202) 663-6000**  
**(202) 663-6363 (fax)**

**Jeffrey D. Karpf, Esq.**  
**Cleary Gottlieb Steen & Hamilton LLP**  
**One Liberty Plaza**  
**New York, New York 10006**  
**(212) 225-2000**  
**(212) 225-3999 (fax)**

**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.

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.  \_\_\_\_\_

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.  \_\_\_\_\_

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.  \_\_\_\_\_

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**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.**

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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 June 25, 2007

## Shares



### Class A Common Stock

Sucampo Pharmaceuticals, Inc. is offering \_\_\_\_\_ shares of class A common stock and the selling stockholders are offering \_\_\_\_\_ shares of class A common stock. This is the initial public offering of our class A common stock. No public market currently exists for our class A common stock. We will not receive any of the proceeds from the sale of class A common stock by the selling stockholders. 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	\$ _____	\$ _____
Proceeds to selling stockholders	\$ _____	\$ _____

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 and one of the selling stockholders have granted the underwriters the right to purchase up to an additional \_\_\_\_\_ shares of our class A common stock to cover over-allotments. 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 \_\_\_\_\_, 2007.

**Leerink Swann & Company**

, 2007

You should rely only on the information contained in this prospectus. We and the selling stockholders have not, and the underwriters have not, authorized anyone to provide you with information or information different from that contained in this prospectus. We and the selling stockholders 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 consolidated subsidiaries, Sucampo Pharma Europe Ltd. and Sucampo Pharma, Ltd.

SUCAMPO® and AMITIZA® are our registered trademarks and our logo is our 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 consolidated 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 recently completed two pivotal Phase III clinical trials and a long-term safety trial of AMITIZA for the treatment of irritable bowel syndrome with constipation. Based on the results of these trials, we expect to seek marketing approval for AMITIZA for the treatment of this indication by submitting a supplement to our existing new drug application, or NDA, for AMITIZA by July 2007. In addition, we plan to commence Phase III pivotal clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction by the third quarter of 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. We have performed all of the development activities with respect to AMITIZA and Takeda has funded a portion of the cost for these activities. We have retained the rights to develop and commercialize AMITIZA outside the United States and Canada and to develop and commercialize it in the United States and Canada for indications other than gastrointestinal indications.

### **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, disorders associated with cystic fibrosis and chronic obstructive pulmonary disease. We have completed Phase I trials of SPI-8811 for NSAID-induced ulcers and a Phase II trial in patients with cystic fibrosis. We plan to commence a Phase II clinical trial of SPI-8811 to treat NSAID-induced ulcers by the third quarter of 2007, a Phase II proof of concept study of SPI-8811 in patients with portal hypertension in 2007, and a Phase II trial of SPI-8811 for gastrointestinal disorders associated with cystic fibrosis by the second quarter of 2008. This last Phase II trial is different than the Phase II trial we have already completed for cystic fibrosis. 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 commence Phase I clinical trials of the intravenous formulation of SPI-017 and Phase I clinical trials of the oral formulation in 2008.

### **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 commercialization 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, with a particular focus on treating indications in the elderly population.
- Seek marketing approval for AMITIZA and our other product candidates outside the United States.
- 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 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 June 30, 2011 or the date upon which our founders, Drs. Sachiko Kuno and Ryuji Ueno, no longer control our company, then the commercial rights to that compound will revert to Sucampo AG, subject to a 15-month 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 extension period.

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. Kuno and Dr. 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 controlling stockholders of our company and are married to each other. Dr. Ueno is our chief executive officer and the chairman of our board of directors and Dr. Kuno was, until recently, also an executive officer and director of our company.

#### **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, 2007, we had an accumulated deficit of \$22.9 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 Dr. Ueno, our chief executive and chief scientific officer, and our other key executives. 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 bowel 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. In September 2006, we acquired 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 were previously under common control with us. Sucampo Europe and Sucampo Japan are now wholly owned subsidiaries of our company.



	<b>The Offering</b>
Class A common stock we are offering	shares
Class A common stock the selling stockholders are offering	<u>shares</u>
Total class A common stock offered	shares
Common stock to be outstanding after this offering:	
Class A	shares
Class B	<u>3,081,300 shares</u>
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 over-allotment 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 function; additional clinical trials and sales and marketing efforts by our European and Asian operating subsidiaries; development of other prostate 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." We will not receive any of the proceeds from the sale of shares of our class A common stock by the selling stockholders.
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, 2007. The number of shares to be outstanding after this offering excludes:
	<ul style="list-style-type: none"><li>• 135,400 shares of our class A common stock issuable upon the exercise of stock options outstanding as of May 31, 2007 at a weighted average exercise price of \$70.51 per share; and</li><li>• 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.</li></ul>
	Unless otherwise noted, all information in this prospectus assumes:
	<ul style="list-style-type: none"><li>• no exercise of the outstanding options described above;</li><li>• no exercise by the underwriters of their option to purchase up to      shares of class A common stock to cover over-allotments; and</li><li>• the conversion of all outstanding shares of our preferred stock into an aggregate of 378,000 shares of class A common stock, which will occur automatically upon the closing of this offering.</li></ul>

### Summary Consolidated Financial Data

The following is a summary of our consolidated financial information. You should read this information together with our consolidated 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.

In September 2006, we acquired all of the capital stock of Sucampo Europe and Sucampo Japan. Accordingly, we have presented our financial statements on a consolidated basis as a merger of entities under common control for all periods presented to reflect this transaction. The pro forma net income per share amounts and the number of shares used in computing pro forma per share amounts give effect to the conversion of our convertible preferred stock into class A common stock.

The pro forma as adjusted balance sheet data set forth below gives 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.

As discussed in note 2 to our consolidated financial statements, we have restated our consolidated financial statements for the years ended December 31, 2004 and 2005 and the three months ended March 31, 2006 to correct for revenue recognition errors.

	Years Ended December 31,			Three Months Ended March 31,	
	2004 (Restated)	2005 (Restated)	2006	2006 (Restated)	2007
	(in thousands, except per share data)				
<b>Statement of operations data:</b>					
Revenues	\$ 3,839	\$ 40,205	\$59,267	\$ 24,168	\$ 12,960
Operating expenses:					
Research and development	14,036	31,167	16,392	6,120	5,946
General and administrative	8,216	7,760	14,587	2,968	2,834
Selling and marketing	—	295	11,103	948	3,231
Milestone royalties — related parties	1,000	1,500	1,250	1,250	—
Product royalties — related parties	—	—	1,172	—	410
(Loss) income from operations	(19,413)	(517)	14,763	12,882	539
Total non-operating (expense) income, net	(56)	990	2,141	425	318
(Loss) income before income taxes	(19,469)	473	16,904	13,307	857
Income tax (provision) benefit	—	(789)	4,897	—	(341)
Net (loss) income	\$ (19,469)	\$ (316)	\$21,801	\$ 13,307	\$ 516
Basic net (loss) income per share	\$ (5.08)	\$ (0.08)	\$ 5.39	\$ 3.47	\$ 0.13
Diluted net (loss) income per share	\$ (5.08)	\$ (0.08)	\$ 5.34	\$ 3.41	\$ 0.12
Weighted average common shares outstanding — basic	3,835	3,835	4,045	3,836	4,117
Weighted average common shares outstanding — diluted	3,835	3,835	4,081	3,898	4,168
Basic pro forma net income per share					\$ 0.11
Diluted pro forma net income per share					\$ 0.11
Pro forma weighted average common shares outstanding — basic					4,495
Pro forma weighted average common shares outstanding — diluted					4,546

As of March 31, 2007

<u>Actual</u>	<u>Pro Forma As Adjusted</u>
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(in thousands)

**Balance sheet data:**

Cash and cash equivalents	\$ 15,692
Short-term investments	29,399
Working capital	40,483
Total assets	62,168
Total liabilities	23,253
Accumulated deficit	(22,850)
Total stockholders' equity	38,915

## 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 consolidated 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 initiated commercial sales of our first product, AMITIZA, for the treatment of chronic idiopathic constipation in adults in April 2006, and we first generated product royalty revenue in the quarter ended June 30, 2006. Since our formation, we have incurred significant operating losses and, as of March 31, 2007, we had an accumulated deficit of \$22.9 million. Our net losses were \$19.5 million in 2004 and \$316,000 in 2005. Although we had net income of \$21.8 million in 2006 and \$516,000 in the first quarter of 2007, this was primarily attributable to our receipt of development milestone payments totaling \$50.0 million in 2005 and 2006, which we are recognizing as revenue over the development period, which we estimate will be completed by June 2007. 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 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 increased significantly in 2006 and the first quarter of 2007. Whether we are able to achieve operating profitability in the future will depend upon our ability to generate revenues that exceed our expenses. Changes in market conditions, including the failure or approval of competing products, may require us to incur more expenses or change the timing of expenses such that we may incur unexpected losses. 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, including irritable bowel syndrome with constipation, 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 recorded our first product royalty revenue from AMITIZA in the quarter ended 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 our internal specialty sales force, 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 irritable bowel syndrome with constipation, and acceptance of the results of these trials by regulatory authorities; 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 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 accomplishing this transition. Our operations to date have been limited largely 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 continue 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 are currently utilizing 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 chief executive and chief scientific officer and other key executives, we may not be able to successfully develop and commercialize our products, particularly in light of the recent resignation of our president and chair of our board of directors.***

We are highly dependent on Dr. Ryuji Ueno, our chief executive officer and chief scientific officer, and the other principal members of our executive and scientific teams, including Ronald Kaiser, our chief financial officer, Mariam Morris, our chief accounting 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 company 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 and it might be difficult to recruit a replacement executive for any of their positions. 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.

Dr. Sachiko Kuno, who had been serving as our president and chair of our board of directors, resigned as an executive officer and director of our company effective May 31, 2007. Although we expect that Dr. Kuno will continue to work for our company as a part-time employee, many of her duties will need to be assumed by our existing senior executives until we are able to identify and hire one or more additional senior executives to take her place. This could distract our senior management from their existing responsibilities and compromise our ability to effectively manage our company.

***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. The challenges of managing our growth will become more significant as we expand the operations of Sucampo Europe and Sucampo Japan. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***We previously 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 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.

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- 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.

In connection with the restatement of our consolidated financial statements as of and for the year ended December 31, 2005 for errors in our deferred tax assets and our accounting for fully vested non-employee options granted, we identified additional control deficiencies that constitute material weaknesses in the design and operation of our internal controls over financial reporting. In particular:

- We did not maintain effective controls over the completeness, accuracy and valuation of accounting for certain income tax balances. Specifically, effective controls were not designed and in place to periodically assess, at an appropriate level of detail, the "more likely than not" criteria for recognition of deferred tax assets. This control deficiency resulted in adjustments to the deferred tax asset valuation allowance and the income tax provision accounts, which resulted in a restatement of our consolidated financial statements as of and for the year ended December 31, 2005. Additionally, this control deficiency could result in a misstatement of the deferred tax asset valuation allowance and income tax provision 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 valuation and accuracy of accounting for non-employee stock options. Specifically, effective controls were not designed and in place to value the options using the contractual term as opposed to an expected term. This control deficiency resulted in adjustments to the research and development expenses and additional paid-in capital accounts and resulted in a restatement of our financial statements as of and for the year ended December 31, 2005. Additionally, this control deficiency could result in a misstatement of operating expenses and additional paid-in capital accounts that would result in a material misstatement to our interim or annual financial statements that would not be prevented or detected.

The remediation of one of these material weaknesses is ongoing as described in "Management's Discussion and Analysis of Financial Condition and Results of Operations." We cannot assure you that we will be able to remediate this weakness.

If we are unable to remediate our remaining material weakness, 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. 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 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, or Sarbanes-Oxley, 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 June 30, 2011 or the date upon which Drs. Kuno and Ueno no longer control our company. Following 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 15 months following the expiration of the specified period. At the end of that 15-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 end of the specified period, 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 24 months after the end of the specified period, 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 II trials of SPI-8811, specifically the trials for the treatment of non-alcoholic fatty liver disease and for the treatment of symptoms associated with cystic fibrosis, were inconclusive. Therefore, further clinical testing will be required in connection with the development of this compound for these indications;
- design of or 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, or perform additional 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 or contrary to 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, in patients with renal impairment and in patients with 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 broadly market AMITIZA for the treatment of chronic idiopathic constipation in adults and for other constipation-related gastrointestinal indications, if approved, 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.

In accordance with the terms of our agreement with Ventiv, we have notified Ventiv that we intend to terminate our agreement with them effective July 1, 2007 and to internalize a significant portion of their sales staff as employees of our company. This internalization effort may not succeed and our ability to generate revenues and profits may be adversely affected.

***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. A competitive product might become more popular if it is approved for sale over the counter. 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<sup>®</sup>, 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 March 2007, Zelnorm was withdrawn from the U.S. market by Novartis at the request of the FDA, but continues to be sold in other countries and may be acquired for use by individuals in the United States and in other markets. Zelnorm may be re-introduced to the U.S. and other markets at a later date and the FDA has indicated that it may allow Zelnorm to be prescribed to some patients under a special program in the meantime. In addition, the osmotic laxatives MiraLax<sup>™</sup> (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 short-term treatment of occasional constipation. Miralax was recently approved for sale as an over-the-counter treatment.

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 DDP733, being developed by Dynogen Pharmaceuticals, Inc. and currently in Phase II clinical trials; and
- Opioid antagonists such as methylnaltrexone, being developed by Progenics Pharmaceuticals, Inc., for the treatment of opioid-induced bowel dysfunction. Progenics and its partner Wyeth Pharmaceuticals recently filed an NDA with the FDA for a subcutaneous formulation of this drug for the treatment of opioid-induced bowel dysfunction in patients receiving palliative care.

Many patients are treated for chronic idiopathic constipation with competing over-the-counter products that are sold for occasional or infrequent use or for recurring use and that are directly competitive with our products.

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 for the treatment of chronic idiopathic constipation 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.

The recent withdrawal of Zelnorm from the U.S. market might adversely affect market acceptance of AMITIZA. The FDA requested that Novartis discontinue marketing Zelnorm based on a recently identified finding of an increased risk of serious cardiovascular adverse events associated with use of the drug. Although the mechanism of action of AMITIZA is different from that of Zelnorm, and although AMITIZA has not been associated with serious adverse cardiovascular events, nonetheless the withdrawal of Zelnorm may result in heightened concerns in the minds of some patients or physicians about the safety of using alternative treatments such as AMITIZA.

In addition, Adolor Corporation, the developer of an opioid antagonist, Entereg® (alvimopan), for the treatment of opioid-induced bowel dysfunction, recently announced that it was withdrawing its protocol for an additional Phase III clinical trial of Entereg to treat this condition, which had previously been filed with the FDA. This decision was reportedly based upon preliminary Phase III trial safety results that suggest potential links between use of Entereg and adverse cardiovascular events, tumor development and bone fractures. It is possible that this development, coming so shortly after the withdrawal of Zelnorm, could further confuse patients and physicians and lead to reluctance on their part to use and to prescribe new drugs to treat gastrointestinal conditions, even those with different mechanisms of action such as AMITIZA.

***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 and profitably distribute products in these countries could 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 in adult patients and our commercial sales of AMITIZA up to an annual aggregate limit of \$20.0 million and that covers our clinical trials of AMITIZA in pediatric patients up to an annual aggregate limit of \$5.0 million, in each case subject to a per claim deductible. 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;
- our ability to recruit and retain internal staff resources to conduct these activities;
- 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 prostate compounds that we may determine to develop or commercialize. We have granted R-Tech the exclusive right to manufacture and supply AMITIZA to meet our commercial and clinical requirements in the Americas, Europe, the Middle East and Africa until 2026, and we do not have an alternative source of supply for AMITIZA in these or any other territories. 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. In addition, we currently do not have a manufacture or supply arrangement for the supply of AMITIZA in Asia. Our ability to market and sell AMITIZA in Asia also would be significantly impaired if we are unable to enter into a supply and manufacture arrangement with R-Tech or another suitable manufacturer for the supply of AMITIZA in that territory.

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 prostates, 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 prostates 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 prostates. 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 adequate supplies of 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 potential 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 or other regulatory agencies outside the United States may at any time audit or inspect a manufacturing facility to ensure compliance with cGMP or similar regulations. 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. In

addition, if we applied for, but failed to receive, marketing approval from the FDA for this indication, we might not receive up to \$60.0 million of development milestone payments that Takeda is obligated to pay us upon our achievement of future regulatory milestones relating to AMITIZA. We also might not receive up to \$50.0 million of commercial milestone payments that Takeda is obligated to pay us upon the achievement of specified targets for annual net sales revenue from AMITIZA in the United States and Canada.

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 or may use committed resources inefficiently;
- 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.

***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 sales force, we may be exposed to increased risks arising from any misconduct or improper activities of these sales representatives, including the potential off-label promotion of our products or their failure to adhere to standard requirements in connection with product promotion. In addition, we will be exposed to similar risks arising from our previous use of Ventiv's employees to market AMITIZA. Although our agreement with Ventiv will terminate effective July 1, 2007, any misconduct or inappropriate activities by Ventiv employees prior to termination could create future liabilities for us, and any misconduct or inappropriate activities might not come to light for an extended period after the termination. 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. For example, approximately 130 separate clinical investigators participated in our trials for irritable bowel syndrome with constipation. We use multiple contract research organizations to coordinate the efforts of our clinical investigators and to accumulate the results of our trials. 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. Kuno and Dr. Ueno are married to each other. Ownership interests of our founders in the stock of R-Tech or Sucampo AG, and Dr. Ueno's service as a director and executive officer of our company, 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 end of the specified period; 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, we 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 subsidiaries and 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 prostate 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.

Because we rely on Takeda to provide a significant portion of the sales force that is selling AMITIZA, we are dependent to some degree on Takeda to promptly and properly report any safety issues encountered in the field. If Takeda or their sales representatives fail to provide timely and accurate reporting of any safety issues that arise in connection with AMITIZA, our business and reputation could be harmed.

***Failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our products outside the United States and could adversely affect our reputation and our product marketing activities within 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 competitive with one or more 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 our product candidate SPI-8811 for the treatment of disorders associated with 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. 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, who was, until recently, an executive officer and director of our company, and Dr. Ryuji Ueno, our chief executive officer, chief scientific officer and a director, will together beneficially own 317,765 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, who are married, 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, 2007, we had outstanding stock options to purchase an aggregate of 135,400 shares of class A common stock at a weighted average exercise price of \$70.51 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, the \_\_\_\_\_ 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 \_\_\_\_\_ 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 estimate that the net proceeds from this offering will be approximately \$      million, or approximately \$      million if the underwriters exercise their over-allotment option in full, assuming an 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. A \$1.00 increase or decrease in the assumed initial public offering price of \$      per share would increase or decrease the net proceeds to us from this offering by \$      million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We will not receive any of the proceeds from the sale of shares of our class A common stock in this offering by the selling stockholders.

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

- up to \$1.0 million to fund our share of two post-marketing studies of AMITIZA to evaluate its safety in patients with renal impairment and patients with hepatic impairment;
- up to \$2.0 million to fund our share of development expenses for AMITIZA for the treatment of opioid-induced bowel dysfunction, including the Phase III pivotal clinical trials we plan to initiate by the third quarter of 2007;
- approximately \$18.0 million to fund development and regulatory 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 II proof-of-concept study of SPI-8811 in patients with portal hypertension;
  - a Phase II clinical trial of SPI-8811 in patients with cystic fibrosis; and
  - Phase I clinical trials of an intravenous formulation of SPI-017 for peripheral arterial and vascular disease and stroke;
- up to \$12.0 million to fund the expansion of our commercialization activities in the United States and the initiation of commercialization efforts in non-U.S. markets;
- up to \$3.0 million to fund additional clinical trials and regulatory efforts by Sucampo Europe and Sucampo Japan for AMITIZA and SPI-8811;
- up to \$6.0 million for research 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:
  - the 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, 2007:

- on an actual basis; and
- on a pro forma basis to give effect to 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 consolidated financial statements and the related notes appearing elsewhere in this prospectus and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	<u>As of March 31, 2007</u>		
	<u>Actual</u>	<u>Pro Forma</u>	<u>Pro Forma</u>
	<u>(in thousands)</u>		
Cash and cash equivalents	\$ 15,692	\$ 15,692	\$
Short-term investments	29,399	29,399	
<b>Stockholders’ equity:</b>			
Series A convertible preferred stock, \$0.01 par value; 3,780 shares issued and outstanding, actual; no shares issued and outstanding, pro forma and pro forma as adjusted	\$ 20,288	\$ —	\$
Class A common stock, \$0.01 par value; 1,035,222 shares issued and outstanding, actual; 1,413,222 shares issued and outstanding, pro forma; and        shares issued and outstanding, pro forma as adjusted	10	14	
Class B common stock, \$0.01 par value; 3,081,300 shares outstanding, actual, pro forma and pro forma as adjusted	31	31	
Additional paid-in capital	41,709	61,993	
Accumulated other comprehensive loss	(273)	(273)	
Accumulated deficit	(22,850)	(22,850)	
Total stockholders’ equity	38,915	38,915	
<b>Total capitalization</b>	<b>\$ 38,915</b>	<b>\$ 38,915</b>	<b>\$</b>

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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:

- 137,000 shares of our class A common stock issuable upon the exercise of stock options at a weighted average exercise price of \$70.68 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 net tangible book value as of March 31, 2007 was \$34.4 million, or \$8.35 per share of common stock. Net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding. On a pro forma basis, after giving effect to 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, our net tangible book value as of March 31, 2007 was \$7.64 per share of common stock.

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, 2007 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	\$ _____
Actual net tangible book value per share as of March 31, 2007	\$8.35
Decrease per share attributable to conversion of preferred stock	<u>0.71</u>
Pro forma net tangible book value per share as of March 31, 2007	7.64
Increase per share attributable to new investors	<u>          </u>
Pro forma as adjusted net tangible book value per share after this offering	_____
Dilution per share to new investors	<u>          </u> <u>          </u>

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.

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The following table summarizes as of March 31, 2007, 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.

	<b>Total Class A and Class B Shares</b>		<b>Total Consideration</b>		<b>Average Price Per Share</b>
	<b>Number</b>	<b>%</b>	<b>Amount</b>	<b>%</b>	
Existing stockholders	4,494,522	%	\$ 55,273,011	%	\$ 12.30
New investors					
<b>Total</b>		<b>100.0%</b>	<b>\$</b>	<b>100.0%</b>	

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, 2007 and excludes:

- 137,000 shares of our class A common stock issuable upon the exercise of stock options at a weighted average exercise price of \$70.68 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 , or approximately % of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors will be increased to , or approximately %, of the total number of shares of our common stock outstanding after this offering.



## SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data in conjunction with our consolidated 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. In September 2006, we acquired all of the capital stock of Sucampo Europe and Sucampo Japan. Accordingly, we have presented our financial statements on a consolidated basis as a merger of entities under common control for all periods presented to reflect this transaction. The pro forma net income per share amounts and the number of shares used in computing pro forma per share amounts give effect to the conversion of our convertible preferred stock into class A common stock. We have derived the following consolidated financial data as of December 31, 2005 and 2006 and for the four years ended December 31, 2006 from consolidated financial statements audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm. Consolidated balance sheets as of December 31, 2005 and 2006 and the related consolidated 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, 2006 and notes thereto appear elsewhere in this prospectus. We have derived the following consolidated financial data as of December 31, 2002, 2003 and 2004 and for the year ended December 31, 2002 from unaudited consolidated financial statements, which are not included in this prospectus. We have derived the following consolidated financial data as of March 31, 2007 and for the three months ended March 31, 2006 and 2007 from unaudited consolidated financial statements, which appear elsewhere in this prospectus, which we have prepared on the same basis as the audited consolidated financial 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. As discussed in note 2 to our consolidated financial statements, we have restated our consolidated financial statements for the years ended December 31, 2004 and 2005 and the three months ended March 31, 2006 to correct for revenue recognition errors.

	Year Ended December 31,					Three Months Ended March 31,	
	2002	2003	2004 (Restated)	2005 (Restated)	2006	2006 (Restated)	2007
(in thousands, except per share data)							
<b>Statement of operations data:</b>							
Revenues	\$ 8,097	\$ 4,125	\$ 3,839	\$ 40,205	\$ 59,267	\$ 24,168	\$ 12,960
Operating expenses:							
Research and development	12,549	18,445	14,036	31,167	16,392	6,120	5,946
General and administrative	6,536	7,447	8,216	7,760	14,587	2,968	2,834
Selling and marketing	—	—	—	295	11,103	948	3,231
Milestone royalties — related parties	—	—	1,000	1,500	1,250	1,250	—
Product royalties — related parties	—	—	—	—	1,172	—	410
Total operating expenses	19,085	25,892	23,252	40,722	44,504	11,286	12,421
(Loss) income from operations	(10,988)	(21,767)	(19,413)	(517)	14,763	12,882	539
Total non-operating income (expense), net	7,721	(250)	(56)	990	2,141	425	318
(Loss) income before income taxes	(3,267)	(22,017)	(19,469)	473	16,904	13,307	857
Income tax (provision) benefit	(681)	—	—	(789)	4,897	—	(341)
Net (loss) income	\$ (3,948)	\$ (22,017)	\$ (19,469)	\$ (316)	\$ 21,801	\$ 13,307	\$ 516
Basic net (loss) income per share	\$ (1.06)	\$ (5.75)	\$ (5.08)	\$ (0.08)	\$ 5.39	\$ 3.47	\$ 0.13
Diluted net (loss) income per share	\$ (1.06)	\$ (5.75)	\$ (5.08)	\$ (0.08)	\$ 5.34	\$ 3.41	\$ 0.12
Weighted average common shares outstanding — basic	3,720	3,831	3,835	3,835	4,045	3,836	4,117
Weighted average common shares outstanding — diluted	3,720	3,831	3,835	3,835	4,081	3,898	4,168
Basic pro forma net income per share							\$ 0.11
Diluted pro forma net income per share							\$ 0.11
Pro forma weighted average common shares outstanding — basic							4,495
Pro forma weighted average common shares outstanding — diluted							4,546

	As of December 31,				As of	
	2002	2003	2004	2005	2006	March 31,
			(Restated)	(Restated)		2007
			(in thousands)			
<b>Balance sheet data:</b>						
Cash and cash equivalents	\$31,393	\$ 19,070	\$ 21,918	\$ 17,436	\$ 22,481	\$ 15,692
Short-term investments	—	—	3,000	28,435	29,399	29,399
Working capital	27,850	14,834	7,850	10,051	40,623	40,483
Total assets	32,455	20,072	25,837	47,985	67,084	62,168
Notes payable — related parties, current	250	271	4,040	848	—	—
Notes payable — related parties, net of current portion	241	3,352	2,326	2,546	—	—
Total liabilities	4,463	14,196	39,375	58,225	28,551	23,253
Accumulated deficit	(3,366)	(25,382)	(44,852)	(45,167)	(23,366)	(22,850)
Total stockholders' equity (deficit)	27,992	5,876	(13,538)	(10,240)	38,533	38,915

## 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 consolidated 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.*

### **Restatement of Previously Issued Consolidated Financial Statements**

We have restated our previously issued consolidated financial statements and related footnotes as of December 31, 2005, for the years ended December 31, 2004 and 2005 and for the three months ended March 31, 2006. We have restated our consolidated financial statements to correct an error in accounting for the revenue recognition of our collaboration and license agreement and related agreements with Takeda Pharmaceutical Company Limited, or Takeda. All amounts in this discussion and analysis have been updated to reflect this restatement. For additional information regarding this restatement, see note 2 to our consolidated financial statements.

The error we are correcting in the restatement originated in the fourth quarter of 2004 and continued throughout 2005. The identification of this error occurred as a result of our reevaluation of the assumptions we used under Emerging Issues Task Force, or EITF, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables", or EITF 00-21, in accounting for arrangements with multiple deliverables that require significant judgment and estimates.

We reassessed the stand-alone value to Takeda of the deliverables under our joint collaboration and license agreement with Takeda, at the time we became obliged to make such deliverables, by examining objective and reliable evidence of the fair value of the undelivered items. As a result of this reassessment, we determined that the previous application of a single unit of accounting for the deliverables from the joint collaboration and license agreement with Takeda was not appropriate. In addition, we determined that the substantive milestone method of revenue recognition we had been using was not appropriate to account for the cash payments received from Takeda related to our completion of these required deliverables and that a time-based model would be more appropriate to account for these cash payments. Accordingly, in the restated consolidated financial statements for the years ended December 31, 2004 and 2005, we reduced the milestone revenue and increased research and development revenue. Total revenue increased by \$1.2 million for the year ended December 31, 2004 and decreased by \$6.8 million for the year ended December 31, 2005. In addition, related deferred revenue increased by \$5.6 million at December 31, 2005.

We will report the correct balances in our consolidated financial statements for the quarters ended June 30, 2006 and September 30, 2006 when we next file them. All data included in this discussion and analysis for the years ended December 31, 2004 and 2005 and for the three months ended March 31, 2006 are derived from our restated financial statements for those periods.

### **Overview**

We are an emerging pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostanes, 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.

We and Takeda initiated commercial sales of AMITIZA for the treatment of chronic idiopathic constipation in adults in April 2006, and we first generated product royalty revenue in the quarter ended June 30, 2006. Since inception we have incurred operating losses and, as of March 31, 2007, we had an accumulated deficit of \$22.9 million. Our net losses were \$19.5 million in 2004 and \$316,000 in 2005. We recognized net income of \$21.8 million in 2006 and \$516,000 for the three months ended March 31, 2007. The historical 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 for other compounds as they are developed 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 June 30, 2011 or 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 15-month extension in the case of any compound that we designate in good faith as planned for development within that extension period.

In September 2006, we acquired all of the capital stock of two affiliated European and Asian operating companies, Sucampo Europe and Sucampo Japan, that were previously under common control with us. Sucampo Europe and Sucampo Japan are now wholly owned subsidiaries of our company. In this prospectus, we have presented financial statements that reflect our financial position, results of operations and cash flows on a consolidated basis with these two operating companies because the acquisition was consummated during the year ended December 31, 2006, and this management's discussion and analysis of financial condition and results of operations discusses such consolidated 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, in patients with renal impairment and in patients with hepatic impairment. We initiated these studies in January 2007. In addition, we are developing AMITIZA to treat irritable bowel syndrome with constipation and opioid-induced bowel dysfunction. We recently completed two pivotal Phase III clinical trials of AMITIZA for the treatment of irritable bowel syndrome with constipation and a follow-on safety study to assess the long-term use of AMITIZA as a treatment for this indication. Based on the results of these trials, we expect to seek marketing approval for AMITIZA for the treatment of this indication by submitting a supplement to our existing new drug application, or NDA, for AMITIZA by July 2007. In addition, we plan to commence Phase III pivotal clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction by the third quarter of 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 commence a Phase II clinical trial of this product candidate for the treatment of NSAID-induced ulcers by the third quarter of 2007. We also plan to commence a Phase 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 commence Phase I clinical trials of the intravenous formulation of SPI-017 and Phase I clinical trials of the oral formulation in 2008.

#### **Financial Terms of our Collaboration with Takeda**

We entered into a 16-year collaboration agreement with Takeda in October 2004 to jointly develop and commercialize AMITIZA for gastrointestinal indications in the United States and Canada. We also entered into a related supplemental agreement with Takeda in February 2006. Under the terms of these agreements, 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 original agreement with Takeda, we received a non-refundable up-front payment of \$20.0 million. We deferred \$2.4 million of this up-front payment associated with our obligation to participate in joint committees with Takeda and we are recognizing this amount as collaboration revenue ratably over the 16-year life of the agreement. We are recognizing the remaining \$17.6 million as research and development revenue ratably over the estimated development period associated with the chronic idiopathic constipation and irritable bowel syndrome with constipation indications, which we estimate will be completed by June 2007 as evidenced by the filing with the FDA of a supplement to our existing NDA for AMITIZA relating to the treatment of irritable bowel syndrome with constipation.

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

We have also received the following non-refundable 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 are recognizing each of these payments as research and development revenue ratably over the estimated development period associated with the chronic idiopathic constipation and irritable bowel syndrome with constipation indications, which we estimate will be completed by June 2007.

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 research and development revenue ratably over the respective performance periods.

### ***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 are recognizing each of these payments as research and development revenue ratably over the estimated development period associated with the chronic idiopathic constipation and irritable bowel syndrome with constipation indications, which we estimate will be completed by June 2007, 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.

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. Of this next \$20.0 million, we had incurred \$11.0 million through March 31, 2007. 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 impairment and patients with hepatic impairment. We initiated these studies in January 2007. The expenses of these studies, which we began to incur in the quarter ended September 30, 2006, are being shared 70% by Takeda and 30% by us. Through March 31, 2007, we had incurred \$803,000 of these expenses, of which we will be reimbursed \$562,000.
- The expense of Phase IV clinical trials of AMITIZA for the treatment of chronic idiopathic constipation in pediatric patients that we initiated in January 2007 will be borne by Takeda in full. As of March 31, 2007, we had incurred \$2.4 million of these expenses, all of which will be reimbursed by Takeda.
- 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 the third quarter of 2007. We began incurring expenses for these trials in the third quarter of 2006. Currently, we do not anticipate the aggregate expenses necessary to complete our development of AMITIZA for this indication will exceed \$54.0 million, of which Takeda will be responsible for \$52.0 million and we will be responsible for \$2.0 million. As of March 31, 2007, we had incurred \$1.5 million of these expenses.
- 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.

### ***Co-Promotion Expense Reimbursements***

In connection with our exercise of our co-promotion rights under the collaboration agreement and our entry into the related supplemental agreement in February 2006, 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 direct costs for our current sales force of 38 contract sales representatives, which is currently provided under our contract with Ventiv, an independent contract sales organization, but which we plan to internalize beginning in June 2007. We began to receive monthly reimbursement for these expenses during the quarter ended June 30, 2006, reflecting the commencement by our sales representatives of their activities in April 2006, and we had recognized \$3.4 million of co-promotion revenue reflecting these reimbursements through December 31, 2006. In the quarter ended March 31, 2007, we recognized \$974,000 of co-promotion revenue reflecting these reimbursements.

Takeda also agreed in the supplemental agreement to reimburse us for all of the costs we incur in connection with specified miscellaneous marketing activities related to the promotion of AMITIZA. During the year ended December 31, 2006, we recognized \$779,000 of co-promotion revenue reflecting these reimbursements and during the quarter ended March 31, 2007, we recognized \$158,000. We completed the miscellaneous marketing activities to which these reimbursements relate in the quarter ended March 31, 2007 and, accordingly, we do not expect to recognize additional co-promotion revenue related to these activities.

### ***Product Royalty Revenue***

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. We began to recognize product royalty revenue in the quarter ended June 30, 2006, reflecting the commencement of commercial sales of AMITIZA in April 2006. During the year ended December 31, 2006, we recognized a total of \$6.6 million as product royalty revenue under our collaboration agreement with Takeda and during the quarter ended March 31, 2007, we recognized \$2.3 million as product royalty revenue.

### ***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. We had not met these targets as of March 31, 2007.

### ***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.

**Takeda Cash Flows and Revenue**

The following table summarizes the cash streams and related revenue recognition under the Takeda collaboration agreement and the related supplemental agreement:

	Cash Received Through	Revenue Recognized for Year Ended December 31,			Amount Deferred at	Cash Received For the Three	Revenue Recognized For the Three	Amount Deferred at
	December 31, 2006	2004	2005	2006	December 31, 2006	Months Ended March 31, 2007	Months Ended March 31, 2007	March 31, 2007
<i>Collaboration revenue:</i>								
Up-front payment attributable to the joint steering, manufacturing and commercialization committees	\$ 2,376	\$ 24	\$ 147	\$ 147	\$ 2,058	\$ —	\$ 37	\$ 2,021
<i>Research and development revenue:</i>								
Up-front payment — remainder	\$ 17,624	\$ 1,356	\$ 8,134	\$ 6,157	\$ 1,977	\$ —	\$ 1,087	\$ 890
Development milestones	50,000	—	16,154	28,237	5,609	—	3,085	2,524
Reimbursement of research and development expenses	31,507	1,482	14,672	11,988	3,365	3,343	5,194	1,514
Total	\$ 99,131	\$ 2,838	\$ 38,960	\$ 46,382	\$ 10,951	\$ 3,343	\$ 9,366	\$ 4,928
					Accounts Receivable at December 31, 2006			Accounts Receivable at March 31, 2007
Product royalty revenue	\$ 4,561	—	—	\$ 6,590	\$ 2,029	\$ 2,029	\$ 2,309	\$ 2,309
Co-promotion revenue	\$ 3,535	—	—	\$ 4,243	\$ 708	\$ 1,567	\$ 1,132	\$ 273

**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 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 product 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 expensed \$1.2 million in product royalties to Sucampo AG during the year ended December 31, 2006 and \$410,000 during the three months ended March 31, 2007, reflecting 3.2% of net sales for AMITIZA during each of these periods, which we recorded as product royalties to related parties on the consolidated statement of operations.

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. We characterized this payment as a milestone royalty and we expensed it as incurred.



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 December 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, we began recognizing this revenue during the quarter ended June 30, 2006 and will continue recognizing it ratably on a straight-line basis over the remaining life of our supply agreement with R-Tech through 2026. As of March 31, 2007, we had recognized a total of \$419,000 as contract revenue from related parties under our exclusive supply arrangement with R-Tech.

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, 2007.

### **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 non-refundable 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 \$67,000 in revenue under this agreement in 2004, which we characterized as contract revenue. All revenues related to this agreement were recognized by the first quarter of 2004. In 2004, we determined not to continue this relationship, and we allowed the collaboration agreement to expire.

## Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our consolidated 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 3 of our consolidated financial statements.

## Revenue Recognition

### *Collaboration and License Agreements*

Our primary sources of revenue include up-front payments, product development milestone payments, reimbursements of research and development expenses, reimbursement of co-promotion costs related to our specialty sales force and miscellaneous marketing activities, and product royalties. We recognize revenue from these sources in accordance with Staff Accounting Bulletin, or SAB, 104, "Revenue Recognition", EITF No. 99-19, "Reporting Revenue Gross as a Principal Versus Net as an Agent", and EITF No. 00-21, "Revenue Arrangements with Multiple Deliverables". The application of EITF 00-21 requires subjective analysis and requires us to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable from the other aspects of the contractual arrangement into separate units of accounting and, if so, to determine the fair value to be allocated to each unit of accounting.

We evaluated the multiple deliverables within our joint collaboration and license agreement and the related supplemental agreement with Takeda in accordance with the provisions of EITF 00-21 to determine whether our deliverables have value to Takeda on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. We separately evaluate deliverables that meet these criteria for the purposes of revenue recognition. We combine deliverables that do not meet these criteria and account for them as a single unit of accounting.

In accordance with EITF 00-21, we recognize the cash flows associated with the individual units of accounting from the joint collaboration and license agreement as revenue using a time-based model that recognizes the revenue ratably over the period in which we complete our performance requirements. However, revenue is limited to amounts that are non-refundable and that Takeda is contractually obligated to pay. With respect to the portion of the up-front payment we attributed to our obligation to participate in joint committees with Takeda, which we present as collaboration revenue, the performance period is the 16-year term of the collaboration agreement. With respect to the remainder of the up-front payment, the product development milestone payments and the reimbursement of research and development expenses, all of which we present as research and development revenue, the performance period is the estimated development period for AMITIZA to treat chronic idiopathic constipation and irritable bowel syndrome with constipation. We estimate this performance period will be completed by June 2007 as evidenced by the filing with the FDA of a supplement to our existing NDA for AMITIZA relating to the treatment of irritable bowel syndrome with constipation. We have determined that we are acting as a principal under the collaboration agreement and, as such, we record these amounts on a gross basis as collaboration revenue and as research and development revenue.

Reimbursements of co-promotion costs under the supplemental agreement with Takeda, including costs associated with our specialty sales force and miscellaneous marketing activities, are recognized as

co-promotion revenue as the related costs are incurred and Takeda becomes contractually obligated to pay the amounts. We have determined that we are acting as a principal under the supplemental agreement and, as such, we record reimbursements of these amounts on a gross basis as co-promotion revenue.

Product royalty revenue is based on third-party sales of licensed products. We record these amounts on the accrual basis when earned in accordance with contractual terms when third-party results are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met. Because of the lack of historical data regarding sales returns, we do not report as revenue royalty payments related to the portion of sales by Takeda that are subject to a right of return until the right of return lapses.

We do not immediately recognize as revenue option fees received for other potential joint collaboration and license agreements with Takeda because the transactions do not represent a separate earnings process. Our 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 because we will have contingent performance obligations if and when the options are exercised. We record option fees as contract revenue when they are recognized.

#### ***Other Revenue Sources***

We recorded revenues from the performance of research and development cost reimbursement activities under the collaboration agreement for our discontinued ophthalmic collaborative relationship over the period in which the actual research and development activities occurred, similar to the time-based model, which was equivalent to the term of the collaboration agreement.

We recognize contract revenue related to development activities with related parties under the time-based method and we recognize contract revenue related to consulting activities with related parties as performance is rendered. We record cost-sharing payments received in advance as deferred revenue and recognize these payments as revenue over the applicable clinical trial period.

#### ***Accrued Expenses***

As part of our process of preparing our consolidated 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***

Through December 31, 2005, we elected to follow Accounting Principles Board Opinion, or APB, No. 25, "*Accounting for Stock Issued to Employees*", or APB 25, 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”, or SFAS 123. 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 in 2005, although we did award options to non-employees. In note 3 to our consolidated 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 fair value of the equity instruments is calculated based on the guidance of SFAS 123. 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 of common stock. 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 class A common stock for stock option awards. Our board of directors determined this fair value. In establishing the estimates of fair value, our board of directors considered the guidance set forth in the AICPA Practice Guide, “*Valuation of Privately-Held-Company Equity Securities Issued as Compensation*”, and made retrospective determinations of fair value. The board of directors gave significant consideration to the price of the class A common stock sold to unrelated third parties in the first half of 2006 in determining fair value for purposes of the stock options granted to employees shortly after the sales occurred.

Determining the fair value of our class A 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 123. 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-value method of accounting for share-based payments to employees. 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 SFAS 123 pro forma disclosures. On January 1, 2006, we adopted SFAS 123R using the prospective method of implementation. According to the prospective transition method, the previously issued financial statements will not be adjusted.

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.

Our consolidated financial statements as of and for the year ended December 31, 2006 reflect the impact of adopting SFAS 123R. In accordance with the prospective transition method, our consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123R, as all outstanding stock options as of January 1, 2006 were fully vested. During the three months ended March 31, 2007, we recognized stock-based compensation expense of \$203,000 under SFAS 123R, which related to employee stock options granted in May 2006 and August 2006.

### ***Income Taxes***

As part of the process of preparing our consolidated 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, such as deferred revenue, for tax and accounting purposes. These differences have resulted in deferred tax assets and liabilities, which are included in our consolidated balance sheets. We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We consider forecasted earnings, future taxable income, the mix of earnings in the jurisdictions in which we operate, and prudent and feasible tax planning strategies in determining the need for a valuation allowance. In the event we were to determine that we would not be able to realize all or part of our net deferred tax assets in the future, we would charge an adjustment to earnings for the deferred tax assets in the period in which we make that determination. Likewise, if we later determine that it is more likely than not that the net deferred tax assets would be realized, we would reverse the applicable portion of the previously provided valuation allowance. In order for us to realize our deferred tax assets we must be able to generate sufficient taxable income in the tax jurisdictions in which our deferred tax assets are located.

Significant judgment is required in determining the provision for income taxes and, in particular, any valuation allowance recorded against our deferred tax assets. We have recorded a partial valuation allowance of \$9.9 million as of December 31, 2006, which resulted in a net deferred tax asset of \$4.9 million as of December 31, 2006, due to uncertainties related to our ability to utilize a portion of the deferred tax assets in years beyond 2007. Significant future events, including marketing approval by the FDA of AMITIZA for the treatment of irritable bowel syndrome with constipation, are not in our control and could affect our future earnings potential and consequently the amount of deferred tax assets that will be utilized. We determined the amount of the valuation allowance based on our estimates of income in the jurisdictions in which we operate over the periods in which the related deferred tax assets are recoverable.

As of December 31, 2006, we had foreign net operating loss carryforwards of \$2.2 million. The foreign net operating loss carryforwards will begin to expire on December 31, 2010. As of December 31, 2006, we had U.S. general business tax credits of \$4.4 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 partial valuation allowance as an offset to our net deferred tax assets due to the uncertainty in determining the timing of the realization of certain tax benefits. 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 evaluated the terms of transactions similar to those that would have prevailed had the entities not been affiliated.

## Results of Operations

### Comparison of three months ended March 31, 2006 and March 31, 2007

#### Revenues

The following table summarizes our revenues for the three months ended March 31, 2006 and 2007:

	Three Months Ended March 31,	
	2006	2007
	(Restated)	
	(in thousands)	
Research and development revenue	\$ 22,441	\$ 9,366
Contract revenue	1,500	—
Collaboration revenue	37	37
Contract revenue — related parties	29	116
Product royalty revenue	—	2,309
Co-promotion revenue	161	1,132
Total	<u>\$ 24,168</u>	<u>\$12,960</u>

Total revenues were \$13.0 million for the three months ended March 31, 2007 compared to \$24.2 million for the three months ended March 31, 2006, a decrease of \$11.2 million. This decrease was primarily due to a decrease in payments received from Takeda for research and development services performed by us.

Research and development revenue was \$9.4 million for the three months ended March 31, 2007 compared to \$22.4 million for the three months ended March 31, 2006, a decrease of \$13.0 million. This decrease was primarily due to our progress in the development of AMITIZA to treat chronic idiopathic constipation and irritable bowel syndrome with constipation and the recognition of payments previously received from Takeda. We recognize our revenue for this development work ratably over the estimated performance period associated with the development of AMITIZA. We initially estimated the development period would be completed in December 2006. As a result of new study evaluation requirements released by the Rome III Committee on Functional Gastrointestinal Disorders, an international committee of gastroenterologists, we concluded in June 2006 that the completion of the development period would not occur until May 2007. During the three months ended March 31, 2007, we extended the estimated completion of the development period from May 2007 to June 2007 as a result of discussions with Takeda. These determinations to extend the estimated completion date from December 2006 to May 2007 and then to June 2007 had the effect of lengthening the period over which any revenue not then recognized would be recognized.

The specific revenue streams associated with research and development revenue for the three months ended March 31, 2006 and 2007 were as follows:

- In March and May 2005, we received development milestone payments from Takeda totaling \$30.0 million related to our efforts to develop AMITIZA. We are recognizing these payments as research and development revenue ratably over the performance period, resulting in \$3.5 million of research and development revenue for the three months ended March 31, 2006 and \$1.9 million for the three months ended March 31, 2007. The smaller amount of revenue recognized for the three months ended March 31, 2007 is a result of our determinations to extend the estimated completion of the development period.
- In January 2006, we received a \$20.0 million development milestone payment from Takeda related to our efforts to develop AMITIZA, which we are recognizing as research and development revenue ratably over the performance period, resulting in \$13.1 million of research and development revenue for the three months ended March 31, 2006 and \$1.2 million for the three months ended March 31, 2007. We recognized a significant portion of this milestone payment in the three months ended March 31, 2006, the quarter in which it was received, reflecting the fact that we were then well into the estimated development period. The smaller amount of revenue for the three months ended March 31, 2007 also reflects our determinations, subsequent to our receipt of this payment, to extend the estimated completion of the development period.

- We have received a total of \$30.0 million of reimbursement payments for research and development costs from Takeda related to our efforts to develop AMITIZA, which we are recognizing as research and development revenue ratably over the performance period, resulting in \$3.5 million of research and development revenue for the three months ended March 31, 2006 and \$1.9 million for the three months ended March 31, 2007. The smaller amount of revenue recognized for the three months ended March 31, 2007 is a result of our determinations to extend the estimated completion of the development period.
- In October 2004, we received an up-front payment of \$20.0 million from Takeda, of which \$17.6 million was associated with the development of AMITIZA. This amount is being recognized ratably over the estimated performance period, resulting in \$2.0 million of research and development revenue for the three months ended March 31, 2006 and \$1.1 million for the three months ended March 31, 2007. The smaller amount of revenue recognized for the three months ended March 31, 2007 is a result of our determination in June 2006 to extend the estimated completion of the development period from December 2006 to May 2007.
- We also began to perform services and receive payments from Takeda during the third quarter of 2006 for the following three deliverables: post-marketing studies to evaluate the safety of AMITIZA in patients with renal impairment and patients with hepatic impairment, Phase IV clinical trials of AMITIZA for the treatment of chronic idiopathic constipation in pediatric patients and clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction. Total research and development revenue associated with these three deliverables for the three months ended March 31, 2007 was \$3.3 million.

We had no contract revenue for the three months ended March 31, 2007, compared to \$1.5 million for the three months ended March 31, 2006. Contract revenue represents amounts released from 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. We recognized all of this deferred revenue in the three months ended March 31, 2007.

Upon receipt of the \$20.0 million up-front payment in 2004, we deferred \$2.4 million to be recognized using the time-based model over the 16-year performance period of our participation in the committee meetings. During each of the three months ended March 31, 2006 and 2007, we recognized \$37,000 of this deferred amount as collaboration revenue.

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 \$116,000 for the three months ended March 31, 2007 compared to \$29,000 for the three months ended March 31, 2006, an increase of \$87,000.

Product royalty revenue represents payments received from Takeda relating to net sales of AMITIZA. We began to recognize the royalty payments from Takeda as revenue in the second quarter of 2006 following the product launch of AMITIZA. For the three months ended March 31, 2007, we recognized \$2.3 million of product royalty revenue.

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force and costs associated with miscellaneous marketing activities in connection with the commercialization of AMITIZA. For the first quarter of 2006, we received approximately \$161,000 in reimbursement of costs for miscellaneous marketing activities. We began to receive reimbursement of costs for our sales force in the second quarter of 2006 following the product launch of AMITIZA. For the three months ended March 31, 2007, we recognized \$1.1 million of co-promotion revenues, of which approximately \$158,000 was for reimbursement of costs for miscellaneous marketing activities and \$974,000 was for reimbursement of sales force costs.

#### ***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 to minimize our overhead. We expense our research and development costs as incurred.

Total research and development expenses for the three months ended March 31, 2007 were \$5.9 million compared to \$6.1 million for the three months ended March 31, 2006, a decrease of \$174,000. In the three months ended March 31, 2006 and 2007, our research and development expenses were primarily those associated with the ongoing Phase III clinical trials of AMITIZA for the treatment of irritable bowel syndrome with constipation.

It is not practical for us to break out historical research and development expenses by research project or by compound 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 our prostone compounds. Finally, we have not historically maintained records that allocate research and development costs among different compounds, indications or projects.

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, we are obligated to 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 development expenses by approximately \$1.7 million per year. We began to incur patent maintenance costs in late 2006. In the three months ended March 31, 2007, we incurred patent maintenance costs of approximately \$118,000, which are included in research and development expenses.

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.

#### ***General and Administrative Expenses***

General and administrative expenses consist primarily of expenses for salaries and related personnel costs and expenses for corporate activities.



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The following table summarizes our general and administrative expenses for the three months ended March 31, 2006 and 2007:

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2007</b>
	<b>(Restated)</b>	
	<b>(in thousands)</b>	
Salaries, benefits and related costs	\$ 1,389	\$1,547
Legal and consulting expenses	893	720
Other operating expenses	686	567
Total	<u>\$ 2,968</u>	<u>\$2,834</u>

General and administrative expenses were \$2.8 million for the three months ended March 31, 2007 compared to \$3.0 million for the three months ended March 31, 2006, a decrease of \$134,000. This decrease was due primarily to a cumulative out-of-period adjustment of \$358,000 that we recorded during the three months ended March 31, 2007 to reduce stock-based compensation expense that we had previously recorded for the year ended December 31, 2006. This adjustment, which reduced our general and administrative expenses for the three months ended March 31, 2007, was offset in part by approximately \$224,000 of increased general and administrative expenses related to increases in operational headcount and costs related to our operation of Sucampo Europe and Sucampo Japan, whose capital stock we acquired in September 2006. We expect to incur significant increases in our general and administrative expenses as we adopt public reporting requirements, implement enhanced financial reporting controls to comply with Sarbanes-Oxley and improve consolidation procedures and controls related to Sucampo Europe and Sucampo Japan.

In June 2007, the compensation committee of our board of directors authorized a one-time stock and cash award to each of Drs. Kuno and Ueno, which will be made immediately following this offering. These awards are described in more detail under the caption "Certain Relationships and Related Party Transactions — Special Stock and Cash Awards to Drs. Kuno and Ueno". The value of these awards will depend upon the public offering price per share in this offering. Assuming a public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, the aggregate value of these grants would be \$ . We are in the process of determining the accounting for these awards. We expect the value of these awards to result in a material charge to our financial statements in a period subsequent to the three months ended March 31, 2007.

### ***Selling and Marketing Expenses***

Selling and marketing expenses represent costs we incur to co-promote AMITIZA and other selling and marketing expenses, including costs for market research and analysis, marketing and promotional materials, product samples and other costs.

Selling and marketing expenses were \$3.2 million for the three months ended March 31, 2007 compared to \$948,000 for the three months ended March 31, 2006, an increase of \$2.3 million. During the three months ended March 31, 2006, the selling and marketing expenses we incurred were primarily in anticipation of our commercial launch of AMITIZA in April 2006. These expenses were significantly less than those we incurred during the three months ended March 31, 2007, when our co-promotion efforts were fully operational.

In connection with our termination of our contract sales agreement with Ventiv and our internalization of our specialty sales force, we expect to incur approximately \$250,000 of transition expenses, primarily recruiting and training expenses and a termination fee we will pay to Ventiv, which will affect our selling and marketing expenses for the quarter ending September 30, 2007. We also anticipate that our ongoing expenses relating to this sales force will increase by approximately \$400,000 annually over what those expenses would have been if we had maintained the Ventiv relationship, due to compensation increases we expect to implement.

### ***Milestone Royalties to Related Parties***

Milestone royalties to related parties were \$1.3 million for the three months ended March 31, 2006. 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 development milestone payment we received from Takeda during that period, and a \$250,000 milestone payment for regulatory approval of AMITIZA. We did not pay any milestone royalties to related parties in the three months ended March 31, 2007.

### ***Product Royalties to Related Parties***

Product royalties to related parties represent our obligation to pay Sucampo AG a royalty of 3.2% of net sales of AMITIZA in North, Central and South America, including the Caribbean. The product 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 began to incur product royalty expenses for net sales of AMITIZA in the second quarter of 2006 following the product launch of AMITIZA. In the quarter ended March 31, 2007, we expensed \$410,000 in product royalties to related parties. Accordingly, we did not owe any product royalties to related parties for the three months ended March 31, 2006.

### ***Non-Operating Income and Expense***

The following table summarizes our non-operating income and expense for the three months ended March 31, 2006 and 2007:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2006</b>	<b>2007</b>
	<b>(Restated)</b>	
	<b>(in thousands)</b>	
Interest income	\$ 306	\$324
Interest expense	(20)	(4)
Other income (expense), net	139	(2)
Total, net	<u>\$ 425</u>	<u>\$318</u>

Interest income was \$324,000 for the three months ended March 31, 2007 compared to \$306,000 for the three months ended March 31, 2006, an increase of \$18,000. The increase was primarily due to an increase in the funds available for investment. Interest expense was \$4,000 for the three months ended March 31, 2007 compared to \$20,000 for the three months ended March 31, 2006, a decrease of \$16,000. This decrease reflected our repayment in full in June 2006 of related party debt instruments issued by Sucampo Japan and Sucampo Europe. Other income (expense), net represents foreign currency exchange gains and losses, which we expect will fluctuate from period to period.

### ***Income Taxes***

For the three months ended March 31, 2006 and 2007, our consolidated effective tax rate was 0.0% and 39.7%, respectively. The change in the effective tax rate for the three months ended March 31, 2007 from the three months ended March 31, 2006 was due primarily to the utilization of approximately \$340,000 in U.S. deferred tax assets. The utilization of our U.S. deferred tax assets for the three months ended March 31, 2006 was offset by a corresponding release of our valuation allowance.

**Comparison of years ended December 31, 2005 and December 31, 2006****Revenues**

The following table summarizes our revenues for the years ended December 31, 2005 and 2006:

	Year Ended December 31,	
	2005	2006
	(Restated)	
	(in thousands)	
Research and development revenue	\$ 38,960	\$46,382
Contract revenue	1,000	1,500
Collaboration revenue	147	147
Contract revenue — related parties	98	404
Product royalty revenue	—	6,591
Co-promotion revenue	—	4,243
Total	<u>\$ 40,205</u>	<u>\$59,267</u>

Total revenues were \$59.3 million in 2006 compared to \$40.2 million in 2005, an increase of \$19.1 million. This increase was primarily due to an increase in payments received from Takeda for research and development services performed by us, product royalties from AMITIZA sales, and reimbursements of co-promotion efforts performed by us to market and sell AMITIZA.

Research and development revenue was \$46.4 million for the year ended December 31, 2006 compared to \$39.0 million for the year ended December 31, 2005, an increase of \$7.4 million. The specific revenue streams associated with research and development revenue for the years ended December 31, 2005 and 2006 were as follows:

- In March and May 2005, we received development milestone payments from Takeda totaling \$30.0 million related to our efforts to develop AMITIZA. These payments are being recognized as research and development revenue ratably over the performance period, resulting in \$16.2 million of research and development revenue in 2005 and \$10.5 million in 2006. The smaller amount of revenue recognized in 2006 is a result of our determination in June 2006 to extend the estimated completion of the development period from December 2006 to May 2007.
- In January 2006, we received a \$20.0 million development milestone payment from Takeda related to our efforts to develop AMITIZA, which is being recognized as research and development revenue ratably over the performance period, resulting in \$17.8 million of research and development revenue in 2006.
- During the year ended December 31, 2005, we received a total of \$28.5 million of reimbursement payments for research and development costs from Takeda related to our efforts to develop AMITIZA, which are being recognized as research and development revenue ratably over the performance period, resulting in \$14.7 million of research and development revenue in 2005 and \$10.5 million in 2006. The smaller amount of revenue recognized in 2006 is a result of our determination in June 2006 to extend the estimated completion of the development period.
- In October 2004, we received an up-front payment of \$20.0 million from Takeda, of which \$17.6 million was associated with the development of AMITIZA. This amount is being recognized ratably over the estimated performance period, resulting in \$8.1 million of research and development revenue during 2005 and \$6.2 million during 2006. The smaller amount of revenue recognized in 2006 is a result of our determination in June 2006 to extend the estimated completion of the development period.
- We also began to perform services and receive payments from Takeda during the year ended December 31, 2006 for the following three deliverables: post-marketing studies to evaluate the safety of AMITIZA in patients with renal impairment and patients with hepatic impairment, Phase IV clinical trials of AMITIZA for the treatment of chronic idiopathic constipation in pediatric patients and clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction. Total research and development revenue associated with these three deliverables during 2006 was \$1.1 million.

Contract revenue was \$1.5 million for the year ended December 31, 2006 compared to \$1.0 million for the year ended December 31, 2005, an increase of \$500,000. Contract revenue represents amounts released from 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.

Upon receipt of the \$20.0 million up-front payment, we deferred \$2.4 million to be recognized using the time-based model over the 16-year performance period of our participation in the committee meetings. During each of the years ended December 31, 2005 and 2006, we recognized \$147,000 of this deferred amount as collaboration revenue.

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 \$404,000 for the year ended December 31, 2006 compared to \$98,000 for the year ended December 31, 2005, an increase of \$307,000.

Product royalty revenue represents payments received from Takeda relating to net sales of AMITIZA. We began to recognize the royalty payments from Takeda as revenue in the second quarter of 2006 following the product launch of AMITIZA. In the year ended December 31, 2006, we recognized \$6.6 million of product royalty revenue. Of this product royalty revenue, we recognized \$4.5 million in the quarter ended June 30, 2006, which reflected stocking purchases by drug wholesalers to establish their initial inventory levels, and therefore these revenues may not be indicative of product royalty revenue levels that we may achieve in future periods.

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force and costs associated with miscellaneous marketing activities in connection with the commercialization of AMITIZA. We began to receive reimbursement of these expenses in the second quarter of 2006 following the product launch of AMITIZA. In the year ended December 31, 2006, we recognized \$4.2 million of co-promotion revenues.

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

Total research and development expenses for the year ended December 31, 2006 were \$16.4 million compared to \$31.2 million for the year ended December 31, 2005, a decrease of \$14.8 million. The higher costs in 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 2006, our research and development expenses were primarily those associated with the ongoing Phase III clinical trials of AMITIZA for the treatment of irritable bowel syndrome with constipation.

### ***General and Administrative Expenses***

The following summarizes our general and administrative expenses for the years ended December 31, 2005 and 2006:

	<b>Year Ended December 31,</b>	
	<b>2005</b>	<b>2006</b>
	<b>(in thousands)</b>	
Salaries, benefits and related costs	\$3,843	\$ 5,342
Legal and consulting expenses	1,565	3,356
Stock-based compensation	138	2,708
Other operating expenses	2,214	3,181
Total	<u>\$7,760</u>	<u>\$14,587</u>

General and administrative expenses were \$14.6 million for the year ended December 31, 2006 compared to \$7.8 million for the year ended December 31, 2005, an increase of \$6.8 million. This increase was due primarily to recognition of \$2.7 million in stock-based compensation expenses following our adoption of SFAS 123R in January 2006, increases in operational headcount, rent for additional leased office space and a one-time bonus payment to our employees upon receipt of marketing approval for AMITIZA to treat chronic idiopathic constipation in adults, as well as professional fees in connection with our acquisition of the capital stock of Sucampo Europe and Sucampo Japan.

#### ***Selling and Marketing Expenses***

Selling and marketing expenses were \$11.1 million for the year ended December 31, 2006 compared to \$295,000 for the year ended December 31, 2005, an increase of \$10.8 million. This increase was due to costs we incurred to launch AMITIZA in April 2006 and other selling and marketing expenses through the remainder of 2006, including costs for market research and analysis, marketing and promotional materials, product samples and other costs.

#### ***Milestone Royalties to Related Parties***

Milestone royalties to related parties were \$1.3 million for the year ended December 31, 2006 compared to \$1.5 million for the year ended December 31, 2005, a decrease of \$200,000. In the year ended December 31, 2006, we paid Sucampo AG \$1.0 million, reflecting the 5% we owed them in respect of the \$20.0 million development milestone payment we received from Takeda during that period, and a \$250,000 milestone payment for regulatory approval of AMITIZA. In the year ended December 31, 2005, we paid Sucampo AG \$1.5 million, reflecting the 5% we owed them in respect of the \$30.0 million development milestone payments we received from Takeda during that period.

#### ***Product Royalties to Related Parties***

We began to incur product royalty expenses for net sales of AMITIZA in the second quarter of 2006 following the product launch of AMITIZA. In the year ended December 31, 2006, we expensed \$1.2 million in product royalties to related parties.

#### ***Non-Operating Income and Expense***

The following table summarizes our non-operating income and expense for the years ended December 31, 2005 and 2006:

	<b>Year Ended December 31,</b>	
	<b>2005</b>	<b>2006</b>
	<b>(in thousands)</b>	
Interest income	\$1,046	\$1,976
Interest expense	(311)	(90)
Other income	255	255
Total, net	<u>\$ 990</u>	<u>\$2,141</u>

Interest income was \$2.0 million for the year ended December 31, 2006 compared to \$1.0 million for the year ended December 31, 2005, an increase of \$1.0 million. The increase was primarily due to an increase in the funds available for investment as a result of our receipt of development milestone payments from Takeda in March 2005, May 2005 and January 2006. Interest expense was \$90,000 for the year ended December 31, 2006 compared to \$311,000 for the year ended December 31, 2005, a decrease of \$221,000. This decrease reflected our repayment in full in December 2005 and June 2006 of related party debt instruments issued by Sucampo Japan and Sucampo Europe.

### Income Taxes

For the years ended December 31, 2005 and 2006, our consolidated effective tax rate was 166.7% and (29.0%), respectively. The change in the effective tax rate for the year ended December 31, 2006 from the year ended December 31, 2005 was due primarily to the discrete release of \$4.9 million from the valuation allowance on a portion of the U.S. deferred tax assets that we believe is more likely than not to be realized.

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

#### Revenues

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

	Year Ended December 31,	
	2004 (Restated)	2005 (Restated)
	(in thousands)	
Research and development revenue	\$ 2,838	\$ 38,960
Contract revenue	69	1,000
Collaboration revenue	24	147
Contract revenue — related parties	411	98
Other income — gain on sale of patent to related party	497	—
Total	<u>\$ 3,839</u>	<u>\$ 40,205</u>

Total revenues were \$40.2 million in 2005 compared to \$3.8 million in 2004, an increase of \$36.4 million. This increase was primarily due to an increase in payments received from Takeda for research and development services performed by us relating to AMITIZA.

Research and development revenue was \$39.0 million for the year ended December 31, 2005 compared to \$2.8 million for the year ended December 31, 2004, an increase of \$36.2 million. This increase was primarily due to our progress in the development of AMITIZA to treat chronic idiopathic constipation and irritable bowel syndrome with constipation and the recognition of payments received from Takeda related to our development work ratably over the estimated development period, which was previously estimated to be completed by December 2006. The specific revenue streams associated with research and development revenue for the years ended December 31, 2004 and 2005 were as follows:

- During the year ended December 31, 2005, we received \$30.0 million of development milestone payments from Takeda related to our efforts to develop AMITIZA, which are being recognized as research and development revenue ratably over the performance period, resulting in \$16.2 million of revenue during 2005. No development milestones were received and recognized as revenue during the year ended December 31, 2004.
- We received \$1.5 million and \$28.5 million of reimbursement payments for research and development costs from Takeda related to our efforts to develop AMITIZA during the years ended December 31, 2004 and 2005, respectively. We recognized the full \$1.5 million as research and development revenue during 2004 and are recognizing the \$28.5 million ratably over the development period, resulting in \$14.7 million of research and development revenue during 2005.
- During the year ended December 31, 2004, we received an up-front payment of \$20.0 million from Takeda, of which \$17.6 million was associated with the development of AMITIZA. This amount is being recognized ratably over the estimated performance period to develop AMITIZA, resulting in \$1.4 million and \$8.1 million of research and development revenue during the years ended December 31, 2004 and 2005, respectively.

During the year ended December 31, 2005, we received \$30.0 million of development milestone payments and \$28.5 million of reimbursement payments for research and development costs from Takeda related to our efforts to develop AMITIZA. Because these amounts were received during 2005, we recognized a partial year

of research and development revenue for the year ended December 31, 2005. During 2005, we also received a \$20.0 million development milestone payment for our related efforts to develop AMITIZA, which will be recognized through the end of the performance period. Total research and development revenue associated with the development of AMITIZA to treat chronic idiopathic constipation and irritable bowel syndrome with constipation was \$39.0 million for the year ended December 31, 2005. In 2004, we did not receive any development milestone payments.

We recognized contract revenue of \$69,000 in 2004 and \$1.0 million in 2005. Contract revenue in 2004 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.

Upon receipt of the \$20.0 million up-front payment, we deferred \$2.4 million to be recognized using the time-based model over the 16-year performance period of our participation in the committee meetings. During the years ended December 31, 2004 and 2005, we recognized \$24,000 and \$147,000, respectively, of this deferred amount as collaboration revenue.

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 research and development expenses were \$31.2 million in 2005 compared to \$14.0 million in 2004, an increase of \$17.1 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 bowel syndrome with constipation and a related follow-on safety trial.

In 2005, we incurred \$3.4 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 \$3.4 million, and we recognized the related expense in full in the period of the grant.

### ***General and Administrative Expenses***

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

	Year Ended	
	2004	2005
	(in thousands)	
Salaries, benefits and related costs	\$4,160	\$3,843
Legal and consulting expenses	2,131	1,565
Stock-based compensation	68	138
Other operating expenses	1,857	2,214
Total	<u>\$8,216</u>	<u>\$7,760</u>

General and administrative expenses were \$7.8 million in 2005 compared to \$8.2 million in 2004, a decrease of \$456,000. 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.

### ***Selling and Marketing Expenses***

Selling and marketing expenses were \$295,000 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 development milestone payments we received from Takeda during the year. We paid \$1.0 million in milestone royalty payments during 2004 related to the \$20.0 million up-front payment we received from Takeda.

### ***Non-Operating Income and Expense***

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

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2004</b>	<b>2005</b>
	<b>(in thousands)</b>	
Interest income	\$ 96	\$1,046
Interest expense	(173)	(311)
Other income	21	255
Total, net	<u>\$ (56)</u>	<u>\$ 990</u>

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 development 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 \$174,000 in 2004, an increase of \$137,000. 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 \$788,000 for the year ended December 31, 2005 compared to \$0 for the year ended December 31, 2004. The increase of \$788,000 resulted from taxes payable on income we recognized during the year ended December 31, 2005 for tax purposes, which we were not able to offset with tax loss carryforwards or realize through future carrybacks. Our U.S. tax loss carryforwards were fully utilized as of December 31, 2005.



**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.

	<u>United States</u>	<u>Europe</u>	<u>Japan</u>	<u>Intercompany Eliminations</u>	<u>Consolidated</u>
	(in thousands)				
<b>Three months ended March 31, 2007</b>					
Total revenues	\$ 12,949	\$ —	\$ 221	\$ (210)	\$ 12,960
Income (loss) from operations	724	(165)	(20)	—	539
Income (loss) before income taxes	1,041	(168)	(16)	—	857
Identifiable assets (end of period)	64,160	351	2,556	(4,899)	62,168
<b>Three months ended March 31, 2006</b>					
Total revenues (restated)	\$ 22,639	\$ 1,500	\$ 29	\$ —	\$ 24,168
Income (loss) from operations (restated)	11,558	1,345	(21)	—	12,882
Income (loss) before income taxes (restated)	11,876	1,337	78	16	13,307
<b>Year Ended December 31, 2006</b>					
Total revenues	\$ 57,677	\$ 1,500	\$ 161	\$ (71)	\$ 59,267
Income (loss) from operations	13,974	980	(190)	(1)	14,763
Income (loss) before income taxes	16,020	934	(52)	2	16,904
Identifiable assets (end of period)	68,943	496	2,544	(4,899)	67,084
<b>Year Ended December 31, 2005</b>					
Total revenues (restated)	\$ 39,107	\$ —	\$ 1,098	\$ —	\$ 40,205
Income (loss) from operations (restated)	115	(1,475)	843	—	(517)
Income (loss) before income taxes (restated)	899	(1,437)	1,011	—	473
Identifiable assets (end of period) (restated)	45,366	1,363	2,576	(1,320)	47,985
<b>Year Ended December 31, 2004</b>					
Total revenues (restated)	\$ 4,170	\$ —	\$ 82	\$ (413)	\$ 3,839
Loss from operations (restated)	(15,557)	(2,424)	(1,432)	—	(19,413)
Loss before income taxes (restated)	(15,702)	(2,628)	(1,139)	—	(19,469)

**Liquidity and Capital Resources****Sources of Liquidity**

We require cash principally to meet our operating expenses. 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, 2007, we had raised net proceeds of \$55.3 million from private equity financings. From inception through March 31, 2007, 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 year ended December 31, 2006 and the three months ended March 31, 2007, principally as a result of the development milestone payments that we received from Takeda. As of March 31, 2007, we had cash and cash equivalents and short-term investments of \$45.1 million. We began receiving cash royalty payments from Takeda for AMITIZA sales in the quarter ended September 30, 2006.

**Cash Flows**

The following table summarizes our cash flows for the years ended December 31, 2004, 2005 and 2006 and the three months ended March 31, 2006 and 2007:

	<b>Year Ended December 31,</b>			<b>Three Months Ended March 31,</b>	
	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2006</u>	<u>2007</u>
	(in thousands)				
<b>Cash provided by (used in):</b>					
Operating activities	\$ 3,210	\$ 23,815	\$ (10,914)	\$ 6,527	\$(6,353)
Investing activities	(3,016)	(25,474)	(1,413)	(108)	(99)
Financing activities	2,292	(2,278)	17,421	20,501	(361)
Effect of exchange rates	362	(545)	(49)	(4)	24
Net increase (decrease) in cash and cash equivalents	<u>\$ 2,848</u>	<u>\$ (4,482)</u>	<u>\$ 5,045</u>	<u>\$26,916</u>	<u>\$(6,789)</u>

**Three months ended March 31, 2007**

Net cash used by operating activities was \$6.4 million for the three months ended March 31, 2007. This reflected net income of \$516,000. We had an increase in accounts receivable of \$1.4 million, primarily related to product royalty revenue for AMITIZA and co-promotion revenues from Takeda and a decrease in deferred revenue of \$6.2 million. The decrease in deferred revenue primarily related to the amortization of deferred research and development revenue over the performance period of the development of AMITIZA.

Net cash used in investing activities was \$99,000 for the three months ended March 31, 2007. This primarily reflected our purchases of property and equipment.

Net cash used in financing activities was \$361,000 for the three months ended March 31, 2007. This reflected payments incurred for our planned initial public offering.

**Year ended December 31, 2006**

Net cash used in operating activities was \$10.9 million for the year ended December 31, 2006. This reflected net income of \$21.8 million, which included a non-cash charge of \$3.3 million of stock-based compensation expense. We also had an increase in accounts receivable of \$2.8 million, primarily related to product royalty revenue for AMITIZA and co-promotion revenues from Takeda, and a decrease in deferred revenue of \$26.8 million. The decrease in deferred revenue primarily related to the amortization of deferred research and development revenue over the performance period of the development of AMITIZA. The decrease of other liabilities of \$1.5 million was the result of our repayment to Takeda of \$1.5 million for the refundable portion of its option payment upon the expiration of its option to negotiate commercialization rights for AMITIZA in Europe, the Middle East and Africa.

Net cash used in investing activities was \$1.4 million for the year ended December 31, 2006. This reflected our purchases of auction rate securities and property and equipment of \$2.5 million, offset in part by proceeds received from sales and maturities of auction rate securities of \$1.3 million.

Net cash provided by financing activities was \$17.4 million for the year ended December 31, 2006. This reflected \$23.9 million in net proceeds raised in a private placement sale of 282,207 shares of class A common stock, \$1.2 million in funds received from borrowings under related party debt instruments, \$2.9 million of payments incurred for our planned initial public offering and \$4.8 million of repayments under related party debt instruments.

**Year ended December 31, 2005 (Restated)**

Net cash provided by operating activities was \$23.8 million for the year ended December 31, 2005. This reflected a net loss of \$316,000, an increase in our deferred revenue of \$20.4 million from research and development payments from Takeda to be amortized over the performance period of the development of AMITIZA and \$3.6 million of non-cash 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 (Restated)**

Net cash provided by operating activities was \$3.2 million for the year ended December 31, 2004. This reflected a net loss of \$19.5 million and an increase in our deferred revenue of \$20.4 million arising primarily from an up-front payment from Takeda, of which \$2.4 million is being recognized over the 16-year period in which we are required to participate in collaboration committee meetings with Takeda and \$17.6 million is being recognized over the performance period of our development of AMITIZA.

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.

**Commitments and Contingencies**

As of March 31, 2007, our principal outstanding contractual obligations related to our office leases in Bethesda, Maryland, England and Japan. The following table summarizes these significant contractual obligations at December 31 for the indicated year:

	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>Thereafter</u>	<u>Total</u>
				<b>(in thousands)</b>			
<i>Contractual obligations:</i>							
Operating leases	\$829	\$1,429	\$1,321	\$969	\$938	\$ 5,159	\$10,645

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 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, 2007, we had incurred \$11.0 million of these costs. We expect to incur \$2.0 million of additional costs in connection with the development of AMITIZA for the treatment of irritable bowel syndrome with constipation and expect to incur approximately \$2.0 million of additional costs in connection with the development of AMITIZA for other indications, such as the treatment of opioid-induced bowel dysfunction, which will not be reimbursed by Takeda.

- 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 our current commitments to contract research organizations at March 31, 2007 to be \$2.6 million for the nine months ending December 31, 2007.

In addition, the FDA has required us to perform two post-marketing studies to evaluate the safety of AMITIZA in patients with renal impairment and patients with 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:

- 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 impairment and patients with hepatic impairment. We initiated these studies in January 2007.
- Up to \$2.0 million to fund our share of development expenses for AMITIZA for the treatment of opioid-induced bowel dysfunction, including the Phase III pivotal clinical trials we plan to initiate by the third quarter of 2007.
- Approximately \$18.0 million to fund development and regulatory activities for SPI-8811 and SPI-017, which we expect will enable us to substantially 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 by the third quarter of 2007;
  - a Phase II proof-of-concept study of SPI-8811 in patients with portal hypertension, which we plan to commence in 2007;
  - a Phase II clinical trial of SPI-8811 in patients with cystic fibrosis, which we plan to commence by the second quarter of 2008; 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 2008;
- Up to \$12.0 million to fund the expansion of our commercialization activities in the United States and the initiation of commercialization efforts in non-U.S. markets;
- Up to \$3.0 million to fund additional clinical trials and regulatory efforts by Sucampo Europe and Sucampo Japan for AMITIZA and SPI-8811;
- Up to \$6.0 million for research 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:
  - the 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 initiated in January 2007.

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 property-related claims;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to establish and maintain collaborations, such as our collaboration with Takeda; and
- changes in our business plan as a result of changes in the market conditions resulting from withdrawal or approval of competing products, such as recently occurred when Novartis withdrew Zelnorm from the U.S. market.

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 evidentiary 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 provide evidence 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 during 2004 and we recorded the full amount as deferred revenue. We first began to recognize these payments as revenue during the quarter ended June 30, 2006 and will continue to recognize them ratably through 2020. 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 provide evidence the agreement did not conflict with taxing guidelines.

For information regarding additional related party transactions, see notes 8 and 9 to our consolidated 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 Financial Accounting Standards Board, or FASB, issued SFAS 123R, which requires companies to expense the estimated fair value of employee stock options and similar awards. SFAS 123R replaces SFAS 123 and supersedes APB 25. In March 2005, the Securities and Exchange Commission, or SEC, issued SAB Bulletin No. 107, "*Share-Based Payments*", or SAB 107, which generally provides the SEC staff's views regarding SFAS 123R. 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 123R such as income taxes, capitalization of compensation costs, modification of share-based payments prior to adoption and the classification of expenses. We have applied the principles of SAB 107 in conjunction with our adoption of SFAS 123R.

As of January 1, 2006, we adopted the provisions of SFAS 123R using a prospective transition method. There was no impact to our consolidated financial statements as a result of this adoption as of January 1, 2006. Under the prospective transition method, SFAS 123R, 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.

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 154 as of January 1, 2006 did not have a material effect on our consolidated 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 consolidated financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, “Accounting for Uncertainty in Income Taxes”, or FIN 48, which is effective as of the interim reporting period beginning January 1, 2007. The validity of any tax position is a matter of tax law, and generally there is no controversy about recognizing the benefit of a tax position in a company’s financial statements when the degree of confidence is high that the tax position will be sustained upon examination by a taxing authority. The tax law is subject to varied interpretation, however, and whether a tax position will ultimately be sustained may be uncertain. Under FIN 48, the impact of an uncertain income tax position on the income tax provision must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. FIN 48 also requires additional disclosures about unrecognized tax benefits associated with uncertain income tax positions and a reconciliation of the change in the unrecognized benefit. In addition, FIN 48 requires interest to be recognized on the full amount of deferred benefits for uncertain tax positions. An income tax penalty is recognized as expense when the tax position does not meet the minimum statutory threshold to avoid the imposition of a penalty. The adoption of FIN 48 as of January 1, 2007 did not have an impact on our consolidated financial statements.

In September 2006, the FASB Staff issued FASB Statement No. 157, “Fair Value Measurements”, or SFAS 157, which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles. The FASB believes that the new standard will make the measurement of fair value more consistent and comparable and improve disclosures about those measures. We will be required to adopt SFAS 157 for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We are assessing SFAS 157, but we currently do not believe it will have a material impact on our consolidated financial statements.

In September 2006, the SEC Staff issued SAB No. 108, “Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements”, or SAB 108. SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year’s financial statements are materially misstated. SAB 108 will be effective for our consolidated financial statements in the fourth quarter of 2006. We evaluated the requirements of SAB 108 and concluded that its adoption did not have a material effect on our consolidated financial statements.

In February 2007, the FASB Staff issued FASB Statement No. 159, “*The Fair Value Option for Financial Assets and Financial Liabilities*”, or SFAS 159, which provides entities with the opportunity to measure certain financial instruments at fair value. We will be required to adopt SFAS 159 for the year beginning January 1, 2008. We do not believe SFAS 159 will have a material impact on our future consolidated financial statements.

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

In connection with the 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, accrued expenses, 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 2.7% of our total revenues in the year ended December 31, 2006 and 0.1% of our total revenues for the three months ended March 31, 2007.

In connection with the restatement of our consolidated financial statements as of and for the year ended December 31, 2005 for errors in our deferred tax assets and our accounting for fully vested options granted, we identified additional control deficiencies that constitute material weaknesses in the design and operation of our internal controls over financial reporting. In particular:

- We did not maintain effective controls over the completeness, accuracy and valuation of accounting for certain income tax balances. Specifically, effective controls were not designed and in place to periodically assess, at an appropriate level of detail, the “more likely than not” criteria for recognition



of deferred tax assets. This control deficiency resulted in adjustments to the deferred tax asset valuation allowance and the income tax provision accounts, which resulted in a restatement of our consolidated financial statements as of and for the year ended December 31, 2005 and for the three months ended March 31, 2006. Additionally, this control deficiency could result in a misstatement of the deferred tax asset valuation allowance and income tax provision 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 valuation and accuracy of accounting for non-employee stock options. Specifically, effective controls were not designed and in place to value the options using the contractual term as opposed to an expected term. This control deficiency resulted in adjustments to the research and development expenses and additional paid-in capital accounts and resulted in a restatement of our financial statements as of and for the year ended December 31, 2005. Additionally, this control deficiency could result in a misstatement of operating expenses and additional paid-in capital accounts that would result in a material misstatement to our interim or annual financial statements that would not be prevented or detected.

We have taken steps to remediate the material weaknesses in the areas of maintaining effective controls over the completeness and accuracy of revenue recognition and accounting for debt instruments at Sucampo Europe and Sucampo Japan, the completeness, accuracy and valuation of accounting for income tax balances, and the valuation and accuracy of accounting for non-employee stock options, including the implementation of the following controls and processes:

- transferring the authority to execute agreements and incur indebtedness from Sucampo Europe and Sucampo Japan to our headquarters;
- establishing and implementing formal processes for analyzing and approving accounting for contracts and debt agreements;
- establishing formal controls for review of the accuracy and proper cut-off of revenue recognition and accrued expenses at Sucampo Europe and Sucampo Japan to be completed at our headquarters;
- hiring a third-party tax consultant to assist in our calculation and evaluation of our annual and interim income tax accounting, including the deferred tax asset valuation allowance and provision accounts; and
- hiring a third-party specialist to assist in the calculation of the fair value of all non-employee equity awards granted.

We have not yet fully remediated the material weaknesses in the area of effective controls over the preparation, review and presentation of financial information prepared in accordance with U.S. generally accepted accounting principles reflecting Sucampo Europe's and Sucampo Japan's operations. If we are unable to remediate this material weakness, 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.

We have concluded that the control deficiency that resulted in the restatement of the consolidated financial statements for the years ended December 31, 2004 and 2005 as a result of the revenue recognition error did not constitute a material weakness because management determined that there were controls designed and in place to prevent or detect a material misstatement and, therefore, the likelihood of revenue being materially misstated is not more than remote.

The process of improving our internal controls has required and will continue to require us to expend significant resources to design, implement and maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. There can be no assurance that any actions we take will be successful. We will continue to evaluate the effectiveness of our disclosure controls and procedures and internal control over financial reporting on an on-going basis.

## 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 have performed all of the development activities with respect to AMITIZA and Takeda has funded a portion of the cost for these activities. We have retained the rights to develop and commercialize AMITIZA outside the United States and Canada and to develop and commercialize it in the United States and Canada for indications other than gastrointestinal indications.

We also plan to pursue marketing approval for AMITIZA for additional constipation-related gastrointestinal indications with large, underserved markets. We recently completed two pivotal Phase III clinical trials and a long-term safety trial of AMITIZA for the treatment of irritable bowel syndrome with constipation. In these trials, AMITIZA improved overall relief from symptoms associated with irritable bowel syndrome with constipation with statistical significance and was well tolerated. We expect to seek marketing approval for AMITIZA for the treatment of this indication by submitting a supplement to our existing new drug application, or NDA, for AMITIZA by July 2007. In addition, we plan to commence Phase III pivotal clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction by the third quarter of 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, disorders associated with cystic fibrosis and chronic obstructive pulmonary disease. We have completed Phase I clinical trials of SPI-8811 in healthy volunteers and plan to commence a Phase II clinical trial of this product candidate for the treatment of NSAID-induced ulcers by the third quarter of 2007. We also plan to commence a Phase 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 commence Phase I clinical trials of the intravenous formulation of SPI-017 and Phase I clinical trials of the oral formulation in 2008.

We hold an exclusive worldwide royalty-bearing license from Sucampo AG, a Swiss patent-holding company, to develop and commercialize AMITIZA and 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 June 30, 2011 or 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 15-month extension in the case of any compound that we designate in good faith as planned for development within that extension period.

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. We currently hold all of the commercialization rights to the prostone compounds in our product pipeline, other than for commercialization of AMITIZA in the United States and Canada, which is covered by our collaboration and license agreement with Takeda.

<b>Product/ Product Candidate</b>	<b>Target Indication</b>	<b>Development Phase</b>	<b>Next Milestone</b>
AMITIZA	Chronic idiopathic constipation (adult)	Marketed	—
	Chronic idiopathic constipation (pediatric)	Phase IV pediatric trial ongoing	—
	Irritable bowel syndrome with constipation	Phase III trial completed	Supplemental NDA expected to be filed by July 2007
	Opioid-induced bowel dysfunction	Planning Phase III pivotal trial	Phase III pivotal trial planned to commence by the third quarter of 2007
SPI-8811	<i>Gastrointestinal</i>		
	Non-steroidal anti-inflammatory drug (NSAID) induced ulcers	Phase I testing completed	Phase II trial planned to commence by the third quarter of 2007
	Cystic fibrosis — gastrointestinal disorders (oral formulation)	Phase II trial completed	Phase II dose-ranging trial planned to commence in 2008
	<i>Liver</i>		
	Portal hypertension	Preclinical testing completed	Phase II proof-of-concept study planned to commence in 2007
	Non-alcoholic fatty liver disease	Phase II trial completed	Pending availability of new diagnostic tool
	<i>Pulmonary</i>		
	Cystic fibrosis — respiratory symptoms (inhaled formulation)	Preclinical	Finalize inhaled formulation
SPI-017	Peripheral arterial and vascular disease	Preclinical	Phase I trials of intravenous formulation planned to commence in 2008*
	Stroke	Preclinical	
	Alzheimer's disease	Preclinical	Phase I trials of oral formulation planned to commence in 2008*
	* Results from Phase I trials of both intravenous and oral formulations may be useful in development of any of these indications.		

**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 initial 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 commercial sales 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 obligated to provide a dedicated sales force of at least 200 people to promote AMITIZA and a supplemental sales force of at least 500 people to promote AMITIZA together with one other drug product, although Takeda has advised us that their supplemental sales force currently consists of over 600 people. We are complementing Takeda's marketing efforts by promoting AMITIZA in the institutional marketplace through a specialty sales force consisting of 38 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, with a particular focus on treating indications in the elderly population.** 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, disorders associated with 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 outside the United States.** We plan to pursue marketing approval for AMITIZA and our other product candidates in markets outside the United States, including Europe, the Asia Pacific region and Latin America. 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 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 manufactures 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 other gastrointestinal indications in the United States and Canada; 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. In addition, we may decide to outsource clinical development activities for some of the compounds and indications in our product pipeline if we determine it would be more cost-effective to do so. For example, we may conclude that it is more economical to license SPI-8811 for pulmonary indications, such as respiratory symptoms of cystic fibrosis and chronic obstructive pulmonary disease, to a third party who would conduct the necessary clinical development activities in support of those indications.

**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 a specialty sales and marketing function focused on the institutional market and we have significant experience in pharmaceutical research and product development, including clinical trials and regulatory affairs. We believe that the institutional focus of our specialty sales force would facilitate our ability to sell additional products targeted at a variety of indications in several therapeutic fields that are concentrated in the institutional setting. This institutional market is characterized by a concentration of elderly patients. We believe that these capabilities will help us to identify attractive acquisition, in-licensing and co-promotion opportunities to build upon our core clinical development and commercialization capabilities.

## Products and Product Candidates

### AMITIZA® (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 both genders and 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 MiraLax™ (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. MiraLax was recently approved for sale as an over-the-counter treatment. 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, was often prescribed. In March 2007, at the request of the FDA, Zelnorm was withdrawn from the U.S. market by Novartis. The FDA requested that Novartis discontinue marketing Zelnorm based on a recently identified finding of an increased risk of serious cardiovascular adverse events associated with use of the drug. The FDA indicated that it might allow Zelnorm to be prescribed under a special program to some patients for whom no other treatment options are available and in whom the benefits of Zelnorm treatment outweigh the chance of serious side effects. The FDA also indicated a willingness to consider limited re-introduction of Zelnorm in the United States if a population of patients can be identified in whom the benefits of the drug outweigh the risks, following discussion at a public advisory committee meeting. Even before its withdrawal, however, Zelnorm was 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, electrolyte imbalance and cardiovascular ischemic events.

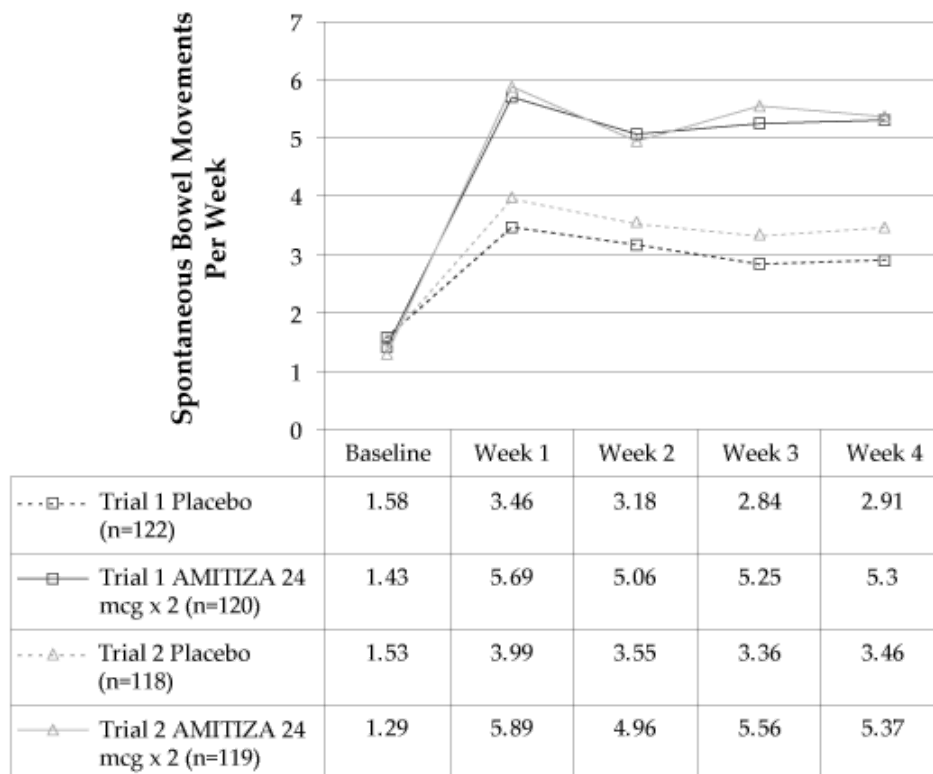
**Clinical Trial Results.** In connection with obtaining FDA marketing approval of AMITIZA, we conducted a comprehensive program of clinical trials of this drug for use in treating chronic idiopathic constipation. This clinical program included two Phase III pivotal trials and three long-term safety 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 statistical significance, increasing the frequency of spontaneous bowel movements from baseline during the first week of treatment by 75% in one pivotal trial and 78% in the second pivotal trial, in each case with a p-value less than 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, open-label, 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, in patients with renal impairment and in patients with hepatic impairment. We initiated the studies in January 2007.

### ***Irritable Bowel Syndrome with Constipation***

We have conducted 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 took 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 March 2007, however, at the request of the FDA, Zelnorm was withdrawn from the U.S. market by Novartis. The FDA requested that Novartis discontinue marketing Zelnorm based on a recently identified finding of an increased risk of serious cardiovascular adverse events associated with use of the drug. The FDA indicated that it might allow Zelnorm to be prescribed under a special program to some patients for whom no other treatment options are available and in whom the benefits of Zelnorm treatment outweigh the chance of serious side effects. The FDA also indicated a willingness to consider limited re-introduction of Zelnorm in the United States if a population of patients can be identified in whom the benefits of the drug outweigh the risks, following discussion at a public advisory committee meeting. 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. Adverse events appeared to be dose-dependent between the 16 and 48 microgram AMITIZA treatment groups and occurred more frequently in the AMITIZA treatment group than in the placebo treatment group. Nausea was reported by 19% of participants dosed at 16 micrograms and 31% of participants dosed at 48 micrograms, and diarrhea was reported by 14% of participants dosed at 16 micrograms and 27% of participants dosed at 48 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 were 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 was a subjective assessment of the participant's overall relief from the symptoms of irritable bowel syndrome

with constipation. The secondary efficacy endpoints were similar to those for our Phase II clinical trials of AMITIZA for this indication and involved subjective assessments of such factors as abdominal discomfort and pain, bloating, straining, stool consistency, severity of constipation and quality of life components. The first of the two pivotal studies was followed by a randomized withdrawal period to assess the effects, if any, associated with withdrawal of AMITIZA over a four-week period. We also initiated an additional follow-on safety study to assess the long-term use of AMITIZA as a treatment for this indication.

In these trials, participants receiving AMITIZA at a dose of 8 micrograms twice daily were more likely to achieve overall relief from symptoms compared to those receiving the placebo, with 17.9% of the AMITIZA group achieving overall relief compared to 10.1% for the placebo group, with a p-value of 0.001. In both trials individually, participants receiving AMITIZA experienced overall relief from symptoms at higher rates than those receiving the placebo, with p-values of 0.009 in one trial and 0.031 in the other. In the combined trials, the secondary endpoints of abdominal discomfort and pain, stool consistency, straining, constipation severity and quality of life were improved with statistical significance in participants receiving AMITIZA compared to those receiving the placebo.

AMITIZA was well-tolerated in these studies, with a similar incidence of serious adverse events, 1% in both the AMITIZA group and the placebo group, and related adverse events, with 22% in the AMITIZA group compared to 21% in the placebo group. The most common treatment-related adverse events were nausea, which was reported by 8% of participants receiving AMITIZA and 4% of those receiving the placebo, and diarrhea, which was reported by 6% of the AMITIZA group and 4% of the placebo group. Abdominal pain was higher in the placebo group, with 5% reporting this adverse event compared to 4% of the AMITIZA group. Discontinuation rates for adverse events were lower in participants receiving AMITIZA, with 5% discontinuing compared to 6% of those receiving the placebo.

Based on these trial results, we expect to seek marketing approval for AMITIZA for the treatment of this indication by submitting a supplement to our existing NDA for AMITIZA by July 2007.

### ***Opioid-Induced Bowel Dysfunction***

We plan to commence Phase III pivotal clinical trials of orally administered AMITIZA gelatin capsules for the treatment of opioid-induced bowel dysfunction by the third quarter of 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, portal hypertension and gastrointestinal disorders associated with cystic fibrosis. We also plan to develop an inhaled formulation of SPI-8811 for the treatment of respiratory symptoms of 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 commence a Phase II clinical trial of SPI-8811 for the prevention and treatment of NSAID-induced ulcers by the third quarter of 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. By the third quarter of 2007, we plan to commence 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. We believe that SPI-8811 may have utility in preventing other gastric injury in addition to NSAID-induced ulcers. Accordingly, as we progress through our clinical program for SPI-8811, we may seek to broaden our indication for this compound by exploring other gastrointestinal lesions, including hemorrhages, erosions and ulcerations.

#### **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:

- decreased portal pressure in two rodent models of portal hypertension 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 commence a Phase 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 II 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 or alternative diagnostic endpoints 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 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. 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. Although this trial focused primarily on safety, we also examined the effect of SPI-8811 on chloride secretion in cells lining the nose and salivary glands as well as overall quality of life as measured by a questionnaire published by the Cystic Fibrosis Foundation. The results for chloride secretion were inconclusive, which we believe was likely due to the rapid metabolization of the drug in the gastrointestinal tract, the short duration of the trial and the limited number of participants enrolled in the trial. However, we did observe improvements in baseline gastrointestinal disorders associated with cystic fibrosis as measured by the questionnaire. As a result, we determined to focus our initial development efforts on the treatment of gastrointestinal disorders associated with cystic fibrosis and plan to commence a Phase II dose-ranging trial of orally administered SPI-8811 for the treatment of these disorders by the second quarter of 2008. In the future, we also 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 to assess changes in respiratory and pulmonary function, 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 and stroke. We also are developing an oral formulation of SPI-017 for the treatment of Alzheimer's disease. We plan to commence Phase I clinical trials of the intravenous formulation of SPI-017 and Phase I clinical trials of the oral formulation in 2008. Results from the Phase I trials of both the intravenous and the oral formulations may be useful in the development of any of these indications.

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 United 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 required to provide a dedicated sales force of at least 200 people to promote AMITIZA and a supplemental sales force of at least 500 people to promote AMITIZA together with one other drug product. Takeda is currently utilizing TAP Pharmaceutical Products, Inc., or TAP, a joint venture between an affiliate of Takeda and Abbot Laboratories, to provide this supplemental sales force. Takeda has advised us that the supplemental sales force being supplied by TAP consists of over 600 people and is marketing AMITIZA together with Prevacid® (lansoprazole), a product for the treatment of gastroesophageal reflux disease, ulcers and a variety of other gastrointestinal indications.

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 commercial operations, a vice president of marketing, 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 provided us with a contract specialty sales force of 38 field sales representatives to market AMITIZA in our targeted institutional market. Our agreement with Takeda provides that Takeda will fund a significant portion of our contract sales force costs. We initially 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 addition, under the terms of our agreement with Ventiv, we preserved 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 payment of a specified conversion fee to Ventiv.

We have exercised our right to terminate our agreement with Ventiv and to hire a significant portion of their sales staff as employees of our company effective July 1, 2007. We believe this will improve our ability to recruit highly qualified sales staff and will enhance our ability to control our sales force and its deployment. Although these sales representatives will become employees of our company, we intend to continue to outsource most of the operational infrastructure associated with this sales force through a new contract with Ventiv and, in some cases, through other vendors. In connection with this internalization of our specialty sales force, we expect to incur approximately \$250,000 of transition expenses, primarily recruiting and training expenses and a termination fee we will pay to Ventiv, which will affect our sales and marketing expenses for the quarter ending September 30, 2007. We also anticipate that our ongoing expenses relating to this sales force will increase by approximately \$400,000 annually over what those expenses would have been if we had maintained the Ventiv relationship, due to compensation increases we expect to implement.

We believe that the institutional focus of our specialty sales force, which targets academic medical centers and long-term care facilities, would facilitate our ability to sell other products for the treatment of a variety of indications in several therapeutic fields that are concentrated in the institutional setting, as well as additional products in our own pipeline that might be approved. In particular, we expect that our specialty sales force will develop expertise over time that could be useful in marketing additional products for the treatment of gastrointestinal indications and for the treatment of the elderly. We intend to pursue strategic acquisitions, in-licensing or co-promotion opportunities to supplement our existing product pipeline, especially those that would add products complementary to the focus of our specialty sales force.

## **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 for these indications 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. The agreement provides that Takeda will fund a portion of our 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 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 June 30, 2011 or 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 15-month extension in the case of any compound that we designate in good faith as planned for development within that extension period. 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 February 28, 2007, we had licensed from Sucampo AG rights to a total of 51 U.S. patents, 19 U.S. patent applications, 27 European Union patents, 12 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, four 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 nine issued U.S. patents, six 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 regimens, 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-017 licensed by us consist of ten issued U.S. patents, six 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 2022.

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**

On June 30, 2006, we 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 product 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 June 30, 2011 or the date upon which Drs. Kuno and Ueno no longer control our company. Following 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 15 months following the end of the specified period. At the end of the 15-month extension 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 end of the specified period, 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.

We, together with our subsidiary Sucampo Europe, 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 in the Americas, Europe, the Middle East and Africa until 2026. In the future, we intend to expand this arrangement to include our subsidiary Sucampo Japan in order to meet our commercial and clinical requirements for AMITIZA in Asia. 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 up-front and milestone payments. Either we or R-Tech may terminate the supply arrangement with respect to us or Sucampo Europe 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, R-Tech has agreed to maintain at least a six-month supply of AMITIZA and a six-month supply of the active ingredient used in manufacturing AMITIZA as a backup inventory. R-Tech may draw down this backup inventory to supply AMITIZA to us in the event that R-Tech is unable or unwilling to produce AMITIZA to meet our demand. We also have the right to qualify a back-up supplier for AMITIZA. In the event that R-Tech is unwilling or unable to meet our demand, R-Tech will grant to that back-up supplier a royalty-free license to use any patents or know-how owned 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. We may purchase AMITIZA from the back-up supplier until R-Tech is able and willing to meet our demand 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.

We have also entered into an exclusive supply arrangement with R-Tech to provide us with clinical supplies of our product candidates SPI-8811 and SPI-017, as well as any other prostone compound we may designate, 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. This clinical supply arrangement has a two year term which renews automatically unless we and R-Tech agree not to renew it. Either we or R-Tech may terminate the clinical supply arrangement with respect to us or one of our operating subsidiaries in the event of the other party's uncured breach or insolvency.

## **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. A competitive product might become more popular if it is approved for sale over the counter. 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, 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 short-term treatment of occasional constipation. MiraLax was recently approved for sale as an over-the-counter treatment.

Zelnorm, a partial serotonin-receptor agonist, 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 March 2007, however, at the request of the FDA, Zelnorm was withdrawn from the U.S. market by Novartis. The FDA requested that Novartis discontinue marketing Zelnorm based on a recently identified finding of an increased risk of serious cardiovascular adverse events associated with use of the drug. The FDA indicated that it might allow Zelnorm to be prescribed under a special program to some patients for whom no other treatment options are available and in whom the benefits of Zelnorm treatment outweigh the chance of serious side effects. The FDA also indicated a willingness to consider limited re-introduction of Zelnorm in the United States if a population of patients can be identified in whom the benefits of the drug outweigh the risks, following discussion at a public advisory committee meeting.

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 DDP733, being developed by Dynogen Pharmaceuticals, Inc. and currently in Phase II clinical trials; and
- Opioid antagonists such as methylnaltrexone, being developed by Progenics Pharmaceuticals, Inc., for the treatment of opioid-induced bowel dysfunction. Progenics and its partner Wyeth Pharmaceuticals recently filed an NDA with the FDA for a subcutaneous formulation of this drug for the treatment of opioid-induced bowel dysfunction in patients receiving palliative care. Adolor Corporation, the developer of another opioid antagonist, Entereg® (alvimopan), recently announced that it was withdrawing its protocol for an additional Phase III clinical trial of Entereg to treat opioid-induced bowel dysfunction, which had previously been filed with the FDA, based upon preliminary Phase III trial safety results that suggest potential links between use of Entereg and adverse cardiovascular events, tumor development and bone fractures.

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 I, 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 our product candidate SPI-8811 for the treatment of disorders associated with 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 will consider introducing 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 2006 biannual review, the Japanese government reduced the overall drug reimbursement rates. We expect similar price reviews in the future, in line with the government's previously announced plan for controlling health care costs. It is not possible to predict the outcome of these reviews, 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 recently entered into a



lease for a new headquarters location in Bethesda, Maryland comprising 25,016 square feet of office space to support growth in our business. This lease expires in February 2017. We expect to relocate to our new headquarters in July 2007, but it is not clear whether, or on what terms, we might be able to sublease our current headquarters space for the duration of our current leases. We also rent space under short-term leases in Oxford, England and Tokyo and Osaka, Japan.

**Employees**

As of May 31, 2007, we had 52 full-time employees, including 18 with doctoral or other advanced degrees. Of our workforce, 22 employees are engaged in research and development, nine are engaged in marketing and sales, and 21 are engaged in business development, legal, finance and administration. Effective July 1, 2007, when we terminate our agreement with Ventiv, we expect to hire 38 sales representatives as employees of our company. 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.

**Legal Proceedings**

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

## MANAGEMENT

Our current executive officers and directors, and their ages as of June 1, 2007, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Ryuji Ueno, M.D., Ph.D., Ph.D.	53	Chief Executive Officer, Chief Scientific Officer and Director, Chairman of the Board of Directors
Ronald W. Kaiser	52	Chief Financial Officer
Mariam E. Morris	39	Chief Accounting Officer and Treasurer
Brad E. Fackler	53	Executive Vice President of Commercial Operations
Gayle R. Dolecek	64	Senior Vice President of Research and Development
Kei S. Tolliver	33	Vice President of Business Development and Company Operations and Secretary
Charles S. Hrushka	56	Vice President of Marketing
Michael J. Jeffries(1)(2)(3)(4)	64	Director
Timothy I. Maudlin(1)(3)	56	Director
Hidetoshi Mine(2)(3)	57	Director
V. Sue Molina(1)(2)	58	Director

(1) Member of Audit Committee.

(2) Member of Compensation Committee.

(3) Member of Nominating and Corporate Governance Committee.

(4) Lead independent director.

*Ryuji Ueno, M.D., Ph.D., Ph.D.* Dr. Ueno is a founder of our company and has been our Chief Executive Officer since September 2006 and our Chief Scientific Officer since August 2004. Dr. Ueno also became the Chairman of our Board of Directors effective June 1, 2007 following the resignation of Dr. Kuno from that position. Dr. Ueno also served as Chief Operating Officer from December 1996 to November 2000 and again from March 2006 to September 2006 and as Chief Executive Officer from December 2000 to September 2003. Dr. Ueno has been a director since 1996 and served as Chairman of our Board of Directors from December 2000 to September 2006. 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.

*Ronald W. Kaiser.* Mr. Kaiser became our Chief Financial Officer in January 2007. From March 2005 to December 2006, Mr. Kaiser served as Vice President and Chief Financial Officer of PharmAthene, Inc, a bio-defense company. From February 2003 to March 2005, Mr. Kaiser served as Chief Financial Officer, Treasurer and Secretary of Air Cargo, Inc., a freight logistics and bill processing provider. Air Cargo filed for Chapter 11 bankruptcy on December 7, 2004. From June 2002 to January 2003, Mr. Kaiser was self-employed. From May 1998 to June 2002, Mr. Kaiser served as Chief Financial Officer, Treasurer and Secretary of OTG Software, Inc., a storage software development, manufacturing, sales and distribution company. Mr. Kaiser also serves as a member of the board of directors of OPNET Technologies, Inc. and Vocus, Inc. Mr. Kaiser holds Bachelors degrees in accounting and in multidisciplinary pre-law from Michigan State University.

*Mariam E. Morris.* Ms. Morris has been our Chief Accounting Officer and Treasurer since January 2007. Ms. Morris served as our Chief Financial Officer from March 2006 to December 2006 and as our Director of Finance from February 2004 to March 2006. 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 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 and has served as lead independent director since September 2006. 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 became 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. Mr. Maudlin is a director of Website Pros, Inc., a web services company. Mr. Maudlin served on the board of directors of Curative Health Services, Inc., a biopharmaceutical company, from 1984 until May 2006. On March 27, 2006, Curative filed a voluntary petition for bankruptcy under Chapter 11. In May 2006, the bankruptcy court approved Curative's plan of reorganization under Chapter 11. 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 Ridgeway Capital 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 became 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, serving from 2000 until May 2004 as the National Partner in Charge of Deloitte's Initiative for the Retention and Advancement of Women. Prior to that, she spent 16 years with Ernst & Young LLP, an international accounting firm, the last ten years as a partner. Ms. Molina serves as Vice Chair of the Board of Directors and the Audit Committee Chair of Royal Neighbors of America, a fraternal insurance company. She holds a B.S.B.A. and a Masters of Accounting degree from the University of Arizona.

### **Board Composition**

Our board of directors is currently authorized to have seven 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 directors will be Mr. Jeffries and Mr. Maudlin;
- the class II directors will be Dr. Ueno and Mr. Mine; and
- the class III director will be Ms. Molina.

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 Global Market and the applicable rules and regulations of the Securities Exchange Commission. Our board has determined that each of Messrs. Jeffries, Maudlin, and Mine and Ms. Molina qualify as independent under the NASDAQ and SEC rules. We refer to these directors as our independent directors. Each of these independent directors serves or, upon closing of this offering, will serve on one or more of our audit committee, compensation committee and nominating and corporate governance committee.

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 the nominating and corporate governance committee will be effective upon closing of this offering.

### ***Audit Committee***

Messrs. Jeffries and Maudlin and Ms. Molina are the members of our audit committee. Our audit committee assists 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.

Our audit committee's responsibilities, as set forth in the written charter adopted by our board in June 2006, 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. Jeffries chairs 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 Global 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 Mr. Jeffries qualifies as an "audit committee financial expert" under Securities and Exchange Commission rules by virtue of the experience described above.

### ***Compensation Committee***

Messrs. Jeffries and Mine and Ms. Molina are the members of our compensation committee. Ms. Molina chairs 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 assists our board of directors in the discharge of its responsibilities relating to the compensation of our executive officers.

Our compensation committee's responsibilities, as set forth in the written charter adopted by the board in June 2006, 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, Maudlin and Mine will become members of our nominating and corporate governance committee upon the closing of this offering. Mr. Mine 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.

#### **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.

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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 for 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.

## EXECUTIVE COMPENSATION

### Compensation Discussion and Analysis

#### *Our Executive Compensation Process*

Our executive compensation program for 2006 was implemented while we were a private company. Accordingly, our compensation program, as well as the policies and practices we used to develop and approve that program, reflected less formality than we would expect after we become a public company. Drs. Kuno and Ueno, our senior executives in 2006 and our principal stockholders, have historically taken the lead in shaping our executive compensation program. Dr. Kuno served as our chief executive officer until September 2006 and as our president and chair of the board from September 2006 through May 2007, when she resigned as an executive officer and director of our company.

In connection with structuring our 2007 compensation program, our compensation committee is currently conducting a comprehensive review of our executive compensation practices. The compensation committee is evaluating a variety of matters in this review, including:

- our overall compensation philosophy,
- the appropriate elements of executive compensation and the allocation of compensation among those elements,
- our overall compensation levels,
- the structure of our incentive compensation,
- how our compensation program compares to that of similar companies, and
- our procedures for designing, approving and evaluating the compensation program.

As a result of this review by our compensation committee, our executive compensation program for 2007 might reflect significant changes in structure and philosophy as compared to our historic compensation practices.

#### *Overview of Our Compensation Program*

The primary goal of our executive compensation program has been to provide compensation levels sufficient to retain our existing executives and, when necessary, to attract new executives. A further goal of our executive compensation program is to reward, on an annual basis, individual performance that promotes the success of our company and to provide longer-term incentives that align the financial interests of our executives with the long-term performance of our company.

The key elements of our executive compensation program have been:

- cash compensation in the form of salary,
- eligibility for an annual discretionary cash bonus,
- equity incentives in the form of stock options, and
- employee benefits, such as 401(k) plan matching payments and health and life insurance.

We believe that each of these elements, and all the elements together, must be competitive in order to meet our principal objective of attracting and retaining our executives. Potential employees and existing employees will compare the overall compensation package available at our company to the compensation package offered by other potential employers as they decide whether to join us in the first place and whether to stay with us after they do join. Accordingly, we have attempted to maintain our overall compensation package at levels sufficient to retain our current executives and attract new ones.

We have not currently adopted any formal or informal policy for allocating compensation between long-term and short-term compensation, between cash and non-cash compensation or among the different forms of



non-cash compensation. We view each of the elements of our compensation program as related but distinct. Our decisions about each individual element do not necessarily affect the decisions we make about other elements. For example, we do not believe that significant compensation derived from one element of compensation should necessarily negate or reduce compensation from other elements.

We provide a portion of our executive compensation in the form of incentive compensation that rewards executives for both short-term and long-term contributions. Short-term incentive compensation has historically taken the form of eligibility for annual discretionary cash bonus payments. Long-term incentives have taken the form of stock option grants, which are designed to reward executives for the longer term success of our company as reflected in appreciation of our stock value.

Drs. Kuno and Ueno, our two most senior executives in 2006, are founders of our company and together hold a significant majority of our common stock. Accordingly, in determining our executive compensation for 2006, we considered that the retention and long-term incentives of Drs. Kuno and Ueno derived more from their equity ownership than from their annual or incentive compensation.

### **2006 Salary Levels**

Initial 2006 salary levels for our executives who continued with our company from 2005 were based largely on their salaries from the prior year. In March 2006, we increased the salaries of some of our executives in an effort to reflect more closely their levels of responsibility. In particular, we increased Mr. Fackler's salary from \$190,000 to \$220,000 and Ms. Morris' salary from \$118,700 to \$138,000. The amounts of these increases were determined by Drs. Kuno and Ueno after informal consultation with our compensation committee. Ms. Morris' salary was increased again to \$160,000 in April 2006, reflecting her promotion to chief financial officer. This increase was recommended by Drs. Kuno and Ueno and approved by our compensation committee.

In June 2006, in anticipation of this offering, we entered into employment agreements with our executive officers, including Drs. Kuno and Ueno. At that time, the base salary for Dr. Kuno was increased from \$304,800 to \$380,000 to reflect her increased responsibilities as we prepared to be a public company. The salary levels of the other executives were maintained substantially at their existing levels. The base salary levels for all of our executives were approved by our compensation committee at this time, based on the recommendations of Drs. Kuno and Ueno. In connection with its approval of the salaries of Drs. Kuno and Ueno, the compensation committee reviewed data collected at its request by one of our outside law firms. This data focused on the compensation levels for the two most senior executives at each of several public companies in the biotech, pharmaceutical and life sciences fields. In most cases, this data covered the chief executive officer of the applicable company, while the second executive varied among a range of other positions, such as chief operating officer, chief scientific or medical officer, or head of research and development. The committee utilized this data to confirm that the salary and other elements of compensation for Drs. Kuno and Ueno, when viewed as a package, were not out of line generally with the overall compensation packages paid to the two most senior executives in those companies. We have not otherwise benchmarked our executive compensation levels to those of other comparable companies.

The salary level for Dr. Dolecek, who was hired as an executive during 2006, was negotiated with him by Drs. Kuno and Ueno at the time of his hire and was approved by the compensation committee based on their recommendation. Among the factors considered in determining the proposed base salary for Dr. Dolecek was Dr. Dolecek's desire to have a flexible work schedule reflecting less than a full-time work week. In February 2007, the compensation committee approved a 15% increase in Dr. Dolecek's salary to reflect that he now works full time.

### **2006 Annual Cash Bonuses**

In February 2007, our compensation committee approved cash bonuses for our executive officers relating to their performance in 2006. We had not previously established any specific individual performance goals for any of our executive officers, including Drs. Kuno and Ueno, in order for them to achieve a bonus for 2006. Although we had communicated overall company goals to our executives in early 2006, we had not directly

tied their bonus opportunities to the achievement of particular company goals. Accordingly, the actual bonuses paid to our executive officers were determined entirely at the discretion of the compensation committee based on its subjective assessment of the overall performance of each executive and his or her contribution to the achievement of the overall company goals, as described more fully below. The compensation committee also took into consideration a proposal by Dr. Kuno, made in consultation with Dr. Ueno and Mr. Kaiser, about individual bonuses for each executive.

For each executive, a target bonus was established based on a percentage of base salary. This percentage was 50% in the case of Drs. Kuno and Ueno, consistent with their employment agreements, and 25% for the other executives. In each case, 70% of this target was allocated to the achievement of overall company goals for 2006 and 30% was allocated to individual performance. The company goals for 2006 included the FDA approval of AMITIZA, the successful commercial launch of AMITIZA, the filing of the registration statement for this offering, significant progress toward the completion of our Phase III clinical trials of AMITIZA for the treatment of irritable bowel syndrome with constipation and the completion of this offering. Because all but the last of these corporate goals were achieved, the compensation committee determined to award 80% of the portion of the target bonus allocated to achievement of corporate goals. The committee's assessment of individual performance was subjective in each case, focusing principally on the individual's contribution to the corporate goals described above, and resulted in the award of between 100% and 120% of the portion of the target bonus allocated to individual performance. In addition, the committee awarded an additional bonus amount to some of the executives, ranging between 1.0 and 1.5 months of base salary, based on performance the committee felt reflected special dedication and effort by the executive on behalf of our company.

Overall, these discretionary bonuses averaged 39.9% of the base salary for all the executive officers named in our Summary Compensation Table below, 43.0% for Drs. Kuno and Ueno together, and 35.7% for the other named executive officers together.

#### ***One-Time Bonuses***

In January 2006, the board of directors approved a special one-time cash bonus for all employees of our company, to be paid upon the receipt of FDA approval for AMITIZA to treat chronic idiopathic constipation. The particular bonus for each employee was calculated in an amount between 5% and 10% of base salary, depending upon the length of service of the employee. We received the FDA approval, and the bonuses were paid, in February 2006. Each of our executive officers at the time of the bonus payment, including Drs. Kuno and Ueno, received their portion of the bonus calculated in this fashion.

All of our executives, except Drs. Kuno and Ueno, were paid \$1,000 in June 2006 in consideration for executing new employment agreements with additional restrictive covenants in favor of our company.

#### ***2006 Stock Option Grants***

Our board of directors approved a broad-based grant of incentive stock options to most of our employees on May 1, 2006. Each of our executive officers at the time, including Drs. Kuno and Ueno, received options in this grant. The amount of options to be granted to each employee was proposed by Dr. Kuno, then our chief executive officer, and was based on a variety of factors, including length of service, salary level and individual performance. The exercise price of these stock options, \$85.00 per share for employees other than Drs. Kuno and Ueno, was based on a valuation of our class A common stock performed by an independent valuation firm and was consistent with the price at which we had recently sold shares of our class A common stock to investors. The exercise price of the options granted to Drs. Kuno and Ueno was \$93.50 per share, or 110% of fair market value. This higher exercise price for Drs. Kuno and Ueno was required by tax regulations as a condition to granting incentive stock options to them in light of their significant stock holdings in our company. These options were granted under our 2001 stock incentive plan. Prior to this grant, the only grants of stock options we had made to executives were to Drs. Kuno and Ueno.

We believe that the equity incentive portion of our executive compensation package is relatively small compared to other companies we consider comparable to our company. We have historically utilized equity incentive compensation sparingly, and this was true again in 2006. The appropriate levels of equity incentive

compensation for our executives is one of the matters being reviewed by our compensation committee in connection with developing our 2007 compensation program.

Our employment agreements with Drs. Kuno and Ueno provide that they will not become eligible for additional stock options or other equity incentive awards until they collectively own less than 50% of our total equity. This limitation reflects the belief of our compensation committee that the current equity holdings of Drs. Kuno and Ueno provide them with significant long-term incentives that are tied to the appreciation of our common stock and that, accordingly, additional equity-based incentives would not provide materially better alignment between their interests as executives and the interests of our stockholders.

We currently do not have any policy or practice of granting, or not granting, equity compensation on specified dates. Because we have been a private company, we have not coordinated the timing of equity awards with the release or withholding of material non-public information.

We do not have any equity ownership guidelines for our executive officers.

### ***2006 Employee Benefits***

Each executive has the opportunity to participate in our 401(k) plan, which provided a 50% match on every dollar contributed by any participating employee up to 10% of his or her compensation in 2006. In addition, every executive has the opportunity to select insurance coverage at the same cost as every other employee, including health and life insurance. We pay the premiums for the life insurance benefit for each executive, subject to a specified maximum amount of coverage, and 70% of the premiums for the health insurance benefit. We also pay for parking at our headquarters facility for each of our executives. Dr. Kuno's employment agreement requires us to provide her with additional life insurance, for which the premium in 2006 was \$24,750.

### ***Severance and Change of Control Benefits***

Pursuant to the employment agreements we entered into with our named executive officers in June 2006, each is entitled to specified benefits in the event of a change of control of our company or the termination of the employment of the executive under specified circumstances. We have provided estimates of the value of these severance and change of control benefits under various circumstances under "— Potential Payments upon Termination or Change of Control" below. For more information about these agreements and a summary of severance and change of control benefits of Mr. Kaiser, who joined us as chief financial officer in January 2007, see "— Employment Agreements".

**Summary Compensation**

The following table sets forth the total compensation earned for the year ended December 31, 2006 by our chief executive officer, our former chief executive officer, our chief financial officer and our three other most highly compensated executive officers for the year ended December 31, 2006. We refer to these officers as our named executive officers.

**Summary Compensation Table**

<b>Name and Principal Position</b>	<b>Salary (\$)</b>	<b>Bonus (\$)(1)</b>	<b>Option Awards (\$)(2)</b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Ryuji Ueno, M.D., Ph.D., Ph.D. Chief Executive Officer, Chief Scientific Officer and Director	452,132	238,500	379,353	12,144(3)	1,082,129
Sachiko Kuno, Ph.D. Former Chief Executive Officer, President and Chair of the Board of Directors(4)	341,440	193,400	474,192	28,050(5)	1,037,082
Mariam E. Morris Chief Accounting Officer(6)	150,217	66,270	359,867	14,389(7)	590,743
Brad E. Fackler Executive Vice President of Commercial Operations	214,891	76,058	296,373	22,398(8)	609,720
Gayle R. Dolecek Senior Vice President of Research and Development(9)	85,673	31,743	185,233	3,151(10)	305,800
Kei S. Tolliver Vice President of Business Development and Company Operations	112,465	44,762	244,658	4,939(11)	406,824

- (1) The amounts shown in this column represent a one-time special bonus paid to all employees in connection with the FDA approval of AMITIZA (\$45,000 for Dr. Ueno, \$30,000 for Dr. Kuno, \$11,870 for Ms. Morris, \$7,125 for Mr. Fackler and \$11,100 for Ms. Tolliver) and annual discretionary bonuses awarded in February 2007 for 2006 performance.
- (2) The assumptions used in valuing the options we granted during 2006 are described under the caption "Employee Stock-Based Compensation" in note 3 to our consolidated financial statements included in this prospectus. This column reflects the amount we recorded under FAS 123R as stock-based compensation in our financial statements for 2006 in connection with these options. Unlike the amount reflected in our consolidated financial statements, however, this amount does not reflect any estimate of forfeitures related to service-based vesting. Instead, it assumes that the executive will perform the requisite service to vest in the award.
- (3) Represents \$972 in life and disability insurance premiums, \$8,652 in health insurance premiums and \$2,520 in reimbursement of parking expenses.
- (4) Dr. Kuno served as our Chief Executive Officer until September 2006. Dr. Kuno served as President and Chair of the Board of Directors until May 2007, when she resigned as an executive officer and director of our company.
- (5) Represents \$25,530 in life and disability insurance premiums and \$2,520 in reimbursement of parking expenses.
- (6) Ms. Morris served as our Chief Financial Officer until January 1, 2007. On January 2, 2007, we entered into an employment agreement with our new chief financial officer, Ronald W. Kaiser, whose compensation and benefits are described below under "— Employment Agreements".
- (7) Represents \$7,500 in matching contributions under our 401(k) plan, \$703 in life and disability insurance premiums, \$3,926 in health insurance premiums, \$1,260 in reimbursement of parking expenses and \$1,000 in consideration of signing an employment agreement with us.
- (8) Represents \$10,000 in matching contributions under our 401(k) plan, \$780 in life and disability insurance premiums, \$4,791 in health insurance premiums, \$1,260 in reimbursement of parking expenses, \$4,567 in housing expenses and \$1,000 in consideration of signing an employment agreement with us.

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- (9) Dr. Dolecek joined our company in May 2006.
- (10) Represents \$1,038 in matching contributions under our 401(k) plan, \$273 in life and disability insurance premiums, \$840 in reimbursement of parking expenses and \$1,000 in consideration of signing an employment agreement with us.
- (11) Represents \$2,089 in matching contributions under our 401(k) plan, \$590 in life and disability insurance premiums, \$1,260 in reimbursement of parking expenses and \$1,000 in consideration of signing an employment agreement with us.

For more information about the employment agreements between our company and our executive officers, see “— Employment Agreements”.

### Supplemental Information Regarding Option Grants

The following table sets forth additional information regarding the options we granted to our named executive officers in the year ended December 31, 2006. All of these options were granted under our 2001 stock incentive plan.

#### 2006 Grants of Plan-Based Awards

Name	Grant Date	Number of Shares of Class A Common Stock Underlying Option Awards (#)	Exercise Price of Option Awards (\$/Share)(1)	Grant Date Fair Value of Option Awards \$(2)
Ryuji Ueno, M.D., Ph.D., Ph.D.	May 1, 2006	8,000 <sup>(3)</sup>	93.50	413,840
Sachiko Kuno, Ph.D.	May 1, 2006	10,000 <sup>(3)</sup>	93.50	517,300
Mariam E. Morris	May 1, 2006	8,000 <sup>(4)</sup>	85.00	431,840
Brad E. Fackler	May 1, 2006	8,000 <sup>(5)</sup>	85.00	444,560
Gayle R. Dolecek	May 1, 2006	5,000 <sup>(5)</sup>	85.00	277,850
Kei S. Tolliver	May 1, 2006	5,000 <sup>(3)</sup>	85.00	266,900

- (1) The exercise price of these options was equal to the fair market value of our class A common stock, or 110% of fair market value in the case of options granted to Drs. Kuno and Ueno, as valued by our board of directors on the date of grant. Our class A common stock was not publicly traded in 2006 and accordingly no actual closing price for that stock on the grant date is available.
- (2) The assumptions used in valuing the options we granted during 2006 are described under the caption “Employee Stock-Based Compensation” in note 3 to our consolidated financial statements included in this prospectus. This column reflects the full amount we will record under FAS 123R as stock-based compensation in our financial statements in connection with these options over the entire term of the options. Unlike the amount reflected in our consolidated financial statements, however, this amount does not reflect any estimate of forfeitures related to service-based vesting. Instead, it assumes that the executive will perform the requisite service to vest in the award.
- (3) These options vest 75% on May 1, 2006 and 25% on May 1, 2007.
- (4) These options vest in two equal annual installments beginning on May 1, 2006.
- (5) These options vest 50% on May 1 2006, 25% on May 1, 2007 and 25% on May 1, 2008.

**Outstanding Equity Awards; Option Exercises and Stock Vesting**

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2006. All of these options were granted under our 2001 stock incentive plan. Our named executive officers did not hold restricted stock or other stock awards at the end of 2006. Our named executive officers did not exercise any options in 2006 and they did not have any stock awards that vested in 2006.

**Outstanding Equity Awards at 2006 Fiscal Year-End**

Name	Number of Shares of Class A Common Stock Underlying Unexercised Options		Option Exercise Price (\$)	Option Expiration Date
	Exercisable (#)	Unexercisable (#)		
Ryuji Ueno, M.D., Ph.D., Ph.D.	11,000	—	25.15	Mar. 13, 2007
	6,000	2,000 <sup>(1)</sup>	93.50	May 1, 2011
Sachiko Kuno, Ph.D.	5,000	—	25.15	Mar. 13, 2007
	7,500	2,500 <sup>(1)</sup>	93.50	May 1, 2011
Mariam E. Morris	4,000	4,000 <sup>(1)</sup>	85.00	May 1, 2016
Brad E. Fackler	4,000	4,000 <sup>(2)</sup>	85.00	May 1, 2016
Gayle R. Dolecek	15,000 <sup>(3)</sup>	—	49.75	Aug. 9, 2015
	2,500	2,500 <sup>(2)</sup>	85.00	May 1, 2016
Kei S. Tolliver	3,750	1,250 <sup>(1)</sup>	85.00	May 1, 2016

(1) These options vest on May 1, 2007.

(2) These options vest 50% on May 1, 2007 and 50% on May 1, 2008.

(3) This option was originally granted to Dr. Dolecek in his capacity as a consultant to our company, prior to the time he became an employee.

**Potential Payments upon Termination or Change of Control**

Our named executive officers are entitled to specified benefits in the event of the sale or merger of our company or the termination of their employment under some circumstances. Dr. Kuno is no longer entitled to these benefits as a result of her resignation as an executive officer of our company effective May 31, 2007. These benefits as of December 31, 2006 are:

- In the event our company is acquired, is the non-surviving party in a merger, or sells all or substantially all of its assets, or in the event of the death of the executive, all then unvested restricted stock and stock options issued to him or her shall immediately vest.
- Upon termination or non-renewal by us of the executive's employment without cause or upon the disability of the executive, 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 a specified number of months of current base salary and to receive reimbursement for the cost of continued health insurance coverage for a specified period of months. In these circumstances, Drs. Kuno and Ueno will be entitled to receive a lump sum severance payment equal to 24 months of base salary and to receive reimbursement for the cost of continued health insurance coverage for a period of 18 months after termination. Our other executives will be entitled to receive a lump sum severance payment equal to two months of base salary and to receive reimbursement for the cost of continued health insurance coverage for a period of two months after termination.
- If the executive is terminated other than for cause within 18 months after a change in control of our company, he or she will be entitled to receive a lump sum severance payment equal to a specified number of months of current base salary. The specified number of months is 48 for Drs. Kuno and Ueno and four for our other executives.

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The payment of severance benefits to an executive is, in all cases, conditioned upon our receipt of a release of claims from the executive.

*Potential Benefits upon Sale of our Company or Executive's Death.* The following table sets forth an estimate of the benefits that would have accrued to each of our named executive officers assuming that our company was acquired, was the non-surviving party in a merger or sold all or substantially all of its assets, or upon the death of the executive, in each case assuming that the applicable triggering event occurred as of December 31, 2006.

<u>Name</u>	<u>Option Shares as to Which Vesting Accelerated(1)</u>	<u>Value of Option Acceleration(2)</u>
Ryuji Ueno, M.D., Ph.D., Ph.D.	2,000	\$
Sachiko Kuno, Ph.D.	2,500	
Mariam E. Morris	4,000	
Brad E. Fackler	4,000	
Gayle R. Dolecek	2,500	
Kei S. Tolliver	1,250	

(1) Reflects shares as to which options are unvested at December 31, 2006.

(2) Based on the number of shares as to which options are unvested at December 31, 2006 multiplied by the difference between \$ , the mid-point of the range set forth on the cover of this prospectus, and the per-share exercise price of each option.

*Potential Benefits upon Termination Without Cause, Upon Disability or With Good Reason.* The following table sets forth an estimate of the benefits that would have accrued to each of our named executive officers assuming that we had terminated the executive's employment without cause, other than within 18 months after a change of control as discussed in the following table, or upon the disability of the executive, or the executive terminated his or her employment with good reason, in each case assuming that the applicable triggering event occurred as of December 31, 2006.

<u>Name</u>	<u>Lump Sum Severance Payment(1)</u>	<u>Value of Benefit Continuation(2)</u>
Ryuji Ueno, M.D., Ph.D., Ph.D.	\$ 900,000	\$ 12,978
Sachiko Kuno, Ph.D.	760,000	—
Mariam E. Morris	26,667	654
Brad E. Fackler	36,667	799
Gayle R. Dolecek	22,500	—
Kei S. Tolliver	18,805	—

(1) Represents 24 months of salary for Drs. Ueno and Kuno and two months of salary for others, based on salary in effect as of December 31, 2006.

(2) Represents reimbursement of premiums to continue health insurance coverage for 18 months for Dr. Ueno and for two months for others who currently participate in our health insurance plan, based on premiums in effect as of December 31, 2006.

*Potential Benefits upon Termination Without Cause Following a Change of Control.* The following table sets forth an estimate of the benefits that would have accrued to each of our named executive officers assuming that we, or a successor to our company, had terminated the executive's employment without cause as

of December 31, 2006 and that such termination had occurred within 18 months after a change of control of our company.

Name	Lump Sum Severance Payment(1)	Value of Benefit Continuation(2)
Ryuji Ueno, M.D., Ph.D., Ph.D.	\$ 1,800,000	\$ 12,978
Sachiko Kuno, Ph.D.	1,520,000	—
Mariam E. Morris	53,333	654
Brad E. Fackler	73,333	799
Gayle R. Dolecek	45,000	—
Kei S. Tolliver	37,611	—

(1) Represents 48 months of salary for Drs. Ueno and Kuno and four months of salary for others, based on salary in effect as of December 31, 2006.

(2) Represents reimbursement of premiums to continue health insurance coverage for 18 months for Dr. Ueno and for two months for others who currently participate in our health insurance plan, based on premiums in effect as of December 31, 2006.

### Director Compensation

In June 2006, our board of directors approved a compensation program pursuant to which we 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 also receives 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 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. Effective January 2007, we will also pay an annual retainer of \$5,000 to the chair of the audit committee, \$3,000 to the chairs of each of the compensation committee and the nominating and corporate governance committee and \$10,000 to the lead independent director. In establishing the levels of cash compensation included in our director compensation program, our board of directors took into consideration the absence of any equity element of that program. As part of the comprehensive review of our overall executive compensation program being conducted by our compensation committee, it is possible that we may determine to modify our director compensation program after this offering.

The following table sets forth information regarding the compensation of our directors in the year ended December 31, 2006. Our named executive officers who also served as directors are not included in this table because they were not separately compensated for their service as directors. Our directors received compensation only in the form of cash fees and held no stock options or other stock awards at year end.

#### 2006 Director Compensation

Name	Fees Earned or Paid in Cash (\$)	Total (\$)
Michael J. Jeffries	100,000	100,000
Timothy I. Maudlin <sup>(1)</sup>	30,000	30,000
Hidetoshi Mine	93,000	93,000
V. Sue Molina <sup>(1)</sup>	34,000	34,000
George M. Lasezkay <sup>(2)</sup>	38,000	38,000
Myra L. Patchen <sup>(2)</sup>	10,000	10,000
Gregory D. Perry <sup>(3)</sup>	32,000	32,000

(1) Mr. Maudlin and Ms. Molina joined our board of directors in September 2006.

(2) Mr. Lasezkay and Ms. Patchen served as directors through May 2006.

(3) Mr. Perry served as a director from May 2006 to September 2006.



## Employment Agreements

**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. In October 2006, we amended this agreement to provide that Dr. Ueno would be employed as Chief Executive Officer and Chief Scientific Officer. 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 our company is acquired, is the non-surviving party in a merger, or sells all or substantially all of its assets, or in the event of 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 without cause or upon the disability of Dr. Ueno, 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 receive reimbursement for the cost of continued health insurance coverage 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. Dr. Ueno has also agreed not to compete with our company for a period of 12 months following termination of his employment.

**Ronald W. Kaiser.** Pursuant to an employment agreement effective January 2, 2007, we agreed to employ Ronald W. Kaiser as our Chief Financial Officer for a term of two years. This agreement renews automatically each year for a period of one year unless earlier terminated by Mr. Kaiser or us. Under this agreement, Mr. Kaiser is entitled to receive an annual base salary of \$200,000, to be reviewed annually by our compensation committee and our board of directors, but not to be decreased unless agreed by Mr. Kaiser and us. Mr. Kaiser also is eligible for a signing bonus of \$100,000, 50% of which was payable on the date of the agreement and 50% of which will be payable in July 2007, and an annual bonus of up to 25% of his base salary as determined by our compensation committee based on his contribution to our company's success. In addition, Mr. Kaiser is eligible to participate in all employee benefit plans offered to other employees. The agreement provides that Mr. Kaiser will ordinarily work four days per week for us, but will devote such additional time as may be required to meet the particular demands of his position. Upon termination or non-renewal by us of Mr. Kaiser's employment without cause or upon the disability of Mr. Kaiser, or upon termination by Mr. Kaiser for specified good reasons, including diminution of authority and duties, Mr. Kaiser will be entitled to receive a lump sum severance payment equal to six months of current base salary, if termination occurs within the first 12 months of employment, or 12 months of current base salary, if termination occurs thereafter. In addition, Mr. Kaiser will be entitled to receive reimbursement for the cost of continued health insurance coverage for a period corresponding to the six- or 12-month period used to determine his lump sum severance payment. If Mr. Kaiser is terminated other than for cause within 18 months after a change of control of our company, he will be entitled to receive a lump sum severance payment equal to twice the amount of the severance payment to which he would otherwise be entitled. Under this agreement, Mr. Kaiser 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. Mr. Kaiser has also agreed not to compete with our company for a period of 12 months following termination of his employment.

**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, as amended on May 12, 2007, we agreed to employ Ms. Morris as our Chief Accounting 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 our company is acquired, is the non-surviving party in a merger, or sells all or substantially all of its assets, or in the event of 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 without cause or upon the disability of the executive, 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 receive reimbursement for the cost of continued health insurance coverage 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. Each of these employees has also agreed not to compete with our company for a period of 12 months following termination of his or her employment.

## **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, 2007, there were options to purchase 135,400 shares of class A common stock outstanding under the 2001 plan and options to purchase 2,000 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 September 5, 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 2007 and ending on the second day of fiscal year 2016. 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; or
- 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 September 5, 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 or (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.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Since January 1, 2004, 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.

<u>Name</u>	<u>Number of Shares of Class A Common Stock</u>	<u>Aggregate Purchase Price</u>
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 Ridgeway Capital Partners Limited for an aggregate purchase price of \$5,999,980.

Mr. Hidetoshi Mine, one of our directors, is the President and Chief Executive Officer of Ridgeway Capital 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

Until recently, we have conducted our operations as one of three affiliated operating companies, each focused on developing and commercializing prostones licensed from Sucampo AG in separate territories. Our company had rights to develop and commercialize Sucampo AG's technology in North, Central and South America, while two other companies under common control with our company, Sucampo Pharma Europe Ltd., or Sucampo Europe, and Sucampo Pharma, Ltd., or Sucampo Japan, had rights to develop and commercialize this technology in Europe, Asia and the rest of the world. In anticipation of this offering, our board of directors approved a series of transactions intended to create a company with worldwide rights to develop and commercialize these prostone compounds. These transactions were proposed by our management, in consultation with the underwriters for this offering and other advisors.

On September 28, 2006, we acquired all of the capital stock of Sucampo Europe and Sucampo Japan. Prior to this acquisition, each of Sucampo Europe and Sucampo Japan was wholly owned, indirectly, by Drs. Ueno and Kuno. In this acquisition, we issued 211,765 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 the acquisition, these two companies are now wholly owned subsidiaries of our company.

On June 30, 2006, we entered into an amended and restated license agreement with Sucampo AG to provide that our company, together with its new wholly owned subsidiaries, will have 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. This amended and restated license agreement is described more fully below under the caption “License Agreements with Sucampo AG — Restated Sucampo AG License” and under “Business — License from Sucampo AG”. Sucampo AG is wholly owned by Drs. Ueno and Kuno.

Following the completion of this offering, we also anticipate that the personnel of Sucampo AG who currently perform research in the field of prostones will be transferred to Sucampo Japan, our wholly owned Asian subsidiary.

### **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 know-how in North and South America. In consideration of the license, we were required to make an up-front 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 up-front 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 December 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 up-front 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. 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, pursuant to a term sheet executed in March 2003, we entered into a 20-year exclusive supply arrangement with R-Tech. Drs. Kuno and Ueno directly and indirectly own a majority of the capital stock of R-Tech. Under this arrangement we granted to R-Tech the exclusive right to manufacture and supply AMITIZA and RUG-015, a prostone compound that we are no longer developing, 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 December 31, 2006. In March 2005, we determined to discontinue any further research and development related to RUG-015 and, with the agreement of R-Tech, terminated the exclusive supply arrangement with respect to this compound.

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. 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 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 to be equal to the minimum rate of interest permitted by the Swiss Federal Tax Administration per annum on the outstanding principal balance. We paid a total of \$2,651,951 in principal and interest upon repayment of the note in full in June 2006.

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. S&R Technology Holdings, LLC is wholly owned by Drs. Ueno and Kuno. 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. We paid a total of \$969,198 in principal and interest upon repayment of the note in full in June 2006.

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. We paid a total of \$1,220,225 in principal and interest upon repayment of the note in full in June 2006.

#### **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. 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 April 2003, we entered into a research agreement with R-Tech whereby R-Tech agreed to perform a toxicology study of SPI-8811 for us at quoted rates. The study was completed in March 2005, and we paid an aggregate of \$364,000 in fees to R-Tech under this agreement.

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 December 31, 2006, we had paid an aggregate of \$75,000 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 2004 through the date of their transfer in August 2004.

### **Part-Time Employment Agreement with Dr. Kuno**

Following Dr. Kuno's resignation as an executive officer and director of our company effective May 31, 2007, we entered into an employment agreement with her effective June 1, 2007. This new agreement superseded her previous employment agreement.

Pursuant to the new employment agreement, we agreed to employ Dr. Kuno on a part-time basis as our Advisor, International Business Development, with the additional titles of Founding CEO and Co-Founder, for a term of one year. This agreement renews automatically each year for a period of one year unless earlier terminated by Dr. Kuno or us. This agreement provides that Dr. Kuno will work eight hours per week. Under this agreement, Dr. Kuno is entitled to receive an annual base salary of \$76,000, 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, targeted at 50% of her base salary, as determined by the compensation committee based on its assessment of Dr. Kuno's achievement of annual objectives. As a part-time employee, Dr. Kuno will not be eligible to participate in employee benefit plans, but we have agreed to reimburse her for parking expenses. 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. Kuno has also agreed not to compete with our company for a period of 12 months following termination of her employment.

### **Special Stock and Cash Awards to Drs. Kuno and Ueno**

On June 19, 2007, the compensation committee of our board of directors authorized a one-time stock and cash award to each of Drs. Kuno and Ueno, which will be made immediately following this offering. These awards were intended by the compensation committee to compensate Drs. Kuno and Ueno for the lost value of stock options that had been granted to them in 2001 and 2002 and had been understood by them to have ten-year terms, but which had expired in 2006 and early 2007 as a result of the terms of our 2001 stock incentive plan. The expired options would have entitled Dr. Kuno to purchase 17,000 shares of class A common stock at a price of \$1.86 per share and 5,000 shares at a price of \$25.15 per share and they would have entitled Dr. Ueno to purchase 51,000 shares of class A common stock at a price of \$1.86 per share and 11,000 shares at a price of \$25.15 per share.

These stock and cash awards will have an aggregate value equal to the difference between the value of the shares that could have been purchased under each of the expired options, determined on the basis of the public offering price per share in this offering, and the respective aggregate exercise prices for such shares as provided in the option agreements. Assuming a public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, the aggregate value of these grants would be \$ for Dr. Kuno and \$ for Dr. Ueno.

These awards will consist of a combination of cash and shares of class A common stock. Of the aggregate value of each award, 40% will be paid in cash and 60% will be paid in stock. For purposes of determining the number of shares of class A common stock to be issued in connection with each award, the stock will be valued on the basis of the public offering price per share in this offering. Assuming a public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, these awards would consist of \$ in cash and shares of class A common stock for Dr. Kuno and \$ in cash and shares of class A common stock for Dr. Ueno. The stock component of these awards will be fully vested immediately upon grant.

We are in the process of determining the accounting for these awards. We expect the value of these awards to result in a material charge to our financial statements in a period subsequent to the three months ended March 31, 2007.

### **Director Compensation**

See “Executive Compensation — Director Compensation” for a discussion of compensation paid to our non-employee directors.

### **Executive Compensation and Employment Agreements**

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

### **Review and Approval of Transactions with Related Parties**

Since April 2004, the charter of our audit committee has required that all related-party transactions involving our company be approved by the committee. This policy did not define related-party transactions and the committee has not adopted formal procedures or standards for this approval. Prior to April 2004, we did not have a policy relating to the approval of transactions between our company and related parties.

We have adopted a revised audit committee charter, which will be in effect after the closing of this offering. That charter will also require that the committee review and approve all related-party transactions, which it defines as any transaction that must be reported under applicable rules of the SEC. We currently expect to adopt more formal procedures for review and approval of these transactions after the closing of this offering.

All of the transactions between our company and related parties described above that were required to have been approved by our audit committee were so approved, except the following:

- Our grant of registration rights, our making of representations and warranties and our waiver of rights of first refusal, all in connection with the sale by R-Tech of shares of our class A common stock to other investors on March 31, 2006, and the agency agreements we entered into with Sucampo Europe and Sucampo Japan in October 2004 were approved unanimously by our board of directors, but were not separately approved by our audit committee;
- Our acquisition of the capital stock of Sucampo Europe and Sucampo Japan on September 28, 2006 was not approved by our audit committee, but was approved by a special committee of our board of directors comprising the same membership as our audit committee at the time;
- The license agreement we entered into with Sucampo AG in October 2004 in respect of the development and commercialization of AMITIZA in North, Central and South America, including the Caribbean, the termination of our research agreement with Sucampo AG in August 2004, and the consulting agreement we entered into with Sucampo AG in April 2005 were not approved by our audit committee; and
- The letter of intent we entered into with Sucampo AG in April 2005 in respect of the development and commercialization of SPI-017 in North, Central and South America, including the Caribbean, was not approved by our audit committee, although the definitive agreement we entered into in February 2006 was approved by our audit committee.

**PRINCIPAL AND SELLING STOCKHOLDERS**

The following tables set forth certain information regarding the beneficial ownership of our class A and class B common stock as of May 31, 2007 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 stockholders selling shares in this offering;
- each of our directors;
- each of our named executive officers and Mr. Ronald W. Kaiser, who joined us as chief financial officer in January 2007; and
- all of our directors and executive officers as a group.

The percentages shown are based on 1,413,222 shares of class A common stock and 3,081,300 shares of class B common stock outstanding as of May 31, 2007, 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, 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, 2007. 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 these tables 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.

The following table sets forth the number of shares of our common stock beneficially owned by the indicated parties, aggregating together all shares of class A common stock and class B common stock.

Beneficial Owner	Shares Beneficially Owned Prior to the Offering		Shares Offered in the Offering <sup>(1)</sup>	Shares Beneficially Owned After the Offering		Percentage of Total Voting Power After the Offering
	Number	Percentage		Number	Percentage	
R-Tech Ueno, Ltd. <sup>(2)</sup> 10F, Yamato Life Insurance Building 1-1-7 Uchisaiwaicho, Chiyoda-ku Tokyo 100-0011 Japan	365,900	8.1%			%	%
S&R Technology Holdings, LLC <sup>(3)</sup> 7201 Wisconsin Avenue Suite 700 Bethesda, Maryland 20814	3,301,565	73.5	— <sup>(1)</sup>	3,301,565		
Ridgeway Capital Partners Limited 6th Floor 3-12 Kioi-cho Chiyoda-ku, Tokyo 102-0094 Japan	233,376 <sup>(4)</sup>	5.2	—	233,376 <sup>(4)</sup>		
Astellas Pharma, Inc. 3-11 Nihonbashi-Honcho 2-chome Chuo-ku, Tokyo 103-8411 Japan	147,500	3.3	—	147,500		

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Beneficial Owner	Shares Beneficially Owned Prior to the Offering		Shares Offered in the Offering(1)	Shares Beneficially Owned After the Offering		Percentage of Total Voting Power After the Offering
	Number	Percentage		Number	Percentage	
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	2.2	—	100,000		
Mizuho Capital Co., Ltd. 4-3, Nihonbashi-Kabutocho Chuo-ku, Tokyo 103-0026 Japan	90,595(5)	2.0%	—	90,595(5)	%	%
Mitsubishi UFJ Capital Co., Ltd.(6) 2-14-1 Kyobashi, Kanematsu Building 9th Floor Chuo-Ku, Tokyo 104-0031 Japan	83,000	1.8	—	83,000		
<b>Directors and Executive Officers:</b>						
Sachiko Kuno	3,311,565(7)	73.5	—			
Ryuji Ueno	3,309,565(8)	73.5	—			
Ronald W. Kaiser	—	—	—	—	—	—
Mariam E. Morris	8,000(9)	*	—	8,000(9)	*	
Brad E. Fackler	6,000(10)	*	—	6,000(10)	*	
Gayle R. Dolecek	18,750(11)	*	—	18,750(11)	*	
Kei S. Tolliver	5,000(12)	*	—	5,000(12)	*	
Michael J. Jeffries	—	—	—	—	—	—
Timothy I. Maudlin	—	—	—	—	—	—
Hidetoshi Mine	233,376(13)	5.2	—	233,376(13)		
V. Sue Molina	—	—	—	—	—	—
All executive officers and directors as a group (12 persons)	3,590,691(14)	78.9	—	3,590,691		

The following table sets forth information regarding the shares of class A common stock and class B common stock beneficially owned by the indicated parties as of May 31, 2007, both before and after giving effect to the shares to be sold by each party in the offering.

Beneficial Owner	Shares Beneficially Owned Prior to the Offering		Percentage of Shares Beneficially Owned Prior to the Offering		Shares Beneficially Owned After the Offering		Percentage of Shares Beneficially Owned After the Offering	
	A Shares	B Shares	A Shares	B Shares	A Shares	B Shares	A Shares	B Shares
R-Tech Ueno, Ltd.(2) 10F, Yamato Life Insurance Building 1-1-7 Uchisaiwaicho, Chiyoda-ku Tokyo 100-0011 Japan	365,900	—	25.9%	—%		—	%	—%
S&R Technology Holdings, LLC(3) 7201 Wisconsin Avenue Suite 700 Bethesda, Maryland 20814	220,265	3,081,300	15.6	100.0	220,265(1)	3,081,300		100.0

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Beneficial Owner	Shares Beneficially Owned Prior to the Offering		Percentage of Shares Beneficially Owned Prior to the Offering		Shares Beneficially Owned After the Offering		Percentage of Shares Beneficially Owned After the Offering	
	A Shares	B Shares	A Shares	B Shares	A Shares	B Shares	A Shares	B Shares
Ridgeway Capital Partners Limited 6th Floor 3-12 Kioi-cho Chiyoda-ku, Tokyo 102-0094 Japan	233,376(4)	—	16.5	—	233,376(4)	—	—	—
Astellas Pharma, Inc. 3-11 Nihonbashi-Honcho 2-chome Chuo-ku, Tokyo 103-8411 Japan	147,500	—	10.4	—	147,500	—	—	—
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%	—%	100,000	—	%	—%
Mizuho Capital Co., Ltd. 4-3, Nihonbashi-Kabutocho Chuo-ku, Tokyo 103-0026 Japan	90,595(5)	—	6.4	—	90,595(5)	—	—	—
Mitsubishi UFJ Capital Co., Ltd.(6) 2-14-1 Kyobashi, Kanematsu Building 9th Floor Chuo-Ku, Tokyo 104-0031 Japan	83,000	—	5.9	—	83,000	—	—	—
<b>Directors and Executive Officers:</b>								
Sachiko Kuno	230,265(15)	3,081,300(16)	16.2	100.0	230,265(15)(1)	3,081,300(16)	—	100.0
Ryuji Ueno	228,265(17)	3,081,300(16)	16.1	100.0	228,265(17)(1)	3,081,300(16)	—	100.0
Ronald W. Kaiser	—	—	—	—	—	—	—	—
Mariam E. Morris	8,000(9)	—	*	—	8,000(9)	—	*	—
Brad E. Fackler	6,000(10)	—	*	—	6,000(10)	—	*	—
Gayle R. Dolecek	18,750(11)	—	*	—	18,750(11)	—	*	—
Kei S. Tolliver	5,000(12)	—	*	—	5,000(12)	—	*	—
Michael J. Jeffries	—	—	—	—	—	—	—	—
Timothy I. Maudlin	—	—	—	—	—	—	—	—
Hidetoshi Mine	233,376(13)	—	16.5	—	233,376(13)	—	—	—
V. Sue Molina	—	—	—	—	—	—	—	—
All executive officers and directors as a group (12 persons)	509,391(14)	3,081,300(16)	34.1	100.0	509,391(14)(1)	3,081,300(16)	—	100.0

\* Represents beneficial ownership of less than 1%.

- (1) If the underwriters exercise their over-allotment option in full, we will sell additional shares and S&R Technology Holdings, LLC will sell shares. If the underwriters exercise their over-allotment option only in part, we will sell the first shares and S&R Technology Holdings, LLC will sell any remaining shares as to which the option was exercised.
- (2) 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. Drs. Kuno and Ueno directly and indirectly own a majority of the capital stock of R-Tech but do not have or share voting or dispositive power with respect to the shares of our stock held by R-Tech.



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- (3) Voting and dispositive power with respect to the shares held by S&R Technology Holdings, LLC is shared by Drs. Kuno and Ueno.
- (4) Consists of 162,788 shares held by OPE Limited Partnership 1 and 70,588 shares held by OPE Limited Partnership 2. Ridgeway Capital Partners Limited 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 Ridgeway Capital Partners Limited, who are Hidetoshi Mine, one of our directors, Kenji Ogawa, Mitsunaga Tada, Kiyoyuki Katsumata, Koji Abe, Isao Nishimuta and Takumi Sakagami.
- (5) 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.
- (6) 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.
- (7) Includes 10,000 shares issuable upon exercise of stock options exercisable within 60 days of May 31, 2007. Also includes 3,301,565 shares held by S&R Technology Holdings, LLC, as to which Dr. Kuno shares voting and dispositive control. Excludes 365,900 shares held by R-Tech. See note 2 above.
- (8) Includes 8,000 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2007. Also includes 3,301,565 shares held by S&R Technology Holdings, LLC, as to which Dr. Ueno shares voting and dispositive control. Excludes 365,900 shares held by R-Tech. See note 2 above.
- (9) Consists of 8,000 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2007.
- (10) Consists of 6,000 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2007.
- (11) Consists of 18,750 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2007.
- (12) Consists of 5,000 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2007.
- (13) Consists of 162,788 shares held by OPE Limited Partnership 1 and 70,588 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.
- (14) Includes 57,750 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2007.
- (15) Includes 10,000 shares issuable upon exercise of stock options exercisable within 60 days of May 31, 2007. Also includes 220,265 shares held by S&R Technology Holdings, LLC, as to which Dr. Kuno shares voting and investment control. Excludes                      shares held by R-Tech. See note 2 above.
- (16) 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.
- (17) Includes 8,000 shares of class A common stock issuable upon exercise of stock options exercisable within 60 days of May 31, 2007. Also includes 220,265 shares held by S&R Technology Holdings, LLC, as to which Dr. Ueno shares voting and dispositive control. Excludes                      shares held by R-Tech. See note 2 above.

## 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, 2007, there were 1,035,222 shares of class A common stock outstanding held by 22 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, 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

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- 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 A common stock and only shares of class B 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

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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 American Stock Transfer & Trust Company.

### **NASDAQ Global 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 December 31, 2006. Each share of class B common stock is convertible into one share of class A 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 \_\_\_\_\_ shares of class A common stock will be eligible for sale under Rule 144(k).

### **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 \_\_\_\_\_, 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. \_\_\_\_\_ 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.

\_\_\_\_\_ 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, \_\_\_\_\_ 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 \_\_\_\_\_ 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, 2007, we had outstanding options to purchase 135,400 shares of class A common stock, of which options to purchase 122,650 shares of class A common stock were vested. Following this offering, we intend to file a registration statement 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 “Executive Compensation — 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 and the selling stockholders are offering the shares of class A common stock described in this prospectus through a number of underwriters. , and Leerink Swann & Co., Inc. are the representatives of the underwriters. We and the selling stockholders have entered into a firm commitment underwriting agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, we and the selling stockholders 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>Underwriter</u>	<u>Number of Shares</u>
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 and the selling stockholders.

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 and S&R Technology Holdings, LLC, or S&R, have granted the underwriters an over-allotment option to buy up to additional shares of our class A common stock ( shares from us and shares from S&R) 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 in whole or in part at any time within 30 days after the date of this prospectus. If the underwriters exercise this option only in part, we will sell the first shares and S&R will sell any remaining shares. To the extent that the underwriters exercise this option, each underwriter will purchase additional shares from us and S&R 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 and by the selling stockholders. 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 \$ .

	<u>No Exercise</u>	<u>Full Exercise</u>
Per Share	\$	\$
Total paid by us	\$	\$
Total paid by selling stockholders	\$	\$

*Listing.* We have applied to have our class A common stock approved for quotation on The NASDAQ Global 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 \_\_\_\_\_ 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 \_\_\_\_\_. 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.

\_\_\_\_\_ 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, \_\_\_\_\_ 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.

*Directed Share Program.* At our request, the underwriters have reserved for sale to our employees, directors, families of employees and directors, business associates and other third parties, including existing stockholders, at the initial public offering price up to 10% of the shares of class A common stock being offered by this prospectus. The sale of the reserved shares of class A common stock to these purchasers will be made by \_\_\_\_\_. The purchasers of these shares of class A common stock will not be subject to a lock-up except as required by the Conduct Rules of the NASD, which require a 90-day lock-up if they are affiliated with or associated with NASD members or if they or members of their immediate families hold

senior positions at financial institutions, or to the extent the purchasers are subject to a lock-up agreement with the underwriters as described above. We do not know if our employees, directors, families of employees and directors, business associates and other third parties will choose to purchase all or any portion of the reserved shares of class A common stock, but any purchases they do make will reduce the number of shares of class A common stock available to the general public. If all of these reserved shares of class A common stock are not purchased, the underwriters will offer the remainder to the general public on the same terms as the other shares of class A common stock offered by this prospectus.

*Indemnification.* We and the selling stockholders will indemnify the underwriters against some liabilities, including liabilities under the Securities Act. If we and the selling stockholders are unable to provide this indemnification, we and the selling stockholders 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.

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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.

*Japan.* The shares of our class A common stock have not been and will not be registered under the Securities and Exchange Law of Japan, or the Securities and Exchange Law, and the underwriters have agreed that they will not offer or sell any shares of our class A common stock, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Securities and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

## 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 consolidated financial statements as of December 31, 2005 and 2006 and for each of the three years in the period ended December 31, 2006 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm 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 consolidated balance sheets and the related consolidated 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 subsidiaries (collectively, the "Company") at December 31, 2005 and December 31, 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 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.

As discussed in Note 2 to the consolidated financial statements, the Company has restated its financial statements for the years ended December 31, 2004 and 2005.

As discussed in Note 3 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland  
May 14, 2007

SUCAMPO PHARMACEUTICALS, INC.

Consolidated Balance Sheets

	December 31,		March 31, 2007	
	2005	2006	Actual	Pro Forma
	(Restated)		(Unaudited)	(Unaudited)
<b>ASSETS:</b>				
Current assets:				
Cash and cash equivalents	\$ 17,436,125	\$ 22,481,113	\$ 15,692,381	
Short-term investments	28,435,058	29,399,176	29,399,486	
Accounts receivable	584,444	3,565,518	4,948,964	
Income taxes receivable	—	2,354,831	2,362,155	
Deferred tax assets	526,752	1,612,414	1,466,360	
Prepaid expenses and other current assets	282,568	536,071	777,853	
Total current assets	47,264,947	59,949,123	54,647,199	
Restricted cash	—	212,737	215,674	
Property and equipment, net	177,460	342,926	415,632	
Deferred tax assets — noncurrent	452,946	3,288,473	3,094,136	
Deposits and other assets	89,727	3,290,439	3,795,419	
Total assets	<u>\$ 47,985,080</u>	<u>\$ 67,083,698</u>	<u>\$ 62,168,060</u>	
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY:</b>				
Current liabilities:				
Accounts payable	\$ 1,900,605	\$ 2,391,296	\$ 3,672,713	
Accrued expenses	2,083,214	5,409,441	4,987,141	
Deferred revenue — current	29,095,717	11,516,979	5,504,002	
Income taxes payable	1,766,172	—	—	
Notes payable — related parties — current	847,733	—	—	
Other current liabilities	1,520,174	8,027	—	
Total current liabilities	37,213,615	19,325,743	14,163,856	
Notes payable — related parties, net of current portion	2,545,800	—	—	
Deferred revenue, net of current portion	18,465,533	9,191,839	9,050,441	
Other liabilities	—	33,453	38,898	
Total liabilities	58,224,948	28,551,035	23,253,195	
Commitments (Note 7)				
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, 2005 and 2006 and March 31, 2007 (unaudited); 0 pro forma shares outstanding at March 31, 2007 (unaudited)	20,288,104	20,288,104	20,288,104	\$ —
Class A Common Stock, \$0.01 par value; 5,000,000 shares authorized; 752,015 shares issued and outstanding at December 31, 2005 and 1,035,222 shares issued and outstanding at December 31, 2006 and March 31, 2007 (unaudited); 1,413,222 pro forma shares outstanding at March 31, 2007 (unaudited)	7,521	10,352	10,352	14,132
Class B Common Stock, \$0.01 par value; 5,000,000 shares authorized; 3,081,300 shares issued and outstanding at December 31, 2005 and 2006 and March 31, 2007 (unaudited)	30,813	30,813	30,813	30,813
Additional paid-in capital	14,695,720	41,864,150	41,709,162	61,993,486
Accumulated other comprehensive loss	(94,951)	(294,486)	(273,538)	(273,538)
Accumulated deficit	(45,167,075)	(23,366,270)	(22,850,028)	(22,850,028)
Total stockholders' (deficit) equity	(10,239,868)	38,532,663	38,914,865	\$ 38,914,865
Total liabilities and stockholders' (deficit) equity	<u>\$ 47,985,080</u>	<u>\$ 67,083,698</u>	<u>\$ 62,168,060</u>	

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

**SUCAMPO PHARMACEUTICALS, INC.**
**Consolidated Statements of Operations and Comprehensive (Loss) Income**

	Year Ended December 31,			Three Months Ended March	
	2004	2005	2006	2006	2007
	(Restated)	(Restated)		(Restated) (Unaudited)	(Unaudited)
<b>Revenues and other income:</b>					
Research and development revenue	\$ 2,838,020	\$ 38,959,446	\$ 46,381,616	\$ 22,440,868	\$ 9,365,761
Contract revenue	68,968	1,000,003	1,500,004	1,500,004	—
Collaboration revenue	24,496	146,977	146,977	36,744	36,744
Contract revenue — related parties	410,799	98,337	404,411	29,524	116,206
Other income — gain on sale of patent to related party	497,000	—	—	—	—
Product royalty revenue	—	—	6,590,479	—	2,309,403
Co-promotion revenue	—	—	4,242,997	161,347	1,132,030
<b>Total revenues and other income</b>	<b>3,839,283</b>	<b>40,204,763</b>	<b>59,266,484</b>	<b>24,168,487</b>	<b>12,960,144</b>
<b>Operating expenses:</b>					
Research and development	14,036,070	31,167,450	16,391,852	6,120,270	5,946,101
General and administrative	8,216,421	7,759,560	14,586,515	2,967,873	2,833,607
Selling and marketing	—	294,744	11,103,013	947,797	3,231,176
Milestone royalties — related parties	1,000,000	1,500,000	1,250,000	1,250,000	—
Product royalties — related parties	—	—	1,171,641	—	410,561
<b>Total operating expenses</b>	<b>23,252,491</b>	<b>40,721,754</b>	<b>44,503,021</b>	<b>11,285,940</b>	<b>12,421,445</b>
<b>(Loss) income from operations</b>	<b>(19,413,208)</b>	<b>(516,991)</b>	<b>14,763,463</b>	<b>12,882,547</b>	<b>538,699</b>
<b>Non-operating income (expense):</b>					
Interest income	96,494	1,045,980	1,976,068	305,628	324,053
Interest expense	(173,519)	(310,771)	(90,025)	(20,248)	(3,597)
Other income (expense), net	20,861	254,560	254,559	139,143	(2,522)
<b>Total non-operating (expense) income, net</b>	<b>(56,164)</b>	<b>989,769</b>	<b>2,140,602</b>	<b>424,523</b>	<b>317,934</b>
<b>(Loss) income before income taxes</b>	<b>(19,469,372)</b>	<b>472,778</b>	<b>16,904,065</b>	<b>13,307,070</b>	<b>856,633</b>
Income tax (provision) benefit	—	(788,341)	4,896,740	—	(340,391)
<b>Net (loss) income</b>	<b><u>\$(19,469,372)</u></b>	<b><u>\$(315,563)</u></b>	<b><u>\$21,800,805</u></b>	<b><u>\$13,307,070</u></b>	<b><u>\$516,242</u></b>
<b>Net (loss) income per share (Note 4):</b>					
Basic net (loss) income per share	\$ (5.08)	\$ (0.08)	\$ 5.39	\$ 3.47	\$ 0.13
Diluted net (loss) income per share	\$ (5.08)	\$ (0.08)	\$ 5.34	\$ 3.41	\$ 0.12
Weighted average common shares outstanding — basic	3,835,257	3,835,378	4,045,044	3,835,862	4,116,522
Weighted average common shares outstanding — diluted	3,835,257	3,835,378	4,081,195	3,898,012	4,168,128
<b>Pro forma net income per share (Note 4)</b>					
<b>(unaudited):</b>					
Basic pro forma net income per share					\$ 0.11
Diluted pro forma net income per share					\$ 0.11
Pro forma weighted average common shares outstanding — basic					4,494,522
Pro forma weighted average common shares outstanding — diluted					4,546,128
<b>Comprehensive (loss) income:</b>					
Net (loss) income	\$(19,469,372)	\$ (315,563)	\$ 21,800,805	\$ 13,307,070	\$ 516,242
Other comprehensive (loss) income:					
Foreign currency translation	(13,108)	32,688	(199,535)	(4,318)	20,948
<b>Comprehensive (loss) income</b>	<b><u>\$(19,482,480)</u></b>	<b><u>\$(282,875)</u></b>	<b><u>\$21,601,270</u></b>	<b><u>\$13,302,752</u></b>	<b><u>\$537,190</u></b>

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

**SUCAMPO PHARMACEUTICALS, INC.**  
**Consolidated Statements of Changes in Stockholders' (Deficit) Equity**

	Series A Convertible Preferred Stock		Class A Common Stock		Class B Common Stock		Additional Paid-In Capital	Deferred Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at December 31, 2003	3,780	\$ 20,288,104	249,765	\$ 2,498	3,581,300	\$ 35,813	\$ 11,047,074	\$ (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	—	—	5,000	50	—	—	129,000	(129,050)	—	—	—
Foreign currency translation	—	—	—	—	—	—	—	—	(13,108)	—	(13,108)
Net loss (restated)	—	—	—	—	—	—	—	—	—	(19,469,372)	(19,469,372)
Balance at December 31, 2004 (restated)	3,780	20,288,104	254,765	2,548	3,581,300	35,813	11,176,074	(61,828)	(127,639)	(44,851,512)	(13,538,440)
Amortization of deferred compensation	—	—	—	—	—	—	—	26,210	—	—	26,210
Conversion of class B common stock to class A common stock	—	—	500,000	5,000	(500,000)	(5,000)	—	—	—	—	—
Issuance of stock options and vesting modifications	—	—	—	—	—	—	3,614,546	—	—	—	3,614,546
Forfeitures of 3,750 shares of restricted class A common stock	—	—	(3,750)	(37)	—	—	(96,750)	35,618	—	—	(61,169)
Exercise of 1,000 options for 1,000 shares of class A common stock	—	—	1,000	10	—	—	1,850	—	—	—	1,860
Foreign currency translation	—	—	—	—	—	—	—	—	32,688	—	32,688
Net loss (restated)	—	—	—	—	—	—	—	—	—	(315,563)	(315,563)
Balance at December 31, 2005 (restated)	3,780	20,288,104	752,015	7,521	3,081,300	30,813	14,695,720	—	(94,951)	(45,167,075)	(10,239,868)
Issuance of class A common stock at \$85 per share, net of offering costs of \$91,792	—	—	282,207	2,821	—	—	23,892,981	—	—	—	23,895,802
Exercise of 1,000 options for 1,000 shares of class A common stock	—	—	1,000	10	—	—	1,850	—	—	—	1,860
Stock-based compensation	—	—	—	—	—	—	3,273,599	—	—	—	3,273,599
Foreign currency translation	—	—	—	—	—	—	—	—	(199,535)	—	(199,535)
Net income	—	—	—	—	—	—	—	—	—	21,800,805	21,800,805
Balance at December 31, 2006	3,780	20,288,104	1,035,222	10,352	3,081,300	30,813	41,864,150	—	(294,486)	(23,366,270)	38,532,663
Stock-based compensation (unaudited) (Note 3)	—	—	—	—	—	—	(154,988)	—	—	—	(154,988)
Foreign currency translation (unaudited)	—	—	—	—	—	—	—	—	20,948	—	20,948
Net income (unaudited)	—	—	—	—	—	—	—	—	—	516,242	516,242
Balance at March 31, 2007 (unaudited)	<u>3,780</u>	<u>\$ 20,288,104</u>	<u>1,035,222</u>	<u>\$ 10,352</u>	<u>3,081,300</u>	<u>\$ 30,813</u>	<u>\$ 41,709,162</u>	<u>\$ —</u>	<u>\$ (273,538)</u>	<u>\$ (22,850,028)</u>	<u>\$ 38,914,865</u>

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

**SUCAMPO PHARMACEUTICALS, INC.**  
**Consolidated Statements of Cash Flows**

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
	(Restated)	(Restated)		(Restated) (Unaudited)	(Unaudited)
<b>Cash flows from operating activities:</b>					
Net (loss) income	\$ (19,469,372)	\$ (315,563)	\$ 21,800,805	\$ 13,307,070	\$ 516,242
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:					
Depreciation and amortization	95,412	61,764	68,615	16,995	24,039
Amortization of discount on note	63,558	—	—	—	—
Deferred tax (benefit) provision	(302,276)	(683,822)	(4,034,507)	(979,698)	340,391
Stock-based compensation	68,418	3,614,546	3,273,599	—	(154,988)
Changes in operating assets and liabilities:					
Accounts receivable	13,353	(488,826)	(2,842,121)	110,240	(1,383,195)
Deposits and other assets	7,297	15,362	(83,978)	(156,531)	—
Prepaid expenses and other current assets	223,732	(103,357)	(253,658)	(120,645)	(239,001)
Accounts payable	(1,904,079)	609,654	437,379	2,580,402	1,177,907
Accrued expenses	1,134,442	354,637	3,022,722	(958,755)	(463,507)
Income taxes payable and receivable, net	376,579	1,463,896	(4,007,459)	(2,165,754)	(8,862)
Deferred revenue	20,358,750	20,363,559	(26,828,580)	(3,586,456)	(6,167,662)
Other liabilities	2,544,578	(1,076,363)	(1,466,547)	(1,520,174)	5,446
Net cash provided by (used in) operating activities	<u>3,210,392</u>	<u>23,815,487</u>	<u>(10,913,730)</u>	<u>6,526,694</u>	<u>(6,353,190)</u>
<b>Cash flows from investing activities:</b>					
Investments in restricted cash	—	—	(212,737)	—	(2,937)
Purchases of short-term investments	(3,000,000)	(28,435,058)	(2,309,118)	(102,268)	(310)
Proceeds from the sale and maturities of short-term investments	—	3,000,000	1,345,000	—	—
Purchases of property and equipment	(17,971)	(38,512)	(236,488)	(5,548)	(95,945)
Proceeds from disposal of property and equipment	2,202	—	116	—	—
Net cash used in investing activities	<u>(3,015,769)</u>	<u>(25,473,570)</u>	<u>(1,413,227)</u>	<u>(107,816)</u>	<u>(99,192)</u>
<b>Cash flows from financing activities:</b>					
Proceeds from exercise of stock options	—	1,860	1,860	—	—
Issuance of common stock, net of offering costs	—	—	23,895,802	19,448,975	—
Payments of capitalized IPO costs	—	—	(2,922,907)	(156,084)	(360,425)
Issuance of notes payable — related parties	2,607,958	—	1,200,000	1,208,182	—
Payments on notes payable — related parties	(316,550)	(2,280,356)	(4,753,740)	—	—
Net cash provided by (used in) financing activities	<u>2,291,408</u>	<u>(2,278,496)</u>	<u>17,421,015</u>	<u>20,501,073</u>	<u>(360,425)</u>
Effect of exchange rates on cash and cash equivalents	361,528	(544,989)	(49,070)	(4,317)	24,075
Net increase (decrease) in cash and cash equivalents	2,847,559	(4,481,568)	5,044,988	26,915,634	(6,788,732)
Cash and cash equivalents at beginning of year	19,070,134	21,917,693	17,436,125	17,436,125	22,481,113
Cash and cash equivalents at end of year	<u>\$ 21,917,693</u>	<u>\$ 17,436,125</u>	<u>\$ 22,481,113</u>	<u>\$ 44,351,759</u>	<u>\$ 15,692,381</u>
<b>Supplemental cash flow disclosures:</b>					
Cash paid for interest	\$ 68,312	\$ 250,868	\$ 85,802	\$ 20,439	\$ 3,597
Tax refunds received	\$ 84,460	\$ —	\$ —	\$ —	\$ —
Tax payments made	\$ —	\$ —	\$ 3,161,490	\$ 3,145,453	\$ —
<b>Supplemental disclosure of non-cash investing and financing activities:</b>					
Conversion of class B common stock to class A common stock	\$ —	\$ 5,000	\$ —	\$ —	\$ —
Capitalized IPO costs included in accounts payable and accrued expenses	\$ —	\$ —	\$ 196,349	\$ —	\$ 143,248

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

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated 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 23, 2006, SPI's Board of Directors approved a transaction to have SPI acquire the capital stock of its affiliated European and Asian operating companies, Sucampo Pharma Europe, Ltd. (SPE) and Sucampo Pharma, Ltd. (SPL). On September 28, 2006, SPI completed this reorganization transaction and acquired the capital stock of SPE and SPL. The reorganization was accounted for as a merger of companies under common control, and accounted for at historical cost as of the earliest period presented. Hereinafter, SPI, SPE and SPL are referred to collectively as the "Company." The financial information of these three entities is presented in these consolidated 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 Executive Officer and Chief Scientific Officer of the Company (see Notes 8 and 9 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® (lubiprostone), to treat chronic idiopathic constipation (Constipation) in adults. Commercialization of AMITIZA began in April 2006 throughout the United States.

***Basis of Presentation and Principles of Consolidation***

The financial statements for all periods presented have been prepared on a consolidated basis. All significant inter-company accounts and transactions among these three entities have been eliminated. The consolidated financial statements have been prepared on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America.

***Interim Financial Data***

The unaudited interim consolidated financial statements as of March 31, 2007 and for the three months ended March 31, 2006 and 2007 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, 2007 are not necessarily indicative of the results to be expected for the year ending December 31, 2007. 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 for interim financial statements.

***Unaudited Pro Forma Balance Sheet***

In connection with the Company's proposed initial public offering, its 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, 2007 is presented to give effect to the above capital transaction.

***Capital Resources***

The Company has a limited operating history and its expected activities will necessitate significant uses of working capital throughout 2007 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

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

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 cash received from the joint collaboration and license agreement and the supplemental agreement entered into with Takeda Pharmaceutical Company Limited (Takeda) (see Note 11).

**2. Restatement of Previously Issued Consolidated Financial Statements**

The Company has restated its previously issued consolidated financial statements and related footnotes as of December 31, 2005, for the years ended December 31, 2004 and 2005 and for the three months ended March 31, 2006, as set forth in these consolidated financial statements. The Company has restated its consolidated financial statements to correct an error in accounting for the revenue recognition of the collaboration and license agreements with Takeda. All amounts in these consolidated financial statements have been updated to reflect this restatement.

***Description of Errors***

The Company identified an error at its operating company in the United States. This error originated in the fourth quarter of 2004 and continued throughout 2005 and part of 2006. The identification of this error occurred as a result of the Company evaluating its assumptions under Emerging Issues Task Force (EITF) 00-21, "*Revenue Arrangements with Multiple Deliverables*" (EITF 00-21), in accounting for arrangements with multiple deliverables that require significant judgment and estimates.

The Company reassessed whether each of its required deliverables under the 16-year joint collaboration and license agreement with Takeda (Takeda Agreement) had value to Takeda on a stand-alone basis and whether there is objective and reliable evidence of the fair value of each of those deliverables. This reassessment determined that the previous assessment of a single unit of accounting for the deliverables under the Takeda Agreement was not appropriate. In addition, the Company determined that the substantive milestone method was not appropriate to account for the cash payments received from Takeda related to the Company completing these required deliverables and a time-based model would be more appropriate to account for such cash payments from Takeda. Accordingly, in the restated consolidated financial statements for the years ended December 31, 2004 and 2005 and for the three months ended March 31, 2006, the Company reduced the milestone revenue and increased research and development revenue. Total revenues and other income increased by approximately \$1.2 million for the year ended December 31, 2004, decreased by approximately \$6.8 million for the year ended December 31, 2005 and decreased by approximately \$1.5 million for the three months ended March 31, 2006 (unaudited). In addition, related deferred revenue increased by approximately \$5.6 million at December 31, 2005.

**SUCAMPO PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements — (Continued)**

The following tables present the effects of the restatement adjustments on the affected line items in the previously reported consolidated statements of operations and comprehensive (loss) income for the years ended December 31, 2004 and 2005 and for the three months ended March 31, 2006 and consolidated balance sheet as of December 31, 2005. The restatement adjustments did not affect the overall cash (used in) provided by operating, investing or financing activities or the effect of exchange rates on cash and cash equivalents in the consolidated statements of cash flows for the years ended December 31, 2004 and 2005 and for the three months ended March 31, 2006.

**Impact on Consolidated Statement of Operations and Comprehensive (Loss) Income Items**

	Year Ended December 31, 2004		
	As Reported	Adjustment	Restatement
Collaboration revenue	\$ —	\$ 24,496	\$ 24,496
Research and development revenue	1,482,337	1,355,683	2,838,020
Contract revenue	275,154	(206,186)	68,968
Total revenues and other income	2,665,290	1,173,993	3,839,283
General and administrative expenses	8,226,730	(10,309)	8,216,421
Milestone royalties — related parties	—	1,000,000	1,000,000
Loss from operations	(19,597,510)	184,302	(19,413,208)
Loss before income taxes	(19,653,674)	184,302	(19,469,372)
Net loss	(19,653,674)	184,302	(19,469,372)
Basic net loss per share	(5.12)	0.04	(5.08)
Diluted net loss per share	(5.12)	0.04	(5.08)
Comprehensive loss	(19,666,782)	184,302	(19,482,480)

	Year Ended December 31, 2005		
	As Reported <sup>(1)</sup>	Adjustment	Restatement
Collaboration revenue	\$ —	\$ 146,977	\$ 146,977
Milestone revenue	30,000,000	(30,000,000)	—
Research and development revenue	14,671,508	24,287,938	38,959,446
Contract revenue	2,237,115	(1,237,112)	1,000,003
Total revenues and other income	47,006,960	(6,802,197)	40,204,763
General and administrative expenses	7,821,419	(61,859)	7,759,560
Income (loss) from operations	6,223,347	(6,740,338)	(516,991)
Income before income taxes	7,213,116	(6,740,338)	472,778
Net income (loss)	6,424,775	(6,740,338)	(315,563)
Basic net income (loss) per share	1.68	(1.76)	(0.08)
Diluted net income (loss) per share	1.63	(1.71)	(0.08)
Comprehensive income (loss)	6,457,463	(6,740,338)	(282,875)



SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

	Three Months Ended March 31, 2006		
	As Reported (Unaudited)	Adjustment (Unaudited)	Restatement (Unaudited)
Collaboration revenue	\$ —	\$ 36,744	\$ 36,744
Milestone revenue	20,000,000	(20,000,000)	—
Research and development revenue	3,868,885	18,571,983	22,440,868
Contract revenue	1,809,279	(309,275)	1,500,004
Co-promotion revenue	—	161,347	161,347
Total revenues and other income	25,707,688	(1,539,201)	24,168,487
General and administrative expenses	3,019,694	(51,821)	2,967,873
Selling and marketing expenses	750,094	197,703	947,797
Total operating expenses	11,140,058	145,882	11,285,940
Income from operations	14,567,630	(1,685,083)	12,882,547
Other income	139,672	(529)	139,143
Income before income taxes	14,992,682	(1,685,612)	13,307,070
Income tax (provision) benefit	(3,727,873)	3,727,873	—
Net income	11,264,809	2,042,261	13,307,070
Comprehensive income	11,260,491	2,042,261	13,302,752

Impact on Consolidated Balance Sheet Items

	December 31, 2005		
	As Reported(1)	Adjustment	Restatement
ASSETS			
Deferred tax assets	\$ 292,404	\$ 234,348	\$ 526,752
Deferred licensing fees	61,860	(61,860)	—
Total current assets	47,092,459	172,488	47,264,947
Deferred tax assets — noncurrent	687,294	(234,348)	452,946
Deferred licensing fees, net of current portion	865,972	(865,972)	—
Total assets	48,912,912	(927,832)	47,985,080
LIABILITIES AND STOCKHOLDERS' DEFICIT			
Deferred revenue — current	\$ 16,599,457	\$ 12,496,260	\$ 29,095,717
Total current liabilities	24,717,355	12,496,260	37,213,615
Deferred revenue, net of current portion	25,333,589	(6,868,056)	18,465,533
Total liabilities	52,596,744	5,628,204	58,224,948
Accumulated deficit	(38,611,039)	(6,556,036)	(45,167,075)
Total stockholders' deficit	(3,683,832)	(6,556,036)	(10,239,868)

(1) The as-reported amounts in the above tables were previously restated for errors in the Company's deferred tax assets as of December 31, 2005 and fully vested non-employee options granted during the year ended December 31, 2005. The restated consolidated financial statements to correct these two errors were included in the amendment to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 20, 2006.

**SUCAMPO PHARMACEUTICALS, INC.**  
**Notes to Consolidated Financial Statements — (Continued)**

### **3. Summary of Significant Accounting Policies**

#### ***Cash and Cash Equivalents***

For the purpose of the consolidated 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.

#### ***Restricted Cash***

Restricted cash consists of approximately \$213,000 and \$216,000 at December 31, 2006 and March 31, 2007 (unaudited), respectively, of cash securing a letter of credit related to the Company's new headquarters lease agreement dated December 18, 2006 (see Note 7). This letter of credit renews automatically each year and is required until the lease expires on February 15, 2017.

#### ***Short-term Investments***

Short-term investments consist entirely of auction rate securities and a money market account. The Company's investments in these securities are classified as available-for-sale securities under Statement of Financial Accounting Standards (SFAS) No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*" (SFAS 115). Although the auction rate securities have variable interest rates which typically reset every 7 to 35 days, they have long-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, 2005 and 2006 and March 31, 2007 (unaudited), 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, 2005 and 2006 and the three months ended March 31, 2006 and 2007 (unaudited), 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 years ended December 31, 2004, 2005 and 2006 and the three months ended March 31, 2006 and 2007 (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 of cash and cash equivalents, restricted cash and short-term investments. The Company places its cash and cash equivalents, restricted cash and short-term investments with highly rated financial institutions. At December 31, 2005 and 2006 and March 31, 2007 (unaudited), the Company had approximately \$44.9 million, \$49.9 million and \$44.6 million, respectively, of cash and cash equivalents, restricted cash 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, restricted cash, 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

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

with related parties (see Note 8) 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 11). The Company did not record an allowance for doubtful accounts at December 31, 2005 or 2006 or at March 31, 2007 (unaudited) because it believes that its accounts receivable are fully collectible and it does not have a history of credit losses or write-offs of its 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.

***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 the carrying value. There have been no impairment charges recorded during the years ended December 31, 2004, 2005 or 2006 or during the three months ended March 31, 2006 or 2007 (unaudited) because there have been no indicators of impairment during those periods.

***Deposits and Other Assets***

Deposits and other assets represent capitalized costs incurred for the Company's registration statement and certain deposits made for the Company's office leases.

***Revenue Recognition***

***Collaboration and License Agreements***

The Company's primary sources of revenue include up-front payments, development milestone payments, reimbursements of development and co-promotion costs and royalties. The Company recognizes revenue from these sources in accordance with Staff Accounting Bulletin (SAB) 104, "Revenue Recognition" (SAB 104), EITF No. 99-19, "Reporting Revenue Gross as a Principal Versus Net as an Agent" (EITF 99-19), and EITF No. 00-21. The application of EITF 00-21 requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable from the other aspects of the contractual arrangement into separate units of accounting and to determine the fair value to be allocated to each unit of accounting.

The Company entered into the Takeda Agreement with Takeda in October 2004 and a supplemental agreement to the Takeda Agreement (Supplemental Agreement) in February 2006. The Company evaluated the multiple deliverables within the Takeda Agreement and the Supplemental Agreement in accordance with the provisions of EITF 00-21 to determine whether the delivered elements that are the obligation of the Company have value to Takeda on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. Deliverables that meet these criteria are considered a separate unit of accounting.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate recognition of revenue is then applied to each separate unit of accounting.

The Company's deliverables under the Takeda Agreement and the Supplemental Agreement, including the related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 11.

The Takeda Agreement consists of the following key funding streams: an up-front payment, product development milestone payments, reimbursements of development costs and product royalty payments. The cash flows associated with the individual units of accounting from the Takeda Agreement are recognized as revenue using a time-based model. Under this model, cash flow streams related to each unit of accounting are recognized as revenue over the estimated performance period. Upon receipt of cash payments, revenue is recognized to the extent the accumulated service time, if any, has occurred. The remainder is deferred and recognized as revenue ratably over the remaining estimated performance period. A change in the period of time expected to complete the deliverable is accounted for as a change in estimate on a prospective basis. Revenue is limited to amounts that are nonrefundable and that Takeda is contractually obligated to pay to the Company.

Of the \$20.0 million upfront payment the Company received from Takeda in October 2004, the Company deferred approximately \$2.4 million associated with its obligation to participate in joint committees with Takeda, as described more fully in Note 11, and is recognizing this amount as collaboration revenue using the time-based model over the applicable performance period, which is equivalent to the 16-year life of the Takeda Agreement. The Company is recognizing the remaining \$17.6 million of the upfront payment as research and development revenue using the time-based model over the performance period, which began when the Takeda Agreement was executed and continues through June 2007, reflecting the estimated development period for the submissions related to Constipation and to irritable bowel syndrome with constipation (IBS-C). The Company is also recognizing product development milestone payments and reimbursements of development costs as research and development revenue using the time-based model over the same performance period through June 2007.

Based on the guidance of EITF 99-19, the Company has determined that it is acting as a principal under the Takeda Agreement and, as such, records these amounts as collaboration revenue and research and development revenue.

Royalties from licensees are based on third-party sales of licensed products and are recorded on the accrual basis when earned in accordance with contractual terms when third-party results are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met. 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 are not reported as revenue until the right of return lapses.

The Supplemental Agreement consists of the following key funding streams: reimbursements of co-promotion costs based upon a per-day rate and reimbursements of the costs of miscellaneous marketing activities.

Reimbursements of co-promotion costs for the Company's sales force efforts and reimbursements of miscellaneous marketing costs under the Supplemental Agreement are recognized as revenue as the related costs are incurred and Takeda becomes contractually obligated to pay the amounts. Based on the guidance of EITF 99-19, the Company has determined that it is acting as a principal as it relates to these activities under the Supplemental Agreement and, as such, records reimbursements of these amounts as co-promotion revenue.

Option fees received for other potential joint collaboration and license agreements with Takeda are not recognized as revenue immediately because the transactions do not represent a separate earnings process. Because 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

**SUCAMPO PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements — (Continued)**

revenue recognition upon exercise of the option and continue recognition over the estimated performance period. When recognized, option fees are recorded as contract revenue.

***Other Revenue Sources***

Revenues from the performance of research and development cost reimbursement activities under a long-term strategic alliance agreement (see Note 10) were recognized based on the time-based model. Under this model, the cash flow stream related to this unit of accounting is recognized as revenue over the estimated performance period. Upon receipt of cash payment, revenue is recognized to the extent the accumulated service time, if any, has occurred. The remainder is deferred and recognized as revenue ratably over the remaining estimated performance period. A change in the period of time expected to complete the deliverable is accounted for as a change in estimate on a prospective basis. Revenue is limited to amounts that are nonrefundable and that the customer is contractually obligated to pay to the Company.

Contract revenue related to development and consulting activities with related parties is also accounted for under the time-based model.

***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. Deferred revenue is classified as current if management believes the Company will complete the earnings process and be able to recognize the deferred amount as revenue within 12 months of the balance sheet date. At December 31, 2005 and 2006 and March 31, 2007 (unaudited), total deferred revenue was approximately \$47.6 million, \$20.7 million and \$14.6 million, respectively.

Total deferred revenue consists of the following as of:

	<u>December 31,</u>		<u>March 31,</u>
	<u>2005</u>	<u>2006</u>	<u>2007</u>
	<u>(Restated)</u>		<u>(Unaudited)</u>
Deferred revenue-current	\$ 29,095,717	\$ 11,516,979	\$ 5,504,002
Deferred revenue, net of current portion	18,465,533	9,191,839	9,050,441
	<u>\$ 47,561,250</u>	<u>\$ 20,708,818</u>	<u>\$ 14,554,443</u>

***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 11).

***Research and Development Expenses***

Research and development costs are expensed in the period in which they are incurred and include the 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.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

***General and Administrative Expenses***

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. Other costs include facility costs and professional fees for legal and accounting services.

Reimbursement of the Company's safety costs is recorded as a reduction of safety expenses and is included in general and administrative expenses. The Company has determined, in accordance with EITF 99-19, that it is acting as an agent in this arrangement and, as such, records reimbursements of these expenses on a net basis, offsetting the underlying expenses.

***Selling and Marketing Expenses***

Selling and marketing expenses are expensed as incurred and consist primarily of salaries and related costs for personnel, sales force fees and certain marketing expenditures.

***Milestone Royalties — Related Parties***

Milestone royalties — related parties are expensed as incurred immediately when the related milestone payments are due from Takeda. 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 (SAG), (Switzerland), affiliated through common ownership (see Note 9 for additional information on the lubiprostone license agreement between SAG and the Company). The Company expensed \$1.0 million, \$1.5 million and \$1.25 million in royalties for the years ended December 31, 2004, 2005 and 2006, respectively, and \$1.25 million for the three months ended March 31, 2006 (unaudited) and did not incur such expenses during the three months ended March 31, 2007 (unaudited).

***Product Royalties — Related Parties***

Product royalties — related parties represent the Company's obligation to SAG for 3.2% of net sales for AMITIZA and are expensed as incurred. The Company expensed approximately \$1.2 million in product royalties for the year ended December 31, 2006 and \$411,000 for the three months ended March 31, 2007 (unaudited). The Company has recorded a corresponding liability of approximately \$361,000 and \$771,000 as of December 31, 2006 and March 31, 2007 (unaudited), respectively.

***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 related party notes payable.

***Employee Stock-Based Compensation***

On January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123R, "*Share-Based Payment*" (SFAS 123R), under the prospective transition 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 had 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 is based on the intrinsic value of awarded stock options, which 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. Stock-based compensation, 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*"

## SUCAMPO PHARMACEUTICALS, INC.

## Notes to Consolidated Financial Statements — (Continued)

(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.

**Pro forma information for period prior to adoption of SFAS 123R:** 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 for the years ended December 31, 2004 and 2005 would have been changed to the following pro forma amounts:

	Year Ended December 31,	
	2004	2005
Net loss	<u>\$ (19,469,372)</u>	<u>\$ (315,563)</u>
Add: Stock-based employee compensation expense included in net loss	—	316,561
Less: Stock-based employee compensation expense determined under SFAS 123	<u>(107,032)</u>	<u>(530,695)</u>
Pro forma net loss	<u>\$ (19,576,404)</u>	<u>\$ (529,697)</u>

The Company had elected to recognize stock-based employee compensation expense under SFAS 123 for its fixed awards with pro-rata vesting based on a straight-line basis.

There were no such options issued to employees for the year ended December 31, 2005. 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 grant using the Black-Scholes 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:** SFAS 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statements of operations and comprehensive (loss) income.

Adoption of SFAS 123R was implemented utilizing the prospective transition method. Under this method, stock-based compensation expense is recognized for all share-based payment awards granted to employees or directors or modified subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R.

Upon adoption of SFAS 123R, the Company decided to utilize the straight-line method of allocating compensation expense over the vesting term of the stock-based awards and continued to use the Black-Scholes Model which was previously used for the Company's pro forma information required under SFAS 123. The Company's determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's expected stock price volatility over the expected term of the awards. The Company also utilizes the "simplified" method

## SUCAMPO PHARMACEUTICALS, INC.

## Notes to Consolidated Financial Statements — (Continued)

to calculate the expected term for options and the estimated volatility based on historical volatility of similar publicly traded companies as discussed under Staff Accounting Bulletin No. 107, “Share-Based Payment” (SAB 107).

The options granted in 2006 qualified as “plain vanilla” options under SAB 107 because the options were granted with an exercise price at least equal to the then fair value of the underlying stock, the only conditions for the awards were service conditions, the unvested options are forfeited upon employee termination, limited time exists for exercising vested options upon employee termination, and the options are not transferable.

The assumptions used to estimate the fair value of stock options granted for the year ended December 31, 2006 were as follows:

Expected volatility	54.0% - 75.7%
Risk-free interest rate	4.72% - 4.93%
Expected term (in years)	2.63 - 5.75
Dividend yield	0.00%

There were no stock options granted to employees during the three months ended March 31, 2006 or 2007.

**Expected Volatility:** The Company evaluated the assumptions used to estimate expected volatility, including whether implied volatility of its options appropriately reflects the market’s expectations of future volatility. The Company determined that it would use historical stock prices obtained from comparable publicly traded companies to calculate the expected volatility rate based on the expected term of the equity instruments because of the limited history of the Company’s common stock activity.

**Risk-Free Interest Rate:** The risk-free interest rate is based on the market yield currently available on U.S. Treasury securities with an equivalent remaining term.

**Expected Term:** Due to the limited history of employee stock options granted by the Company, the Company elected to use the “simplified” method allowed under SAB 107 to calculate its expected term. Under this method, the expected term is the average of the vesting term and the contractual term.

**Expected Dividend:** The Company has not paid, and does not anticipate paying, any dividends in the foreseeable future.

The compensation cost under SFAS 123R that has been recorded in the Company’s consolidated statements of operations and comprehensive income for the year ended December 31, 2006 and the three months ended March 31, 2007 was as follows (in thousands):

	<u>Year Ended</u> <u>December 31, 2006</u>	<u>Three Months Ended</u> <u>March 31, 2007</u> <u>(Unaudited)</u>
Selling and marketing expense	\$ 566	\$ 50
General and administrative expense	2,708	153
Cumulative out-of-period adjustment	—	(358)
Stock-based compensation expense included in operating expenses	<u>\$ 3,274</u>	<u>\$ (155)</u>

The adoption of SFAS 123R had no effect on the consolidated statement of cash flows for the year ended December 31, 2006.

Stock-based awards prior to January 1, 2006 did not affect the consolidated financial statements for the year ended December 31, 2006 because all outstanding stock options at January 1, 2006 were fully vested.



**SUCAMPO PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements — (Continued)**

Also, prior periods do not need to be restated for this adoption because the prospective method was chosen by the Company.

The Company recorded a cumulative out-of-period adjustment of approximately \$358,000 during the three months ended March 31, 2007 (unaudited) to reduce an overstatement of additional paid-in capital and general and administrative expenses that had been recorded as of and for the year ended December 31, 2006 in connection with certain employee stock options awarded in 2006. The error resulted from applying the incorrect contractual term for certain employee stock options. The impacts of this adjustment were not material to the consolidated financial statements for the year ended December 31, 2006, for the corresponding interim periods or for the period in which it was recorded, as the adjustment consisted of insignificant amounts related to each of the quarterly reporting periods dating back to the quarter ended June 30, 2006. The error did not affect the Company's consolidated financial statements prior to 2006.

***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 \$3,443,026 in research and development expense during the year ended December 31, 2005 because the stock option awards were fully vested and 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 date of grant using the fair value method as calculated using the Black-Scholes Model with the following assumptions:

Contractual term	10 years
Risk-free interest rate	4.4%
Expected volatility	75.0%
Expected dividend rate	0%

The weighted average fair value per share of non-employee options granted for the year ended December 31, 2005 was \$57.38. There were no stock options granted to non-employees during the years ended December 31, 2004 or 2006 or during the three months ended March 31, 2006 or 2007.

***Income Taxes***

As part of the process of preparing its consolidated financial statements, the Company is required to estimate its income taxes in each of the jurisdictions in which it operates. The Company follows SFAS No. 109, "Accounting for Income Taxes" (SFAS 109). This process requires the Company to estimate its actual current tax exposure while assessing its temporary differences resulting from the differing treatment of items, such as deferred revenue, for tax and accounting purposes. These differences have resulted in deferred tax assets and liabilities, which are included in the Company's consolidated balance sheets. The Company recorded a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. The Company considered forecasted earnings, future taxable income, the mix of earnings in the jurisdictions in which it operates, and prudent and feasible tax planning strategies in determining the need for a valuation allowance. In the event the Company were to determine that it would not be able to realize all or part of the net deferred tax assets in the future, an adjustment to the net deferred tax assets would be charged to earnings in the period in which such determination is made. Likewise, if the Company were later to determine that it is more likely than not that the net deferred tax assets would be realized, the Company would reverse the applicable portion of the previously provided valuation allowance. In order for the net deferred tax assets to be realized, the Company must be able to generate sufficient taxable income in the tax jurisdictions in which the net deferred tax assets are located.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

Significant judgment is required in determining the provision for income taxes and, in particular, any valuation allowance recorded against the Company's net deferred tax assets. The Company has recorded a partial valuation allowance, which resulted in a net deferred tax asset of approximately \$4.9 million and approximately \$4.6 million as of December 31, 2006 and March 31, 2007 (unaudited), due to uncertainties related to its ability to utilize a portion of the net deferred tax assets in years beyond 2007. Significant future events, including marketing approval by the FDA of AMITIZA for the treatment of IBS-C, are not in the control of the Company and will impact the amount of net deferred tax assets that will be utilized. The amount of the valuation allowance has been determined based on management's estimates of income by jurisdiction in which the Company operates over the periods in which the related deferred tax assets are recoverable.

For all significant transactions between SPI, 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 on similar terms 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.

***Accounting for the Uncertainty of Income Taxes***

On January 1, 2007, the Company adopted Financial Accounting Standards Board (FASB) Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes*" (FIN 48). FIN 48 prescribes a recognition threshold that a tax position is required to meet before being recognized in the financial statements and provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition issues. The adoption of FIN 48 did not have an impact on the Company's financial statements.

The Company conducts business in the U.S., Japan and the United Kingdom and is subject to those jurisdictions. As a result of its business activities, the Company files tax returns that are subject to examination by the respective federal, state, local and foreign tax authorities. For income tax returns filed by the Company, the Company is no longer subject to U.S. federal, state and local, or foreign income tax examination by tax authorities for years before 2003, although carryforward tax attributes that were generated prior to 2003 may still be adjusted upon examination by tax authorities if they either have been or will be utilized. The Company is not currently under examination by the tax authorities in any of the jurisdictions in which it operates.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits as a component of tax expense. For the three months ended March 31, 2007, there have been no interest and penalties accrued.

***Foreign Currency Translation***

The Company translates the assets and liabilities of its foreign subsidiaries, SPE and SPL, into U.S. dollars at the current exchange rate in effect at the end of the year. 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. The gains and losses that result from this process are included in accumulated other comprehensive loss in the stockholders' (deficit) equity section of the consolidated balance sheet.

***Foreign Currency Transactions***

Realized and unrealized foreign currency gains or losses on assets and liabilities denominated in a currency other than the functional currency are included in net (loss) income.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

**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' (deficit) equity. The Company has reported the comprehensive (loss) income in the consolidated statements of operations and comprehensive (loss) income.

**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, Takeda, accounted for 66%, 99%, 99%, 100% and 99% of the Company's total revenues and other income for the years ended December 31, 2004, 2005 and 2006 and the three months ended March 31, 2006 and 2007 (unaudited), respectively. Accounts receivable from one unrelated party, Takeda, accounted for \$0, \$2,029,237 and \$2,308,878 of the Company's accounts receivable at December 31, 2005 and 2006 and March 31, 2007 (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 (see Note 14).

**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.

**Change in Estimate**

Effective June 1, 2006, as a result of new study evaluation requirements released by the Rome III Committee on Functional Gastrointestinal Disorders, an international committee of gastroenterologists, management of the Company concluded that the completion of the final analysis of data from its clinical trials of AMITIZA for the treatment of IBS-C will be extended from December 2006 to May 2007. As such, the Company determined in June 2006 that the recognition period for associated research and development revenue should be extended and it is deferring the remaining \$10,951,395 as of December 31, 2006 and recognizing the revenues ratably through the anticipated completion date of June 2007. Under the provisions of SFAS No. 154, "Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3" (SFAS 154), the Company will recognize this as a change in estimate on a prospective

## SUCAMPO PHARMACEUTICALS, INC.

## Notes to Consolidated Financial Statements — (Continued)

basis from June 1, 2006. The effect on net income and basic and diluted pro forma net income per share for the year ended December 31, 2006 is as follows:

Decrease in revenue and net income	\$ 10,951,395
Impact on basic net income per share	(2.71)
Impact on diluted net income per share	(2.68)
Impact on basic pro forma net income per share	(2.48)
Impact on diluted pro forma net income per share	(2.46)

During the three months ended March 31, 2007, the Company reassessed the completion date of the development of AMITIZA for the treatment of IBS-C due to changes in market conditions during 2007. The Company determined that the completion date will be extended from May 2007 to June 2007 and recorded the associated impact during the three months ended March 31, 2007. This did not have a significant impact on net income and basic and diluted earnings per share for the three months ended March 31, 2007.

**Recent Accounting Pronouncements**

In December 2004, the FASB issued SFAS 123R, a revision of SFAS No. 123. 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, as discussed previously, the Company adopted SFAS 123R using the prospective transition method of implementation. According to the prospective transition method, the previously issued financial statements will not be adjusted.

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 154 as of January 1, 2006 did not have a material effect on the Company's consolidated 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 consolidated financial statements.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

In September 2006, the FASB Staff issued FASB Statement No. 157, “*Fair Value Measurements*” (SFAS 157), which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles. The FASB believes that the new standard will make the measurement of fair value more consistent and comparable and improve disclosures about those measures. The Company will be required to adopt SFAS 157 for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is assessing SFAS 157 and its impact on the Company’s future consolidated financial statements.

In February 2007, the FASB Staff issued FASB Statement No. 159, “*The Fair Value Option for Financial Assets and Financial Liabilities*” (SFAS 159), which provides entities with the opportunity to measure certain financial instruments at fair value. The Company will be required to adopt SFAS 159 for the year beginning January 1, 2008. The Company is assessing SFAS 159 and its impact on the Company’s future consolidated financial statements.

**4. Earnings per Share**

***Historical***

Basic 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. Diluted net (loss) income per share is computed by dividing net (loss) income by the weighted average common shares and potential dilutive common shares outstanding.

***Pro Forma Net Income Per Share (unaudited)***

Basic pro forma net income per share is computed by dividing net income for the three months ended March 31, 2007 by the sum of the weighted average class A and B common shares outstanding at March 31, 2007, giving effect to the conversion of the Company’s convertible preferred stock into class A common stock. Diluted pro forma net income per share is computed by dividing net income for the three months ended March 31, 2007 by weighted average common shares, giving effect to the conversion of the Company’s convertible preferred stock into class A common stock, and potential dilutive common shares outstanding.

**SUCAMPO PHARMACEUTICALS, INC.**  
**Notes to Consolidated Financial Statements — (Continued)**

**Computation of Earnings per Share**

The computation of historical net (loss) income per share for the years ended December 31, 2004, 2005 and 2006 and the three months ended March 31, 2006 and 2007 is shown below:

	Year Ended December 31,			Three Months Ended March 31,	
	2004 (Restated)	2005 (Restated)	2006	2006 (Restated) (Unaudited)	2007 (Unaudited)
<b>Basic net (loss) income per share:</b>					
Net (loss) income	\$ (19,469,372)	\$ (315,563)	\$ 21,800,805	\$ 13,307,070	\$ 516,242
Weighted average class A and B common shares outstanding	3,835,257	3,835,378	4,045,044	3,835,862	4,116,522
Basic net (loss) income per share	\$ (5.08)	\$ (0.08)	\$ 5.39	\$ 3.47	\$ 0.13
<b>Diluted net (loss) income per share:</b>					
Net (loss) income	\$ (19,469,372)	\$ (315,563)	\$ 21,800,805	\$ 13,307,070	\$ 516,242
Weighted average class A and B common shares outstanding for diluted net (loss) income per share	3,835,257	3,835,378	4,045,044	3,835,862	4,116,522
Assumed exercise of stock options under the treasury stock method	—	—	36,151	62,150	51,606
	3,835,257	3,835,378	4,081,195	3,898,012	4,168,128
Diluted net (loss) income per share	\$ (5.08)	\$ (0.08)	\$ 5.34	\$ 3.41	\$ 0.12

The computation of pro forma net income per share for the three months ended March 31, 2007 is shown below:

	Three Months Ended March 31, 2007 (Unaudited)
<b>Basic pro forma net income per share:</b>	
Net income	\$ 516,242
Weighted average class A and B common shares outstanding for basic net income per share	4,116,522
Automatic conversion of series A preferred stock into class A common stock	378,000
	4,494,522
Basic pro forma net income per share	\$ 0.11
<b>Diluted pro forma net income per share:</b>	
Net income	\$ 516,242
Weighted average class A and B common shares outstanding for diluted net income per share	4,116,522
Automatic conversion of series A preferred stock into class A common stock	378,000
Assumed exercise of stock options under the treasury stock method	51,606
	4,546,128
Diluted pro forma net income per share	\$ 0.11

**SUCAMPO PHARMACEUTICALS, INC.**  
**Notes to Consolidated Financial Statements — (Continued)**

The potentially dilutive securities used in the calculations of diluted historical and pro forma net (loss) income per share for the years ended December 31, 2004, 2005 and 2006 and the three months ended March 31, 2006 and 2007 are as follows:

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006 (Unaudited)	2007 (Unaudited)
Series A preferred stock	3,780	3,780	3,780	3,780	3,780
Employee stock options*	—	—	97,200	43,000	77,000
Non-employee stock options*	—	—	60,000	60,000	60,000

\* Employee and non-employee stock options of 208,375 and 171,000 for 2004 and 2005, respectively, are not included as they were considered to be anti-dilutive.

**5. Property and Equipment**

Property and equipment consists of the following as of:

	December 31,		March 31,
	2005	2006	2007 (Unaudited)
Computer and office machines	\$ 390,058	\$ 586,758	\$ 683,080
Furniture and fixtures	274,526	290,323	290,323
Leasehold improvements	48,776	68,608	69,031
Total cost	713,360	945,689	1,042,434
Less: accumulated depreciation and amortization	(535,900)	(602,763)	(626,802)
	<u>\$ 177,460</u>	<u>\$ 342,926</u>	<u>\$ 415,632</u>

Depreciation and amortization expense for the years ended December 31, 2004, 2005 and 2006 was \$95,412, \$61,764 and \$68,615, respectively. Depreciation and amortization expense for the three months ended March 31, 2006 and 2007 (unaudited) was \$16,995 and \$24,039, respectively.

**6. Accrued Expenses**

Accrued expenses consist of the following as of:

	December 31,		March 31,
	2005	2006	2007 (Unaudited)
Research and development costs	\$ 1,406,893	\$ 2,460,367	\$ 2,030,654
Selling and marketing costs	—	985,556	1,346,782
Employee compensation	487,240	1,238,167	518,857
Legal service fees	89,803	212,859	57,130
Royalty liability—related party	—	360,828	771,388
Other expenses	99,278	151,664	262,330
	<u>\$ 2,083,214</u>	<u>\$ 5,409,441</u>	<u>\$ 4,987,141</u>

**7. Commitments**

**Operating Leases**

The Company leases office spaces in the United States, United Kingdom and Japan under operating leases through 2017. The leases require the Company to make certain non-cancelable lease payments until

**SUCAMPO PHARMACEUTICALS, INC.**  
**Notes to Consolidated Financial Statements — (Continued)**

expiration. Total future minimum lease payments under operating leases are as follows as of December 31, 2006:

2007	\$ 829,324
2008	1,429,235
2009	1,320,777
2010	968,994
2011	937,352
Thereafter	5,159,467
Total minimum lease payments	<u>\$ 10,645,149</u>

Rent expense for all operating leases was \$490,241, \$538,092 and \$572,466 for the years ended December 31, 2004, 2005 and 2006, respectively. Rent expense for all operating leases was \$132,209 and \$166,333 for the three months ended March 31, 2006 and 2007 (unaudited), respectively.

#### **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, 2006 are as follows:

2007	\$ 3,030,416
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#### **8. 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 year ended December 31, 2004 was \$63,558. The effective interest rate on the debt for the year 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 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 six-month Tokyo InterBank Offered Rate 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 to be 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. The note balance of \$2,606,727 was completely paid off in the year ended December 31, 2006.

On February 20, 2004 and March 29, 2004, SPL issued three-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



**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

\$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.

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 was 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 was extended, the interest was to be paid on June 30th and December 31st of each year. The note balance of \$947,013 was completely paid off in the year ended December 31, 2006.

On February 27, 2006, SPE entered into a note agreement with SAG, pursuant to which SPE borrowed \$1.2 million. The rate of interest charged on the loan was 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 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 was extended, the interest was to be paid on June 30th and December 31st of each year. The note balance of \$1.2 million was completely paid off in the year ended December 31, 2006.

**9. Related Party Transactions**

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: \$1.0 million upon execution of the agreement, \$2.0 million upon commencement of a first Phase II lubiprostone trial, \$3.0 million upon commencement of a first Phase II RUG-015 trial and \$2.0 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 — \$1.0 million for the agreement execution, \$2.0 million for the commencement of the first Phase II lubiprostone trial, and \$3.0 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 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.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

The abandonment of RUG-015 changed the amortization period of the \$6.0 million deferred revenue to the commercialization period of lubiprostone (AMITIZA), which began April 2006. The Company has recognized revenue of \$313,955 for the year ended December 31, 2006 and \$0 and \$104,651 for the three months ended March 31, 2006 and 2007 (unaudited), respectively, which is recorded as contract revenue — related party.

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 year ended December 31, 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<sup>®</sup> for \$497,000. For the year ended December 31, 2004, the entire proceeds from the sale of the Rescula<sup>®</sup> 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<sup>®</sup> 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 up-front 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 11) and received a \$20.0 million of up-front payment during 2004. The Company paid SAG \$1.0 million during 2004 for the 5% royalty on the up-front payment, which was expensed immediately.

During the year ended December 31, 2005, the Company paid SAG \$1.5 million in milestone royalty payments upon receiving \$30.0 million in development milestone payments from Takeda for work surrounding lubiprostone. During the year ended December 31, 2006, the Company paid SAG milestone royalty payments of \$1.0 million and \$250,000 upon receiving a \$20.0 million development milestone payment from Takeda for the FDA approval of lubiprostone. The milestone royalty payments of \$1.5 million, \$1.25 million and \$1.25 million to SAG during the years ended December 31, 2005 and 2006 and for the three months ended March 31, 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 a research and development expense 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 \$1.1 million to SAG upon final execution. This payment was recorded as a research and development expense for the year ended December 31, 2006. Additionally, the Company will pay SAG milestone payments as follows: \$1.0 million upon initiation of Phase II of the first indication, \$2.0 million upon filing of each new drug application (NDA) (not to exceed \$6.0 million), \$2.0 million upon approval of each NDA (not to exceed \$6.0 million) 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.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

On June 24, 2005, the Company 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 within Europe. In consideration of the exclusive rights, RTU paid the Company \$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. As lubiprostone has not been approved within Europe, the \$2.0 million has been recorded as non-current deferred revenue as of December 31, 2005 and 2006 and March 31, 2007 (unaudited).

On September 7, 2006, the Company's Board of Directors approved an agreement which amends the exclusive manufacturing agreement with RTU. This agreement allows the Company to elect a back-up supplier for the supply of drug substance and drug product. In addition, the agreement provides that RTU shall maintain at least a six-month inventory of drug substance and at least a six-month inventory of intermediate drug product.

On October 4, 2006, the Company entered into a two-year exclusive clinical manufacturing and supply agreement with RTU for two of its drug compounds, SPI-8811 and SPI-017. Under the terms of this agreement, RTU agreed to manufacture and supply the necessary drug substance and drug product for the purpose of clinical development. Under the terms of the agreement, pricing for clinical supply is determined on a batch-by-batch basis and shall not exceed a certain mark-up percentage. Unless this agreement is terminated by mutual written consent within 90 days of expiration, it will automatically be renewed for an additional two years.

***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 SAG'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 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.

**10. 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 \$8.0 million, 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 \$67,000 for the year ended December 31, 2004 under this agreement. All revenues related to this agreement were recognized by December 31, 2004.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

**11. Collaboration and License Agreements**

The following table summarizes the cash streams and related revenue recognition under the Takeda Agreement and the Supplemental Agreement, which are described in more detail below:

	Cash Received Through	Revenue Recognized for Year Ended			Amount Deferred at	Cash Received For the Three	Revenue Recognized For the Three	Amount Deferred at
	December 31, 2006	2004	2005	December 31, 2006	December 31, 2006	Months Ended March 31, 2007 (Unaudited)	Months Ended March 31, 2007 (Unaudited)	March 31, 2007 (Unaudited)
<i>Collaboration revenue:</i>								
Up-front payment attributable to the joint steering, manufacturing and commercialization committees	\$ 2,376,125	\$ 24,496	\$ 146,977	\$ 146,977	\$ 2,057,675	\$ —	\$ 36,744	\$ 2,020,931
<i>Research and development revenue:</i>								
Up-front payment — remainder	\$ 17,623,875	\$ 1,355,683	\$ 8,134,096	\$ 6,157,059	\$ 1,977,037	\$ —	\$ 1,087,370	\$ 889,667
Development milestones	50,000,000	—	16,153,846	28,237,180	5,608,974	—	3,084,936	2,524,038
Reimbursement of research and development expenses	31,506,601	1,482,337	14,671,504	11,987,377	3,365,383	3,342,493	5,193,455	1,514,421
<b>Total</b>	<b>\$ 99,130,476</b>	<b>\$ 2,838,020</b>	<b>\$ 38,959,446</b>	<b>\$ 46,381,616</b>	<b>\$ 10,951,394</b>	<b>\$ 3,342,493</b>	<b>\$ 9,365,761</b>	<b>\$ 4,928,126</b>
					Accounts Receivable at December 31, 2006			Accounts Receivable at March 31, 2007 (Unaudited)
Product royalty revenue	\$ 4,561,242	—	—	\$ 6,590,479	\$ 2,029,237	\$ 2,029,762	\$ 2,309,403	\$ 2,308,878
Co-promotion revenue	\$ 3,534,598	—	—	\$ 4,242,997	\$ 708,399	\$ 1,567,371	\$ 1,132,030	\$ 273,058

On October 29, 2004, the Company entered into the Takeda Agreement to exclusively co-develop, commercialize and sell products that contain lubiprostone for gastroenterology indications in the United States and Canada. Payments to the Company under the Takeda Agreement include a non-refundable up-front payment, non-refundable development and commercial milestone payments, reimbursement of certain development and co-promotion costs and royalties.

Upon execution of the Takeda Agreement, the Company was required to complete several deliverables, which Takeda is responsible to fund. The following are the required deliverables of the Company, along with the related contractual cash flows from Takeda and the associated obligations and performance period of the Company, as of the execution of the Takeda Agreement:

- The Company granted Takeda an exclusive license of lubiprostone to co-develop, commercialize, and sell products for gastroenterology indications in the United States and Canada. There are no defined contractual cash flows within the Takeda Agreement for the grant of this license, but the Company did receive a non-refundable up-front payment of \$20.0 million upon executing the Takeda Agreement. The license was granted to Takeda on October 29, 2004 and will expire when the Takeda Agreement expires or is terminated. Upon commercial launch, Takeda shall, for the products sold by Takeda during the term of the Takeda Agreement, pay the Company pre-determined royalties on net revenues on a quarterly basis. The level of royalties is tiered based on the net sales recognized by Takeda. Royalty payments, which the Company began to earn in April 2006 and receive in July 2006, will cease when the Takeda Agreement is terminated and all cash payments due to the Company are paid. The Company has recorded product royalty revenue of approximately \$6.6 million for the year ended December 31,

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**Notes to Consolidated Financial Statements — (Continued)**

2006 and \$2.3 million for the three months ended March 31, 2007 (unaudited). This revenue is recorded as product royalty revenue in the consolidated statements of operations and comprehensive (loss) income.

- The Company shall participate in the following committees, along with Takeda: Joint Steering Committee, Joint Development Committee, Joint Commercialization Committee and Joint Manufacturing Committee. There are no separate cash flows identified within the Takeda Agreement associated with the participation by the Company in these committees. There is no defined performance period for this obligation, but the performance period will not exceed the term of the Takeda Agreement. The Company expects its participation on all committees to continue throughout the term of the Takeda Agreement, except for the Joint Development Committee, which will continue until development work is complete.
- The Company shall provide development work necessary for an NDA submission to the FDA for the treatment of Constipation and IBS-C indications. Takeda shall fund the initial \$30.0 million of development costs and the two parties shall equally share any required development costs in excess of \$50.0 million. Although there is no defined performance period for this development work, the period to perform the work will not exceed the term of the Takeda Agreement. In January 2006, the Company received approval for its NDA for AMITIZA to treat Constipation and estimates that the NDA for IBS-C will be completed and submitted to the FDA in June 2007.

As a result of its reassessment of the deliverables under the Takeda Agreement (see Note 2), the Company determined there were four separate units of accounting as of the inception of the Takeda Agreement. The Company has assessed these required deliverables under the guidance of EITF 00-21 to determine which deliverables are considered separate units of accounting. The Company determined that its participation in the Joint Steering Committee, the Joint Manufacturing Committee and the Joint Commercialization Committee has value to Takeda on a stand-alone basis because the individual committee participants provided by the Company have valuable expertise that the Company believes support the success of the Takeda Agreement. Takeda could have obtained similar expertise by hiring independent consultants, but is relying instead on the expertise of the Company.

The Company was also able to determine objective and reliable evidence of the fair value of these deliverables, including anticipated expenses expected to be incurred to meet its obligations, in the form of contract agreements between the Company and specialized consultants for other development projects the Company is and has been involved with currently and in the past. The Company was not, however, able to distinguish stand-alone value for participation in the Joint Development Committee separate from the Company's obligations to perform development work of Constipation and IBS-C because the participation in the Joint Development Committee was to occur concurrently with the development work. Thus, the Company has determined that there were four separate units of accounting when the Takeda Agreement was executed — (1) participation in the Joint Steering Committee, (2) participation in the Joint Manufacturing Committee, (3) participation in the Joint Commercialization Committee and (4) the combined requirement of the development work of Constipation and IBS-C and participation in the Joint Development Committee.

Upon receipt of the \$20.0 million up-front payment, the Company deferred approximately \$2.4 million to be recognized using the time-based model over the performance period of the participation in these meetings. During the years ended December 31, 2004, 2005 and 2006 and during the three months ended March 31, 2006 and 2007 (unaudited), the Company recognized approximately \$24,000, \$147,000, \$147,000, \$37,000 and \$37,000, respectively, of this deferred amount as collaboration revenue on the consolidated statements of operations and comprehensive (loss) income. The related deferred revenue as of December 31, 2005 and 2006 and March 31, 2007 (unaudited) was approximately \$2.2 million, \$2.1 million and \$2.0 million, respectively.

**SUCAMPO PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements — (Continued)**

Since the execution of the Takeda Agreement through December 31, 2006, the Company deferred the residual amount of the \$20.0 million up-front payment totaling approximately \$17.6 million, development milestone payments received totaling \$50.0 million, and reimbursement of the initial \$30.0 million of research and development costs for the development of AMITIZA for Constipation and IBS-C indications. These deferred amounts were applied towards the unit of accounting combining the participation in the Joint Development Committee and the development of Constipation and IBS-C and are being recognized using the time-based model over the performance period of developing the Constipation and IBS-C NDA submissions. The Company had originally estimated that it would complete the development of the Constipation and IBS-C NDA submissions in December 2006. The Company concluded in June 2006 that the estimated completion date should be revised to May 2007. Subsequent to December 31, 2006, the Company further extended the estimated completion date from May 2007 to June 2007. See Note 3 for a discussion of the accounting treatment of these changes in estimates. During the years ended December 31, 2004, 2005 and 2006, the Company recognized approximately \$2.8 million, \$39.0 million and \$45.4 million, respectively, of these deferred amounts as research and development revenue in the consolidated statements of operations and comprehensive (loss) income. During the three months ended March 31, 2006 and 2007 (unaudited), the Company recognized approximately \$22.0 million and \$6.0 million of these deferred amounts as research and development revenue in the consolidated statements of operations and comprehensive (loss) income. The related deferred revenue as of December 31, 2005 and 2006 and March 31, 2007 (unaudited) was approximately \$35.8 million, \$11.0 million and \$4.9 million, respectively.

The Company incurred research and development costs for this development work of approximately \$1.5 million, \$25.9 million, \$11.6 million, \$2.9 million, and \$2.0 million for the years ended December 31, 2004, 2005 and 2006 and for the three months ended March 31, 2006 and 2007 (unaudited), respectively. The Company has an express contractual obligation to perform the development work under the Takeda Agreement, including for periods after receipt of funding by Takeda. Funding from Takeda is received, in advance, on a quarterly basis based on estimated costs to be incurred by the Company.

On February 1, 2006, the Company entered into the Supplemental Agreement with Takeda, which amends the responsibilities of both the Company and Takeda for the co-promotion of AMITIZA and clarifies the responsibilities and funding arrangements for other marketing services to be performed by both parties.

Upon execution of the Supplemental Agreement, the Company was required to complete several deliverables, which Takeda was responsible to fund. The following are the required deliverables of the Company, along with the related contractual cash flows from Takeda and the associated obligations and performance period of the Company, when the Supplemental Agreement was executed:

- The Company shall co-promote AMITIZA with Takeda by employing a sales force of approximately 38 representatives to supplement Takeda's sales activities. Takeda shall reimburse the Company a specified amount per day per sales force representative, but such reimbursements shall not exceed certain pre-defined amounts. The term of this reimbursement arrangement ceases five years following the first date that the Company deployed sales representatives, which was in April 2006. The Company has recognized approximately \$3.4 million of revenues for the year ended December 31, 2006 and \$974,000 for the three months ended March 31, 2007 (unaudited) reflecting these co-promotion reimbursements, which is recorded as co-promotion revenue in the consolidated statements of operations and comprehensive (loss) income.
- The Company shall perform miscellaneous marketing activities for AMITIZA, which will be fully reimbursed by Takeda. There is no defined performance period, but the performance period will not extend beyond January 31, 2007. The Company has recorded approximately \$779,000 of reimbursements of miscellaneous marketing costs for the year ended December 31, 2006 and \$161,000 and \$158,000 for the three months ended March 31, 2006 and 2007 (unaudited), respectively. This amount

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

is recorded as co-promotion revenue in the consolidated statements of operations and comprehensive (loss) income.

The Company has determined that the required deliverables under the Supplemental Agreement are economically independent of those in the original Takeda Agreement. The Company had no obligations to perform any of the deliverables under the Supplemental Agreement at the time the original Takeda Agreement was executed and the activities were not considered to be, or contemplated as, deliverables at that time. Subsequent to the execution of the original Takeda Agreement, the Company agreed to perform co-promotion and other marketing services for a fee that was negotiated at the time of the Supplemental Agreement. The negotiated rates were determined to be market compensation for services agreed to in the Supplemental Agreement based upon the stand-alone value of the economics of the new obligations. Therefore, the Company views the deliverables under the Supplemental Agreement as economically independent of those in the original Takeda Agreement.

The Company has assessed these required deliverables under the guidance of EITF 00-21 to determine which deliverables are considered separate units of accounting. The Company was able to determine that its sales force has value to Takeda on a stand-alone basis because the Company provided coverage in a market segment which could increase the sales of AMITIZA. In negotiating the Supplemental Agreement, the Company established the fair value for the per-day co-promotion rate using third-party evidence from contract sales organizations. The Company has also determined that the miscellaneous marketing activities have stand-alone value to Takeda separate from the Company's efforts to perform its obligations to implement and maintain its sales force. These miscellaneous marketing services, which related primarily to documenting and publicizing the medical benefits of the product, could have been outsourced directly to a number of different third parties (as the Company ultimately did), performed by Takeda staff or eliminated entirely if not judged to have a benefit which exceeded the related costs. Accordingly, these deliverables are treated as separate units of accounting. The Company is recognizing the cost reimbursements received for these deliverables as co-promotion revenues when services are performed and the reimbursement payments are due under the Supplemental Agreement. For the year ended December 31, 2006 and for the three months ended March 31, 2006 and 2007 (unaudited), the Company recognized approximately \$3.4 million, \$0 and \$974,000, respectively, of co-promotion revenue for its sales force efforts and approximately \$779,000, \$161,000 and \$158,000, respectively, for its miscellaneous marketing efforts.

During the quarter ended June 30, 2006, the Joint Commercialization Committee granted approval for the Company and Takeda to begin three new studies related to funding arrangements discussed in both the Takeda Agreement and the Supplemental Agreement. The following are the three additional deliverables of the Company, along with the related contractual cash flows from Takeda and the associated obligations and performance period of the Company, when the three studies were agreed upon:

- The Company shall perform studies in connection with changes to labeling for Constipation or IBS-C. Takeda shall fund 70% of the labeling studies and Sucampo shall fund the remaining 30%. There is no defined performance period, but the performance period will not exceed the term of the Takeda Agreement. The Company initiated the first labeling study for Constipation in August 2006, which is expected to be completed in January 2008.
- The Company shall perform all development work for the development of an additional indication for opioid-induced bowel dysfunction. Takeda shall fund all development work up to a maximum aggregate of \$50.0 million and \$20.0 million for each additional indication and new formulation, respectively. If development costs exceed these amounts, Takeda and the Company shall equally share such excess costs. There is no defined performance period, but the performance period will not exceed the term of the Takeda Agreement. The Company initiated work on the first additional indication for AMITIZA in July 2006, which is estimated to be completed in June 2009 and is expected to exceed \$50.0 million in development costs.

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**Notes to Consolidated Financial Statements — (Continued)**

- The Company shall perform all development work necessary for Phase IV studies, for which Takeda shall fund all development work. There is no defined performance period, but the performance period will not exceed the term of the Supplemental Agreement. The Company began work on a Phase IV study for Constipation in August 2006, which is estimated to be completed in January 2008.

The Company has assessed these required deliverables under the guidance of EITF 00-21 to determine which deliverables are considered separate units of accounting. As a result of the Company and Takeda agreeing to perform and fund these studies simultaneously, the Company determined that there is no objective and reliable evidence to determine the fair value for each of the studies. Accordingly, the Company has combined these three new required deliverables as a single unit of accounting. All cash payments from Takeda related to these three deliverables will be deferred upon receipt and recognized over the entire period to complete the three studies using the time-based model. The estimated completion date is June 2009. During the year ended December 31, 2006, the Company recognized approximately \$1.1 million and for the three months ended on March 31, 2007 (unaudited), the Company recognized approximately \$3.3 million related to these three deliverables as research and development revenue on the consolidated statements of operations and comprehensive (loss) income.

The Company received \$5.0 million as an option payment in 2004 to continue negotiations for additional territories held by SPE and SPL. This agreement provided for negotiation terms of 12 months for the SPL territory and until NDA approval of AMITIZA for the SPE territory. Of the \$5.0 million payment received, if negotiations did not succeed, a total of \$2.5 million would be required to be returned to Takeda (\$1.0 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 (\$2.0 million), the Company recorded \$1.0 million as current deferred revenue and \$1.0 million as other liabilities — short term in 2004. As to the option payment relating to SPE (\$3.0 million), the Company recorded \$1.5 million as long term deferred revenue and \$1.5 million as other liabilities — long term in 2004. Upon receipt of the payments from Takeda, the refundable portions were recorded as other liability and the non-refundable portions were recorded as deferred revenue. The option right expired for SPL during 2005 and \$1.0 million was returned to Takeda and the Company recognized the deferred \$1.0 million as contract revenue for the year ended December 31, 2005. The option right expired for SPE during the three months ended March 31, 2006 (unaudited) and \$1.5 million was returned to Takeda and the Company recognized the deferred \$1.5 million as contract revenue for the three months ended March 31, 2006 (unaudited) and the year ended December 31, 2006. See Note 3 for a discussion of the revenue recognition policy for option payments received by the Company.

## **12. Stockholders' (Deficit) 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 convertible 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 consolidated financial statements and notes to the consolidated 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



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**Notes to Consolidated Financial Statements — (Continued)**

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.

On March 18, 2005, R-Tech converted all shares of its class B common stock into 500,000 shares of class A common stock.

During the year ended December 31, 2006, the Company sold 282,207 shares of class A common stock in a private transaction. As a result, the Company received net proceeds of \$23,895,802.

On September 28, 2006, the Company completed its reorganization in which it issued 211,765 shares of SPI class A common stock for the acquisition of common stock of SPE and SPL. All outstanding shares have been retroactively reflected in the accompanying notes to the consolidated financial statements for all periods presented.

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.

***Stock Option Plan***

On February 15, 2001, the Company adopted the 2001 Stock Incentive Plan (the 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 December 31, 2006, approximately 774,800 shares were available for future grants under the Plan.

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 2006 Stock Option Plan and the Employee Stock Purchase Plan will not become effective until the closing of the Company's anticipated initial public offering is completed.

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**Notes to Consolidated Financial Statements — (Continued)**

A summary of the activity under the Company's Plan is presented below for the three years ended December 31, 2004, 2005 and 2006 and for the three months ended March 31, 2007 (unaudited):

	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value</u>
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 granted	85,600	85.00	
Options exercised	(1,000)	1.86	
Options forfeited	(2,800)	85.00	
Options expired	(95,600)	3.62	
Options outstanding, December 31, 2006	97,200	76.72	\$ 957,600
Options forfeited	(3,050)	85.00	
Options expired	(17,150)	29.16	
Options outstanding, March 31, 2007 (unaudited)	77,000	86.99	\$ 2,029,950
Options exercisable at December 31, 2006	60,950	71.17	\$ 957,600
Options exercisable at March 31, 2007 (unaudited)	43,800	87.62	\$ 1,126,980

The weighted average grant date fair value of options granted during the years ended December 31, 2004 and 2006 was \$1.70 and \$54.52 per share. As of December 31, 2006 and March 31, 2007 (unaudited), approximately \$1.1 million and \$677,000, respectively, of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested awards is expected to be recognized over a weighted average period of 5.34 years and 4.73 years, respectively. The intrinsic value of options exercised in 2006 was \$83,140.

The following table summarizes information about employee stock options outstanding and exercisable at December 31, 2006:

<u>Outstanding (Employee)</u>				<u>Exercisable (Employee)</u>			
<u>Exercise Price</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Years of Contractual Life</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Years of Contractual Life</u>	
\$ 25.15	16,000	\$ 25.15	0.19	16,000	\$ 25.15	0.19	
85.00	63,200	85.00	9.33	31,450	85.00	9.33	
93.50	18,000	93.50	4.33	13,500	93.50	4.33	
	<u>97,200</u>	76.72	6.90	<u>60,950</u>	71.17	6.90	

As of December 31, 2006, these employee stock options have a maximum term of 10 years.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

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 approximately \$172,000, 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 stock option awards 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 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 expense 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 under the Plan and recorded a charge of \$3.4 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:

<b>Outstanding and Exercisable (Non-employee)</b>	
<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
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, 2006 was 8.25 years.

**13. Income Taxes**

The provision (benefit) for income taxes consists of the following as of December 31:

	<b>2004</b>	<b>2005</b>	<b>2006</b>
		<b>(Restated)</b>	
<b>Current tax provision (benefit):</b>			
Federal	\$ —	\$ 1,504,922	\$ (714,432)
State	—	261,250	(261,119)
Foreign	303,050	(294,009)	—
Total current tax provision (benefit)	303,050	1,472,163	(975,551)
<b>Deferred (benefit) provision:</b>			
Federal	—	(862,500)	(4,182,189)
State	—	(117,198)	261,000
Foreign	(303,050)	295,876	—
Total deferred benefit	(303,050)	(683,822)	(3,921,189)
<b>Total income tax provision (benefit)</b>	\$ —	\$ 788,341	\$ (4,896,740)

**SUCAMPO PHARMACEUTICALS, INC.**  
**Notes to Consolidated Financial Statements — (Continued)**

Deferred tax assets, net, consist of the following as of December 31:

	<u>2005</u> <u>(Restated)</u>	<u>2006</u>
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 481,913	\$ 682,636
Deferred revenue	16,901,540	7,408,561
General business credit carryforwards	3,252,452	4,365,889
Accrued expenses	523,939	197,837
Tax benefits on stock options	1,342,156	2,005,464
Other	—	124,162
Gross deferred tax assets	<u>22,502,000</u>	<u>14,784,549</u>
<b>Deferred tax liabilities:</b>		
Property and equipment	(39,657)	(11,484)
Other	(24,139)	(21,445)
Gross deferred tax liabilities	<u>(63,796)</u>	<u>(32,929)</u>
Less: valuation allowance	<u>(21,458,506)</u>	<u>(9,850,733)</u>
Net deferred tax assets	<u>\$ 979,698</u>	<u>\$ 4,900,887</u>

During the year ended December 31, 2005, the Company recognized a net deferred tax asset of approximately \$980,000, which represented the expected realization of deferred tax assets with the carryback of anticipated taxable losses in future years.

The Company continued to assess its ability to realize certain deferred tax assets in the year ended December 31, 2006. During the fourth quarter of 2006, the Company performed an analysis of future projections due to an additional year of profitability in 2006 and the expectation of profitability in 2007. As a result of this analysis, the Company reversed an additional \$4.9 million of valuation allowance on its U.S. deferred tax assets. The net deferred tax asset as of December 31, 2006 represents the expected net utilization of the Company's deferred tax assets in 2007.

The provision (benefit) 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:

	<u>2004</u> <u>(Restated)</u>	<u>2005</u> <u>(Restated)</u>	<u>2006</u>
Federal tax provision at statutory rate	34.0%	34.0%	34.0%
State taxes, net of federal tax benefit	5.0	(52.1)	2.3
General business credits	2.9	(361.0)	(2.6)
Changes in valuation allowance	(40.8)	272.2	(69.6)
Adjustment to net operating loss carryforward	—	248.3	(0.1)
Changes in other tax matters	(1.1)	25.3	7.0
Total	<u>0.0%</u>	<u>166.7%</u>	<u>(29.0)%</u>

At December 31, 2005 and 2006, the Company had foreign net operating loss carryforwards (NOLs) of \$1.4 million and \$2.2 million, respectively. The foreign NOLs begin to expire in December 2010. At December 31, 2005 and 2006, the Company had U.S. general business credits of \$4.4 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.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

14. 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.

	United States	Europe	Japan	Intercompany Eliminations	Consolidated
	(in thousands)				
<b>Three Months Ended March 31, 2007 (unaudited)</b>					
Research and development revenue	\$ 9,366	\$ —	\$ —	\$ —	\$ 9,366
Contract revenue	—	—	—	—	—
Contract revenue — related parties	105	—	221	(210)	116
Collaboration revenue	37	—	—	—	37
Product royalty revenue	2,309	—	—	—	2,309
Co-promotion revenue	1,132	—	—	—	1,132
Total revenues	<u>12,949</u>	<u>—</u>	<u>221</u>	<u>(210)</u>	<u>12,960</u>
Depreciation and amortization	21	—	3	—	24
Other operating expenses	12,204	165	238	(210)	12,397
Income (loss) from operations	724	(165)	(20)	—	539
Interest income	320	—	4	—	324
Interest expense	(4)	—	—	—	(4)
Other non-operating income (expense), net	1	(3)	—	—	(2)
Income (loss) before income taxes	<u>\$ 1,041</u>	<u>\$ (168)</u>	<u>\$ (16)</u>	<u>\$ —</u>	<u>\$ 857</u>
Capital expenditures	<u>\$ 96</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 96</u>
<b>Three Months Ended March 31, 2006 (unaudited)</b>					
Research and development revenue (restated)	\$ 22,441	\$ —	\$ —	\$ —	\$ 22,441
Contract revenue (restated)	—	1,500	—	—	1,500
Contract revenue — related parties	—	—	29	—	29
Collaboration revenue (restated)	37	—	—	—	37
Product royalty revenue	—	—	—	—	—
Co-promotion revenue (restated)	161	—	—	—	161
Total revenues (restated)	<u>22,639</u>	<u>1,500</u>	<u>29</u>	<u>—</u>	<u>24,168</u>
Depreciation and amortization	14	—	2	—	16
Other operating expenses (restated)	11,067	155	48	—	11,270
Income (loss) from operations (restated)	11,558	1,345	(21)	—	12,882
Interest income	304	1	1	—	306
Interest expense	(4)	—	(16)	—	(20)
Other non-operating income (expense), net (restated)	18	(9)	114	16	139
Income before income taxes (restated)	<u>\$ 11,876</u>	<u>\$ 1,337</u>	<u>\$ 78</u>	<u>\$ 16</u>	<u>\$ 13,307</u>
Capital expenditures	<u>\$ 6</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6</u>

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

	<u>United States</u>	<u>Europe</u>	<u>Japan</u>	<u>Intercompany Eliminations</u>	<u>Consolidated</u>
	(in thousands)				
<b>Year Ended December 31, 2006</b>					
Research and development revenue	\$ 46,382	\$ —	\$ —	\$ —	\$ 46,382
Contract revenue	—	1,500	—	—	1,500
Contract revenue — related parties	314	—	161	(71)	404
Collaboration revenue	147	—	—	—	147
Product royalty revenue	6,591	—	—	—	6,591
Co-promotion revenue	4,243	—	—	—	4,243
Total revenues	57,677	1,500	161	(71)	59,267
Depreciation and amortization	59	2	8	—	69
Other operating expenses	43,644	518	343	(70)	44,435
Income (loss) from operations	13,974	980	(190)	(1)	14,763
Interest income	2,035	2	4	(65)	1,976
Interest expense	(20)	(71)	(67)	68	(90)
Other non-operating income, net	31	23	201	—	255
Income (loss) before income taxes	\$ 16,020	\$ 934	\$ (52)	\$ 2	\$ 16,904
Capital expenditures	\$ 196	\$ —	\$ 40	\$ —	\$ 236
<b>Year Ended December 31, 2005</b>					
Research and development revenue (restated)	\$ 38,960	\$ —	\$ —	\$ —	\$ 38,960
Contract revenue (restated)	—	—	1,000	—	1,000
Contract revenue — related parties	—	—	98	—	98
Collaboration revenue (restated)	147	—	—	—	147
Total revenues (restated)	39,107	—	1,098	—	40,205
Depreciation and amortization	60	—	1	—	61
Other operating expenses (restated)	38,932	1,475	254	—	40,661
Income (loss) from operations (restated)	115	(1,475)	843	—	(517)
Interest income	941	3	136	(34)	1,046
Interest expense	(157)	(139)	(49)	34	(311)
Other non-operating income, net	—	174	81	—	255
Income (loss) before income taxes (restated)	\$ 899	\$ (1,437)	\$ 1,011	\$ —	\$ 473
Capital expenditures	\$ 39	\$ —	\$ —	\$ —	\$ 39

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

	United States	Europe	Japan	Intercompany Eliminations	Consolidated
	(in thousands)				
<b>Year Ended December 31, 2004</b>					
Research and development revenue (restated)	\$ 2,838	\$ —	\$ —	\$ —	\$ 2,838
Contract revenue (restated)	69	—	—	—	69
Contract revenue and other income — related parties	1,239	—	82	(413)	908
Collaboration revenue (restated)	24	—	—	—	24
Total revenues (restated)	4,170	—	82	(413)	3,839
Depreciation and amortization	83	2	11	—	96
Other operating expenses (restated)	19,644	2,422	1,503	(413)	23,156
Loss from operations (restated)	(15,557)	(2,424)	(1,432)	—	(19,413)
Interest income	94	3	162	(162)	97
Interest expense	(260)	(43)	(33)	162	(174)
Other non-operating income (expense), net	21	(164)	164	—	21
Loss before income taxes (restated)	\$ (15,702)	\$ (2,628)	\$ (1,139)	\$ —	\$ (19,469)
Capital expenditures	\$ 14	\$ —	\$ 4	\$ —	\$ 18
<b>March 31, 2007 (unaudited)</b>					
Property and equipment, net	\$ 328	\$ 1	\$ 87	\$ —	\$ 416
Identifiable assets	\$ 64,160	\$ 351	\$ 2,556	\$ (4,899)	\$ 62,168
<b>December 31, 2006</b>					
Property and equipment, net	\$ 253	\$ 2	\$ 88	\$ —	\$ 343
Identifiable assets	\$ 68,943	\$ 496	\$ 2,544	\$ (4,899)	\$ 67,084
<b>December 31, 2005</b>					
Property and equipment, net	\$ 116	\$ 3	\$ 58	\$ —	\$ 177
Identifiable assets (restated)	\$ 45,366	\$ 1,363	\$ 2,576	\$ (1,320)	\$ 47,985

**15. Subsequent Event (unaudited)**

On June 19, 2007, the Compensation Committee of the Company's Board of Directors authorized a one-time stock and cash award to each of the Company's founders. These awards would be made immediately upon the completion of the initial public offering. If the initial public offering were to not occur in the near future, the Company expects that the awards would be based on a value determined by the Board of Directors at that time. These awards are intended by the Compensation Committee to compensate the founders for the lost value of stock options that had been granted to them in 2001 and 2002 and had been understood by them to have ten-year terms, but which had expired in 2006 and early 2007 as a result of the terms of the 2001 Stock Incentive Plan. The expired options would have entitled the founders to purchase an aggregate of 68,000 shares of class A common stock at a price of \$1.86 per share and 16,000 shares at a price of \$25.15 per share.

Assuming the completion of the initial public offering, these stock and cash awards will have an aggregate value equal to the difference between the value of the shares that could have been purchased under each of the expired options, determined on the basis of the public offering price per share in the initial public offering, and the respective aggregate exercise prices for such shares as provided in the option agreements.

These awards will consist of a combination of cash and shares of class A common stock. Of the aggregate value of each award, 40% will be paid in cash and 60% will be paid in stock. For purposes of determining the number of shares of class A common stock to be issued in connection with each award, assuming the completion of the initial public offering, the stock will be valued on the basis of the public offering price per share in the initial public offering. The stock component of these awards will be fully vested immediately upon grant.

The Company is in the process of determining the accounting for these awards. The value of these awards is expected to result in a material charge to the Company's consolidated financial statements in a period subsequent to the three months ended March 31, 2007. The stock and cash awards did not impact the Company's consolidated financial statements for any period prior to the authorization of the awards.



Shares

**Class A Common Stock**

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Prospectus  
, 2007

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**Leerink Swann & Company**

Until \_\_\_\_\_, 2007, all dealers that buy, sell or trade the class A common stock may be required to deliver a prospectus, regardless of whether they are 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.

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**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.

	<u>Amount</u>
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	<u>\$ *</u>

\* 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 us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

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 or in reliance on Section 4(2) of the Securities Act, as transactions by an issuer not involving a public offering.

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Pursuant to our stock plans, as of May 31, 2007, we have issued options to purchase an aggregate of 341,100 shares of class A common stock. Of these options:

- options to purchase 203,700 shares of class A common stock have been canceled or lapsed without being exercised;
- options to purchase 2,000 shares of class A common stock have been exercised; and
- options to purchase a total of 135,400 shares of class A common stock are currently outstanding, at a weighted average exercise price of \$70.51 per share.

### **Item 16. Exhibits and Financial Statement Schedules.**

#### **(a) Exhibits**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
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	[Intentionally left blank]
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
10.12*	Indemnification Agreement, dated May 26, 2004, between the Registrant and Dr. Ryuji Ueno
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	[Intentionally left blank]
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
10.20**	Exclusive Manufacturing and Supply Agreement, dated June 23, 2004, between the Registrant and R-Tech Ueno, Ltd., as amended on October 2, 2006

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<u>Exhibit</u> <u>Number</u>	<u>Description of Exhibit</u>
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
10.27*	Indemnification Agreement, dated September 7, 2006, between the Registrant and Mr. Timothy Maudlin
10.28*	Indemnification Agreement, dated September 7, 2006, between the Registrant and Ms. Sue Molina
10.29**	Exclusive Manufacturing and Supply Agreement, dated June 24, 2005, between Sucampo Pharma Europe Ltd. and R-Tech Ueno, Ltd., as amended on October 2, 2006
10.30	[Intentionally left blank]
10.31**	SPI-8811 and SPI-017 Exclusive Clinical Manufacturing and Supply Agreement, dated October 4, 2006, between the Registrant and R-Tech Ueno, Ltd.
10.32*	Lease Agreement, dated December 18, 2006, between the Registrant and EW Bethesda Office Investors, LLC
10.33*	Employment Agreement, dated January 2, 2007, between the Registrant and Mr. Ronald Kaiser
10.34	[Intentionally left blank]
10.35*	Amendment to Employment Agreement, dated November 20, 2006, between the Registrant and Dr. Ryuji Ueno
10.36*	Letter agreement, dated January 29, 2007, between the Registrant and Takeda Pharmaceutical Company Limited
10.37***	Employment Agreement, effective June 1, 2007, between the Registrant and Dr. Sachiko Kuno
10.38	Amended Employment Agreement, dated May 12, 2007, between the Registrant and Ms. Mariam Morris
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
24.4***	Power of Attorney for Ronald Kaiser
99.1*	Consent of Leerink Swann & Co., Inc.

\* Previously filed.

\*\* Previously filed. Confidential treatment has been requested for portions of this exhibit.

\*\*\* To be filed by amendment.

**(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.

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 25th day of June, 2007.

SUCAMPO PHARMACEUTICALS, INC.

By: /s/ RYUJI UENO

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Ryuji Ueno, M.D., Ph.D., Ph.D

Chief Executive Officer, Chief Scientific Officer and Chair of the Board of Directors

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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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<hr/> <u>/s/ RYUJI UENO</u> Ryuji Ueno, M.D., Ph.D., Ph.D.	Chief Executive Officer (Principal Executive Officer), Chief Scientific Officer and Director	June 25, 2007
<hr/> <u>/s/ RONALD W. KAISER</u> Ronald W. Kaiser	Chief Financial Officer (Principal Financial Officer)	June 25, 2007
<hr/> <u>/s/ MARIAM E. MORRIS</u> Mariam E. Morris	Chief Accounting Officer (Principal Accounting Officer)	June 25, 2007
<hr/> * Michael J. Jeffries	Director	June 25, 2007
<hr/> * Timothy I. Maudlin	Director	June 25, 2007
<hr/> * Hidetoshi Mine	Director	June 25, 2007
<hr/> * V. Sue Molina	Director	June 25, 2007
*By: <hr/> <u>/s/ KEI TOLLIVER</u> Kei Tolliver Attorney-in-Fact		

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
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	[Intentionally left blank]
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
10.12*	Indemnification Agreement, dated May 26, 2004, between the Registrant and Dr. Ryuji Ueno
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	[Intentionally left blank]
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
10.20**	Exclusive Manufacturing and Supply Agreement, dated June 23, 2004, between the Registrant and R-Tech Ueno, Ltd., as amended on October 2, 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.



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<b>Exhibit Number</b>	<b>Description of Exhibit</b>
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
10.27*	Indemnification Agreement, dated September 7, 2006, between the Registrant and Mr. Timothy Maudlin
10.28*	Indemnification Agreement, dated September 7, 2006, between the Registrant and Ms. Sue Molina
10.29**	Exclusive Manufacturing and Supply Agreement, dated June 24, 2005, between Sucampo Pharma Europe Ltd. and R-Tech Ueno, Ltd., as amended on October 2, 2006
10.30	[Intentionally left blank]
10.31**	SPI-8811 and SPI-017 Exclusive Clinical Manufacturing and Supply Agreement, dated October 4, 2006, between the Registrant and R-Tech Ueno, Ltd.
10.32*	Lease Agreement, dated December 18, 2006, between the Registrant and EW Bethesda Office Investors, LLC
10.33*	Employment Agreement, dated January 2, 2007, between the Registrant and Mr. Ronald Kaiser
10.34	[Intentionally left blank]
10.35*	Amendment to Employment Agreement, dated November 20, 2006, between the Registrant and Dr. Ryuji Ueno
10.36*	Letter agreement, dated January 29, 2007, between the Registrant and Takeda Pharmaceutical Company Limited
10.37***	Employment Agreement, effective June 1, 2007, between the Registrant and Dr. Sachiko Kuno
10.38	Amended Employment Agreement, dated May 12, 2007, between the Registrant and Dr. Mariam Morris
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
24.4***	Power of Attorney for Ronald Kaiser
99.1*	Consent of Leerink Swann & Co., Inc.

\* Previously filed.

\*\* Previously filed. Confidential treatment has been requested for portions of this exhibit.

\*\*\* To be filed by amendment.

## AMENDED EMPLOYMENT AGREEMENT

**THIS AMENDED EMPLOYMENT AGREEMENT** (the "Agreement"), dated as of May 12, 2007 (the "Execution Date"), is hereby entered into in the State of Maryland by and between SUCAMPO PHARMACEUTICALS, INC., a Delaware corporation (the "Company"), and Mariam Morris ("Executive").

**WHEREAS**, Executive has been employed by the Company since February 2, 2004, most recently pursuant to the terms of an Employment Agreement effective as of June 16, 2006 (the "Effective Date") and amended effective January 2, 2007;

**WHEREAS**, Executive possesses certain skills, experience or expertise which will be of use to the Company;

**WHEREAS**, the parties acknowledge that Executive's abilities and services are unique and will 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 Accounting Officer and Executive desires to remain in such employment, and the parties mutually desire to enter into this Agreement to reflect the current terms of their understanding;

**NOW, THEREFORE**, in consideration of the promises and the mutual covenants and agreements herein contained, the Company and Executive hereby agree as follows:

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## **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 Accounting Officer, and in connection therewith, to perform such duties as Executive shall reasonably be assigned by the Company's Chief Financial Officer and/or 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). 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 Term**

The term of Executive's employment hereunder (the "Term") shall be deemed to commence on the Effective Date and shall end on the second 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) Base Salary. The Company shall pay Executive a salary at an annual rate that is not less than \$160,000, to be paid in bi-weekly installments, in arrears (the "Base Salary"). Thereafter, the Base Salary will be reviewed by the Compensation Committee of the Board of Directors ("Compensation Committee") at least annually, and the Committee's recommendation shall be reviewed and approved by the Board of Directors. The Base Salary may, in the sole discretion of the Board of Directors, be increased, but not decreased (unless mutually agreed by Executive and the Company).

(b) Stock Compensation. At least annually for the Term of this Agreement, 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 initially by the

Compensation Committee, subject to review and approval by the Board of Directors. 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.

(c) Bonuses. 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. Recommendations concerning the decision to make an award and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.

(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 fifteen (15) vacation days 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: (i) the two (2) month period which coincides with the two (2) month period for determining the amount of the lump sum severance payment described in Section 4.4(a)(iii) 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), or (ii) a period ending when Executive becomes eligible as an employee or spouse of an employee of another firm for group medical benefits coverage, whichever is shorter. Executive shall give prompt written notice to the Company when Executive becomes eligible for group medical benefits coverage as an employee or spouse of an employee of another firm.

(b) "Cause" shall mean any of the following as determined by the Board of Directors or a committee of the Board of Directors designated for this purpose:

(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 Chief Executive Officer, the Chief Financial Officer, or 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; provided, however, 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 (including rules and regulations promulgated by the SEC, IRS or other applicable governmental agency).

(c) "Date of Termination" 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); provided, however, 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 after 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/her consent, move his/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) Severance. 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 two (2) 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. 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 Internal Revenue 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) Change in Control. 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 Internal Revenue Code of 1986, as amended (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) Release. 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, licensors, 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 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 employment with the Company, Executive 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. 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 which Executive may be subject relating to the protection of Confidential Information.

#### 5.7 Assignment of Confidential Information and Inventions; Works Made for Hire

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 or 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 he or 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 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.

5.11 Covenant Not to Compete

Executive agrees to be bound and abide by the following covenant not to compete:

(a) Term and Scope. During Executive's employment with the Company and for a period of twelve (12) months after the Term, 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) Judicial Construction. 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 that was provided or under development by the Company or any of its Affiliates at the time Executive’s employment with the Company terminates, or about which Executive acquired any Confidential Information or developed any Executive Work Product.

“Conflicting Organization” means any person or organization which is engaged in research on or development, production, marketing, licensing, selling or servicing of any Conflicting Product.

#### 5.12 Non-Solicitation

For a period of 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.

#### 5.13 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: Chief Executive Officer

To Executive:     Mariam Morris  
                      8742 Delcris Drive  
                      Montgomery Village, Maryland 20886

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 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 December 6, 2005.

#### 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; provided, however, 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.

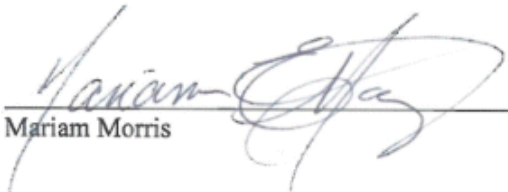
#### 6.9 Read and Understood

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 Execution Date.

**SUCAMPO PHARMACEUTICALS, INC.**

By:   
Ryuji Ueno, M.D., PhD.  
Chief Executive Officer

  
Mariam Morris

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the use in this Amendment No. 7 to the Registration Statement on Form S-1 of our report dated May 14, 2007 relating to the consolidated financial statements of Sucampo Pharmaceuticals, Inc. and its subsidiaries, which appears in such Registration Statement. We also consent to the references to us under the headings "Experts" and "Selected Consolidated Financial Data" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland

June 22, 2007

June 25, 2007

BY EDGAR AND HAND DELIVERY

Jeffrey P. Riedler  
Assistant Director  
U.S. Securities and Exchange Commission  
100 F Street N.E.  
Washington, D.C. 20549

Re: Sucampo Pharmaceuticals, Inc.  
Amendment No. 7 to Registration Statement on Form S-1, filed June 22, 2007  
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 May 30, 2007 to Ryuji Ueno, the Chief Executive Officer of Sucampo, regarding the filing of Amendment No. 6 to the Registration Statement on Form S-1 (the “Registration Statement”). Sucampo is filing Amendment No. 7 to the Registration Statement (“Amendment No. 7”) today.

**Summary, page 1**

1. We refer to your statements on page 1 regarding the Phase III clinical trials and a long-term safety trial of AMITIZA for the treatment of irritable bowel syndrome with constipation and that, “Preliminary results of these trials indicate AMITIZA improved overall relief from symptoms associated with irritable bowel syndrome with constipation with statistical significance and was well tolerated.” We believe discussions regarding the results of clinical trials are better placed in the Business section where investors have more complete disclosure about the trials, the results and the FDA process. Please revise your disclosure accordingly.

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Page 2

**RESPONSE:**

In response to this comment, the Company has removed the discussion of the clinical trial results on pages 1, 40 and 71, and has limited its discussion of these results to the portion of the Business section on page 80 where they are discussed in detail.

**Risk Factors, page 8**

**If we are unable to establish sales and marketing capabilities or successfully use third parties to market and sell our products . . . , page 14**

2. To the extent that the internalization of the Ventiv sales forces will result in a material increase in sales and marketing expenditures, please quantify this expected increase in this risk factor and in the MD&A on page 53.

**RESPONSE:**

In response to this comment, the Company has quantified the expected increase in sales and marketing expenses on pages 53 and 88.

**Management's Discussion and Analysis, page 39**

**Critical Accounting Policies and Estimates, page 46**

**Stock-Based Compensation, page 47**

3. Your disclosure of a "retrospective valuation obtained from an independent third-party valuation specialist . . ." equates to the use of an expert. Please identify the valuation expert in your disclosures and in the Experts section. Also provide the consent from the valuation expert in your exhibits. Alternatively, remove all mention of the valuation expert.

**RESPONSE:**

In response to this comment, the Company has eliminated the reference to the valuation specialist from page 48 and added language regarding the board's reliance upon recent third-party stock sales.

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Page 3

**Business, page 66**

**Products and Product Candidates, page 71**

4. Regarding your disclosure of the preliminary results of the Phase III clinical trials and a long-term safety trial of AMITIZA for the treatment of irritable bowel syndrome, we have the following comments:
- Explain the progress made in the study and why the results are preliminary.
  - Clarify whether the results are preliminary because the duration of the measurement period for all or some subjects has not yet concluded or because only some of the subjects intended to be studied have been enrolled and fully studied.
  - Provide appropriate quantitative information explaining what is needed to complete the study.
    - a. If the preliminary results refer to not having enrolled and fully studied the number of intended subjects, disclose the number who have completed the study whose results are included, the number currently being studied whose results are not included and the total number to be studied but not yet enrolled.
    - b. If the preliminary nature of the results refers to the fact that the study is ongoing because the measurement period for some or all of the subjects has not concluded, disclose the total number of subjects that will be studied, the number of subjects who have and have not completed the measurement period, how much longer the ongoing subjects will have to go to complete it and the number of partial and completed measurements included in the preliminary results.
    - c. If the preliminary results refer to the fact that the study has ended but all of the statistical analysis has not yet been performed, disclose what analysis you have and have not yet performed and what the different analyses are intended to measure. Provide the results of any statistical analysis and the relevant p-values.

**RESPONSE:**

The Company advises you that, as of the date of its filing of Amendment No. 6, the statistical analysis of the results of these trials had not yet been finalized. The Company has now received the final results of these trials and has included more detailed disclosure of those final results on page 80.

**Marketing and Sales, page 82**

5. We note your statement that you intend to continue to outsource most of the operational infrastructure associated with the new sales force. Given that your agreement with
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Page 4

Ventiv will terminate effective July 1, 2007, please describe your plan regarding the outsourcing. Will you enter into an agreement with another vendor? Will you enter into a new agreement with Ventiv?

**RESPONSE:**

In response to this comment, the Company has added disclosure on page 87 describing its plans for the procurement of the outsourced infrastructure services.

**Consolidated Financial Statements, page F-2**

6. Please update your financial statements to include the most recent interim period. Additionally, please update the balance of your filing to include such information, as appropriate.

**RESPONSE:**

The Company has included interim financial statements for the three months ended March 31, 2007 and related disclosures in Amendment No. 7.

\* \* \* \* \*

As noted above, the Company's responses to the staff's comments are reflected in Pre-Effective Amendment No. 7 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.
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If you have any questions or comments on the application, please contact me at (202) 663-6224.

Respectfully,

/s/ Brent B. Siler

Brent B. Siler

cc: Ms. Sonia Barros  
Ms. Christine Allen  
Mr. Kevin Woody  
Securities and Exchange Commission  
Ryuji Ueno, M.D., Ph.D., Ph.D.  
Mr. Ronald W. Kaiser  
Jeffrey D. Karpf, Esq.