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#### 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. Registration Statement on Form S-l File No. 333-135133

## Dear Mr. Riedler:

On behalf of Sucampo Pharmaceuticals, Inc. ("Sucampo" or the "Company"), this letter responds to the comment in your letter dated November 27, 2006 to Sachiko Kuno, the President and Chair of the Board of Directors of Sucampo, regarding the filing of Amendment No. 4 to the Registration Statement on Form S-1 (the "Registration Statement"). The Company originally responded to your November 27, 2006 comment in a letter addressed to you and dated December 15, 2006. Based on several telephonic conversations with various members of the Staff since that date, and at the suggestion of the Staff, the Company is today revising its response to your original comment. We have reproduced the original comment below for your convenience. As discussed with the Staff, the Company intends to file an amendment to the Registration Statement after the Staff has had the opportunity to review this revised response, which would include (1) restated financial statements for the years ended December 31, 2004 and 2005 reflecting the revised accounting treatment described in the response below, including revised footnote disclosure, and (2) financial statements for the year ended December 31, 2006 reflecting the revised accounting treatment.

## **ORIGINAL STAFF COMMENT:**

## **Financial Statements**

## Note 11. Collaboration and License Agreements, page F-26

1. We have reviewed your response to our previous comment number 13 and the collaboration and License Agreement included as Exhibit 10.21. Please revise your

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disclosure of the Agreement with Takeda to include a description of all your rights and obligations, the performance period, all deliverables, and the contractual cash flows as stipulated within the agreement. Please identify each unit of accounting pursuant to EITF 00-21, the revenue recognition method you employ for each unit, and the basis for using each revenue recognition method. Please tell us and disclose if you have bundled several deliverables into one single unit of accounting and how management determined the revenue recognition model to be used for this single unit of accounting. Lastly, it appears that there is an obligation of management to participate in several committees defined within the Agreement without a specifically associated cash flow stream. Please tell us and disclose how you have incorporated what appears to be an obligation of the company into your EITF 00-21 analysis.

## **REVISED RESPONSE:**

## Background

On October 29, 2004, Sucampo Pharmaceuticals, Inc. ("Sucampo" or the "Company") and Takeda Pharmaceutical Company Limited ("Takeda") entered into a Collaboration and License Agreement (the "Agreement"), which was filed as Exhibit 10.21 to the Registration Statement. The purpose of this Agreement was for the two parties to co-develop, commercialize, and sell products for gastroenterology indications ("Products") in the United States and Canada. The Products are pharmaceutical drugs that contain the compound SPI-0211, or lubiprostone. Amitiza, the only Product to date, was approved by the United States Food and Drug Administration (the "FDA") for the treatment of chronic idiopathic constipation ("Constipation") in January 2006. A second indication for Amitiza for the treatment of irritable bowel syndrome with constipation ("C-IBS") continues to be developed. Prior to the execution of the Agreement, the Company had been in the process of developing SPI-0211 for both the Constipation and the C-IBS indications. At the time the Agreement was signed, the Company had completed Phase III trials for the Constipation indication and was in the process of initiating a Phase III trial for the C-IBS indication. The Agreement also contemplated that the Company and Takeda could subsequently jointly agree to pursue the development and commercialization of additional indications in the U.S. and Canadian gastroenterology market.

The term of the Agreement is from October 29, 2004 through December 31, 2020, unless terminated earlier. The Agreement is terminable for the following reasons:

A material breach of obligations by either party;

- A change of control of either party occurs, unless the change of control party confirms its agreement to comply with its obligations in the Agreement;
- A change of control of Takeda occurs and the surviving entity is developing or marketing a product that competes with Sucampo Products;
- A bankruptcy, insolvency or similar event of either party;
- Sucampo may terminate if Takeda fails to achieve specified net sales revenue targets; and
- If a New Drug Application ("NDA") approval for C-IBS cannot be obtained in the United States, the parties will negotiate in good faith whether to continue future development and commercialization of Products. If the parties cannot agree, then either party will have the right to terminate.

The effect of termination is as follows:

- Takeda is not required to make additional payments for which services have not yet been rendered or which are not due to Sucampo as of the termination date; and
- The licenses granted to Takeda will terminate and the related rights will revert to Sucampo.

The Agreement includes several deliverables that Sucampo is responsible to complete and Takeda is responsible to fund. The following table summarizes the key deliverables by Sucampo within the Agreement as of its execution on October 29, 2004:

	Deliverable (with related			
	Agreement		Performance	
	sections) Contractual Cas	Sucampo Obligations	Period	
ial cash	License of the compound SPI- There are no defined co	Sucampo shall provide Takeda with an	The license was granted upon execution	-
ise to	0211 to Takeda (2.1) flows for the grant of the	exclusive license to co- develop, use,	of the Agreement in October 2004 and	
	Takeda.	sell, promote, offer for sale, import and	will expire when the Agreement expires	
		distribute the Products during the	in 2020 or	
	If Sucampo achieves	Agreement period.		
s, Takeda	commercialization of P			
ring the	shall, for the Products s			
	term of the			
s, Takeda	Takeda. If Sucampo achieves commercialization of P shall, for the Products s	sell, promote, offer for sale, import and distribute the Products during the Agreement period.	will expire when the Agreement expire	

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Deliverable (with related Agreement sections)	Contractual Cash Flows	Sucampo Obligations	Performance Period
	Agreement, pay Sucampo royalties on net sales. The level of royalty payments is tiered based on the level of net sales revenue earned by Takeda.		when it is earlier terminated. Royalty payments, which Sucampo began to receive in July 2006, will cease when the Agreement is terminated (except with respect to unsold inventory) and all cash payments due to Sucampo are paid.
Development for NDA submission for Constipation and C-IBS (4.2(i) and 7.2).	Takeda shall fund the initial \$30 million of development costs, after which Sucampo shall fund the next \$20 million and the parties shall equally share any required funding in excess of \$50 million.	Sucampo shall conduct all development work necessary for an NDA submission (in the United States and Canada) for Constipation and C- IBS.	There was no defined performance period inherent in the Agreement, however as of October 29, 2004 the Company estimated that it would complete the research & development in December 2006.
	Takeda shall pay Sucampo non- refundable milestone payments for the Products upon certain development events as related to specific indications.		An NDA for Amitiza (for Constipation) was submitted in March 2005 and approved by the FDA in January 2006.
	1		During the second quarter of 2006, the Company estimated that the NDA submission for C-IBS would be completed in

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Deliverable (with related Agreement sections)	Contractual Cash Flows	Sucampo Obligations	Performance Period May 2007 and, as of the date of this letter, the Company estimates that the completion will be June 2007.
			•
Participate in the following committees:	No separate cash flows were established for these activities at the inception of the agreement.	Sucampo agreed to participate in the committees during the respective periods in which each committee was	There is no defined performance period for each committee. None of the committees will extend beyond the term
Joint Steering Committee ("JSC")(3.1)		active	of the Agreement. The Company expects participation within all committees,
Joint Development Committee ("JDC")(4.1)			except the JDC, to occur throughout the Agreement term. The Company expects participation in JDC meetings to
Joint Commercialization Committee ("JCC") (5.1)			continue only while development activities are in process.
Joint Manufacturing Committee ("JMC") (6.1)			

<sup>1</sup> The following is a listing of the up-front payment and development milestone events and the milestone and research and development payments that have been received by Sucampo from Takeda after the occurrence of the applicable event through December 31, 2006.

Description	Payment (i	in millions)
Execution of Agreement	\$	20
NDA filing for Constipation		10
Phase III entered for C-IBS		20
NDA approved for Constipation		20
Constipation and C-IBS research and development revenue		30
	\$	100

As discussed in the table above, there are significant contractual cash payments, including a nonrefundable up-front payment, nonrefundable milestone payments and reimbursements of development costs owed to Sucampo upon completion of the associated deliverables. As of December 31, 2006, approximately two years after the Agreement was executed, the Company had received (a) the \$20 million nonrefundable up-front payment, (b) \$50 million of nonrefundable milestone payments, (c) \$30 million of reimbursements of development costs, and (d) approximately \$4.5 million of royalty payments on Takeda's net sales of Amitiza.

## **Technical Accounting Research Considerations**

The Company has performed the following steps in determining the appropriate accounting model for its above mentioned deliverables and associated cash payments that Sucampo has received and will receive from Takeda:

- 1. Consideration of the contract deliverables, pursuant to EITF 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"), to determine whether separate units of accounting exist;
- 2. Selection of an accounting model for revenue recognition; and
- 3. Evaluation of EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent* ("EITF 99-19"), and EITF 01-14, *Income Statement Characterization of Reimbursements Received for 'Out of Pocket' Expenses Incurred* ("EITF 01-14"), to determine the appropriate presentation of certain revenue streams.

## <u>Step 1 – Identification of deliverables and evaluation of EITF 00-21:</u>

As discussed in the previous chart, at the time of its original execution, the Agreement included multiple deliverables that the Company was responsible to perform. The original assessment of EITF 00-21 by the Company resulted in a single unit of accounting for the deliverables within the Agreement, including the participation in the committees. As of December 31, 2006, the Company re-assessed each deliverable using the guidance of EITF 00-21 to determine which deliverables should be considered as separate units of accounting.

The re-assessment identified four separate units of accounting: (1) the development of Constipation and C-IBS in order to file an NDA for each indication, which also includes participating in the JDC, (2) participation in the JCC, (3) participation in the JSC and (4)

participation in the JMC. The evaluation of EITF 00-21 to determine the four separate units of accounting is discussed in the following paragraph.

The Company has now determined stand-alone values for the participation in the three identified committees (the JCC, JMC and JSC), which are not associated with development. The Company was able to specifically identify stand-alone value for the participation in each meeting of these committees, including anticipated expenses expected to be incurred to meet its obligations, by obtaining objective and reliable evidence of the fair value of this deliverable 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, and applying that to the number of required meetings throughout the Agreement term. The Company is not, however, able to distinguish the stand-alone value for participation in the JDC from its obligations to perform research and development of Constipation and C-IBS because the participation in the JDC was to occur concurrently with the development work. As a result, the recognition of revenue of the residual amounts received from Takeda related to the development work under the Agreement, after the attribution of amounts to the participation in the JDC, JSC and JMC, will be associated with the combined requirement of the development work of Constipation and C-IBS and participating in the JDC.

## Step 2 – Selection of accounting model:

In 2004, when the Agreement was executed and the Company began to receive payments from Takeda, the Company attempted to determine a systematic and rational attribution pattern that was representative of and faithful to the economic substance of the Agreement, but that would not result in revenue being recognized at any time in excess of the accumulated amounts owed to the Company from Takeda. The Company had originally recorded the cash payments from Takeda as revenue using the substantive milestone method. The method is frequently used as industry practice by other comparable companies with similar collaboration and license arrangements. Under the substantive milestone method, revenue for the payment is recognized once the milestone is achieved, SAB No. 104, *Revenue Recognition* ("SAB 104") criteria are met and the following substantive-milestone-method criteria are met:

- A substantive effort must be involved in achieving each milestone;
- Milestone payments must be reasonable in relation to the effort expended;
- A reasonable amount of time should pass between the up-front payment and the first milestone as well as between successive milestones;
- Risk should be considered; and

• All milestone payments in an agreement should be compared to the effort needed to achieve the milestone with one another and with the up-front payment.

If these criteria are not met, then that milestone payment is deemed to be non-substantive and the related payment is recognized separately over the term of the deliverable period. Accordingly, while there is a single unit of accounting, there are two different attribution models for revenue recognition resulting from the application of the substantive milestone method — one for substantive milestones and one for all other amounts. One could argue the application of the substantive milestone method conflicts with a literal application of EITF 00-21 (i.e., two revenue attribution methods applied to one unit of accounting). The re-assessment by the Company to literally apply EITF 00-21 and further analyze its use of the substantive milestone method resulted in the Company concluding that one attribution model to recognize revenue should be applied against each unit of accounting in this Agreement. Accordingly, the Company determined that the substantive milestone method would not be appropriate.

The Company then evaluated two separate attribution models, the EITF 91-6 model and the time-based model, in determining which revenue model would be more appropriate, considering the specific economic substances of research and development activities and the respective earnings processes associated with the funding arrangements from Takeda. The following summarizes the results of the Company's assessment of these two models:

#### The EITF 91-6 model

The Company assessed the application of a revenue model similar to the guidance discussed in EITF 91-6, *Revenue Recognition of Long-Term Power Sales Contracts*, which relates to accounting for long-term power sales contracts. Under this model, revenue is recognized using the lesser of non-refundable cash received or the result achieved using percentage-of-completion accounting using cost of efforts. The Company determined that the EITF 91-6 model was not appropriate for the facts and circumstances of the Agreement because the Company would not have been able to reasonably estimate its costs for its research and development due to the significant amount of volatility in its costs, FDA regulations, and reliance on third parties to complete studies.

## The Time-Based Model

The Company also assessed a revenue model similar to the EITF 91-6 model, with the performance period being the revenue-recognition driver instead of expenses. The Company has concluded that this time-based model is appropriate and has determined to utilize this model to recognize revenue under the Agreement. In applying this model, the Company made the following assumptions for each unit of accounting:

- The cash flow streams related to the unit of accounting are ratably recognized as revenue over the estimated performance period.
- Upon receipt of cash payments during the performance period, revenue is recognized to the extent the accumulated service time has occurred. The remainder is deferred and recognized ratably over the expected remainder of the performance period.
- A change in the period of time expected to complete the deliverable is accounted for on a prospective basis as a change in estimate through the remainder of performance period.

The cash flow items for each unit of accounting will be deferred upon receipt and recognized as revenue ratably over the respective service periods. The accumulated revenue recognized will at no time exceed the accumulated amounts owed to the Company from Takeda.

The cash flow amounts received from Takeda through December 31, 2006 associated with each unit of accounting are as follows:

•	Participation in JCC <sup>2</sup>	\$ 675,568
•	Participation in JSC <sup>2</sup>	\$ 1,273,485
•	Participation in JMC <sup>2</sup>	\$ 427,071
•	Development of Constipation and C-IBS <sup>3</sup>	\$97,623,876

- <sup>2</sup> The amount is based on estimated fair value of the undelivered services, including anticipated expenses expected to be incurred to meet its obligations, when the Company became required to participate in the meetings and is deferred as a separate component of the up-front \$20 million payment.
- <sup>3</sup> The amount is the remaining cash flows received from Takeda related to the required undelivered services (development of Constipation and C-IBS and participation in the JDC), including the residual amount totaling \$17,623,876 of the up-front \$20 million payment after deferring the fair value of the three committee meetings.

## Step 3 – Evaluation of EITF 99-19 and EITF 01-14:

The Company further evaluated the presentation of the cash flows received from Takeda on a gross versus net basis in accordance with EITF 99-19. Based on the evaluation of the indicators within this guidance, the Company determined that the cash payments from Takeda should be recognized as revenue on a gross basis and reported as revenue in the consolidated statements of operations. In particular, the Company deemed itself to be the principal of the Agreement because it is the primary obligor under the Agreement since it is responsible for executing the development plan. Additionally, the Company has complete supplier discretion, the Company is involved in determining the service specifications, and the Company assumes credit risk for all expenses incurred during the service periods. This is consistent with the

responses to comments 50 and 51 in the Company's response letter to the Staff dated August 11, 2006.

Additionally, the consensus in EITF 01-14 reinforces the Company's assertion that reimbursements received for out-of-pocket expenses incurred should be characterized as revenue.

## Supplemental Agreement with Takeda

On August 18, 2005, Sucampo notified Takeda in writing that Sucampo believed Takeda was in material breach of the Agreement and that the Agreement would be terminated if disputed actions surrounding the marketing and co-promotion of the drug candidate, which had since become Amitiza, could not be resolved. On February 1, 2006, the two parties settled the disputed items claimed by the Company by entering into a supplemental agreement to the Agreement (the "Supplemental Agreement"). The Supplemental Agreement was filed as Exhibit 10.25 to the Registration Statement.

The purpose of the Supplemental Agreement was to amend and clarify for both Sucampo and Takeda their respective responsibilities for the copromotion of Amitiza, specifically the responsibilities and funding arrangements for other commercialization and marketing services to be performed by Sucampo and Takeda. There were no monies paid by either party for the execution of the Supplemental Agreement. The term of the Supplemental Agreement ends when the Agreement expires or is terminated.

As previously noted, Amitiza was approved by the FDA in January 2006 for the treatment of Constipation. The commercial launch of Amitiza began in April 2006.

The Supplemental Agreement includes several deliverables that Sucampo is responsible to complete and Takeda is responsible to fund. The following table summarizes the key deliverables by Sucampo under the Supplemental Agreement as of its execution on February 1, 2006:

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Deliverable (with related Supplemental Agreement section) Co-promote Amitiza with Takeda (5.4 (a) of Agreement and 6.2 of Supplemental Agreement)	<u>Contractual Cash Flows</u> Takeda shall pay Sucampo a specified amount per day per Sucampo's sales force representative, but not to exceed certain pre-defined amounts.	Sucampo Obligations Sucampo shall employ a sales force of approximately 38 representatives to supplement Takeda's sales activities.	Performance Period 60 months following the first date (April 2006) that Sucampo deployed sales representatives.
		The terms within the Agreement for co- promotion activities were superseded by the Supplemental Agreement. The Agreement stated Sucampo had the option to employ sales representatives. The Supplemental Agreement amended the Agreement to state that Sucampo shall employ approximately 38 sales representatives for such purposes. Detailed plans and strategies must be approved by the JCC.	
Perform miscellaneous marketing activities for Amitiza (Article 3 of Supplemental Agreement)	Takeda shall reimburse Sucampo for all approved external costs incurred for such miscellaneous marketing activities.	Sucampo shall conduct all miscellaneous marketing activities as approved by the JCC.	There is no defined performance period, but it will not exceed the term of the Agreement. Such marketing activities are expected to occur throughout the Agreement term.

The deliverables under the Supplemental Agreement are viewed as economically independent of those in the Agreement. The Company will recognize the cost reimbursements received for these deliverables as revenue when due under the Supplemental Agreement.

## **Additional Required Deliverables**

In the second quarter of 2006, the Company and Takeda agreed to begin three new studies related to funding arrangements discussed in both the Agreement and Supplemental Agreement. The deliverables that Sucampo is responsible to complete and Takeda is primarily responsible to fund in connection with these new studies are summarized in the following schedule:

Deliverable (with related Agreement section) Changes to labeling (4.2 (iii) of Agreement)	<u>Contractual Cash Flows</u> Takeda shall fund 70% of labeling studies and Sucampo shall fund the remaining 30%	Sucampo Obligations Sucampo shall conduct all studies required to modify, change or expand the labeling of Products for Constipation and C- IBS as approved by the JCC.	Performance Period Sucampo estimates that the Renal/Hepatic labeling studies that were initiated in August 2006 will be completed in January 2008.
Perform Phase IV studies (4.2 (vi) of Agreement and 5.1 of Supplemental Agreement)	Takeda shall fund all Phase IV studies.	The terms within the Agreement for Phase IV studies were superseded by the Supplemental Agreement. The Agreement states Takeda shall conduct all Phase IV studies. The Supplemental Agreement has amended the Agreement to state that Sucampo shall conduct all Phase IV studies approved by the JCC.	The Company has begun incurring development expenses related to its Phase IV studies for the Constipation indication of Amitiza, which are estimated to be completed in January 2008.

## U.S. Securities and Exchange Commission March 29, 2007 Page 13

Deliverable

(with related Agreement section)	Contractual Cash Flows	Sucampo Obligations	Performance Period
Development of additional	Per each additional indication, Takeda	Sucampo shall conduct all development	Sucampo has recently begun work on
ndication (4.2 (iv))	shall fund all internal and external	of the additional indication(s) as	the first additional indication for
	development work up to a maximum	approved by the JCC.	Amitiza, for the treatment of opioid-
	aggregate of \$50 million. If		induced bowel dysfunction ("OBD").
	development costs exceed these		Development costs are currently estimated to exceed \$50 million for thi
	amounts, Takeda and Sucampo shall equally share such excess costs.		indication.
	equally share such encess costs.		indication.
			Sucampo has begun incurring development expenses related to its pivotal Phase II/III OBD study, for which Sucampo expects to file an IND in early 2007. At the time of its agreement to conduct these additional deliverables, Sucampo estimated that this study would be completed in June
			2009.

As noted in the previous table, upon joint agreement with Takeda through the JCC, the Company became obligated to complete three deliverables in the second quarter of 2006 and began work on these deliverables during the third quarter of 2006. These deliverables are viewed as economically independent from the deliverables agreed to when the Agreement and the Supplemental Agreement were executed. The Company was under no obligation to perform the three new studies prior to the second quarter of 2006 when the two parties agreed on the studies. The Company re-assessed each deliverable using the guidance of EITF 00-21 to determine which deliverables should be considered as separate units of accounting. Consistent with the Company's initial EITF 00-21 assessment of the Constipation and C-IBS deliverable,

the Company was unable to obtain objective and reliable evidence of the fair value of the undelivered studies. Accordingly, the Company has combined these three new required deliverables as a single unit of accounting. Consistent with the discussion above, the Company has applied the time-based model, by which the Company will ratably recognize this revenue over the estimated performance period of the combined deliverables. The estimated completion date is June 2009.

The Company also re-assessed this revenue under EITF 99-19 and EITF 01-14 and concluded that the Company is the principal with respect to these deliverables and revenues should be presented gross.

#### Summary

The Company entered into the Agreement with Takeda in October 2004. The Company then expected, and continues to expect, the Agreement and the Supplemental Agreement to be profitable, particularly in light of receiving the up-front and milestone payments for development events and payments for commercial events and the ongoing royalty revenue stream for the Amitiza sales.

The Company had originally identified the required deliverables as a single unit of accounting and recognized such revenue under the substantive milestone method. The Company has reassessed all of the deliverables when they became requirements for both the Agreement and Supplemental Agreement pursuant to EITF 00-21 and the revenue recognition model to be applied to the separate units of accounting. This re-assessment resulted in a different revenue model, a time-based model, to be applied against multiple units of accounting. In reviewing and assessing SFAS 154, the Company will restate its 2004 and 2005 consolidated financial statements to reflect a correction of an error in the next amendment to the Registration Statement.

\* \* \* \* \*

## **Proposed Revised Footnote Disclosures**

In response to the Staff's comment, the Company has included the following proposed revised footnote disclosures for the restatement of previously issued consolidated financial statements (Note 2), revenue recognition (Note 3) and the details of the collaboration and license agreements with Takeda (Note 11). The Company intends to include these revised footnotes to its consolidated financial statements in an amendment to the Registration Statement after the Staff has had the opportunity to review the proposed language. The Company also intends, at

that time, to modify its "Management's Discussion and Analysis" section as appropriate to reflect similar modifications.

#### Restatement of Previously Issued Consolidated Financial Statements (Note 2)

The Company has restated its previously issued consolidated financial statements and related footnotes as of December 31, 2005 and for the years ended December 31, 2004 and 2005, 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 statement.

## 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. The identification of this error occurred as a result of the Company evaluating its assumptions under EITF 00-21, *"Revenue Arrangements with Multiple Deliverables"*, in accounting for arrangements with multiple deliverables that require significant judgment and estimates.

The Company reassessed the stand-alone value to Takeda when deliverables from the joint collaboration and license agreement with Takeda became a requirement of the Company by examining objective and reliable evidence of the fair value of the undelivered items. This re-assessment determined that the previous assessment of a single unit of accounting for the deliverables from the joint collaboration and license agreement with Takeda 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 applicable to account for such cash payments from Takeda. Accordingly, in the restated consolidated financial statements for the years ended December 31, 2004 and 2005, the Company reduced the milestone revenue and increased research and development revenue. Total revenue increased by approximately \$1.2 million for the year ended December 31, 2004 and decreased by approximately \$6.8 million for the year ended December 31, 2005. In addition, related deferred revenue increased by approximately \$5.6 million at December 31, 2005.

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 income for the years ended December 31, 2004 and 2005 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.

## Impact on Consolidated Statements of Operations and Comprehensive Income Items

	As Reported	Year Ended December 31, 2004 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
Loss from operations	(19,597,510)	1,173,993	(18,423,517)
Loss before income taxes	(19,653,674)	1,173,993	(18,479,681)
Net loss	(19,653,674)	1,173,993	(18,479,681)
Basic net loss per share	(5.12)	0.30	(4.82)
Diluted net loss per share	(5.12)	0.30	(4.82)
Comprehensive loss	(19,666,782)	1,173,993	(18,492,789)

	As Reported1	Year Ended December 31, 2005 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
Income (loss) from operations	6,223,347	(6,802,197)	(578,850)
Income before income taxes	7,213,116	(6,802,197)	410,919
Net income (loss)	6,424,775	(6,802,197)	(377,422)
Basic net income (loss) per share	1.68	(1.78)	(0.10)
Diluted net income (loss) per share	1.63	(1.73)	(0.10)
Comprehensive income (loss)	6,457,463	(6,802,197)	(344,734)

## **Impact on Consolidated Balance Sheet Items**

	As Reported <sup>1</sup>	December 31, 2005 Adjustment	Restatement
	ASSETS:	ngustinent	Restatement
Deferred tax assets	\$ 292,404	\$ 234,348	\$ 526,752
Total current assets	47,092,459	234,348	47,326,807
Deferred tax assets — noncurrent	687,294	(234,348)	452,946
LIABILITIES AND	STOCKHOLDERS' EQUITY (DEF	ICIT)	
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)	(5,628,204)	(44,239,243)
Total stockholders' (deficit) equity	(3,683,832)	(5,628,204)	(9,312,036)

<sup>1</sup> 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.

## **Revenue Recognition (Note 3)**

## Collaboration and License Agreements

The Company's primary sources of revenue include up-front payments, 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), Emerging Issues Task Force (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"* (EITF 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 a sixteen-year collaboration and license agreement (Takeda Agreement) with Takeda in October 2004 and a supplemental agreement to the Takeda Agreement (Supplemental Agreement) in February 2006 (see Note 11). 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 do meet these criteria are evaluated separately for the purposes of revenue recognition. Deliverables that do not meet these criteria are combined and accounted for as a single 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 and the Supplemental Agreement consist of the following key funding streams: up-front and milestone payments, reimbursements of development and co-promotion costs and royalties. In accordance with EITF 00-21, the cash flows associated with the individual units of accounting from the Agreement and the Supplemental Agreement are recognized as revenue using a time-based model that recognizes the revenue ratably over the period in which the Company completes its performance requirements. However, revenue is limited to amounts that are nonrefundable and that Takeda is contractually obligated to pay to the Company. The Company has determined that it is acting as a principal under the 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. For the year ended December 31, 2006, the Company recognized approximately \$6.6 million in royalty revenues.

Reimbursement of co-promotion costs under the Supplemental Agreement is recognized as revenue as the related costs are incurred. The Company has determined that it is acting as a principal under the Supplemental Agreement and, as such, records reimbursements of these amounts as co-promotion revenue. For the year ended December 31, 2006 the Company recognized approximately \$3.5 million of 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 revenue recognition upon exercise of the option and continue recognition over the estimated performance period. When recognized, option fees are recorded as contract revenue.

Contract revenue related to development and consulting activities with related parties is accounted for under the time based method and as performance is rendered, respectively. Cost sharing payments received in advance are recorded as deferred revenue and recognized as revenue over the applicable clinical trial period.

#### Other Revenue Sources

Revenues from the performance of research and development cost reimbursement activities under a long-term strategic alliance agreement (see Note 10) are recorded over the period in which the actual research and development activities have occurred, similar to the time-based model, which was equivalent to the term of this agreement.

Contract revenue related to development and consulting activities with related parties is accounted for over the period in which the services are completed, similar to the time-based model. Cost sharing payments received in advance are initially recorded as deferred revenue.

## **Collaboration and License Agreements (Note 11)**

On October 29, 2004, the Company entered into a 16-year collaboration and license agreement with Takeda to exclusively co-develop, commercialize and sell products that contain lubiprostone for gastroenterology indications in the United States and Canada. Payments to the Company under the Takeda Agreement include a nonrefundable up-front payment, nonrefundable 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 the nonrefundable up-front payment of \$20 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 earlier. Upon commercial launch, Takeda shall, for the products sold by Takeda during the term of the Takeda Agreement, pay Sucampo 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 Sucampo 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 Sucampo are paid. The Company has recorded royalty revenues of approximately \$6.6 million for the year ended December 31, 2006. This revenue is recorded as 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 a New Drug Application (NDA) for the treatment of chronic idiopathic constipation (Constipation) and irritable bowel syndrome with constipation (C-IBS) indications. Takeda shall fund the initial \$30 million of development costs and the two parties shall equally share any required development costs in excess of \$50 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 C-IBS will be completed and submitted to the FDA in June 2007.

The Company has assessed these required deliverables to determine which deliverables are considered separate units of accounting under the guidance of EITF 00-21. The Company was able to specifically identify stand-alone value for the participation in the Joint Steering Committee, the Joint Manufacturing Committee and the Joint Commercialization Committee by obtaining 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 the stand-alone value for participation in the Joint Development Committee from its obligations to perform research and development of Constipation and C-IBS because the participation in the Joint Development Committee was to occur concurrently with the development work. Thus, the Company 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 C-IBS and participation in the Joint Development Committee.

The fair value associated with the three separately identified units of accounting related to participation of committee meetings were based on obtaining objective and reliable evidence of the fair value of these deliverables 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. Upon receipt of the \$20 million up-front payment, the Company deferred approximately \$2.4 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, the Company recognized approximately \$24,000, \$147,000, and \$147,000, 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 was approximately \$2.2 million and \$2.1 million, respectively.

Since the execution of the Takeda Agreement through December 31, 2006, the Company deferred the residual amount of the \$20 million up-front payment totaling approximately \$17.6 million, milestone payments received totaling \$50 million, and reimbursement of the initial \$30 million of research and development costs for the development of AMITIZA for Constipation and C-IBS 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 C-IBS and are being recognized using the time-based model over the performance period of developing the Constipation and C-IBS NDA submissions, which is estimated to be completed by June 2007. During the years ended December 31, 2004, 2005 and 2006, the Company recognized approximately \$2.8 million, \$39.0 million and \$46.4 million, respectively, of these deferred amounts as research and development revenue on the consolidated statements of operations and comprehensive (loss) income. The related deferred revenue as of December 31, 2005 and 2006 was approximately \$35.8 million and \$11.0 million, respectively

The Company incurred research and development costs for this development work of approximately \$1.5 million, \$25.9 million and \$11.6 million for the years ended December 31, 2004, 2005 and 2006, 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 in 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, 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 \$3.5 million of revenues for the year ended December 31, 2006 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 exceed the term of the Supplemental Agreement. The Company began performing these activities in January 2006. The Company has recorded approximately \$779,000 of reimbursements of marketing costs for the year ended December 31, 2006. This amount is recorded as a reduction to selling and marketing expenses in the consolidated statements of operations and comprehensive (loss) income.

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 C-IBS. 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 (OBD). Takeda shall fund all development work up to a maximum aggregate of \$50 million and \$20 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 million in development costs.
- 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 to determine which deliverables are considered separate units of accounting under the guidance of EITF 00-21. 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 standalone 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 \$1.0 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 an 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 immediately recognized the deferred \$1.0 million as contract revenue for the year ended December 31, 2005. The option right expired for SPE during the first quarter of 2006 and \$1.5 million was returned to Takeda and the Company immediately recognized the deferred \$1.5 million as contract revenue for the year ended December 31, 2005. See Note 3 for a discussion of the revenue recognition policy for option payments received by the Company.

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Under SFAS 154, paragraph 2h, the Company has a correction of an error as of December 31, 2006 and will restate its 2004 and 2005 consolidated financial statements under paragraph 25 and corresponding disclosures under paragraph 26.

The management of the Company has discussed the matters above with PricewaterhouseCoopers LLP, the Company's independent registered public accountants, who concur that the Company's conclusions are acceptable.

If you have any questions or comments on the above, please contact either me at (202) 663-6224 or Bryant Morris at (202) 663-6058.

Respectfully, /s/ Brent B. Siler Brent B. Siler

cc: Ms. Sonia Barros Ms. Christine Allen Mr. Kevin Woody Mr. Mark Barrysmith Securities and Exchange Commission Sachiko Kuno, Ph.D Mr. Ron Kaiser Ms. Mariam Morris Jeffrey D. Karpf, Esq.