



December 15, 2006

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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.  
Amendment No. 4 to Registration Statement on Form S-1, filed November 14, 2006  
File No. 333-135133

Dear Mr. Riedler:

On behalf of Sucampo Pharmaceuticals, Inc. ("Sucampo" or the "Company"), this letter responds to the comments in your letter dated 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").

**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 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.

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**RESPONSE:****Background**

On October 29, 2004, Sucampo 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”) is currently being developed. Numerous other product-candidates using the compound SPI-0211 are currently in the development phase. 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 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;
  - The bankruptcy, insolvency or similar event of either party;
  - Sucampo may terminate if Takeda fails to achieve specified net sales revenue targets; and
  - If New Drug Application (“NDA”) approval for C-IBS cannot be obtained in the United States, the parties will in good faith negotiate whether to continue future development and commercialization of Products. If the parties cannot agree, then either party will have the right to terminate.
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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:

Deliverable	Contractual Cash Flows	Obligations	Performance Period
1 License of the compound SPI-0211 to Takeda ( 2.1 )	<p>There are no defined contractual cash flows for the grant of the license to Takeda, but the Company did receive an up-front non-refundable \$20 million payment from Takeda upon executing the Agreement.<sup>1</sup></p> <p>If Sucampo achieves commercialization of Products, Takeda shall, for the Products sold during the term of the Agreement, pay Sucampo royalties on net sales. The level of royalty payments are tiered based on the level of net sales revenue earned by Takeda.</p>	Sucampo shall provide Takeda with an exclusive license to co-develop, use, sell, promote, offer for sale, import and distribute the Products for specified indications within specified territories.	<p>The license was granted upon execution of the Agreement in October 2004 and will expire when the Agreement expires in 2020 or when it is earlier terminated.</p> <p>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.</p>
2 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	Sucampo shall conduct all development work necessary for an NDA submission (in the United States and Canada) for	There is no defined performance period, but it will not exceed the term of the Agreement.

Deliverable	Contractual Cash Flows	Obligations	Performance Period
	in excess of \$50 million.  Takeda shall pay Sucampo non-refundable milestone payments for the Products. <sup>1</sup>	Constipation and C-IBS.	An NDA for Amitiza (for Constipation) was approved by the FDA in January 2006. Sucampo estimates that the NDA submission for C-IBS will be completed in May 2007.
3 Perform regulatory required studies ("RRS") for Constipation and C-IBS (4.2(ii)).	Takeda and Sucampo shall equally share in the external costs of RRS, but Sucampo will not be required to incur costs of more than \$20 million.	Sucampo shall conduct all additional studies required by the regulatory authority for Constipation and C-IBS.  Such studies will be performed throughout the term of the Agreement when the studies are required by the FDA.	There is no defined performance period, but it will not exceed the term of the Agreement.  Currently, no such studies have begun as the FDA has not required additional studies.
4 Changes to labeling for Constipation and C-IBS (4.2(iii)).	Takeda shall fund 70% of labeling studies and Sucampo shall fund the remaining 30%.	Sucampo shall conduct all studies required to modify, change or expand the labeling of Products for Constipation and C-IBS.  Such studies will be performed throughout the term of the Agreement when the studies are deemed appropriate by the committees (any deadlock on this decision would be broken by Takeda).  Labeling studies are normally performed after a drug is approved by the FDA.	There is no defined performance period, but it will not exceed the term of the Agreement.  Sucampo estimates that the Renal/Hepatic labeling study that was initiated in August 2006 will be completed in September 2007.
5 Development of additional indication(s)	Per each additional indication, Takeda shall fund all internal and external development work up to a	Sucampo shall conduct all development of the additional indication(s)	There is no defined performance period, but it will

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Deliverable and/or new formulation(s) (4.2(iv)).	Contractual Cash Flows maximum aggregate of \$50 million.	Obligations and/or new formulation(s).	Performance Period not exceed the term of the Agreement.
	<p>Per each new formulation, Takeda shall fund all development work up to a maximum aggregate amount of \$20 million.</p> <p>If development costs exceed these amounts, Takeda and Sucampo shall equally share such excess costs.</p>	<p>Such studies will be performed throughout the term of the Agreement when the studies are deemed necessary by the committees (any deadlock on this decision would be broken by the Company).</p>	<p>Sucampo has recently begun work on the first additional indication for AMITIZA, opioid-induced bowel dysfunction ("OBD"), which is currently estimated to exceed \$50 million in costs.</p> <p>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 and which Sucampo currently expects will be completed in June 2009.</p>
<p>6 Participate in the following committees:</p> <ul style="list-style-type: none"> <li>— Joint Steering Committee (3.1)</li> <li>— Joint Development Committee (4.1)</li> <li>— Joint Commercialization Committee (5.1)</li> <li>— Joint Manufacturing Committee (6.1)</li> </ul>	<p>No separate cash flows.</p>	<p>See discussion below.</p>	<p>There is no defined performance period for each committee. None of the committees will extend beyond the term of the Agreement. The Company expects participation within all 4 committees to occur throughout the Agreement term.</p>

- 1 The following is a listing of the development milestone events and the milestone payments due to Sucampo from Takeda after the occurrence of the applicable event. As discussed below, the development milestones are substantive and are expected to meet the criteria discussed within Step 2 of the Technical Accounting Considerations section below:

Development Event (all within US)	Payment (in millions)
Execution of Agreement	\$ 20
NDA filing for Constipation	10
Phase III entered for C-IBS	20
NDA approved for Constipation	20
Additional regulatory milestones specified in section 7.2	90
	<u>\$ 160</u>
Commercial Event	Payment (in millions)
Specified targets for annual sales of Amitiza in territories as provided in Section 7.2	\$ 50

Upon execution of the Agreement, the Company expected the Agreement to be profitable. 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 and selling costs, owed to Sucampo upon completion of the associated deliverables. Also, the royalty payments on potential sales of products were foreseeable in the near future when the Agreement was signed because the drug candidate that became Amitiza had successfully completed its Phase III trials and would be eligible for an NDA submission, which was filed on March 31, 2005. Today, approximately two years after the Agreement was executed, the Company has received the \$20 million nonrefundable up-front payment, \$50 million of nonrefundable milestone payments, \$30 million of reimbursements of development costs and \$4.5 million of royalty payments on Takeda's net sales of Amitiza. The recognition of revenue on these streams of cash flows is disclosed in detail in the table below. The actual cash payments and recognized revenue supports the Company's expectation upon execution of the Agreement that it would be profitable.

#### Technical Accounting Research Considerations

The Company has performed the following steps in determining the appropriate accounting model for the cash payments Sucampo has received and will receive from Takeda related to the Agreement:

1. Identification of the contract deliverables and evaluation of EITF 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"), to determine whether separate units of accounting exist;

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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 appropriate presentation of certain revenue streams.

Step 1 — Identification of deliverables and evaluation of EITF 00-21:

With the exception of the committee participation, which was not originally identified by the Company as a deliverable, the table included above summarizes the identified contract deliverables under the Agreement, including the expected timing of performance by Sucampo.

As the Company was unable to determine the stand-alone value of the delivered items and obtain verifiable objective evidence to determine the fair value of the undelivered items, the Company concluded that there is a single unit of accounting due to the fact that the criteria required under EITF 00-21 were not met to treat the deliverables in the arrangement as separate units of accounting.

In 2004, when it completed its initial assessment of the deliverables under the Agreement, the Company did not believe that its participation in the various committees was deemed to be a deliverable as contemplated in EITF 00-21 as the committee participation was considered an operational, governance and dispute-resolution structure, designed to promote the ability for the Company and Takeda to work together and communicate effectively during the development and commercialization period, not impacting the revenue recognition assessment. Based on the Staff's request, the Company's analysis of its committee participation is as follows:

Committee	Structure and Purpose	Duration
1. Joint Steering Committee ("JSC")	Comprised of 3 members from each party. Meets on a semi-annual basis, at a minimum. Responsibilities include (i) review development plan, (ii) coordinate development and commercialization efforts with other committees (described below) (iii) discuss and decide necessary actions when the sales of the Product stagnate and (iv) resolve any conflicts arising from the other committees. In this regard, if conflicts are not resolved by the JSC, then Sucampo casts deciding vote for disputes arising from the Development and Manufacturing Committees and Takeda casts the deciding vote for disputes arising from the Commercialization Committee.	Expected to last the duration of the Agreement.



	Committee	Structure and Purpose	Duration
2.	Joint Development Committee (“JDC”)	Comprised of 2 members from each party. Meets on a quarterly basis, at a minimum. Responsibilities include (i) manage and oversee development of Products, (ii) develop, approve and modify development plan (iii) develop regulatory strategy and protocol for the Products, (iv) manage development budget, and (v) oversee approval process.	Expected to last the duration of the Agreement or, if earlier, the completion of all development work.
3.	Joint Commercialization Committee (“JCC”)	Comprised of 2 members from each party. Meets on a quarterly basis, at a minimum. Responsibilities include (i) developing, managing and overseeing commercialization plan, (ii) approving Phase IV studies for marketing purposes, (iii) managing and overseeing commercialization budgets, (iv) checking status of planned activities, (v) determining go/no go of labeling changes, additional indications and new formulations and (vi) setting number of sales representatives and product positioning.	Expected to last the duration of the Agreement or, if earlier, the completion of all commercialization work.
4.	Joint Manufacturing Committee (“JMC”)	Comprised of 2 members from each party. Meets on a quarterly basis, at a minimum. Responsibilities include (i) manage and oversee manufacturing of the Products and, (ii) develop and review manufacturing specifications, quality control and assurance plans.	Expected to last the duration of the Agreement or, if earlier, the completion of all manufacturing work.

The Company evaluated the Agreement and concluded that its participation in all the committees listed above was obligatory, but the requirement to participate is fulfilled ratably over the term of the Agreement. In no event would the Company’s obligation to participate extend beyond the term of the Agreement. The minimum frequency of committee meetings is specified in the Agreement and, as there is no systematic pattern of performance, a ratable attribution model best represents the fulfillment of these committee participation requirements. As there is no stand alone value for the committee participation and it is not possible to determine its fair value, this possible deliverable would not have been separated into a new unit of accounting. The committee participation obligation would have been combined with all the other deliverables in the single unit of accounting. The Company does not anticipate that it will incur significant incremental costs in participating in these committee meetings. While there are no contractual cash flows between Takeda and Sucampo directly associated with the committees, the \$20 million nonrefundable up-front fee received may be associated with compensating the Company for previous research and development efforts, the grant of the license for compound SPI-0211, as well as participating in future committee meetings. Accordingly, the attribution model for revenue recognition for the up-front fee (also discussed below) is ratable recognition over the term of the Agreement. This model matches the way in which the committee

participation is fulfilled. Therefore, the Company believes that the committee obligation does not change its assessment of units of accounting pursuant to EITF 00-21 and the subsequent revenue recognition model discussed in Step 2 below.

Step 2 — Selection of accounting model:

The Company attempted to determine a systematic and rational attribution pattern that is fairly representative of and faithful to the economic substance of the single unit of accounting, but that would in no event result in premature revenue recognition.

The Company looked to the Substantive Milestone method which is frequently used in similar biotech collaboration and license arrangements. Under the Substantive Milestone method, revenue for the single unit of accounting is recognized once the milestone is achieved, SAB No. 104, *Revenue Recognition* (“SAB 104”) criteria are met and certain additional criteria are met as follows:

- 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 is deemed to be non-substantive and the related payment is recognized separately over the term of the agreement. 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. The Company’s participation on the committees will not extend beyond the term of the Agreement. Arguably 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), but the Company understands this method has been accepted as industry practice for biotech collaboration agreements by the Staff.

Therefore, within the single unit of accounting, the Company applied the Substantive Milestone method which recognizes milestones as revenue when achieved and when the above

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criteria are met and recognizes other amounts (e.g., up-front fees or any milestones not meeting the above criteria) over the term of the Agreement. The remaining cash flow items in the single unit of accounting are the cost reimbursements which are recorded on a proportional performance basis as long as the overall Agreement is profitable.

The Company determined the revenue attribution model for each component within the single unit of accounting as follows:

1. Upfront fees and substantive milestone payments (deliverables #1 and #2 in the Agreement deliverables table above) are recognized using the Substantive Milestone method. As a result, the upfront fee was deferred and recognized on a straight-line basis over the term of the Agreement (approximately 16 years) as there was no systematic pattern of effort by the Company. Milestones will be recognized once the milestone is achieved and amounts are due and payable and all other SAB 104 revenue recognition criteria and Substantive Milestone method criteria discussed above are met.
2. The cash flow items from cost reimbursements (deliverables #2 – 5 in the Agreement deliverables table above), are recognized using a proportional performance model where revenue is recognized to the extent of direct reimbursable costs incurred but limited to the amount of cash received or amounts receivable under the Agreement. These reimbursements do not include any profit elements. The Company uses direct costs as its input-based measure to determine proportional performance because direct costs represent the value of the services being performed and the value being transferred to Takeda. The direct costs include both third party and internal costs associated with all the deliverables in the Agreement.

Any amounts received in advance of the revenue being recognized are reported as deferred revenue in accordance with the proportional performance model as the Company fulfils its obligations under the Agreement.

The Company's basis for this proportional performance model is by an analogy to SOP 81-1, par 25 (c). While the Company acknowledges that the Agreement is not within the scope of SOP 81-1, given the limited guidance for this industry and for these arrangements, there is support for using a zero profit proportional performance model. As discussed in the Background section of this analysis, the Company has evaluated the profitability of this Agreement and determined that this Agreement is expected to be profitable.

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As discussed above, in cases where the funding of the cost reimbursement was made on a prepayment basis, then the pre-funding was deferred and recognized over the estimated development period for related projects.

For example with respect to deliverable #2 in the Agreement deliverable table above, as discussed in the Company's previous responses to the SEC staff, Takeda funded the initial \$30 million of the development costs for the development of additional indications with Sucampo funding the next \$20 million (Takeda and Sucampo would equally share any remaining development costs in excess of the \$50 million). For this example, the initial \$30 million of funding has an element of prepayment for future services because the total costs of the development are estimated to approximate \$50 million. Therefore, these earned payments were recognized as revenue over the total estimated development period. The Company considered recognizing the \$30 million as incurred in order to "match" the related expenses; however, this did not give sufficient consideration to the subsequent obligation of the Company to continue the development after the first \$30 million of costs were incurred. In substance, for this element, Takeda paid (or reimbursed) Sucampo \$30 million for \$50 million of development costs.

With regard to the development cost reimbursements, the Company evaluated alternative models for attributing revenue given the Company's accounting policy election of utilizing the Substantive Milestone method, taking into consideration the specific economic substance and earnings processes associated with the third party development expense reimbursements as follows:

Alternative Model 1:

- Consider the development cost reimbursements as either an upfront payment or as non-substantive milestone payments. As a result, the Company would amortize all consideration associated with the development cost reimbursements over the term of the arrangement in the same manner as the upfront payments.

Alternative Model 2:

- Consider the development cost reimbursements as akin to substantive milestones and recognize all reimbursement as revenue when earned, regardless of the pattern of funding.

However, the Company believes that neither of these alternative models fairly represented the earnings process or the true economics of the arrangement. In lieu of selecting alternative Model 1 or 2, the Company selected the model described above as it best represents the economics of the Agreement, without prematurely recognizing revenue.

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The Company's objective in determining this accounting model was to represent the economics of the Agreement. The Company had completed its Phase III trials for the development of Amitiza for a Constipation indication when the Agreement was signed. The Company negotiated the nonrefundable up-front payment and milestone payments to be commensurate with the level of effort expended. In protecting itself from an economic perspective, the Company also negotiated various cost reimbursement streams so that it would never be in a net loss position. As most of the work is being performed on a sequential basis, each step needed to be achieved before moving to the next step. Accordingly, neither party has an inducement to accelerate or decelerate the economics or cash flows at each stage. The Company is providing value in the form of research and development experience with SPI-0211 to Takeda in the cost reimbursement streams — so there is clearly something that has stand alone value from the customer's perspective. However, as there is no available fair value for this unique product, it is not possible to separate out the cost reimbursements from a pure and literal application of EITF 00-21. Given that the use of the Substantive Milestone method, which the Company believes is industry practice, is acceptable even though it conflicts with a pure application of EITF 00-21, the Company believed that recognizing the cost reimbursements separately from the up-front fees and milestone payments respected the economics of the Agreement. If the Agreement was terminated today, the Company would not have to return any of the cost reimbursement amounts. Due to the limited guidance, the Company attempted to develop the most appropriate accounting model that represented the economics of the Agreement. In simple terms, the model is as follows:

- i) substantive milestones are recognized when achieved and certain criteria are met;
- ii) up-front fees are spread ratably over the term of the Agreement based on the application of the Substantive Milestone method; and
- iii) cost reimbursements, which economically ensure that the Company is not in a loss position, are recognized as costs are incurred.

While one could argue this model is not a direct and pure application of EITF 00-21, the Company believes that there are few biotech agreements that would fit squarely into the EITF 00-21 model. A pure application of EITF 00-21 would certainly eliminate the usage of the Substantive Milestone method. Using an analogy to SOP 97-2, where the attribution model is based on the last undelivered element and the recognition trigger is when there is one undelivered element left, is also challenging since it is difficult to determine what the last deliverable is in a biotech agreement due to the variety of services being performed. If this model were used, then the Company would defer all up-

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front fees, all milestone payments and all cost reimbursement payments until the earlier of (i) when the last deliverable is identified or (ii) when all obligations are fulfilled. This would result in either significant back loading of revenue or full deferral until the end of the contract. The Company asserts that neither a pure EITF 00-21 model nor an analogy to SOP 97-2 appropriately reflects the economics of the Agreement.

The Company's model respects economics when factoring in both parties' perspectives without getting ahead of the cash received and receivable — so as to clearly avoid any premature revenue recognition. In fact, the Company adopted a more conservative view on some of the cost reimbursements for which funding was obtained in advance of the work being performed. Rather than record revenue as these direct reimbursable costs were incurred, the Company decided to defer these over the estimated development period (which in no case can exceed the Agreement term). Specifically, the revenue that was recognized for these reimbursement payments were the lesser of (i) the straight-line amount of total cash to be reimbursed over the estimated term of the deliverable or (ii) the reimbursable costs incurred by the Company.

The Company continually evaluates the overall profitability of this Agreement. At inception, as the Company was in later phases of its clinical trials than is typical for most biotech collaboration agreements, the Company felt strongly, based on the up-front fees, achievable milestone payments and cost reimbursements, that it would be able to successfully recoup its costs. The Company has determined the potential market for its Products is lucrative and, accordingly, the royalty payments were negotiated. Within two years of signing the Agreement, the Company received FDA approval on Amitiza for the Constipation indication. This, while not known by the Company at the inception of the Agreement, demonstrates that the Company had completed sufficient amounts of development work to the point that the Company was confident of getting to the commercialization stages. A typical biotech arrangement does not result in FDA approval of drug candidates within such a short timeframe.

3. Running royalties (deliverable #1 in Agreement deliverables table above) will be recognized when earned and all SAB 104 criteria are met. The earnings process for the royalties on each product is completed as each finished product is sold by Takeda during the co-promotion period.

The Company acknowledges that the accounting for these types of collaboration arrangements is a complex area. The Company also acknowledges that there is minimal authoritative guidance on the attribution models that should be used in determining the appropriate recognition pattern within a single unit of accounting. Generally, the Company

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evaluates all its revenue recognition models under the premise that premature revenue recognition is inappropriate unless all revenue recognition criteria pursuant to SAB 104 are met.

The Company believes that its selected approach best serves the interest of the users of the financial statements in understanding the correspondence between revenues and expenses associated with work actually performed under the Agreement.

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

The Company further evaluated the presentation of the reimbursements of development expenses on a gross versus net basis in accordance with EITF 99-19. Based on the evaluation of all these indicators, the Company determined that reimbursements of development costs should be recognized on a gross basis and reported as revenue — reimbursement of research and development costs in the consolidated statement of operations. In particular, the Company 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 these expenses. This is consistent with responses 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 has 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 ("Supplemental Agreement"). The Supplemental Agreement was filed as Exhibit 10.25 to the Registration Statement.

The purpose of this Agreement was mainly to amend the responsibilities for both Sucampo and Takeda for the co-promotion of Amitiza and to clarify the responsibilities and funding arrangements for other marketing services to be performed by Sucampo and Takeda. In connection with the Supplemental Agreement, the responsibilities for performing Phase IV studies changed from Takeda to Sucampo. There were no monies paid by either party for the

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execution of the Supplemental Agreement. The term of the Supplemental Agreement ends when the Agreement expires or is terminated.

As discussed above, 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 terminates simultaneously with the termination of the Agreement.

The Supplemental Agreement contains the following deliverables:

	<u>Deliverable</u>	<u>Contractual Cash Flows</u>	<u>Obligations</u>	<u>Performance Period</u>
1	Perform Phase IV studies (4.2(vi) of Agreement and 5.1 of Supplemental Agreement)	Takeda shall fund all Phase IV studies.	<p>Sucampo shall conduct all Phase IV studies.</p> <p>Such studies will be performed throughout the term of the Agreement when the studies are deemed necessary by the committees.</p> <p>The terms within the Agreement for Phase IV studies were superseded with 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.</p>	<p>There is no defined performance period, but it will not exceed the term of the Agreement.</p> <p>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.</p>
2	Co-promote Amitiza with Takeda (5.4 (a) of Agreement and 6.2 of Supplemental Agreement)	Takeda shall pay Sucampo a specified amount per day per Sucampo's sales force representative, but not to exceed certain pre-defined amounts.	<p>Sucampo shall employ a sales force of approximately 38 representatives to supplement Takeda's sales activities. The terms within the Agreement for co-promotion activities were superseded with the Supplemental Agreement.</p> <p>The Agreement states Sucampo has the option to employ sales representatives. The Supplemental Agreement has amended the Agreement to state that Sucampo shall employ approximately 38 sales representatives for such purposes.</p>	60 months following the first date (April 2006) that Sucampo deployed sales representatives.

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	<u>Deliverable</u>	<u>Contractual Cash Flows</u>	<u>Obligations</u>	<u>Performance Period</u>
3	Perform miscellaneous marketing activities for Amitiza (Article 3 of Supplemental Agreement)	Takeda shall reimburse Sucampo all approved external costs incurred for such miscellaneous marketing activities.	Sucampo shall conduct all such miscellaneous marketing activities	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 cost reimbursements received for these deliverables will be recognized in a manner consistent with the cost reimbursements in the Agreement, described above.

### 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, as a whole, to be profitable, mainly due to the expected receipts of 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 evaluated all the deliverables in both agreements pursuant to EITF 00-21 and determined that there was a single unit of accounting because the Company was unable to determine the fair value of the undelivered elements. The Company then applied the Substantive Milestone method to recognize revenue for substantive milestones once SAB 104 criteria and certain other criteria were met. Any non-substantive fees and up-front fees are recognized ratably over the term of the Agreement as there is no systematic pattern of performance. The Company further segregated reimbursements for direct costs to better reflect the economics of the arrangement and recognized these reimbursements either as earned and when all SAB 104 criteria are met or, if received in advance, over the obligation period. The Company acknowledges that accounting for agreements of this type is complex and that there is limited guidance in this area. The Company's accounting model attempts to reflect the

economics of the Agreement and the Supplemental Agreement while ensuring that premature revenue recognition does not occur.

As a result of the Company's analysis and revenue recognition policies, the revenue from the agreements were recognized in the following quarters (\$ in 000's):

	2004	2005				2006		
	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Up-front payments (deliverable #1)	\$ 206	\$ 309	\$ 309	\$ 309	\$ 309	\$ 309	\$ 309	\$ 309
Milestone payments (deliverable #2)	—	10,000	20,000	—	—	20,000	—	—
Reimbursements of development and co-promotion costs (deliverables #2 - #5)	1,482	4,289	3,461	3,461	3,461	3,868	4,087	3,368
Royalty payments (deliverable #1)	—	—	—	—	—	—	4,485	79
<b>Total</b>	<b>\$ 1,688</b>	<b>\$ 14,598</b>	<b>\$ 23,770</b>	<b>\$ 3,770</b>	<b>\$ 3,770</b>	<b>\$ 24,177</b>	<b>\$ 8,881</b>	<b>\$ 3,756</b>

#### Proposed Revised Footnote Disclosures

In response to the Staff's comment, the Company has included below proposed revised footnote disclosures for 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 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.

**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 about the fair value to be allocated to each unit of accounting.

The Company entered into a 16-year collaboration and license agreement (Takeda Agreement) with Takeda in October 2004 and a supplemental agreement to the Takeda Agreement (Supplemental Agreement) in January 2006 with Takeda (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. As a result of the Company's analysis of the Agreement and the Supplemental Agreement, the Company was unable to determine the stand-alone value of the delivered items within these agreements and obtain verifiable objective evidence to determine the fair value of the undelivered items. The Company, therefore, concluded that there was a single unit of accounting for the Takeda Agreement and the Supplemental Agreement in accordance with EITF 00-21.

The Company's deliverables under the Takeda Agreement and the Supplemental Agreement, including the rights and obligations, contractual cash flows and performance period, are more fully described in Note 11. The Takeda Agreement and the Supplemental Agreement consist of the following key revenue funding streams: up-front and milestone payments, reimbursements of development and co-promotion costs and running royalties.

For the nonrefundable up-front and milestone payments, the Company recognizes revenue under the Substantive Milestone method under SAB 104. Under the Substantive Milestone method, a milestone is deemed to be substantive if the following criteria are met:

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- A substantive effort is involved in achieving the milestone;
- Milestone payments are reasonable in relation to the effort expended and in relation to one another and with any up-front payments;
- A reasonable amount of time passes between the up-front payment and the first milestone, as well as between successive milestones; and
- Relevant risks of achieving each milestone are considered.

If the milestone is deemed to be substantive, revenue is recognized once the milestone is achieved, amounts are due and payable and all other revenue recognition criteria under SAB 104 are met. If the criteria listed above are not met, then the milestone is deemed to be non-substantive and is deferred upon receipt and recognized separately on a straight-line basis over the term of the Takeda Agreement as there is no systematic pattern of effort by the Company. The nonrefundable up-front payment received by the Company of \$20 million is considered to be non-substantive and is, therefore, being deferred and recognized as revenue over the 16-year term of the Takeda Agreement, through December 2020. The milestone payments received by the Company are considered to be substantive and are recognized in accordance with the policy outlined above.

The Company accounts for reimbursements of development costs under the Takeda Agreement and the Supplemental Agreement using a zero-profit proportional performance model where the Company recognizes revenue based on the respective reimbursable costs incurred, but not to exceed the amount of cash received or amounts contractually owed to the Company under the agreements, assuming the overall agreement is expected to be profitable. These reimbursements do not include any profit elements. The Company has express contractual obligations to provide services under each agreement, including for periods after receipt of funding from Takeda. Revenue from up-front reimbursements is therefore recognized on a straight-line basis over the estimated development period of the related projects or the development activity period. The Company believes a straight-line basis is representative of the level of effort and pattern in which performance takes place. The revenue recognized is limited to the lesser of the cumulative straight-line amount or the cumulative reimbursable portion of the research and development costs incurred (see Note 11). Some reimbursements are not funded up-front or are partially funded by Takeda as the Company incurs development costs. The Company recognizes these reimbursements as revenue as the costs are incurred and the development service is provided by the Company. The Company has determined that it is acting as a principal for all deliverables under the Takeda Agreement and, as such, has recorded reimbursements of development costs as revenue.

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The Company assesses the profitability of the agreements with Takeda throughout their term on a periodic basis when significant relevant changes in facts occur. The Company views profitability to be an overall net cash inflow resulting from the two agreements over the term. Such an assessment is based on significant estimates and assumptions to determine the most likely outcome based on the most recent information available to the Company at each assessment date. The estimates and assumptions include the consideration of factors such as the progress and timing of the development of drug candidates, the acceptance of the Company's products within the relevant markets and historical internal and external costs incurred compared to the Company's budgeted costs.

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 nine months ended September 30, 2006 (unaudited), the Company recognized \$4,563,342 in royalty revenues. As of September 30, 2006, the Company has recorded unbilled accounts receivable and deferred revenue of \$954,148 related to the Takeda Agreement.

Reimbursement of co-promotion costs under the Supplemental Agreement is recognized as revenue as the related costs are incurred using the zero-profit proportional performance model as described above. 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 revenues. For the nine months ended September 30, 2006 (unaudited), the Company recognized \$2,266,594 of co-promotion revenues.

The Takeda Agreement obligates the Company to participate with Takeda in certain committees ratably throughout the 16-year term of the Takeda Agreement, but in no event do these obligations extend beyond this term. As there is no systematic pattern of participation in these committees and no significant incremental costs to the Company will arise from these committees, the Company has applied a ratable attribution model to represent the fulfillment of the Company's participation requirements. As there is no stand-alone value for this participation and it is not possible to determine its fair value, the participation deliverable has not been separated into a new unit of accounting. The Company has associated the straight-line revenue recognition of the up-front fee (as discussed below) with the committee participation requirements of the Company.

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Up-front option fees received by the Company related to other potential joint collaboration and license agreements with Takeda are not recognized as revenue immediately since the transactions do not represent a separate earnings process. Since there are contingent performance obligations by the Company when and if the options are exercised, the Company's policy is to recognize revenue immediately upon expiration of the option or to commence revenue recognition upon exercise of the option and continue recognition over the estimated performance period. When recognized, option fees are recorded as contract revenues.

#### ***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, which was equivalent to the term of this agreement, in accordance with SAB 104. This methodology has been utilized for all payments received in advance by the Company.

Contract revenue related to development and consulting activities with related parties is accounted for under the proportional performance method and as services are rendered, respectively. Cost sharing payments received in advance are recorded as deferred revenue and recognized as revenue over the applicable clinical trial period. The application of this revenue recognition method is based on the proportional clinical trial costs incurred against total expected costs relative to the respective cost sharing agreement.

#### ***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 received a nonrefundable up-front payment of \$20 million. In accordance with the Substantive Milestone method, this nonrefundable up-front payment was considered to be non-substantive (Note 3) and, therefore, was deferred and is being amortized as revenue over the term of the Takeda Agreement. The Company has recognized revenue of \$206,186 and \$1,237,115 for the years ended December 31, 2004 and 2005, respectively. The Company has recognized

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revenue of \$927,836 for each of the nine months ended September 30, 2005 and 2006 (unaudited), respectively. This revenue is recorded as contract revenue in the consolidated statements of operations and comprehensive (loss) income.

The Takeda Agreement includes several deliverables that the Company is responsible to complete and Takeda is responsible to fund. The following are the significant deliverables of the Company under the Takeda Agreement, along with the related contractual cash flows from Takeda and the associated obligations and performance period of the Company.

- 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 upon executing the Takeda Agreement, as discussed above. 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 product 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 \$4,563,342 for the nine months ended September 30, 2006 (unaudited). This revenue is recorded as royalties revenue in the consolidated statements of operations and comprehensive (loss) income.
- 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 May 2007.

The Company incurred research and development costs for this development work of \$1,482,337 and \$25,867,306 for the years ended December 31, 2004 and 2005,

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respectively, and \$18,909,781 and \$10,231,983 for the nine months ended September 30, 2005 and 2006 (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. The Company defers the reimbursements of development costs upon receipt and recognizes revenue over the estimated development period (see Note 3 for a discussion of the zero-profit proportional performance model). The Company has recognized revenue of \$1,482,337 and \$14,671,508 for the years ended December 31, 2004 and 2005, respectively, and \$11,209,970 and \$8,868,885 for the nine months ended September 30, 2005 and 2006 (unaudited), respectively. This revenue is recorded as reimbursements of research and development costs in the consolidated statements of operations and comprehensive (loss) income.

- The Company shall provide development work and use its best efforts to achieve certain other milestones. The Company has achieved certain development milestones in accordance with the Takeda Agreement. The Company considers these milestones to be substantive milestones and recognizes them as revenue once the milestone is achieved, amounts are due and payable and all other revenue recognition criteria under SAB 104 are met (see Note 3 for a discussion of the Substantive Milestone method). The Company has recognized revenue of \$30 million and \$20 million for the year ended December 31, 2005 and the nine-months ended September 30, 2006 (unaudited), respectively. This revenue is recorded as milestone revenue in the consolidated statements of operations and comprehensive (loss) income. The Company has the opportunity to receive substantial additional non-refundable milestone payments in the future.
  - The Company shall perform regulatory required studies (RRS) for Constipation and C-IBS. Takeda and the Company shall equally share in the funding of external RRS costs in an aggregate of \$40 million. Takeda will fund all development costs in excess of an aggregate \$40 million. There is no defined performance period, but the performance period will not exceed the term of the Takeda Agreement. To date, no RRS have begun. Upon initiation of the services, the Company will recognize reimbursement revenues under the zero-profit proportional performance model.
  - The Company shall perform studies surrounding 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
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September 2007. The Company has recognized \$93,366 of revenues for the nine months ended September 30, 2006 (unaudited) based on the zero-profit proportional performance model. This revenue is recorded as reimbursements of research and development costs in the consolidated statements of operations and comprehensive (loss) income.

- The Company shall perform all development work for additional indications (other than Constipation or C-IBS) and new formulations that the Company and Takeda agree upon. 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 has recognized \$52,395 of revenues for the nine months ended September 30, 2006 (unaudited) based on the zero-profit proportional performance model. This revenue is recorded as reimbursements of research and development costs 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 the Joint Manufacturing Committee. There were no separate cash flows 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.

On February 1, 2006, the Company entered into the Supplemental Agreement with Takeda, which amends the responsibilities for 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. In connection with the Supplemental Agreement, the responsibilities for performing Phase IV studies were moved from Takeda to the Company. There were no monies paid by either party for the execution of the Supplemental Agreement and the term of the Supplemental Agreement ends when the Takeda Agreement expires or is terminated.

The Supplemental Agreement includes several deliverables that the Company is responsible to complete and Takeda is responsible to fund. The following are the

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significant deliverables of the Supplemental Agreement, along with the related contractual cash flows from Takeda and the associated obligations and performance period of the Company:

- 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 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. The Company has recognized \$255,616 of revenues for the nine months ended September 30, 2006 (unaudited) based on the zero-profit proportional performance model. This revenue is recorded as reimbursements of research and development costs in the consolidated statements of operations and comprehensive (loss) income.
- 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 April 2006. The Company has recognized \$2,266,594 of revenues for the nine months ended September 30, 2006 (unaudited) based on the zero-profit proportional performance model. This revenue 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 \$206,416 of reimbursements of marketing costs for the nine months ended September 30, 2006 (unaudited). This amount is recorded as a reduction to selling and marketing expenses in the consolidated statements of operations and comprehensive (loss) income.

The Company received \$5 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 million payment received, if negotiations did not succeed, a total of \$2.5 million would be required to be returned to Takeda (\$1 million for the SPL territory and \$1.5 million for the SPE territory). The remaining \$2.5 million was retained

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by the Company. As to that portion of the option agreement relating to SPL (\$2 million), the Company recorded \$1 million as current deferred revenue and \$1 million as other liabilities — short term in 2004. As to the option payment relating to SPE (\$3 million), the Company recorded \$1.5 million as long term deferred revenue and \$1.5 million as other liabilities — long term in 2004. The option right expired for SPL during 2005 and \$1 million was returned to Takeda and the Company recorded the other non-refundable \$1 million in contract revenue for the year ended December 31, 2005. The option right expired for SPE during the first quarter of 2006 and \$1.5 million was returned to Takeda and the Company recorded the other non-refundable \$1.5 million in contract revenue for the nine months ended September 30, 2006 (unaudited). See Note 3 for a discussion of the revenue recognition policy for option payments received by the Company.

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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.

Upon review of the above, the Company respectfully requests to hold a telephonic meeting with the Staff to further discuss the background, accounting and disclosures associated with the Takeda Agreement and the Supplemental Agreement.

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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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December 15, 2006  
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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  
Securities and Exchange Commission  
Sachiko Kuno, Ph.D  
Ms. Mariam Morris  
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