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

FORM 10-Q

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

For the quarterly period ended March 31, 2009

or

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

For the transition period from _____ to _____.

Commission file number: 000-23265

SALIX PHARMACEUTICALS, LTD.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3267443
(I.R.S. Employer
Identification No.)

**1700 Perimeter Park Drive
Morrisville, North Carolina 27560**
(Address of principal executive offices, including zip code)

(919) 862-1000
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES NO

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

The number of shares of the Registrant's Common Stock outstanding as of May 5, 2009 was 48,174,990.

SALIX PHARMACEUTICALS, LTD.

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PART I. FINANCIAL INFORMATION.**Item 1. Financial Statements****SALIX PHARMACEUTICALS, LTD.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(U.S. dollars, in thousands, except share amounts)

	<u>March 31,</u> <u>2009</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2008</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 83,468	\$ 120,153
Accounts receivable, net	54,087	40,461
Inventory, net	21,734	17,311
Prepaid and other current assets	10,210	8,295
Total current assets	<u>169,499</u>	<u>186,220</u>
Property and equipment, net	5,320	4,849
Restricted cash	15,000	15,000
Goodwill	85,257	85,257
Product rights and intangibles, net	104,320	106,822
Other assets	<u>2,206</u>	<u>2,336</u>
Total assets	<u>\$ 381,602</u>	<u>\$ 400,484</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 10,497	\$ 10,099
Accrued liabilities	28,752	27,443
Reserve for product returns, rebates and chargebacks	25,169	34,034
Current portion of capital lease obligations	<u>866</u>	<u>849</u>
Total current liabilities	65,284	72,425
Long-term liabilities:		
Convertible senior notes	45,369	44,759
Borrowings under credit facility	15,000	15,000
Lease incentive obligations	2,022	2,108
Long term portion of capital lease obligations	<u>767</u>	<u>791</u>
Total long-term liabilities	63,158	62,658
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, issuable in series, none outstanding	—	—
Common stock, \$0.001 par value; 80,000,000 shares authorized, 48,157,463 shares issued and outstanding at March 31, 2009 and 48,078,200 shares issued and outstanding at December 31, 2008	48	48
Additional paid-in capital	419,423	417,698
Accumulated deficit	<u>(166,311)</u>	<u>(152,345)</u>
Total stockholders' equity	<u>253,160</u>	<u>265,401</u>
Total liabilities and stockholders' equity	<u>\$ 381,602</u>	<u>\$ 400,484</u>

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

SALIX PHARMACEUTICALS, LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(U.S. dollars, in thousands, except per share data)

	Three months ended	
	March 31,	
	2009	2008
Revenues:		
Net product revenues	\$ 44,774	\$ 34,254
Costs and expenses:		
Cost of products sold (excluding \$2,502 and \$2,271 in amortization of product rights and intangible assets for the three-month periods ended March 31, 2009 and 2008, respectively)	9,905	7,256
Fees and costs related to license agreements	—	1,500
Amortization of product rights and intangible assets	2,502	2,271
Research and development	20,074	25,898
Selling, general and administrative	25,015	21,177
Total cost and expenses	<u>57,496</u>	<u>58,102</u>
Income (loss) from operations	(12,722)	(23,848)
Interest income (expense) and other income, net	<u>(1,291)</u>	<u>461</u>
Income (loss) before provision for income tax	(14,013)	(23,387)
Provision for income tax	<u>47</u>	<u>(610)</u>
Net income (loss)	<u><u>\$(13,966)</u></u>	<u><u>\$(23,997)</u></u>
Net income (loss) per share, basic	<u><u>\$ (0.29)</u></u>	<u><u>\$ (0.50)</u></u>
Net income (loss) per share, diluted	<u><u>\$ (0.29)</u></u>	<u><u>\$ (0.50)</u></u>
Shares used in computing net income (loss) per share, basic	<u>48,111</u>	<u>47,722</u>
Shares used in computing net income (loss) per share, diluted	<u>48,111</u>	<u>47,722</u>

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

SALIX PHARMACEUTICALS, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(U.S. dollars, in thousands)

	Three months ended March 31,	
	2009	2008
Cash flows from operating activities		
Net income (loss)	\$ (13,966)	\$ (23,997)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:		
Depreciation and amortization	3,212	3,021
Amortization of debt discount	610	—
Loss on disposal of property and equipment	3	7
Stock-based compensation expense	1,398	1,013
Changes in operating assets and liabilities:		
Accounts receivable, inventory, prepaid expenses and other assets	(19,834)	26,470
Accounts payable, accrued and other liabilities	1,621	1,076
Reserve for product returns, rebates and chargebacks	(8,865)	(6,735)
Net cash provided (used) by operating activities	(35,821)	855
Cash flows from investing activities		
Purchases of property and equipment	(944)	(303)
Net cash used in investing activities	(944)	(303)
Cash flows from financing activities		
Principal payments on capital lease obligations	(247)	(311)
Proceeds from issuance of common stock upon exercise of stock options	327	2
Net cash provided (used) by financing activities	80	(309)
Net increase (decrease) in cash and cash equivalents	(36,685)	243
Cash and cash equivalents at beginning of period	120,153	111,272
Cash and cash equivalents at end of period	<u>\$ 83,468</u>	<u>\$ 111,515</u>

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

SALIX PHARMACEUTICALS, LTD.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2009
(Unaudited)

1. Organization and Basis of Presentation

Salix Pharmaceuticals, Ltd., a Delaware corporation (“Salix” or the “Company”), is a specialty pharmaceutical company dedicated to acquiring, developing and commercializing prescription drugs used in the treatment of a variety of gastrointestinal diseases, which are those affecting the digestive tract.

These consolidated financial statements are stated in United States dollars and are prepared under accounting principles generally accepted in the United States, or GAAP. The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in the consolidation.

The accompanying consolidated financial statements include all adjustments that, in the opinion of management, are necessary for a fair presentation of financial position, results of operations and cash flows. These financial statements should be read in conjunction with the audited consolidated financial statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2008 filed with the Securities and Exchange Commission. The results of operations for interim periods are not necessarily indicative of results to be expected for a full year or any future period. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been omitted in accordance with the SEC’s rules and regulations for interim reporting.

2. Revenue Recognition

The Company recognizes revenue in accordance with the SEC’s Staff Accounting Bulletin No. 101, “Revenue Recognition in Financial Statements” as amended by Staff Accounting Bulletin No. 104 (together, “SAB 101”), and FASB Statement No. 48 “Revenue Recognition When Right of Return Exists” (“SFAS 48”). SAB 101 states that revenue should not be recognized until it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (a) persuasive evidence of an arrangement exists; (b) delivery has occurred or services have been rendered; (c) the seller’s price to the buyer is fixed or determinable; and (d) collectibility is reasonably assured.

SFAS 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if (1) the seller’s price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer’s obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated. The Company recognizes revenues for product sales at the time title and risk of loss are transferred to the customer, and the other criteria of SAB 101 and SFAS 48 are satisfied, which is generally at the time products are shipped. The Company’s net product revenue represents the Company’s total revenues less allowances for customer credits, including estimated discounts, rebates, chargebacks, and product returns.

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

The Company establishes allowances for estimated rebates, chargebacks and product returns based on numerous qualitative and quantitative factors, including:

- the number of and specific contractual terms of agreements with customers;
- estimated levels of inventory in the distribution channel;
- historical rebates, chargebacks and returns of products;
- direct communication with customers;
- anticipated introduction of competitive products or generics;
- anticipated pricing strategy changes by the Company and/or its competitors;
- analysis of prescription data gathered by a third-party prescription data provider;
- the impact of changes in state and federal regulations; and
- estimated remaining shelf life of products.

In its analyses, the Company uses prescription data purchased from a third-party data provider to develop estimates of historical inventory channel pull-through. The Company utilizes an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, it develops an estimate of the quantity of product in the channel which may be subject to various rebate, chargeback and product return exposures. At least quarterly for each product line, the Company prepares an internal estimate of ending inventory units in the distribution channel by adding estimated inventory in the channel at the beginning of the period, plus net product shipments for the period, less estimated prescriptions written for the period. Based on that analysis, the Company develops an estimate of the quantity of product in the channel that might be subject to various rebate, chargeback and product return exposures. This is done for each product line by applying a rate of historical activity for rebates, chargebacks and product returns, adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product estimated to be in the distribution channel. Internal forecasts that are utilized to calculate the estimated number of months in the channel are regularly adjusted based on input from members of the Company's sales, marketing and operations groups. The adjusted forecasts take into account numerous factors including, but not limited to, new product introductions, direct communication with customers and potential product expiry issues.

The Company periodically offers promotional discounts to the Company's existing customer base. These discounts are calculated as a percentage of the current published list price and are treated as off-invoice allowances. Accordingly, the discounts are recorded as a reduction of revenue in the period that the program is offered. In addition to promotional discounts, at the time that the Company implements a price increase, it generally offers its existing customer base an opportunity to purchase a limited quantity of product at the previous list price. Shipments resulting from these programs generally are not in excess of ordinary levels, therefore, the Company recognizes the related revenue upon shipment and includes the shipments in estimating various product related allowances. In the event the Company determines that these shipments represent purchases of inventory in excess of ordinary levels for a given wholesaler, the potential impact on product returns exposure would be specifically evaluated and reflected as a reduction in revenue at the time of such shipments.

Allowances for estimated rebates and chargebacks were \$8.7 million and \$7.4 million as of March 31, 2009 and December 31, 2008, respectively. These allowances reflect an estimate of the Company's liability for items such as rebates due to various governmental organizations under the Medicare/Medicaid regulations, rebates due to managed care organizations under specific contracts and chargebacks due to various organizations purchasing our products through federal contracts and/or group purchasing agreements. The Company estimates its liability for rebates and chargebacks at each reporting period based on a methodology of applying quantitative and qualitative assumptions discussed above. Due to the subjectivity of the Company's accrual estimates for rebates and chargebacks, the Company prepares various sensitivity analyses to ensure the Company's final estimate is within a reasonable range as well as review prior period activity to ensure that the Company's methodology continues to be appropriate.

Allowances for product returns were \$8.2 million and \$8.5 million as of March 31, 2009 and December 31, 2008, respectively. These allowances reflect an estimate of the Company's liability for product that may be returned

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

by the original purchaser in accordance with the Company's stated return policy. These balances do not include \$8.3 million and \$18.1 million at March 31, 2009 and December 31, 2008, respectively, reflecting the Company's estimate of Colazal that may be returned to us under our return policy as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007. The Company estimates its liability for product returns at each reporting period based on historical return rates, estimated inventory in the channel and the other factors discussed above. Due to the subjectivity of the Company's accrual estimates for product returns, the Company prepares various sensitivity analyses to ensure the Company's final estimate is within a reasonable range and also reviews prior period activity to ensure that the Company's methodology is still reasonable.

Colazal, the Company's balsalazide disodium capsule, has historically accounted for a majority of the Company's revenue prior to 2008. On December 28, 2007, the Office of Generic Drugs, or OGD, approved three generic balsalazide capsule products. As a result of these generic approvals, the Company expects the future sales of Colazal to be significantly less than historical sales of Colazal. At March 31, 2009 and December 31, 2008, respectively, \$8.3 million and \$18.1 million were recorded as a liability to reflect an estimate of the Company's liability for Colazal that may be returned by the original purchaser in accordance with the Company's stated return policy as a result of these generic approvals. This estimate is based on an estimate of Colazal inventory in the channel and related expiration dates of this inventory, estimated erosion of Colazal demand based on the generic approvals and the resulting estimated pull-through of Colazal, and other factors. Due to the subjectivity of this estimate, the Company prepares various sensitivity analyses to ensure the Company's final estimate is within a reasonable range.

The Company's provision for revenue-reducing items such as rebates, chargebacks, and product returns as a percentage of gross product revenue in the three-month periods ended March 31, 2009 and 2008 was 7.4% and 7.4% for rebates, chargebacks and discounts and was 6.6% and 10.2% for product returns, respectively, excluding the Colazal return reserve.

3. Commitments

Purchase Order Commitments

At March 31, 2009, the Company had binding purchase order commitments for inventory purchases expected to be delivered over the next 4 months aggregating approximately \$18.6 million.

Potential Milestone Payments

The Company has entered into collaborative agreements with licensors, licensees and others. Pursuant to the terms of these collaborative agreements, the Company is obligated to make one or more payments upon the occurrence of certain milestones. The following is a summary of the material payments that the Company might be required to make under its collaborative agreements if certain milestones are satisfied.

License Agreement with Cedars-Sinai Medical Center — In June 2006, the Company entered into a license agreement with Cedars-Sinai for the right to use a patent and a patent application relating to methods of diagnosing and treating irritable bowel syndrome and other disorders caused by small intestinal bacterial overgrowth. Pursuant to the license agreement, the Company is obligated to pay Cedars-Sinai a license fee of \$1.2 million over time. As of March 31, 2009, the Company had paid this license fee in full. The Company may terminate the license agreement upon written notice of not less than 90 days.

License and Supply Agreement with the Debiopharm Group — In September 2006, the Company acquired the exclusive right to sell, market and distribute Sanvar in the United States. Pursuant to the terms of this agreement, the Company is obligated to make an upfront and milestone payments to Debiopharm that could total up to \$8.0 million contingent upon achievement of certain regulatory milestones, and an additional \$6.0 million in milestone payments contingent on reaching certain sales thresholds over the term of the agreement. As of March 31, 2009, the Company had paid \$1.0 million of milestone payments. The remaining milestone payments are contingent upon achievement of regulatory approval and certain sales thresholds.

License Agreement with Dr. Falk Pharma GmbH for granulated mesalamine — In July 2002, the Company and Dr. Falk entered into a license agreement which they amended in November 2003 and February 2005. Pursuant

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

to the license agreement, as amended, the Company acquired the rights to develop and market a granulated formulation of mesalamine. The agreement provides that the Company is obligated to make milestone payments up to an aggregate amount of \$11.0 million to Dr. Falk. As of March 31, 2009, the Company had paid \$9.0 million of milestone payments. The remaining milestone payment is contingent upon achievement of additional regulatory approval.

License Agreement with Dr. Falk Pharma GmbH for budesonide — In March 2008, the Company entered into a License Agreement with Dr. Falk Pharma GmbH. The agreement provides the Company with an exclusive license to develop and commercialize in the United States Dr. Falk Pharma's budesonide products. The products covered in the License Agreement include U.S. patent-protected budesonide rectal foam and budesonide gastro-resistant capsule, patents for which expire in 2015 and 2016, respectively. Pursuant to the license agreement the Company is obligated to make an upfront payment and regulatory milestone payments that could total up to \$23.0 million to Dr. Falk Pharma, with the majority contingent upon achievement of U.S. regulatory approval. As of March 31, 2009, the Company had paid \$1.0 million of these milestone payments.

License Agreement with Merck & Co, Inc. — In February 2007, the Company entered into a Master Purchase and Sale and License Agreement with Merck, paying Merck \$55.0 million to purchase the U.S. prescription pharmaceutical product rights to Pepcid® Oral Suspension and Diuril® Oral Suspension. Pursuant to the license agreement, the Company is obligated to make additional milestone payments to Merck up to an aggregate of \$6.0 million contingent upon reaching certain sales thresholds during any of the five calendar years beginning in 2007 and ending in 2011.

License Agreement with Napo Pharmaceuticals, Inc. — In December 2008 the Company entered into a Collaboration Agreement with Napo. Pursuant to the agreement, the Company has an exclusive, royalty-bearing license to crofelemer for the treatment of HIV-associated diarrhea and additional indications of pediatric diarrhea and acute infectious diarrhea in a certain territory. The Company also has a non-exclusive, worldwide, royalty-bearing license to use Napo-controlled trademarks associated with crofelemer. The Company has made an initial payment of \$5.0 million to Napo and will make up to \$50.0 million in milestone payments to Napo contingent on regulatory approvals and up to \$250.0 million in milestone payments contingent on reaching certain sales thresholds. The Company is responsible for development costs of crofelemer, but costs exceeding \$12.0 million for development of crofelemer used for the HIV-associated diarrhea indication will be credited towards regulatory milestones and thereafter against sales milestones.

License and Supply Agreement with Norgine B.V. — In December 2005, the Company entered into a license and supply agreement with Norgine for the rights to sell NRL944, a bowel cleansing product the Company now markets in the United States under the trade name MoviPrep. Pursuant to the terms of this agreement, the Company is obligated to make upfront and milestone payments to Norgine that could total up to \$37.0 million over the term of the agreement. As of March 31, 2009, the Company had paid \$22.0 million of milestone payments. The remaining milestone payments are contingent upon reaching sales thresholds.

License Agreement with Wilmington Pharmaceuticals, LLC — In September 2007, the Company entered into an Exclusive Sublicense Agreement with Wilmington Pharmaceuticals. The agreement provides that the Company is obligated to make upfront and milestone payments up to an aggregate amount of \$8.0 million to Wilmington. As of March 31, 2009, the Company had paid \$1.0 million of these milestone payments. The remaining milestone payment is contingent upon regulatory approval. The Company also loaned Wilmington \$2.0 million which is due December 31, 2009, or earlier based on regulatory approval.

4. Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and capital lease obligations approximated their fair values as of March 31, 2009 and December 31, 2008 due to the short-term nature of these financial instruments. The carrying amount of the Company's credit facility approximated its fair value at March 31, 2009 and December 31, 2008 due to the fact that interest rate was determined based on prevalent market rates.

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

5. Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities from date of purchase of three months or less to be cash equivalents. The Company maintains its cash and cash equivalents in several different financial instruments with various banks and brokerage houses. This diversification of risk is consistent with Company policy to maintain liquidity and ensure the safety of principal. At March 31, 2009, cash and cash equivalents consisted primarily of demand deposits, overnight investments in Eurodollars, certificates of deposit and money market funds at reputable financial institutions, and did not include any auction rate securities.

6. Inventory

Raw materials, work-in-process and finished goods inventories are stated at the lower of cost (which approximates actual cost on a first-in, first-out cost method) or market value. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life, and current and expected market conditions, including levels of competition, including generic competition.

The Company expenses pre-approval inventory unless the Company believes it is probable that the inventory will be saleable. The Company capitalizes inventory costs associated with marketed products and certain products prior to regulatory approval and product launch, based on management's judgment of probable future commercial use and net realizable value. Capitalization of this inventory does not begin until the product candidate is considered to have a high probability of regulatory approval, which is generally after the Company has analyzed Phase III data or filed an NDA. If the Company is aware of any specific risks or contingencies that are likely to impact the expected regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling of the product candidate, the Company does not capitalize the related inventory. Once the Company capitalizes inventory for a product candidate that is not yet approved, the Company monitors, on a quarterly basis, the status of this candidate within the regulatory approval process. The Company could be required to expense previously capitalized costs related to pre-approval inventory upon a change in its judgment of future commercial use and net realizable value, due to a denial or delay of approval by regulatory bodies, a delay in the timeline for commercialization or other potential factors. On a quarterly basis, the Company evaluates all inventory, including inventory capitalized for which regulatory approval has not yet been obtained, to determine if any lower of cost or market adjustment is required. As it relates to pre-approval inventory, the Company considers several factors including expected timing of FDA approval, projected sales volume and estimated selling price.

Inventory at March 31, 2009 consisted of \$10.4 million of raw materials, \$7.8 million of work-in-process, and \$3.5 million of finished goods. Inventory at December 31, 2008 consisted of \$8.5 million of raw materials, \$6.5 million of work-in-process, and \$2.3 million of finished goods. As of March 31, 2009, inventory reserves totaling \$3.1 million, compared to \$3.8 million as of December 31, 2008, have been recorded to reduce inventories to their net realizable value.

7. Intangible Assets and Goodwill

The Company's intangible assets consist of license agreements, product rights and other identifiable intangible assets, which result from product and business acquisitions. Goodwill represents the excess purchase price over the fair value of assets acquired and liabilities assumed in a business combination.

When the Company makes product acquisitions that include license agreements, product rights and other identifiable intangible assets, it records the purchase price of such intangibles, along with the value of the product related liabilities that it assumes, as intangible assets. The Company allocates the aggregate purchase price to the fair value of the various tangible and intangible assets in order to determine the appropriate carrying value of the acquired assets and then amortizes the cost of the intangible assets as an expense in its consolidated statement of operations over the estimated economic useful life of the related assets. In accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", the Company

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

assesses the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. The Company believes that the following factors could trigger an impairment review: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business; and significant negative industry or economic trends.

In assessing the recoverability of its intangible assets, the Company must make assumptions regarding estimated future cash flows and other factors. If the estimated undiscounted future cash flows do not exceed the carrying value of the intangible assets, the Company must determine the fair value of the intangible assets. If the fair value of the intangible assets is less than the carrying value, the Company will recognize an impairment loss in an amount equal to the difference. The Company reviews goodwill for impairment on an annual basis, and goodwill and other intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

The Company assesses impairment of goodwill on an annual basis in accordance with Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets".

In November 2003, the Company acquired from aaiPharma LLC for \$2.0 million the exclusive right to sell 25, 75 and 100 milligram dosage strengths of azathioprine tablets in North America under the name Azasan. The purchase price was fully allocated to product rights and related intangibles and is being amortized over a period of ten years. Although Azasan does not have any patent protection, the Company believes ten years is an appropriate amortization period based on established product sales history and management's experience. At March 31, 2009 accumulated amortization for the Azasan intangible was \$1.1 million.

In June 2004, the Company acquired the exclusive U.S. rights to Anusol-HC 2.5% (hydrocortisone Cream USP), Anusol-HC 25 mg Suppository (Hydrocortisone Acetate), Proctocort Cream (Hydrocortisone Cream USP) 1% and Proctocort Suppositories (Hydrocortisone Acetate Rectal Suppositories, 30 mg) from King Pharmaceuticals, Inc. for \$13.0 million. The purchase price was fully allocated to product rights and related intangibles and is being amortized over a period of ten years. Although Anusol-HC and Proctocort do not have any patent protection, the Company believes ten years is an appropriate amortization period based on established product sales history and management's experience. At March 31, 2009 accumulated amortization for the King product intangibles was \$6.2 million.

In September 2005, the Company acquired InKine Pharmaceutical Company, Inc. for \$210.0 million. The Company allocated \$74.0 million of the purchase price to in-process research and development, \$9.3 million to net assets acquired and \$37.0 million to specifically identifiable product rights and related intangibles with an ongoing economic benefit to the Company. The Company allocated the remaining \$89.7 million to goodwill, which is not being amortized. The InKine product rights and related intangibles are being amortized over an average period of 14 years, which the Company believes is an appropriate amortization period due to the product's patent protection and the estimated economic lives of the product rights and related intangibles. At March 31, 2009 accumulated amortization for the InKine intangibles was \$10.6 million.

In December 2005, the Company entered into a License and Supply Agreement with Norgine B.V., granting Salix the exclusive right to sell a patented-protected, liquid PEG bowel cleansing product, NRL 944, in the United States. In August 2006, the Company received Food and Drug Administration marketing approval for NRL 944 under the branded name of MoviPrep. In January 2007 the United States Patent Office issued a patent providing coverage to September 1, 2024. In August 2006, pursuant to the terms of the Agreement, Salix made a \$15.0 million payment to Norgine. In December 2008, pursuant to the terms of the Agreement, the Company made a \$5.0 million payment to Norgine. The Company is amortizing these milestone payments over a period of 17.3 years, which the Company believes is an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. At March 31, 2009 accumulated amortization for the MoviPrep intangible was \$3.1 million.

In February 2007, the Company entered into a Master Purchase and Sale and License Agreement with Merck & Co. Inc., to purchase the U.S prescription pharmaceutical product rights to Pepcid Oral Suspension and Diuril Oral Suspension from Merck. The Company paid Merck \$55.0 million at the closing of this transaction. The

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

purchase price was fully allocated to product rights and related intangibles, and is being amortized over a period of 15 years. Although Pepcid and Diuril do not have patent protection, the Company believes 15 years is an appropriate amortization period based on established product history and management experience. At March 31, 2009 accumulated amortization for the Merck products was \$7.8 million.

In July 2002, the Company acquired the rights to develop and market a granulated formulation of mesalamine from Dr. Falk Pharma GmbH. On October 31, 2008, the FDA granted marketing approval for Apriso for the maintenance of remission of ulcerative colitis in adults. In November 2008, the Company made a \$6.0 million milestone payment to Dr. Falk. The Company is amortizing this milestone payment over a period of 9.5 years, which the Company believes is an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. At March 31, 2009, accumulated amortization for the Apriso intangible was \$0.3 million.

8. Credit Facility

In February 2007, the Company entered into a \$100.0 million revolving credit facility that matures in February 2012. On August 4, 2008 the credit facility was amended to waive defaults that may have arisen as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007 and the credit facility was reduced to \$20.0 million. On August 22, 2008 the credit facility was further amended to allow the Company to issue the convertible Notes described in Note 9 below. At March 31, 2009, \$15.0 million was outstanding under the credit facility. Virtually all assets of the Company and its subsidiaries collateralize the Company's obligations under the credit facility. Borrowings under the credit facility may be used for working capital, capital expenditures, acquisitions and other general corporate purposes.

The credit facility bears interest at a rate per annum equal to, at the Company's option, either (a) a base rate equal to the higher of (i) the Federal Funds Rate plus 1/2 of 1% and (ii) the Bank of America prime rate, or (b) a Eurodollar rate (based on LIBOR), plus 0.00% for base rate borrowings and 1.00% for Eurodollar rate borrowings. The Company must maintain an amount equal to the amount outstanding under the credit facility on deposit with the Administrative Agent of the credit facility and maintain a minimum of \$23.0 million in cash on its balance sheet. At March 31, 2009, restricted cash of \$15.0 million represents the collateral on deposit with the Administrative Agent related to the credit facility. At March 31, 2009 the Company was in compliance with applicable covenants under the credit facility.

9. Convertible Senior Notes

On August 22, 2008 the Company closed an offering of \$60 million in Convertible Senior Notes ("Notes") due 2028. Net proceeds from the offering were \$57.3 million. The Notes are governed by an indenture, dated as of August 22, 2008, between the Company and U.S. Bank National Association, as trustee.

The Notes bear interest at a rate of 5.5% per year, payable semiannually in arrears on February 15 and August 15 of each year, beginning on February 15, 2009. The Notes will mature on August 15, 2028, unless previously converted or repurchased in accordance with their terms prior to such date.

The Notes are senior unsecured obligations, and rank (i) equally to any of the Company's existing and future unsecured senior debt, (ii) senior to any of the Company's future indebtedness that is expressly subordinated to these Notes, and (iii) effectively junior to any secured indebtedness to the extent of the value of the assets securing such indebtedness.

The Company may redeem the Notes, in whole or in part, at any time after August 15, 2013 for cash equal to the principal amount of the Notes to be redeemed, plus any accrued and unpaid interest.

On August 15, 2013, August 15, 2018 and August 15, 2023 or upon the occurrence of a "fundamental change", as defined in the indenture, the holders may require the Company to repurchase all or a portion of the Notes for cash at 100% of the principal amount of the Notes being purchased, plus any accrued and unpaid interest.

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

The Notes are convertible into approximately 6,486,000 shares of the Company's common stock under certain circumstances prior to maturity at a conversion rate of 108.0847 shares per \$1,000 principal amount of Notes, which represents a conversion price of approximately \$9.25 per share, subject to adjustment under certain conditions. Holders of the Notes may convert their Notes at their option on any day prior to the close of business on the business day immediately preceding the maturity date of August 15, 2028 only if one or more of the following conditions is satisfied: (1) during any fiscal quarter commencing after September 30, 2008, if the last reported sale price of the Company's common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day of the immediately preceding fiscal quarter is equal to or more than 130% of the conversion price of the Notes on the last day of such preceding fiscal quarter; (2) during the five business day period following any five consecutive trading day period in which the trading price for the Notes, per \$1,000 principal amount of the Notes, for each such trading day was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate of the Notes on such date; (3) if the Company enters into specified corporate transactions; or (4) upon a redemption notice. The Notes will be convertible, regardless of whether any of the foregoing conditions have been satisfied, on or after March 15, 2028 at any time prior to the close of business on the business day immediately preceding the stated maturity date of August 15, 2028. Upon conversion, the Company may pay cash, shares of the Company's common stock or a combination of cash and stock, as determined by the Company in its discretion.

As long as the Notes are outstanding, the Company and its subsidiaries are prohibited from incurring any debt other than "permitted debt," as defined in the indenture, except that the Company and its subsidiaries may incur debt in certain circumstances, including meeting a consolidated leverage ratio test and a consolidated fixed charge coverage ratio test. The Company may refinance its existing credit facility provided the refinanced credit facility contains substantially the same restrictive covenants with respect to financial ratios as the existing credit facility did as of August 22, 2008.

In connection with the issuance of the Notes, the Company incurred \$2.7 million of issuance costs, which primarily consisted of investment banker fees, legal and other professional fees. These costs are being amortized and are recorded as additional interest expense through August 2013, the first scheduled date on which holders have the option to require the Company to repurchase the Notes.

In May 2008, the FASB issued FASB Staff Position ("FSP") No. APB 14-1, "Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (including Partial Cash Settlement)", which is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption is not permitted. This FSP applies to convertible debt instruments that may be settled in cash and requires separate accounting for the liability and equity components of the convertible debt. The Notes may be settled in cash. As a result, the Company adopted this FSP on January 1, 2009, and as required, applied the FSP retrospectively to all periods presented.

This FSP requires the Company to separately account for the liability and equity components of the convertible debt instrument by allocating the proceeds from issuance of the Notes between the liability component and the embedded conversion option, or equity component. This allocation was done by first estimating an interest rate at the time of issuance for similar notes that do not include the embedded conversion option. This interest rate of 12.5% was used to compute the initial fair value of the liability component of \$44.1 million. The excess of the initial proceeds received from the convertible Notes over the initial amount allocated to the liability component, of \$15.9 million, is allocated to the embedded conversion option, or equity component. This excess is reported as a debt discount and subsequently amortized as interest cost, using the interest method, through August 2013, the first scheduled date on which the holders have the option to require the Company to repurchase the Notes.

The balance sheet at December 31, 2008 has been adjusted to reflect the retrospective application of this FSP. The carrying value of the liability component was decreased by \$15.2 million to reflect the initial carrying value, less 2008 amortization of the debt discount of \$0.7 million. Additional paid-in capital was increased by \$15.2 million to reflect the initial value of the equity component of \$15.9 million, less the issuance costs related to the equity component of \$0.7 million. Accumulated deficit was increased by \$0.6 million to reflect the amortization of the debt discount for 2008, less issuance cost amortization for 2008 related to the equity component. Other assets were decreased by \$0.7 million related to the issuance costs related to the equity component.

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

The carrying value of the equity component at March 31, 2009 and December 31, 2008 was \$15.2 million. The effective interest rate on the liability component for the three-month period ended March 31, 2008 was 12.7%. Total interest cost of \$1.5 million was recognized during the three-month period ended March 31, 2008, including \$0.6 million of amortization of debt discount.

The following table summarizes information on our convertible debt as of:

	<u>March 31, 2009</u>	<u>December 31, 2008</u>
Principal amount of the liability component	\$ 60,000	\$ 60,000
Unamortized discount	(14,631)	(15,241)
Net carrying amount	<u>\$ 45,369</u>	<u>\$ 44,759</u>

10. Research and Development

The Company expenses research and development costs, both internal and externally contracted, as incurred. For nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities, the Company initially capitalizes the advance payment. Such amounts are then recognized as an expense as the related goods are delivered or the related services are performed.

11. Comprehensive Income

The Company adopted SFAS No. 130, "Reporting Comprehensive Income" effective January 1, 1998. SFAS 130 requires that the Company display an amount representing comprehensive income (loss) for the year in a financial statement, which is displayed with the same prominence as other financial statements. The Company elected to present this information in the Consolidated Statements of Stockholders' Equity. Other comprehensive income (loss) consists of foreign currency translation gains and losses, as well as any unrealized gains and losses on investments. For the periods presented, comprehensive income (loss) equaled reported net income (loss).

12. Share-Based Compensation

At March 31, 2009, the Company had one active share-based compensation plan, the 2005 Stock Plan, allowing for the issuance of stock options and restricted stock. The Company accounts for share-based compensation under SFAS No 123R, "Share-Based Payment," which requires that companies estimate the fair value of share-based payment awards on the date of the grant. The cost is to be recognized over the period during which an employee is required to provide service in exchange for the award. The valuation provisions of SFAS 123R apply to new grants and grants modified after the adoption date that were outstanding as of the effective date.

Starting in 2006, the Company began issuing restricted shares to employees, executives and directors of the Company. For employees and executives of the Company, restrictions lapse 25% annually over four years or 33% over 3 years. For board members of the company, restrictions lapse 100% after one year. The fair value of the restricted stock was estimated using an assumed forfeiture rate of 8.6% and is being expensed on a straight-line basis over the period during which the restrictions lapse. For the three-month period ended March 31, 2009, the Company recognized \$1.4 million in share based compensation expense related to the restricted shares. As of March 31, 2009, the total amount of unrecognized compensation cost related to nonvested restricted stock awards, to be recognized as expense subsequent to March 31, 2009, was approximately \$9.7 million, and the related weighted-average period over which it is expected to be recognized is approximately 2.2 years.

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

Aggregate stock plan activity is as follows:

	Total Shares Available For Grant	Stock Options		Restricted Shares		Stock Options and Restricted Shares	
		Number	Weighted Average Price	Number Subject to Issuance	Weighted Average Price	Number	Weighted Average Price
Balance at December 31, 2008	836,622	4,617,833	\$ 13.67	1,648,855	\$ 9.39	6,266,688	\$ 12.55
Additional shares authorized		—	—	—	—	—	—
Granted	(38,800)	—	—	38,800	\$ 7.92	38,800	\$ 7.92
Exercised	—	(49,313)	\$ 6.87	—	—	(49,313)	\$ 6.87
Vested	—	—	—	(29,950)	\$ 10.31	(29,950)	\$ 10.31
Canceled	83,785	(113,133)	\$ 17.82	(20,936)	\$ 9.40	(134,069)	\$ 16.50
Balance at March 31, 2009	<u>881,607</u>	<u>4,455,387</u>	<u>\$ 13.64</u>	<u>1,636,769</u>	<u>\$ 9.34</u>	<u>6,092,156</u>	<u>\$ 12.48</u>

For the three-month period ended March 31, 2009, the Company issued 49,313 shares of stock with a market value of \$0.4 million upon the exercise of stock options. The Company recognized no share-based compensation expense related to stock options for the three-month period ended March 31, 2009, nor any income tax benefit. The total intrinsic value of options exercised for the three-month period ended March 31, 2009 was \$0.1 million. As of March 31, 2009, there was no unrecognized compensation cost for stock options due to the fact that all stock options were fully vested. For the three-month period ended March 31, 2009, the Company received \$0.3 million in cash from stock option exercises.

13. Income Taxes

The Company provides for income taxes under the liability method in accordance with SFAS No. 109, "Accounting for Income Taxes". This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of differences between the tax basis of assets or liabilities and their carrying amounts in the consolidated financial statements. The Company provides a valuation allowance for deferred tax assets if it is more likely than not that these items will either expire before the Company is able to realize their benefit or if future deductibility is uncertain.

In June 2006, the FASB issued FASB Interpretation No. 48 "Accounting for Uncertainty in Income Taxes" ("FIN 48"), which is an interpretation of SFAS 109 "Accounting for Income Taxes". This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and also provides guidance on derecognizing, classification, interest and penalties, accounting in interim periods, disclosure and transition.

On January 1, 2007, the Company adopted the provisions of FIN 48. As a result of applying the provisions of FIN 48, the Company recognized an increase of \$2.4 million in the liability for unrecognized tax benefits and a reduction in the valuation allowance as of January 1, 2007, for the same amount. The unrecognized tax benefits as of March 31, 2009 relate to federal tax credit carryforwards. The Company continues to fully recognize its tax benefits which are offset by a valuation allowance to the extent that it is more likely than not that the deferred tax assets will not be realized. The Company does not expect any significant changes in its unrecognized tax benefits for the next twelve months.

The Company files a consolidated U.S. federal income tax return and consolidated and separate company income tax returns in many U.S. state jurisdictions. Generally, the Company is no longer subject to federal and state income tax examinations by U.S. tax authorities for years prior to 1993.

The Company recognizes any interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses. During the three-month periods ended March 31, 2009 and 2008, there was no such interest or penalties.

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

The provision for income taxes reflects the Company's estimate of the effective tax rate expected to be applicable for the full fiscal year. The Company's effective tax rate for the three-month period ended March 31, 2009 was 0.3%. The Company's effective tax rate for the three-month period ended March 31, 2008 was (2.6)%. The Company re-evaluates this estimate each quarter based on the Company's estimated tax expense for the year.

14. Net Income per Share

The Company computes net income (loss) per share in accordance with SFAS No. 128, "Earnings Per Share" ("SFAS 128"). Under the provisions of SFAS 128, basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares and dilutive common share equivalents then outstanding. Common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and the impact of vested restricted stock grants. Under the provisions of SFAS 128, the Company will account for the effect of the convertible Notes on diluted net income (loss) per share using the treasury stock method. As a result, the convertible Notes will have no effect on diluted net income (loss) per share until the Company's stock price exceeds the conversion price of \$9.25 per share. For the three-month period ended March 31, 2009, the effect of approximately 6,486,000 shares that may be issued upon conversion of the Notes were excluded from the diluted net income per share calculation.

The following table reconciles the numerator and denominator used to calculate diluted net income (loss) per share (in thousands):

	Three months ended	
	March 31,	
	2009	2008
Numerator:		
Net income (loss)	\$(13,966)	\$(23,997)
Denominator:		
Weighted average common shares, basic	48,111	47,722
Dilutive effect of restricted stock	—	—
Dilutive effect of stock options	—	—
Weighted average common shares, diluted	<u>48,111</u>	<u>47,722</u>

For the three-month period ended March 31, 2009, weighted average common shares, diluted are equal to weighted average common shares, basic, because inclusion of the effect of 1,032,163 shares of restricted stock and stock options would have an anti-dilutive effect due to the net loss during that period. For the three-month periods ended March 31, 2009 and 2008, there were 3,508,274 and 4,886,929, respectively, potential common shares outstanding that were excluded from the diluted net income per share calculation because their effect would have been anti-dilutive.

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

15. Segment Reporting

The Company operates in a single industry acquiring, developing and commercializing prescription drugs used in the treatment of a variety of gastrointestinal diseases, which are those affecting the digestive tract. Accordingly, the Company's business is classified as a single reportable segment.

The following table presents net product revenues by product category (in thousands):

	Three months ended March 31,	
	2009	2008
Inflammatory Bowel Disease – Colazal/Apriso	\$ 2,757	\$ 1,345
Xifaxan	24,103	16,741
Purgatives – Visicol/OsmoPrep/MoviPrep	12,683	10,268
Other – Anusol/Azasan/Diuril/Pepcid/Proctocort	5,231	5,900
Net product revenues	<u>\$44,774</u>	<u>\$34,254</u>

16. Recently Issued Accounting Pronouncements

In April 2009, the FASB issued FSP No. FAS 157-4, "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly." FSP No. FAS 157-4 amends SFAS No. 157 and provides additional guidance for estimating fair value in accordance with SFAS No. 157 when the volume and level of activity for the asset and liability have significantly decreased, as well as provides guidance on identifying circumstances that indicate a transaction is not orderly. FSP No. FAS 157-4 is effective for interim and annual periods ending after June 15, 2009. The adoption of FSP No. FAS 157-4 is not expected to have a material impact on the Company's consolidated results of operations, cash flows or financial position.

In April 2009, FASB issued FSP No. FAS 115-2 and FAS 124-2, "Recognition and Presentation of Other-Than-Temporary Impairments." FSP No. FAS 115-2 and FAS 124-2 amends SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," and FSP No. FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments." FSP No. FAS 115-2 and FAS 124-2 provides additional guidance to make other-than-temporary impairments more operational and to improve the financial statement presentation of such impairments. FSP No. FAS 115-2 and FAS 124-2 is effective for interim and annual periods ending after June 15, 2009. The adoption of FSP No. FAS 115-2 and FAS 124-2 is not expected to have a material impact on the Company's consolidated results of operations, cash flows or financial position.

In April 2009, FASB issued FSP No. FAS 107-1 and APB 28-1, "Interim Disclosures about Fair Value of Financial Instruments." FSP No. FAS 107-1 and APB 28-1 amends SFAS No. 107, "Disclosures about Fair Value of Financial Instruments," and APB Opinion No. 28, "Interim Financial Reporting," by requiring disclosures about fair value of financial instruments in interim financial statements as well as in annual financial statements. FSP No. FAS 107-1 and APB 28-1 is effective for interim periods ending after June 15, 2009. The adoption of FSP No. FAS 107-1 and APB 28-1 is not expected to have a material impact on the Company's consolidated results of operations, cash flows or financial position.

SALIX PHARMACEUTICALS, LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — Continued

17. Legal Proceedings

From time to time, the Company is party to various legal proceedings or claims, either asserted or unasserted, which arise in the ordinary course of business. Management has reviewed pending legal matters and believes that the resolution of such matters will not have a significant adverse effect on the Company's financial condition or results of operations.

The Company is involved in a lawsuit against a company seeking FDA approval to market a generic version of the Company's MoviPrep product. Norgine, B.V. and Norgine Europe, B.V. own U.S. Patent No. 7,169,381 (the '381 patent). The '381 patent is listed with the FDA as protecting our MoviPrep product. Norgine licensed MoviPrep and the '381 patent to the Company for commercialization in the United States. Novel Laboratories, Inc., filed an Abbreviated New Drug Application, or ANDA, with the FDA seeking approval to market a generic version of MoviPrep in the United States prior to the September 2024 expiration of the '381 patent. On May 14, 2008, the Company and Norgine filed a lawsuit in the United States District Court for the District of New Jersey against Novel for infringement of the '381 patent. Novel filed an Answer and Counterclaims on June 20, 2008. Novel denied infringement and asserted defenses of patent invalidity and unenforceability. No trial date has been set. The Company intends to vigorously defend the patent rights for MoviPrep.

The Company is also involved in a lawsuit against Novel because Novel is seeking FDA approval to market a generic version of the Company's OsmoPrep product. CDC, LLC, owns U.S. Patent No. 5,616,346 (the '346 patent). The '346 patent is listed with the FDA as protecting the Company's OsmoPrep product. CDC, by its predecessor, licensed OsmoPrep and the '346 patent to the Company for commercialization in the United States. Novel filed an ANDA with the FDA seeking approval to market a generic version of OsmoPrep in the United States prior to the May 2013 expiration of the '346 patent. On September 8, 2008, the Company filed a lawsuit in the United States District Court for the District of New Jersey against Novel for the infringement of the '346 patent. The lawsuit also joins CDC as a party. Novel filed an Answer and Counterclaims on December 16, 2008. Novel denied infringement and asserted defenses of patent invalidity. No trial date has been set. The Company intend to vigorously defend the patent rights for OsmoPrep.

On or about July 14, 2008, Strides Arcolab Limited filed a Citizens Petition with the FDA seeking permission to submit an ANDA for change of dosage form from tablet to capsule for a 200mg generic version of Xifaxan. The Company intends to vigorously enforce the regulatory and intellectual property rights regarding Xifaxan. The Company is unable to predict the outcome of any ensuing regulatory action or litigation at the present time.

Regulatory data exclusivity for Xifaxan 200mg tablets ends on or about May 24, 2009. Accordingly, the Office of Generic Drugs would have been able to accept an ANDA for Xifaxan tablets on or any time subsequent to May 24, 2008, if the applicant certified that its generic rifaximin does not infringe Salix's patent. If this occurred, a Paragraph IV notification would have to be provided to the Company by the applicant. Although the Company does not possess any specific knowledge of any such filing at the current time, the expiration of data exclusivity could result in a challenge to the related intellectual property rights of Xifaxan 200mg tablets at any time in the future. The Company intends to vigorously enforce the patent rights for Xifaxan.

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

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2008, and "Cautionary Statement" included in this "Part I. Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results. The following discussion should be read in conjunction with our Condensed Consolidated Financial Statements and notes thereto included elsewhere in this report.

Overview

We are a specialty pharmaceutical company dedicated to acquiring, developing and commercializing prescription drugs used in the treatment of a variety of gastrointestinal disorders, which are those affecting the digestive tract. Our strategy is to:

- identify and acquire rights to products that we believe have potential for near-term regulatory approval or are already approved;
- apply our regulatory, product development, and sales and marketing expertise to commercialize these products; and
- use our approximately 150-member specialty sales and marketing team focused on high-prescribing U.S. gastroenterologists, who are doctors who specialize in gastrointestinal disorders, to sell our products.

Our current products demonstrate our ability to execute this strategy. As of March 31, 2009, our products were:

- XIFAXAN® (rifaximin) Tablets 200 mg;
- MOVIPREP® (PEG 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate and Ascorbic Acid for Oral Solution);
- OSMOPREP™ (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets;
- VISICOL® (sodium phosphate monobasic monohydrate, USP, and sodium phosphate dibasic anhydrous, USP) Tablets;
- AZASAN® Azathioprine Tablets, USP, 75/100 mg;
- ANUSOL-HC® 2.5% (Hydrocortisone Cream, USP), ANUSOL-HC® 25 mg Suppository (Hydrocortisone Acetate);
- PROCTOCORT® Cream (Hydrocortisone Cream, USP) 1% and PROCTOCORT® Suppository (Hydrocortisone Acetate Rectal Suppositories) 30 mg;
- PEPCID® (famotidine) for Oral Suspension;
- Oral Suspension DIURIL® (Chlorothiazide);
- APRISO™ (mesalamine) extended-release capsules 0.375g, and
- COLAZAL® (balsalazide disodium) Capsules 750 mg.

We generate revenue primarily by selling our products, namely prescription drugs, to pharmaceutical wholesalers. These direct customers resell and distribute our products to and through pharmacies to patients who have had our products prescribed by doctors. We currently market our products, and intend to market future products, if approved by the U.S. Food and Drug Administration, or FDA, to U.S. gastroenterologists and other physicians through our own direct sales force. In December 2000, we established our own field sales force to market Colazal in the United States. Currently, this sales force has approximately 100 sales representatives in the field and markets our approved products. Although the creation of an independent sales organization involved substantial costs, we believe that the financial returns from our direct product sales have been and will continue to be more

favorable to us than those from the indirect sale of products through marketing partners. We enter into distribution or licensing relationships outside the United States and in certain markets in the U.S. where a larger sales organization is appropriate. Currently, our sales and marketing staff, including our sales representatives, consists of approximately 150 people.

Because demand for our products originates with doctors, our sales force calls on high-prescribing specialists, primarily gastroenterologists, and we monitor new and total prescriptions for our products as key performance indicators for our business. Prescriptions result in our products being used by patients, requiring our direct customers to purchase more products to replenish their inventory. However, our revenue might fluctuate from quarter to quarter due to other factors, such as increased buying by wholesalers in anticipation of a price increase or because of the introduction of new products. Revenue could be less than anticipated in subsequent quarters as wholesalers' increased inventory is used up.

Our primary product candidates currently under development and their status are as follows:

Compound	Indication	Status
Rifaximin	Hepatic encephalopathy	Phase III
Rifaximin	Irritable bowel syndrome	Phase III
Rifaximin	Travelers' diarrhea prevention	Phase III
Rifaximin	<i>C. difficile</i> — associated diarrhea	Phase III
Vapreotide acetate	Acute esophageal variceal bleeding	Complete response submitted October 27, 2008
Metozolv™ (metoclopramide)	Gastroparesis and refractory gastroesophageal reflux	Complete response letter received February 26, 2009
Crofelemer	HIV-associated diarrhea	Phase III
Balsalazide disodium tablet	Ulcerative colitis	Complete response letter received December 22, 2008

CRITICAL ACCOUNTING POLICIES

Critical Accounting Policies

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, we identified our most critical accounting policies and estimates upon which our financial status depends as those relating to revenue recognition, allowance for product returns, allowance for rebates and coupons, inventory, intangible assets and goodwill, allowance for uncollectible accounts, cash and cash equivalents, and research and development expenses. We reviewed our policies and determined that those policies remained our most critical accounting policies for the three-month period ended March 31, 2009. We did not make any changes in those policies during the quarter.

We recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" as amended by Staff Accounting Bulletin No. 104 (together, "SAB 101"), and FASB Statement No. 48, "Revenue Recognition When Right of Return Exists" ("SFAS 48"). SAB 101 states that revenue should not be recognized until it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (a) persuasive evidence of an arrangement exists; (b) delivery has occurred or services have been rendered; (c) the seller's price to the buyer is fixed and determinable; and (d) collectibility is reasonably assured.

SFAS 48 states that revenue from sales transactions where the buyer has the right to return the product shall be

recognized at the time of sale only if (1) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated. We recognize revenues for product sales at the time title and risk of loss are transferred to the customer, and the other criteria of SAB 101 and SFAS 48 are satisfied, which is generally at the time products are shipped. Our net product revenue represents our total revenues less allowances for customer credits, including estimated discounts, rebates, chargebacks, and product returns.

We establish allowances for estimated rebates, chargebacks and product returns based on numerous quantitative and qualitative factors, including:

- the number of and specific contractual terms of agreements with customers;
- estimated levels of inventory in the distribution channel;
- historical rebates, chargebacks and returns of products;
- direct communication with customers;
- anticipated introduction of competitive products or generics;
- anticipated pricing strategy changes by us and/or our competitors;
- analysis of prescription data gathered by a third-party prescription data provider;
- the impact of changes in state and federal regulations; and
- estimated remaining shelf life of products.

In our analyses, we use prescription data purchased from a third-party data provider to develop estimates of historical inventory channel pull-through. We utilize an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, we develop an estimate of the quantity of product in the channel that might be subject to various rebate, chargeback and product return exposures. At least quarterly for each product line, we prepare an internal estimate of ending inventory units in the distribution channel by adding estimated inventory in the channel at the beginning of the period, plus net product shipments for the period, less estimated prescriptions written for the period. Based on that analysis, we develop an estimate of the quantity of product in the channel that might be subject to various rebate, chargeback and product return exposures. This is done for each product line by applying a rate of historical activity for rebates, chargebacks and product returns, adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product estimated to be in the distribution channel. Internal forecasts that are utilized to calculate the estimated number of months in the channel are regularly adjusted based on input from members of our sales, marketing and operations groups. The adjusted forecasts take into account numerous factors including, but not limited to, new product introductions, direct communication with customers and potential product expiry issues.

Consistent with industry practice, we periodically offer promotional discounts to our existing customers. These discounts are calculated as a percentage of the current published list price and are treated as off-invoice allowances. Accordingly, the discounts are recorded as a reduction of revenue in the period that the program is offered. In addition to promotional discounts, at the time that we implement a price increase, we generally offer our existing customers an opportunity to purchase a limited quantity of product at the previous list price. Shipments resulting from these programs generally are not in excess of ordinary levels, therefore, we recognize the related revenue upon shipment and include the shipments in estimating our various product related allowances. In the event we determine that these shipments represent purchases of inventory in excess of ordinary levels for a given wholesaler, the potential impact on product returns exposure would be specifically evaluated and reflected as a reduction in revenue at the time of such shipments.

Allowances for estimated rebates and chargebacks were \$8.7 million and \$2.9 million as of March 31, 2009 and 2008, respectively. The balances exclude amounts related to Colazal, which are included in the reserve discussed below. These allowances reflect an estimate of our liability for items such as rebates due to various governmental organizations under the Medicare/Medicaid regulations, rebates due to managed care organizations

under specific contracts and chargebacks due to various organizations purchasing certain of our products through federal contracts and/or group purchasing agreements. We estimate our liability for rebates and chargebacks at each reporting period based on a methodology of applying the relevant quantitative and qualitative assumptions discussed above. Due to the subjectivity of our accrual estimates for rebates and chargebacks, we prepare various sensitivity analyses to ensure our final estimate is within a reasonable range as well as review prior period activity to ensure that our methodology is still reasonable. Had a change in one or more variables in the analyses (utilization rates, contract modifications, etc.) resulted in an additional percentage point change in the trailing average of estimated chargeback and rebate activity in 2008, we would have recorded an adjustment to revenues of approximately \$2.1 million, or 1.0%, for the year.

Allowances for product returns were \$8.2 million and \$10.8 million as of March 31, 2009 and 2008, respectively. These allowances reflect an estimate of our liability for product that may be returned by the original purchaser in accordance with our stated return policy. These balances do not include \$8.3 million and \$32.6 million at March 31, 2009 and 2008, respectively, reflecting our estimate of Colazal that may be returned to us under our return policy as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007. We estimate our liability for product returns at each reporting period based on historical return rates, the estimated inventory in the channel, and the other factors discussed above. Due to the subjectivity of our accrual estimates for product returns, we prepare various sensitivity analyses to ensure our final estimate is within a reasonable range as well as review prior period activity to ensure that our methodology is still reasonable. A change in assumptions that resulted in a 10% change in forecasted return rates for all products other than Colazal would have resulted in a change in total product returns liability at December 31, 2008 of approximately \$1.5 million and a corresponding change in 2008 net product revenue of less than 1.0%.

Colazal, our balsalazide disodium capsule, accounted for a majority of the Company's revenue prior to 2008. On December 28, 2007, the Office of Generic Drugs, or OGD, approved three generic balsalazide capsule products. As a result of these generic approvals, the Company expects the future sales of Colazal to be significantly less than historical sales of Colazal. At March 31, 2009 and 2008, respectively, \$8.3 million and \$32.6 million were recorded as a liability to reflect the Company's estimate of the Company's liability for Colazal that may be returned by the original purchaser in accordance with the Company's stated return policy as a result of these generic approvals. This estimate was developed based on the following estimates:

- our estimate of the quantity and expiration dates of Colazal inventory in the distribution channel based on historical net product shipments less estimated historical prescriptions written;
- our estimate of future demand for Colazal based on the actual erosion of product demand for several comparable products that were previously genericized, and the most recent demand for Colazal prior to the generic approvals;
- the actual demand for Colazal experienced during 2008 and 2009 subsequent to the generic approvals;
- our estimate of chargeback and rebate activity based on price erosion as a result of the generic approvals; and
- other relevant factors.

Due to the subjectivity of this estimate, the Company prepares various sensitivity analyses to ensure the Company's final estimate is within a reasonable range. A change in assumptions that resulted in a 10% change in the quantity of Colazal inventory in the distribution channel would have resulted in a change in the Colazal return reserve of approximately \$1.1 million and a corresponding change in 2008 net product revenue of less than 1%. A change in assumptions that resulted in a 10% change in the estimated future demand of Colazal would not have resulted in a change in the Colazal return reserve.

For the three-month periods ended March 31, 2009 and 2008, our absolute exposure for rebates, chargebacks and product returns has grown primarily as a result of increased sales of our existing products, the approval of new products and the acquisition of products, and also as a result of the approval of generic balsalazide capsule products. Accordingly, reductions to revenue and corresponding increases to allowance accounts have likewise increased. The estimated exposure to these revenue-reducing items as a percentage of gross product revenue in the three-month periods ended March 31, 2009 and 2008 was 7.4% and 7.4% for rebates, chargebacks and discounts and was 6.6% and 10.2% for product returns excluding the Colazal return reserve, respectively.

Results of Operations

Three-month Periods Ended March 31, 2009 and 2008

Revenues

The following table summarizes net product revenues for the three months ended March 31:

	2009		2008	
	Net Product Revenues	Percent of Revenue	Net Product Revenues	Percent of Revenue
Inflammatory Bowel Disease – Colazal/Apriso	\$ 2,757	6%	\$ 1,345	4%
Xifaxan	24,103	54	16,741	49
Purgatives – Visicol/OsmoPrep/MoviPrep	12,683	28	10,268	30
Other	5,231	12	5,900	17
Net product revenues	<u>\$44,774</u>	<u>100%</u>	<u>\$34,254</u>	<u>100%</u>

Net product revenues for the three-month period ended March 31, 2009 were \$44.8 million, compared to \$34.3 million for the corresponding three-month period in 2008, a 31% increase. The net product revenue increase for the three-month period ended March 31, 2009 compared to the three-month period ended March 31, 2008 was primarily due to:

- increased unit sales of Xifaxan;
- increased unit sales of MoviPrep;
- sales of Apriso, which was approved by the FDA in October 2008 ; and
- price increases on our products.

These increases were partially offset by decreased unit sales of OsmoPrep. Prescriptions for OsmoPrep for the three-month period ended March 31, 2009 declined approximately 25% compared to prescriptions for the three-month period ended March 31, 2008.

Prescription growth for the three-month period ended March 31, 2009 compared to the corresponding three-month period in 2008 was 11% for Xifaxan and 29% for our purgatives.

Revenue and earnings for the period reflect a one-time adjustment to reserves relating to rebates. Non-GAAP total revenue was \$46.2 million and loss per share was \$0.26 excluding this adjustment. These non-GAAP numbers are not a substitute for GAAP numbers, but we think they are useful in that they provide period-to-period comparisons helpful in analyzing the progress of our business.

On December 28, 2007, the Office of Generic Drugs approved three generic balsalazide capsule products. As a result of these generic approvals, the Company expects the future sales of Colazal to be significantly less than historical sales of Colazal. In the fourth quarter of 2007, the Company recorded a \$34.6 million reserve as a reduction of net product revenues. The balance of this reserve at March 31, 2009 and 2008 was \$8.3 million and \$32.6 million, respectively. This reserve represents an estimate of the Company's liability for Colazal that may be returned by the original purchaser in accordance with the Company's stated return policy as a result of these generic approvals. This estimate was developed based on the following estimates:

- our estimate of the quantity and expiration dates of Colazal inventory in the distribution channel based on historical net product shipments less estimated historical prescriptions written;
- our estimate of future demand for Colazal based on the actual erosion of product demand for several comparable products that were previously genericized, and the actual demand for Colazal experienced during 2008 and 2009 subsequent to the generic approvals;
- our estimate of chargeback and rebate activity based on actual activity during 2008 and 2009 subsequent to the generic approvals; and
- other relevant factors.

Due to the subjectivity of this estimate, the Company prepares various sensitivity analyses to ensure the Company's final estimate is within a reasonable range. A change in assumptions that resulted in a 10% change in the quantity of Colazal inventory in the distribution channel would have resulted in a change in the Colazal return reserve of approximately \$1.1 million and a corresponding change in 2008 net product revenue of approximately of less than 1%. A change in assumptions that resulted in a 10% change in the estimated future demand of Colazal would not have resulted in a change in the Colazal reserve for 2008.

Costs and Expenses

Costs and expenses for the three-month period ended March 31, 2009 were \$57.5 million, compared to \$58.1 million for the corresponding three-month period in 2008. Lower operating expenses in absolute terms were due primarily to decreased research and development costs and decreased fees and costs related to license agreements, offset by increased cost of products sold related to the corresponding increase in product revenue, and increased selling, general and administrative costs.

Cost of Products Sold

Cost of products sold for the three-month period ended March 31, 2009 was \$9.9 million, compared with \$7.3 million for the corresponding three-month period in 2008. The increase in cost of products sold in absolute terms was due to the increase in net product revenues discussed above. Gross margin on total product revenue, excluding \$2.5 million and \$2.3 million in amortization of product rights and intangible assets for the three-month periods ended March 31, 2009 and 2008, respectively, was 77.9% for the three-month period ended March 31, 2009 and 78.8% for the three-month period ended March 31, 2008.

Fees and Costs Related to License Agreements

Fees and costs related to license agreements for the three-month period ended March 31, 2008 consist of a \$0.5 million milestone payment to Wilmington Pharmaceuticals, and a \$1.0 million up-front payment to Dr. Falk Pharma for the exclusive license to develop and commercialize Dr. Falk Pharma's budesonide products in the United States. There were no fees and costs related to license agreements for the three-month period ended March 31, 2009.

Amortization of Product Rights and Intangible Assets

Amortization of product rights and intangible assets consists of amortization of the costs of license agreements, product rights and other identifiable intangible assets, which result from product and business acquisitions. The

increase for the three-month period ended March 31, 2009 compared to the corresponding period in 2008 is primarily a result of payments during the fourth quarter of 2008 related to the approval of Apriso, and a sales milestone payment to Norgine for MoviPrep.

Research and Development

Research and development expenses were \$20.1 million for the three-month period ended March 31, 2009, compared to \$25.9 for the comparable period in 2008. The decrease in research and development expenses for the three-month period ended March 31, 2009 compared to the corresponding period in 2008 was due primarily to:

- reduced expenses related to our development program for our 1100mg balsalazide tablet;
- reduced expenses related to our development program for granulated mesalamine, or Apriso; and
- reduced expenses related to our hepatic encephalopathy development program for rifaximin.

These decreases were partially offset by:

- increased expenses related to our Phase III studies of rifaximin for IBS;
- increased expenses related to the continuation of our development program for crofelemer, which we acquired from Napo in December 2008; and
- increased headcount costs.

Since inception through March 31, 2009, we have incurred research and development expenditures of approximately \$69.8 million for balsalazide, \$114.0 million for rifaximin \$4.7 million for crofelemer and \$36.1 million for granulated mesalamine.

Due to the risks and uncertainties of the drug development and regulatory approval process, research and development expenditures are difficult to forecast and subject to unexpected increases. We expect research and development costs to be higher in the remaining quarters of 2009, and generally we expect research and development costs to increase in absolute terms as we pursue additional indications and formulations for rifaximin, initiate development for the budesonide product candidate we acquired from Dr. Falk, continue the development of crofelemer which we acquired from Napo, and if and when we acquire new products.

Selling, General and Administrative

Selling, general and administrative expenses were \$25.0 million for the three-month period ended March 31, 2009, compared to \$21.2 million in the corresponding three-month period in 2008. This increase was primarily due to:

- expenses related to the launch of Apriso;
- increased legal costs for the patent litigation related to MoviPrep and OsmoPrep; and
- increased headcount costs

We expect selling, general and administrative expenses to increase in absolute terms as we expand our sales and marketing efforts for our current products, the launch of Apriso and potential launches of Metoclopramide-Zydis and other indications for rifaximin, if approved.

Interest and Other Income, Net

Interest income (expense) and other income, net was \$1.3 million in expense for the three-month period ended March 31, 2009, compared to \$0.5 million in income in the corresponding three-month period in 2008. Interest and other income, net for the three-month period ended March 31, 2009 consisted of:

- \$0.1 million of interest expense on our credit facility;
- \$1.5 million of interest expense on our convertible notes issued in August 2008, including \$0.6 million of amortization of debt discount under FSP APB 14-1;
- partially offset by \$0.3 of interest income.

Interest and other income, net for the three-month period ended March 31, 2008 consisted of:

- \$0.9 million of interest income;
- offset by \$0.4 million of interest expense on our credit facility.

The decrease in interest income for the three-month period ended March 31, 2009 compared to the three-month period ended March 31, 2008 is due primarily to lower interest rates on our investments in 2009 and lower cash and cash equivalent balances during 2009 as compared to 2008.

Provision for Income Tax

Income tax benefit was \$47,000 for the three-month period ended March 31, 2009, compared to \$0.6 million in the corresponding three-month period in 2008. Our effective tax rate was 0.3% for the three-month period ended March 31, 2009, and (2.6)% in the corresponding three-month period in 2008.

Net loss was \$14.0 million for the three-month period ended March 31, 2009, compared to \$24.0 million in the corresponding three-month period in 2008.

Liquidity and Capital Resources

From inception until first achieving profitability in the third quarter of 2004, we financed product development, operations and capital expenditures primarily from public and private sales of equity securities and from funding arrangements with collaborative partners. Since launching Colazal in January 2001, net product revenue has been a growing source of cash. On August 22, 2008 we closed an offering of \$60.0 million in convertible senior notes due 2028. Net proceeds from the offering were \$57.3 million. As of March 31, 2009, we had \$83.5 million in cash and cash equivalents compared to \$120.2 million as of December 31, 2008. As of April 30, 2009, we had approximately \$93 million in cash and cash equivalents. We have not encountered any material collection issues with our customers to date.

To date, the decline in the stock market, lack of credit availability and financial institution difficulties have had a limited effect on our business. As a result of the closing of our convertible note offering in August 2008, we believe our cash and cash equivalent balances should be sufficient to satisfy our cash requirements for the foreseeable future. At March 31, 2009, cash and cash equivalents consisted primarily of demand deposits, certificates of deposit, overnight investments in Eurodollars and money market funds at reputable financial institutions, and did not include any auction rate securities. We have not realized any material loss in principal or liquidity in any of our investments to date. However, continued deterioration in the overall economy could lead to a decrease in demand for our marketed products, which could have an adverse effect on our business, financial condition and results of operations.

Net cash used by operating activities of \$35.8 million for the three-month period ended March 31, 2009 was primarily attributable to our net loss for the period, product returns and chargebacks for Colazal, the increase in accounts receivable and the increase in inventory. Net cash provided by operating activities of \$0.9 for the three-month period ended March 31, 2008 was primarily attributable to collection of accounts receivable, offset by our net loss for the period.

Net cash used in investing activities for the three-month period ended March 31, 2009 of \$0.9 million was for the purchases of property and equipment. Net cash used in investing activities for the three-month period ended March 31, 2008 of \$0.3 million was primarily for the purchases of property and equipment.

Net cash provided by financing activities for the three-month period ended March 31, 2009 was \$0.08 million consisting primarily of proceeds from the exercise of stock options. Net cash used by financing activities for the three-month period ended March 31, 2008 was \$0.3 million consisting primarily of principal payments on capital lease obligations.

As of March 31, 2009, we had non-cancelable purchase order commitments for inventory purchases of approximately \$18.6 million. We anticipate significant expenditures related to our on-going sales, marketing, product launch efforts and our on-going development efforts for rifaximin, our budesonide product candidates and crofelemer. To the extent we acquire rights to additional products, we will incur additional expenditures.

Our contractual commitments for non-cancelable purchase commitments of inventory, minimum lease obligations for all non-cancelable operating leases, debt and minimum capital lease obligations (including interest) as of March 31, 2009 were as follows (in thousands):

	Total	< 1 year	1-3 years	3-5 years	> 5 years
Operating leases	\$ 10,434	\$ 1,595	\$ 5,388	\$ 2,951	\$ 500
Purchase commitments	18,653	18,653	—	—	—
Convertible senior notes(1)	124,075	3,300	6,600	6,600	107,575
Borrowings under credit facility(2)	16,379	473	15,906	—	—
Capital lease obligations	1,694	703	991	—	—
Total	<u>\$171,235</u>	<u>\$24,724</u>	<u>\$28,885</u>	<u>\$ 9,551</u>	<u>\$108,075</u>

(1) Contractual interest obligations related to our convertible senior notes total \$64.1 million at March 31, 2009, including \$3.3 million, \$6.6 million, \$6.6 million and \$47.6 million due in one year or less, two to three years, four to five years, and greater than five years, respectively.

(2) Contractual interest obligations related to our credit facility total \$1.4 million based on the interest rate at March 31, 2009, including \$0.5 million and \$0.9 million due in one year or less and two to three years, respectively.

We enter into license agreements with third parties that may require us to make royalty, milestone or other payments that are contingent upon the occurrence of certain future events linked to the successful development and commercialization of pharmaceutical products. Certain of the payments may be contingent upon the successful achievement of an important event in the development life cycle of these pharmaceutical products, which may or may not occur. If required by the agreements, we may make royalty payments based upon a percentage of the sales of a pharmaceutical product if regulatory approval to market this product is obtained and the product is commercialized. Because of the contingent nature of these payments, we have not attempted to predict the amount or period in which such payments would possibly be made and thus they are not included in the table of contractual obligations.

In February 2007, we entered into a \$100.0 million revolving credit facility that matures in February 2012. On August 4, 2008 we amended the credit facility to waive defaults that may have arisen as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007 and reduced the credit facility to \$20.0 million. On August 22, 2008 we further amended the credit facility to allow us to issue the convertible notes described below. At March 31, 2009, \$15.0 million was outstanding under the credit facility. Virtually all of our assets and those of our subsidiaries secure our obligations under the credit facility.

The credit facility contains various representations, warranties and affirmative, negative and financial covenants customary for financings of this type. The credit facility bears interest at a rate per annum equal to, at our option, either (a) a base rate equal to the higher of (i) the Federal Funds Rate plus 1/2 of 1% and (ii) the Bank of America prime rate, or (b) a Eurodollar rate (based on LIBOR), plus 0.00% for base rate borrowings and 1.00% for Eurodollar rate borrowings. The rate as of March 31, 2009 on our outstanding borrowings was 2.25%. We must maintain an amount equal to the amount outstanding under the credit facility on deposit with the Administrative Agent of the credit facility and maintain a minimum of \$23.0 million in cash on our balance sheet. At March 31, 2009, restricted cash of \$15.0 million represents the collateral on deposit with the Administrative Agent related to the credit facility. At March 31, 2009 we were in compliance with applicable covenants under the credit facility.

On August 22, 2008 we closed an offering of \$60 million in convertible senior notes (“Notes”) due 2028. Net proceeds from the offering were \$57.3 million. The Notes are governed by an indenture, dated as of August 22, 2008, between us and U.S. Bank National Association, as trustee. The Notes bear interest at a rate of 5.5% per year, payable semiannually in arrears on February 15 and August 15 of each year, beginning on February 15, 2009. The Notes will mature on August 15, 2028, unless previously converted or repurchased in accordance with their terms prior to such date. The Notes are senior unsecured obligations, and rank (i) equally to any of our existing and future unsecured senior debt, (ii) senior to any of our future indebtedness that is expressly subordinated to these Notes, and (iii) effectively junior to any secured indebtedness to the extent of the value of the assets securing such indebtedness. We may redeem the Notes, in whole or in part, at any time after August 15, 2013 for cash equal to the principal amount of the Notes to be redeemed, plus any accrued and unpaid interest. On August 15, 2013, August 15, 2018 and August 15, 2023 or upon the occurrence of a “fundamental change”, as defined in the Indenture, the holders may require us to repurchase all or a portion of the Notes for cash at 100% of the principal amount of the Notes being purchased, plus any accrued and unpaid interest.

The Notes are convertible into approximately 6,486,000 shares of our common stock under certain circumstances prior to maturity at a conversion rate of 108.0847 shares per \$1,000 principal amount of Notes, which represents a conversion price of approximately \$9.25 per share, subject to adjustment under certain conditions. Holders of the Notes may convert their Notes at their option on any day prior to the close of business on the business day immediately preceding the maturity date of August 15, 2028 only if one or more of the following conditions is satisfied: (1) during any fiscal quarter commencing after September 30, 2008, if the last reported sale price of our common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day of the immediately preceding fiscal quarter is equal to or more than 130% of the conversion price of the Notes on the last day of such preceding fiscal quarter; (2) during the five business day period following any five consecutive trading day period in which the trading price for the Notes, per \$1,000 principal amount of the Notes, for each such trading day was less than 98% of the product of the last reported sale price of our common stock and the conversion rate of the Notes on such date; (3) if we enter into specified corporate transactions; or (4) upon a redemption notice. The Notes will be convertible, regardless of whether any of the foregoing conditions has been satisfied, on or after March 15, 2028 at any time prior to the close of business on the business day immediately preceding the stated maturity date of August 15, 2028. Upon conversion, we will pay cash, shares of our common stock or a combination of cash and stock, as determined by us in our discretion.

As long as the Notes are outstanding, we are prohibited from incurring any debt other than “permitted debt,” as defined in the Indenture, except that we may incur debt in certain circumstances, including meeting a consolidated leverage ratio test and a consolidated fixed charge coverage ratio test. We may refinance our existing credit facility provided the refinanced credit facility contains substantially the same restrictive covenants with respect to financial ratios as the existing credit facility did as of August 22, 2008.

As of March 31, 2009, we had an accumulated deficit of \$166.3 million, and cash and cash equivalent balances of \$83.5 million. We expect to be unprofitable and experience negative cash flow during 2009. We believe our cash and cash equivalent balances should be sufficient to satisfy our cash requirements for the foreseeable future. Based on our current projections, we believe that we will be able to return to a positive cash flow position without requiring additional capital. However, we might seek additional debt or equity financing or both to fund our operations or acquisitions, and our actual cash needs might vary materially from those now planned because of a number of factors including: general economic conditions; FDA and foreign regulatory processes; the status of competitive products, including potential generics; intellectual property risks; the actual amount of Colazal returns we receive compared to our current estimates; our ability to maintain our current credit facility; our success selling products; the results of research and development activities; establishment of and change in collaborative

relationships; technological advances by us and other pharmaceutical companies; and whether we acquire rights to additional products. If we incur more debt, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. If we issue additional equity, our stockholders could suffer dilution. We might also enter into additional collaborative arrangements that could provide us with additional funding in the form of equity, debt, licensing, milestone and/or royalty payments. We might not be able to enter into such arrangements or raise any additional funds on terms favorable to us or at all.

Cautionary Statement

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. The following statement highlights some of these risks. For more detail, see “Part I. Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2008.

Statements contained in this Form 10-Q that are not historical facts are or might constitute forward-looking statements under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Although we believe the expectations reflected in such forward-looking statements are based on reasonable assumptions, our expectations might not be attained. Forward-looking statements involve known and unknown risks that could cause actual results to differ materially from expected results. Factors that could cause actual results to differ materially from our expectations expressed in the report include, among others: general economic conditions; our need to return to profitability; intense competition, including from generics; the high cost and uncertainty of the research, clinical trials and other development activities involving pharmaceutical products; the unpredictability of the duration and results of regulatory review of New Drug Applications and Investigational New Drug Applications; the possible impairment of, or inability to obtain intellectual property rights and the costs of obtaining such rights from third parties; our dependence on a limited number of products, particularly Xifaxan and our purgatives, and the uncertainty of market acceptance of our products; the uncertainty of obtaining, and our dependence on, third parties to manufacture and sell our products; and results of future litigation and other risk factors detailed from time to time in our other SEC filings.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our purchases of raw materials are denominated in Euros. Translation into our reporting currency, the U.S. dollar, has not historically had a material impact on our financial position. Additionally, our net assets denominated in currencies other than the U.S. dollar have not historically exposed us to material risk associated with fluctuations in currency rates. Given these facts, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. However, these circumstances could change.

Item 4. Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and accumulated and communicated to the issuer’s management, including its principal financial officer, or persons performing similar functions, as appropriate to allow timely decision regarding required disclosure. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer and Senior VP, Finance and Administration and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, our President and Chief Executive Officer and Senior VP, Finance and Administration and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to provide the reasonable assurance discussed above.

There was no change in our internal control over financial reporting in the quarter ended March 31, 2009 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are party to various legal proceedings or claims, either asserted or unasserted, which arise in the ordinary course of business. Management has reviewed pending legal matters and believes that the resolution of such matters will not have a significant adverse effect on our financial condition or results of operations.

We are involved in a lawsuit against a company seeking FDA approval to market a generic version of our MoviPrep product. Norgine, B.V. and Norgine Europe, B.V. own U.S. Patent No. 7,169,381 (the '381 patent). The '381 patent is listed with the FDA as protecting our MoviPrep product. Norgine licensed MoviPrep and the '381 patent to us for commercialization in the United States. Novel Laboratories, Inc., filed an Abbreviated New Drug Application, or ANDA, with the FDA seeking approval to market a generic version of MoviPrep in the United States prior to the September 2024 expiration of the '381 patent. On May 14, 2008, we and Norgine filed a lawsuit in the United States District Court for the District of New Jersey against Novel for infringement of the '381 patent. Novel filed an Answer and Counterclaims on June 20, 2008. Novel denied infringement and asserted defenses of patent invalidity and unenforceability. No trial date has been set. We intend to vigorously defend the patent rights for MoviPrep.

We are also involved in a lawsuit against Novel because Novel is seeking FDA approval to market a generic version of our OsmoPrep product. CDC, LLC, owns U.S. Patent No. 5,616,346 (the '346 patent). The '346 patent is listed with the FDA as protecting our OsmoPrep product. CDC, by its predecessor, licensed OsmoPrep and the '346 patent to us for commercialization in the United States. Novel filed an ANDA with the FDA seeking approval to market a generic version of OsmoPrep in the United States prior to the May 2013 expiration of the '346 patent. On September 8, 2008, we filed a lawsuit in the United States District Court for the District of New Jersey against Novel for the infringement of the '346 patent. The lawsuit also joins CDC as a party. Novel filed an Answer and Counterclaims on December 16, 2008. Novel denied infringement and asserted defenses of patent invalidity. No trial date has been set. We intend to vigorously defend the patent rights for OsmoPrep.

On or about July 14, 2008, Strides Arcolab Limited filed a Citizens Petition with the FDA seeking permission to submit an ANDA for change of dosage form from tablet to capsule for a 200mg generic version of Xifaxan. We intend to vigorously enforce the regulatory and intellectual property rights regarding Xifaxan. We are unable to predict the outcome of any ensuing regulatory action or litigation at the present time.

Regulatory data exclusivity for Xifaxan 200mg tablets ends on or about May 24, 2009. Accordingly, the Office of Generic Drugs would have been able to accept an ANDA for Xifaxan tablets on or any time subsequent to May 24, 2008, if the applicant certified that its generic rifaximin does not infringe Salix's patent. If this occurred, a Paragraph IV notification would have to be provided to us by the applicant. Although we do not possess any specific knowledge of any such filing at the current time, the expiration of data exclusivity could result in a challenge to the related intellectual property rights of Xifaxan 200mg tablets at any time in the future. We intend to vigorously enforce the patent rights for Xifaxan.

Item 6. Exhibits

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
10.66*	Commercial Manufacturing Agreement between Salix Pharmaceuticals, Inc. and Catalent Pharma Solutions, LLC				X
31.1	Certification by the Chief Executive Officer pursuant to Section 240.13a-14 or Section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
31.2	Certification by the Chief Financial Officer pursuant to Section 240.13a-14 or Section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification by the Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

* The registrant has requested confidential treatment with respect to portions of this exhibit. Those portions have been omitted from the exhibit and filed separately with the U.S. Securities and Exchange Commission.

SIGNATURES

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

SALIX PHARMACEUTICALS, LTD.

Date: May 6, 2009

By: /s/ Carolyn J. Logan
Carolyn J. Logan
President and
Chief Executive Officer

Date: May 6, 2009

By: /s/ Adam C. Derbyshire
Adam C. Derbyshire
Executive Vice President, Finance & Administration and
Chief Financial Officer

Portions of this document marked [] are requested to be treated confidentially.

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COMMERCIAL MANUFACTURING AGREEMENT
Salix Pharmaceuticals, Inc., Mesalamine Controlled Release Capsules

This Commercial Manufacturing Agreement (“**Agreement**”) is made effective as of this 9th day of September, 2008 (“**Effective Date**”), by and between Salix Pharmaceuticals, Inc., a California corporation, with a place of business at 1700 Perimeter Park Drive, Morrisville, NC, 27560 (“**Client**”), and Catalent Pharma Solutions, LLC, a Delaware limited liability company with a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873 (“**Catalent**”).

RECITALS

- A. Client is a pharmaceutical company that develops, markets and sells pharmaceutical products, including the Product;
- B. Catalent provides contract pharmaceutical development, manufacturing, packaging and analytical services to the pharmaceutical industry;
- C. Client desires to engage Catalent to provide certain services to Client in connection with the processing of Client’s Product, and Catalent desires to provide such services, all pursuant to the terms and conditions set forth in this Agreement.

THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the parties agree as follows:

ARTICLE 1
DEFINITIONS

The following terms have the following meanings in this Agreement:

- 1.1 “**Acknowledgement**” has the meaning set forth in Section 4.3.
- 1.2 “**Affiliate(s)**” means, with respect to Client or any third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity; and with respect to Catalent, Catalent Pharma Solutions, Inc. (“**CPS, Inc.**”) and any corporation, firm, partnership or other entity controlled by CPS, Inc. For the purposes of this definition, “**control**” shall mean the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.
- 1.3 “**Agreement**” has the meaning set forth in the introductory paragraph, and includes all its Attachments and other appendices (all of which are incorporated herein by reference) and any amendments to any of the foregoing made as provided herein or therein.
- 1.4 “**API**” means the compound 5-Amino Salicylic Acid, as further described in the Specifications, as provided in this Agreement.
- 1.5 “**API Inventions**” has the meaning set forth in Article 11.

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- 1.6 “**Applicable Laws**” means all laws, ordinances, rules and regulations of the United States applicable to the Processing or any aspect thereof and the obligations of Catalent or Client, as the context requires, under this Agreement, as amended from time to time, including (A) all applicable federal, state and local laws and regulations of the United States, (B) the U.S. Federal Food, Drug and Cosmetic Act and (C) cGMP.
- 1.7 “**Batch**” means a defined quantity of Product that has been or is being Processed in accordance with the Specifications.
- 1.8 “**Catalent**” has the meaning set forth in the introductory paragraph, or any successor or permitted assign. Catalent shall have the right to cause any of its Affiliates to perform any of its obligations hereunder, and Client shall accept such performance as if it were performance by Catalent; provided that any Affiliate shall, at its cost, comply with all Applicable Laws, including without limitation, the Regulatory Approval for the Product, unless Client requests the addition of the Affiliate to the Regulatory Approval.
- 1.9 “**Catalent Indemnitees**” has the meaning set forth in Section 13.2.
- 1.10 “**Catalent IP**” has the meaning set forth in Article 11.
- 1.11 “**cGMP**” means current Good Manufacturing Practices promulgated by the Regulatory Authorities, including within the meaning of 21 C.F.R. Parts 210 and 211, as amended.
- 1.12 “**Client**” has the meaning set forth in the introductory paragraph, or any successor or permitted assign.
- 1.13 “**Client Indemnitees**” has the meaning set forth in Section 13.1.
- 1.14 “**Client IP**” has the meaning set forth in Article 11.
- 1.15 “**Client-supplied Materials**” means any materials to be supplied by or on behalf of Client to Catalent for Processing, as provided in Attachment B, including API.
- 1.16 “**Commencement Date**” means the first date upon which a Regulatory Authority approves Catalent as a manufacturer of any Product.
- 1.17 “**Confidential Information**” has the meaning set forth in Section 10.2.
- 1.18 “**Contract Year**” means, with respect to Contract Year 1, the period beginning on the Effective Date and ending on December 31st of the first anniversary of the calendar year following the Commencement Date, and with respect to each Contract Year thereafter, each consecutive calendar year period beginning on January 1st and ending on December 31st.
- 1.19 “**Defective Product**” has the meaning set forth in Section 5.1.
- 1.20 “**Effective Date**” has the meaning set forth in the introductory paragraph.
- 1.21 “**Exception Notice**” has the meaning set forth in Section 5.1.

- 1.22 “**Facility**” means Catalent’s facility located in Winchester, Kentucky, USA or such other facility as agreed in writing by the parties.
- 1.23 “**Firm Commitment**” has the meaning set forth in Section 4.2.
- 1.24 “**Invention**” has the meaning set forth in Article 11.
- 1.25 “**Losses**” has the meaning set forth in Section 13.1.
- 1.26 [*].
- 1.27 “**Process**” or “**Processing**” means the compounding, filling or pressing, producing and bulk packaging (but not secondary or retail packaging) of the API and Raw Materials into Product, in accordance with the Specifications and under the terms of this Agreement.
- 1.28 “**Processing Date**” means the day on which Product is scheduled to be compounded by Catalent, as identified in an Acknowledgement in accordance with Section 4.3.
- 1.29 “**Process Inventions**” has the meaning set forth in Article 11.
- 1.30 “**Product**” means the fully compounded bulk pharmaceutical product containing the API that has been Processed in accordance with the Specifications.
- 1.31 “**Product Maintenance Services**” has the meaning set forth in Section 2.3.
- 1.32 “**Purchase Order**” has the meaning set forth in Section 4.3.
- 1.33 “**Quality Agreement**” has the meaning set forth in Section 9.7.
- 1.34 “**Raw Materials**” means all raw materials, supplies, components and packaging necessary to manufacture and ship Product in accordance with the Specifications, as provided in Attachment B, but not including Client-supplied Materials.
- 1.35 “**Recall**” has the meaning set forth in Section 9.6.
- 1.36 “**Regulatory Approval**” means any approvals, permits, product and/or establishment licenses, registrations or authorizations, including approvals pursuant to U.S. Investigational New Drug applications, New Drug Applications and Abbreviated New Drug Applications, as applicable, of any Regulatory Authorities that are necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of Product in the Territory.
- 1.37 “**Regulatory Authority**” means the international, federal, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities in the United States (including the United States Food and Drug Administration) responsible for (A) the regulation

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(including pricing) of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally.

1.38 “**Review Period**” has the meaning set forth in Section 5.1.

1.39 “**Rolling Forecast**” has the meaning set forth in Section 4.2.

1.40 “**Specifications**” means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment B, along with any valid amendments or modifications thereto, in accordance with Article 8.

1.41 “**Supplier**” has the meaning set forth in Section 3.2(B).

1.42 “**Term**” has the meaning set forth in Section 16.1.

1.43 “**Territory**” means the United States of America, and any other country that the parties agree in writing to add to this definition of Territory in an amendment to this Agreement.

1.44 “**Unit Pricing**” has the meaning set forth in Section 7.1(B).

1.45 “**Validation Services**” has the meaning set forth in Section 2.1.

ARTICLE 2 VALIDATION, PROCESSING & RELATED SERVICES

2.1 Validation Services. Catalent shall perform the qualification, validation and stability services described in Attachment A (the “**Validation Services**”). Notwithstanding anything to the contrary in this Agreement, the Validation Services shall apply to Client’s [*] for Contract Year 1.

2.2 Supply and Purchase of Product. Catalent shall Process Product in accordance with the Specifications, the Applicable Laws and the terms and conditions of this Agreement.

2.3 Product Maintenance Services. Client will receive product maintenance services (the “**Product Maintenance Services**”), [*], as applicable. In the event Client does not [*] pursuant to Section 4.1 herein. Catalent shall keep accurate records of any Product Maintenance Services utilized by Client during a given Contract Year. Beginning at the end of Contract Year 2, either party may request an annual review of the actual usage of Product Maintenance Services and Client shall be entitled to audit Catalent’s records regarding Product Maintenance Services rendered to Client. Thereafter, the parties shall [*].

2.4 Other Related Services. Catalent, shall provide such Product-related services, other than Validation Services, Processing or Product Maintenance Services, as agreed to in writing by the parties from time to time. Such writing shall include the scope and fees for any such services and

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be appended to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services.

ARTICLE 3 MATERIALS

3.1 API.

A. Client shall supply to Catalent for Processing, at Client's sole cost and risk, API, and any other Client-supplied Materials, in quantities sufficient to meet Client's requirements for Product, as set forth in Article 4. Client shall deliver such items, together with associated certificates of analysis, to the Facility no later than [*] days before, but not earlier than [*] months prior to, the Processing Date upon which such items will be used by Catalent. Client shall be responsible at its expense for securing any necessary export or import clearances or permits required in respect of supply to Catalent of such items. Catalent shall use such items solely and exclusively for Processing of the Product. Prior to delivery of any such items, Client shall provide to Catalent a copy of all associated material safety data sheets, and shall promptly provide any updates or revisions thereto.

B. Within 30 days of receipt of API or any other Client-supplied Materials by Catalent, Catalent shall inspect such items to verify their identity and test such items to confirm that they meet the associated specifications or certificate of analysis. In the event that Catalent detects a nonconformity with Specifications, Catalent shall give Client prompt oral and written notice of such nonconformity. Catalent shall not be liable for any defects in API or any other Client-supplied Materials, or in Product as a result of defective API or any other Client-supplied Materials, unless Catalent failed to properly perform the foregoing obligations. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective API or any other Client-supplied Materials, at Client's sole cost and risk.

C. Client shall retain title to API and any other Client-supplied Materials at all times and shall [*].

3.2 Raw Materials.

A. Catalent shall be responsible for sourcing and qualifying third-party suppliers of Raw Materials. Catalent shall also be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to, meet the Firm Commitment, unless otherwise agreed to by the parties in writing. Unless a particular Raw Material can be replaced with the same raw material from another supplier, Catalent shall not be liable for any delay in delivery of Product if (i) Catalent, exercising commercially reasonable efforts, is unable to obtain, in a timely manner, a particular Raw Material necessary for Processing and (ii) Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the

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parties will negotiate in good faith an appropriate amendment to this Agreement, including Sections 3.4 and 4.2.

B. In certain instances, Client may require a specific supplier, manufacturer or vendor (“**Supplier**”) to be used for Raw Material. In such an event, (i) such Supplier will be identified in the Specifications, (ii) Client shall be responsible for the timeliness, quantity, and quality of supply of Raw Materials from such Supplier, (iii) Catalent shall not be liable for any defects in Raw Materials from such Supplier, or in Product as a result of such defective Raw Materials, unless Catalent failed to properly perform any testing required by the Specifications, and (iv) the Raw Materials from such Supplier shall be deemed, for purposes of liability hereunder, Client-supplied Materials. If the cost of the Raw Material from any such Supplier is greater than Catalent’s costs for the same raw material of equal quality from other suppliers, Catalent shall notify Client in writing and provide Client with documentary evidence of the same. If Client does not, within 20 business days of its receipt of such notice, designate a lower cost supplier identified in such notice, then Catalent shall [*]. If the documented cost of the Raw Material from any supplier mandated by Client is less than Catalent’s documented cost for the same raw material of equal quality from other suppliers, then Catalent shall [*]. [*] will be responsible for all costs associated with qualification of any such Supplier who has not been previously [*]. Catalent shall maintain an inventory of Raw Materials in sufficient quantities to be able to supply up to [*] per dose strength that is included in the Firm Commitment portion of the most recent Client forecast. Notwithstanding anything to the contrary in this Section 3.2(B), a sole supplier of any Raw Material shall not be deemed a Supplier required by Client, nor shall the Raw Material supplied by such supplier be deemed Client-supplied Materials.

3.3 Artwork and Packaging. Client shall provide or approve, prior to the procurement of applicable components, all artwork, advertising and packaging information necessary for Processing, if any. Such artwork, advertising and packaging information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and packaging information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder.

3.4 Reimbursement for Materials. In the event of (A) a Specification change for any reason, (B) obsolescence of any Raw Material or (C) further to Section 16.3(C), termination or expiration of this Agreement, [*] shall bear the cost of any unused Raw Materials (including packaging), so long as [*].

ARTICLE 4 [*], PURCHASE ORDERS & FORECASTS

4.1 [*].

4.2 Forecast. On or before the 15th day of each calendar month, beginning at least 90 days prior to the anticipated Commencement Date, Client shall furnish to Catalent a written [*] rolling

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forecast of the quantities of Product that Client intends to order from Catalent during such period (“**Rolling Forecast**”). The first [*] months of such Rolling Forecast shall constitute a binding order for the quantities of Product specified therein (“**Firm Commitment**”) and the following [*]; of the Rolling Forecast shall be non-binding, good faith estimates; provided however that Client shall be obligated to provide purchase orders for the Firm commitment. If Client fails to timely provide a Rolling Forecast, the most recently provided Rolling Forecast shall be deemed resubmitted for the then-current [*].

4.3 Purchase Orders.

A. From time to time as provided in this Section 4.3(A), Client shall submit to Catalent a [*] purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch (“**Purchase Order**”); *provided*, that no Purchase Order may be for less than [*]. Concurrently with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the Firm Commitment. Purchase Orders for quantities of Product in excess of the Firm Commitment shall be submitted by Client at least [*] days in advance of the delivery date requested in the Purchase Order (“**Lead Time Requirement**”). Catalent shall be obligated to accept any Purchase Order that meets the Lead Time Requirement and that is for a quantity of Product that does not exceed [*] of the quantity of Product set forth and agreed upon in the Firm Commitment. Catalent may reject Purchase Orders in excess of [*] more than the Firm Commitment. Failure to provide a Purchase Order does not absolve Client of its obligation regarding the Firm Commitment.

B. Catalent shall confirm in writing that a Purchase Order has been accepted within [*] business days of receipt thereof by written acknowledgement (“**Acknowledgement**”) that it accepts or rejects such Purchase Order. Each Acknowledgement shall include the Processing Date and shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date; *provided* that any alternative delivery date proposed by Catalent is within [*] business days of the delivery date set forth in the Purchase Order. Catalent’s failure to timely provide an Acknowledgement shall be deemed an acceptance of Client’s Purchase Order.

C. Notwithstanding Section 4.3(A), Catalent shall use commercially reasonable efforts to supply Client with quantities of Product which are up to [*]% in excess of the quantities specified in the Firm Commitment, subject to Catalent’s other supply commitments and manufacturing, packaging and equipment capacity; *provided*, that Catalent’s failure to supply Client with quantities in excess of the quantities specified in the Firm Commitment shall not constitute a breach of this Agreement by Catalent.

D. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

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4.4 Postponement of Processing Date. Notwithstanding Section 4.5, Catalent reserves the right to postpone the Processing Date of all, or any part of, a Purchase Order upon written notice to Client, if Client refuses or fails to timely supply conforming API or any other Client-supplied Materials in accordance with Section 3.1. In such event, Catalent shall exercise commercially reasonable efforts to reschedule the Processing Date within a reasonable time and the parties shall negotiate in good faith a reasonable alternative delivery date for the Product subject to the affected Purchase Order.

4.5 Modification of Purchase Orders. An accepted Purchase Order may be modified only, by a written change order signed by both parties. Unless otherwise specifically agreed by the parties pursuant to a written change order, both Client shall remain responsible for the Firm Commitment and Catalent shall Process the Product in accordance with the Firm Commitment.

4.6 Delivery. Catalent shall use commercially reasonable efforts to deliver in the quantity and on the shipment date specified for it on the Purchase Order, via the mode(s) of transportation and to the party and destination specified on such Purchase Order. Catalent shall provide Client with as much advance notice as possible (and will use its best efforts to provide at least [*] days advance notice where possible) if Catalent determines that any Processing will be delayed or eliminated for any reason.

4.7 Observation of Processing. In addition to Client's audit right pursuant to Section 9.5, Client may send up to [*] representatives to the Facility to observe Processing for a maximum of [*] days per Contract Year (unless otherwise agreed by Catalent in writing), so long as Client provides Catalent at least [*] days' advance written notice of the attendance of such Client representatives, including the name and title of each such representative. [*] shall be given access to Catalent's Facility only upon Catalent's consent, which consent shall not be unreasonably withheld. Such representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance. [*].

4.8 Inability to Supply. If Catalent determines that it will not be able to supply Products to Client in material satisfaction of the most recent Firm Commitment, Catalent shall promptly notify Client in writing of such determination, which notice shall provide Client with the details on the extent of the expected shortfall of supply, the causes of such inability to supply, and Catalent's proposed solution to the problem. Upon such notice of a supply problem, or in any event upon Catalent's failure to timely deliver Product in accordance with Client's Purchase Order, (i) Client and Catalent will immediately meet and work together, in good faith, to identify an appropriate resolution to the supply problem, provided that Section 4.9 shall become applicable in the absence of any such resolution, and (ii) Catalent shall, during any such shortfall of supply, use commercially reasonable efforts to continue to supply Products to Client.

4.9 Back-Up Trigger. In the event that Catalent is unable for any reason to timely supply Client with Purchase Orders made in accordance with Article 4 other than for reasons attributable to Client's negligence, intentional wrongful actions, failure to supply API, or default

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hereunder and such inability to supply lasts longer than [*] consecutive days, then in addition to, and without limitation of, any legal or equitable remedies available to Client as a result of any breach of this Supply Agreement by Catalent, Client shall be free to engage a third party manufacturer for the Product or manufacture it directly upon written notice to Catalent, and Catalent shall reasonably cooperate with Client and such third party to effectuate the limited transfer of Product from Catalent to Client or such third party, as appropriate, to enable Client or the third party to manufacture Product; provided, however, that, during the Initial Term, upon receiving notice from Catalent that Catalent is in a position to [*].

ARTICLE 5
TESTING; SAMPLES; RELEASE

5.1 Testing; Releasing; Rejection. Within [*] days after Catalent completes Processing of a Batch, Catalent shall provide Client or its designee with a certificate of analysis for such Batch. Client shall be responsible for final release of Product (including testing), at its cost. Following Client's receipt of a shipment of a Batch, Client or Client's designee may test samples of such Batch to confirm that the Specifications have been met. Unless within [*] days after Client's receipt of a Batch ("**Review Period**"), Client or its designee notifies Catalent in writing (an "**Exception Notice**") that such Batch does not meet the warranty set forth in Section 12.1 ("**Defective Product**"), the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch. However, Client's acceptance of a Batch shall not preclude a subsequent rejection of such Batch or any portion thereof following discovery of latent defects in such Batch, including discovery of any substance that would cause Product to be adulterated within the meaning of the United States Food, Drug, and Cosmetic Act. Client must notify Catalent in writing within [*] days of discovery of a latent defect, and such discovery shall not exceed [*] after Processing. Upon timely receipt of an Exception Notice from Client, Catalent shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with Client that Product is Defective Product and to determine the cause of any nonconformity.

If a shipment or partial shipment is rejected by Client pursuant to the provisions of this Section 5.1, Client shall return to Catalent at Catalent's request and expense (or, at the election of Client, destroy and provide evidence of such destruction to Catalent) any such rejected portion of the Batch. Catalent shall (i) credit the original invoice and credit the amount, if any, paid by Client in respect of the rejected portion of the Batch (provided that if there are no additional Purchase Orders under this Agreement, the amount of the credit shall be converted into a refund and Catalent shall refund such amount to Client) if Catalent agrees that the applicable portion of the Batch is non-conforming, and (ii) adjust the invoice to Client for any portion of the Batch that was not rejected, payment of which is due in accordance with the terms of the original invoice. However, the provisions of this Section 5.1 are subject to Limitations of Liability contained in Article 14.

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During the pendency of any rejection discussions Catalent shall, at Client's request, use commercially reasonable efforts to promptly supply Client with additional Product, which Client shall purchase on the same terms as Product that is the subject of the rejection discussions.

5.2 Discrepant Results. In the event of a disagreement between the parties regarding whether Product is Defective Product, which disagreement cannot be resolved by the parties within [*] days of the date of the Exception Notice, the parties shall cause a mutually agreeable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including API and other Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed to by the parties in writing, the costs associated with such testing and review shall be borne by [*]. In the event the cause of nonconformity cannot be determined or assigned, the costs associated with the Defective Product and the replacement of the same shall be shared equally between the parties.

5.3 Defective Processing. Catalent will, at Client's option, either replace any Batch of Defective Product, or credit any payments made by Client for such rejected Batch. THE OBLIGATION OF CATALENT TO REPLACE DEFECTIVE PRODUCT OR CREDIT PAYMENTS MADE BY CLIENT FOR DEFECTIVE PRODUCT SHALL BE [*].

5.4 Supply of Material for Defective Product. In the event Catalent replaces Defective Product pursuant to Section 5.3, Client shall supply, at Catalent's cost, subject to Section 14.1 herein, Catalent with sufficient quantities of API, and other Client-supplied Materials in order for Catalent to complete such replacement Batch.

ARTICLE 6 DELIVERY

6.1 Delivery. Catalent shall segregate and store all Product until acceptance as set forth in Section 5.1. Catalent shall tender Product for delivery [*] the Facility promptly following Catalent's release of Product. [*] shall be responsible for all costs and risk of loss associated with shipment of the Product. Client shall designate a qualified carrier to Catalent.

6.2 Failure to Take Delivery. If Client fails to take delivery of any Product on any scheduled delivery date, Catalent shall store such Product as Client's agent, and [*]. For each such Batch of stored Product, Client agrees that: (A) [*], (B) [*], (C) [*], (D) [*], and (E) [*]. Within 5 days following a written request from Catalent, Client shall provide Catalent with a letter confirming items (A) through (E) of this Section for each Batch of stored Product.

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**ARTICLE 7
PAYMENTS**

7.1 Fees. In consideration for Catalent performing services hereunder:

(A) Client shall pay to Catalent any unpaid fees for Validation Services set forth on Attachment A. Such fees shall be paid within [*] days following invoice, which invoice shall be submitted to Client by Catalent upon the completion of the relevant phase of the Validation Services.

(B) Client shall pay Catalent the unit pricing for Product set forth on Attachment C (“**Unit Pricing**”). Such fees shall be paid within [*] days following invoice, which invoice shall be submitted to Client by Catalent upon tender of delivery of Product as provided in Section 6.1.

(C) Subject to Section 2.3, Client shall [*] set forth on Attachment C. Such [*] shall be submitted to Client by Catalent upon the anniversary of each Contract Year during the Term. However, [*] will be [*].

(C) Other Fees. Client shall pay Catalent for all other fees and expenses of Catalent owing in accordance with the terms of this Agreement, including pursuant to Sections 2.4, [*], [*] and 16.3. Such fees and expenses shall be paid within [*] days [*], which invoice shall be submitted to Client by Catalent as and when appropriate.

7.2 Unit Pricing Adjustments. Beginning on January 1, [*], the Unit Pricing shall be subject to an [*] price adjustment, effective on each anniversary date of the first [*] following the Effective Date. For any increases in Unit Pricing, the increase shall not exceed [*]. Catalent will provide Client with reasonable supporting documentation for such increase at least ninety (90) days prior to a proposed price increase. Alternatively, for any decreases in Unit Pricing that may result from i) cooperative efforts between Catalent and Client relating to the manufacture of the Product, ii) a decrease in the cost of labor or Raw Materials, or iii) Catalent experiencing a decrease in the cost of manufacture of the Product, Catalent shall notify Client and grant Client a reduction in Unit Pricing equal to at least [*] of the related cost reduction.

7.3 Intentionally Omitted.

7.4 Payment Terms. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. In the event payment on an undisputed invoice is not received by Catalent on or before the [*] day after the [*], then Catalent may, in addition to any other remedies available at equity or in law, at its option, elect to do any one or more of the following: (A) [*]; (B) suspend any further performance hereunder until such invoice is paid in full; and/or (C) terminate this Agreement pursuant to Section 16.2(B). For the avoidance of doubt, Catalent shall not be permitted to suspend performance or terminate the Agreement, and [*] on any portion of an invoice disputed in good faith by Client. In the event Client disputes all or any portion of an

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invoice, Client shall notify Catalent of the dispute within [*] days of Client's receipt of the invoice, and the parties shall negotiate in good faith with respect to any disputed amount.

7.5 Taxes. All taxes, duties and other amounts assessed (excluding tax based on net income and franchise taxes) on services, components, API or Product prior to or upon provision or sale to Catalent or Client, as the case may be, and on any other Client-supplied Materials, are the responsibility of Client, and Client shall reimburse Catalent for all such taxes, duties or other expenses paid by Catalent or such sums will be added to invoices directed at Client, where applicable.

7.6. Client and Third Party Expenses. Except as may be expressly covered by Product Maintenance Service [*], Client shall be responsible for [*]% of its own and all third-party expenses associated with the development, Regulatory Approvals and commercialization of Product, including regulatory filings and post-approval marketing studies.

7.7 Development Batches. Each Batch produced under this Agreement, including those necessary to support the validation portion of Client's submissions for Regulatory Approvals, will be considered to be a "development batch" unless and until Processing has been validated. Client shall be responsible for the cost of each such Batch, even if such Batch fails to meet the Specifications, unless Catalent was grossly negligent in the manufacture of the out-of-Specification Batch. Catalent and Client shall cooperate in good faith to resolve any problems causing the out-of-Specification Batch.

ARTICLE 8 CHANGES TO SPECIFICATIONS

All Specifications and any changes thereto agreed to by the parties from time to time shall be in writing, dated and signed by the parties. Any change to the Process requested in writing by Client shall be deemed a Specification change. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing). Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. As soon as possible after a request is made for any change in Specifications, Catalent shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with such agreed upon changes as set forth in a written amendment to the Specifications signed by the parties. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. Catalent reserves the right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the required written amendment.

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**ARTICLE 9
RECORDS; REGULATORY MATTERS**

9.1 Batch Records and Data. Within [*] days following the completion of Processing of each Batch, Catalent shall provide Client with properly completed copies of Batch records prepared in accordance with the Specifications; *provided*, that if testing reveals an out-of-Specification result, Catalent shall provide such Batch records within [*] days following resolution of the out-of Specification result.

9.2 Recordkeeping. Catalent shall maintain materially complete and accurate books, records, test and laboratory data, reports and all other information relating to Processing, including all information required to be maintained by Applicable Laws, in accordance with Catalent standard operating procedures. Such information shall be maintained in forms, notebooks and records for a period of at least [*] years from the relevant finished Product expiration date or longer if required under Applicable Laws.

9.3 Regulatory Compliance. Client shall be solely responsible for and will obtain all Regulatory Approvals, including any applications and amendments in connection therewith. Catalent will be responsible to maintain all permits and licenses required by any Regulatory Authority with respect to the Facility generally, and for its performance of services hereunder. During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client's request and at [*] expense. Each party intends and commits to cooperate to satisfy all Applicable Laws relating to Processing.

9.4 Governmental Inspections and Requests. Catalent shall promptly advise Client, and in any event within [*], if an authorized agent of any Regulatory Authority visits the Facility concerning the Processing. Catalent shall furnish to Client a copy of the report by such Regulatory Authority, if any, within [*] business days of Catalent's receipt of such report. Further, upon receipt of a Regulatory Authority request to inspect the Facility or audit Catalent's books and records with respect to Processing, Catalent shall notify Client within [*], and shall provide Client with a copy of any written document received from such Regulatory Authority within [*] business days.

9.5 Client Inspections and Audits.

A. During the Term, duly-authorized employees, agents and representatives of Client shall be granted access upon at least [*] prior notice and at reasonable times during regular business hours to (i) the portion of the Facility where Catalent performs Processing, (ii) relevant personnel involved in Processing and (iii) Processing records described in Section 9.2, in each case solely for the purpose of inspecting and verifying that Catalent is Processing in accordance with cGMPs, the Specifications and the Product master Batch records. Client shall provide the name and title of each such employee, agent or representative to Catalent. Agents or independent contractors of Client shall be given access to Catalent's Facility [*]. Client shall indemnify

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Catalent for any and all acts or omissions of Client's employees, agents, and representative while on Catalent's premises.

B. Client's Quality Assurance Manager will arrange audit visits with Catalent Quality Management. Inspections shall be designed to minimize disruption of operations at the Facility. Client may not conduct an inspection under this Section 9.5 more than [*] during any 12-month period; *provided*, that additional inspections may be conducted in the event there is a material quality or compliance issue concerning Product or its Processing.

9.6 **Recall.** In the event Catalent believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Product provided under this Agreement, Catalent shall immediately notify Client in writing. Catalent will not act to initiate a Recall without the express prior written approval of Client, unless otherwise required by Applicable Laws. In the event Client believes a Recall may be necessary with respect to any Product provided under this Agreement, Client shall immediately notify Catalent in writing and Catalent shall provide all necessary cooperation and assistance to Client. The cost of any Recall shall be borne by [*] and [*] shall reimburse [*] for expenses incurred with any Recall, in each case unless such Recall is caused solely by [*] breach of its obligations under this Agreement or Applicable Laws or its negligence or willful misconduct, then such cost shall be borne by [*] and [*] shall reimburse [*] for expenses incurred with any Recall. For purposes hereof, such cost shall be limited to reasonable, actual and documented administrative costs incurred by [*] for such Recall and replacement of the Product subject to Recall, in accordance with Article 5; *provided*, that NEITHER PARTY SHALL BE LIABLE IN ANY EVENT FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES PROVIDED, HOWEVER, FOR PURPOSES OF CLARITY, THAT INDEMNIFIABLE LOSSES UNDER ARTICLE 13 SHALL NOT BE CHARACTERIZED AS INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL TO CLIENT OR CATALENT SOLELY ON THE BASIS THAT SUCH LOSSES ARISE FROM SUCH DAMAGES SUFFERED BY THE THIRD PARTY. In the event that a Recall of Product, for which [*].

9.7 **Quality Agreement.** Within [*] months after the Effective Date, the parties shall negotiate in good faith and enter into a Quality Agreement substantially in the form attached hereto as Attachment D (the "**Quality Agreement**"). The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth therein. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

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ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Mutual Obligation. Catalent and Client each agrees that it will not use the other party's Confidential Information except in connection with the performance of its obligations hereunder and will not disclose the other party's Confidential Information to any third party without the prior written consent of the other party, except as required by law, regulation or court or administrative order; *provided*, that prior to making any such legally required disclosure, the party making such disclosure shall give the other party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Notwithstanding the foregoing, each party may disclose the other party's Confidential Information to any of its employees, representatives or Affiliates that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this Article and (C) agree to be bound by the terms of this Article.

10.2 Definition. As used in this Agreement, the term "**Confidential Information**" includes all such information furnished by Catalent or Client, or any of their respective representatives or Affiliates, to the other party or its representatives or Affiliates, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either party, or any of their respective representatives or Affiliates, containing or based in whole or in part on any such information furnished by the other party or its representatives or Affiliates. Confidential Information also includes the existence of this Agreement and its terms.

10.3 Exclusions. Notwithstanding Section 10.2, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by the receiving party at the time of disclosure as evidenced by the receiving party's written records, (C) becomes available to the receiving party on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for the receiving party without reference to the Confidential Information of the other party as evidenced by the receiving party's written records.

10.4 No Implied License. Except as expressly set forth in Section 10.1, the receiving party will obtain no right of any kind or license under any Confidential Information of the disclosing party, including any patent application or patent, by reason of this Agreement. All Confidential Information will remain the sole property of the party disclosing such information or data, subject to Article 11.

10.5 Return of Confidential Information. Upon expiration or termination of this Agreement, the party receiving Confidential Information will cease its use and, upon request, within 30 days

either return or destroy (and certify as to such destruction) all Confidential Information of the other party, including any copies thereof, except for a single copy thereof which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement.

10.6 Survival. The obligations of this Article will terminate [*] years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under applicable law.

ARTICLE 11 INTELLECTUAL PROPERTY

For purposes hereof, “**Client IP**” means all intellectual property and embodiments thereof owned by or licensed to Client as of the date hereof or developed by Client other than in connection with this Agreement; “**Catalent IP**” means all intellectual property and embodiments thereof owned by or licensed to Catalent as of the date hereof or developed by Catalent other than in connection with this Agreement; “**Invention**” means any intellectual property developed by either party in connection with this Agreement; “**API Inventions**” means any Invention that relates exclusively to the Client IP or Client’s patented API; and “**Process Inventions**” means any Invention, other than an API Invention, that relates exclusively to the Catalent IP or relates to developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products generally. All Client IP and API Inventions shall be owned solely by Client and no right therein is granted to Catalent under this Agreement, except that Catalent shall have a non-exclusive, royalty-free license to such items solely to the extent necessary to perform its obligations under this Agreement. All Catalent IP and Process Inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement. The parties shall cooperate to achieve the allocation of rights to Inventions anticipated herein and each party shall be solely responsible for costs associated with the protection of its intellectual property.

ARTICLE 12 REPRESENTATIONS AND WARRANTIES

12.1 Catalent. Catalent represents, warrants and undertakes to Client that

A. at the time of delivery by Catalent as provided in Section 6.1, Product shall have been Processed in accordance with Applicable Laws and in conformance with the Specifications and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided*, that Catalent shall not be liable for defects attributable to API or other Client supplied Materials (including artwork, packaging and labeling); and

B. it shall not employ, contract with, or retain any person directly or indirectly to perform any services under this Agreement if such person (a) is under investigation by the FDA for debarment or is presently debarred by the FDA pursuant to 21 U.S.C. § 335a or its successor

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provisions, or (b) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions, and it has not engaged in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions. If, during the Term, Catalent or any person employed or retained by it (i) comes under investigation by the FDA or other Governmental Authority for a debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, Catalent shall immediately notify Client of the same.

12.2 Client. Client represents, warrants and undertakes to Catalent that:

A. to the best of its knowledge, the API and all other Client-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply, with the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

B. to the best of its knowledge, no material safety data sheets are applicable to Product, API or any other Client-supplied Materials, except as provided to Catalent in writing by Client in sufficient time for review and training by Catalent;

C. all Product delivered to Client by Catalent will be held, used and disposed of by or on behalf of the Client in accordance with Applicable Laws, and Client will otherwise comply with all laws, rules, regulations and guidelines applicable to Client's performance under this Agreement and its use of Product provided by Catalent under this Agreement;

D. Client will not release any Batch of Product if the required certificates of analysis indicate that Product does not comply with the Specifications;

E. to its knowledge, Client has all necessary authority to use and to permit Catalent to use pursuant to this Agreement all intellectual property related to Product, API, all other Client-supplied Materials (including artwork), and the Processing of the foregoing, including any copyrights, trademarks, trade secrets, patents, inventions and developments;

F. the content of all artwork provided to Catalent shall comply with all Applicable Laws; and

G. to its knowledge, the work to be performed by Catalent under this Agreement will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other intellectual property or other right held by any person or entity.

12.3 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTIES OF NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 13 INDEMNIFICATION

13.1 Indemnification by Catalent. Catalent shall defend, indemnify and hold harmless Client, its Affiliates, and their respective directors, officers, employees and agents (“**Client Indemnitees**”) from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys’ fees and reasonable investigative costs) in connection with any suit, demand or action by any third party (“**Losses**”) arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement or (B) any negligence or willful misconduct by Catalent or its Affiliates; in each case except to the extent that any of the foregoing arises out of or results from any Client Indemnitee’s negligence, willful misconduct or breach of this Agreement.

13.2 Indemnification by Client. Client shall defend, indemnify and hold harmless Catalent, its Affiliates, and their respective directors, officers, employees and agents (“**Catalent Indemnitees**”) from and against any and all Losses arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement, (B) any manufacture, packaging, sale, promotion, distribution or use of or exposure to Product, API or any other Client-supplied Materials, including product liability or strict liability, (C) [*], (D) [*], (E) [*], or (F) any negligence or willful misconduct by Client or its Affiliates; in each case except to the extent that any of the foregoing arises out of or results from any Catalent Indemnitee’s negligence, willful misconduct or breach of this Agreement.

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the party seeking indemnification (A) promptly notifying the indemnifying party of any claim or liability of which the party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); *provided*, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is prejudiced by such failure, (B) allowing the indemnifying party, if the indemnifying party so requests, to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party’s expense), (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party’s expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party.

ARTICLE 14 LIMITATIONS OF LIABILITY

14.1 CATALENT’S LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED API OR OTHER CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT SUCH API OR CLIENT-SUPPLIED MATERIALS ARE INCORPORATED INTO PRODUCT, SHALL NOT EXCEED [*].

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14.2 CATALENT'S TOTAL LIABILITY FOR [*] UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED \$[*].

14.3 EXCEPT AS SET FORTH IN SECTION 14.2 ABOVE, OR IN THE EVENT OF CATALENT'S [*], CATALENT'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED \$[*]. THE LIMITATION OF LIABILITY SET FORTH IN THIS SECTION 14.3 SHALL NOT APPLY TO LOSSES OWING TO CLIENT UNDER SECTION 13.1, WITH RESPECT TO AMOUNTS PAID BY CLIENT TO THIRD PARTIES FOR BODILY INJURY.

14.4 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (PROVIDED, HOWEVER, FOR PURPOSES OF CLARITY, THAT INDEMNIFIABLE LOSSES UNDER ARTICLE 13 SHALL NOT BE CHARACTERIZED AS INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL TO CLIENT OR CATALENT SOLELY ON THE BASIS THAT SUCH LOSSES ARISE FROM SUCH DAMAGES SUFFERED BY THE THIRD PARTY) OR LOSS OF REVENUES, REPUTATION, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 15 INSURANCE

15.1 Catalent Insurance. Catalent shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the Term: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than an amount equivalent to \$[*]; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than an amount equivalent to \$[*]; (C) Workers Compensation and Employers Liability Insurance, with statutory limits for Workers Compensation and Employers Liability limits of not less than an amount equivalent to \$[*] per accident; and (D) Professional Services Errors & Omissions Liability Insurance with per-claim and aggregate limits of not less than an amount equivalent to \$[*]. The parties hereby acknowledge and agree that Catalent may self-insure all or any portion of the required insurance. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term and for a period of not less than [*] following the expiration or termination of this Agreement. [*]. Catalent shall furnish to Client a certificate of insurance or other evidence of the required insurance [*] as soon as practicable after the Effective Date and within 30 days after renewal of such policies. Each insurance policy which is required under this Agreement, other than self insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII.

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15.2 Client Insurance. Client shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the Term: (A) Commercial General Liability Insurance with a per occurrence limit of not less than an amount equivalent to \$[*]; (B) Products and Completed Operations Liability Insurance (including coverage for Product used in clinical trials) with a per occurrence limit of not less than an amount equivalent to \$[*]; (C) Workers Compensation and Employers Liability Insurance with statutory limits for Workers Compensation and Employers Liability limits of not less than an amount equivalent to \$[*] per accident; and (D) All Risk Property Insurance, [*], in an amount equal to [*]. The parties hereby acknowledge and agree that Client may self-insure all or any portion of the above-required insurance. Client shall maintain levels of insurance or self insurance sufficient to meet its obligations under this Agreement. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term and for a period of not less than [*] following the expiration or termination of this Agreement. [*]. Client shall furnish certificates of insurance evidencing the required insurance policies and [*] to Catalent as soon as practicable after the Effective Date and within 30 days after renewal of such policies. Each insurance policy that is required under this Agreement shall be obtained, from an insurance carrier with an A.M. Best rating of at least A- VII.

ARTICLE 16 TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the fifth Contract Year, unless earlier terminated in accordance with Section 16.2 (as may be extended in accordance with this Section, the “**Initial Term**”). The Term shall automatically be extended for successive 3-year periods (each, a “**Renewal Term**”), unless and until one party gives the other party at least 24 months’ prior written notice of its desire to terminate as of the end of the then-current Term (the Initial Term and any Renewal Terms are herein collectively referred to as the “Term”).

16.2 Termination. This Agreement may be terminated immediately without further action:

A. by either party if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within 30 days, or takes any equivalent or similar action in consequence of debt in any jurisdiction; or

B. by either party if the other party materially breaches any of the provisions of this Agreement and such breach is not cured within 60 days after the giving of written notice requiring the breach to be remedied.; *provided*, that in the case of a failure of Client to make undisputed payments in accordance with the terms of this Agreement, Catalent may terminate

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this Agreement if such payment breach is not cured within 30 days of receipt of notice of nonpayment from Catalent.

C. by either party for any reason or no reason upon 24 months prior written notice to the other party.

D. by Client upon written notice to Catalent in the event of [*].

16.3 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either party prior to such expiration or termination. In the event of a termination of this Agreement:

A. Catalent shall promptly return to Client, at [*] expense and at Client's direction, any remaining inventory of Product, API or other Client-supplied Materials; *provided*, that Catalent shall have no obligation to so return such items until [*];

B. Client shall pay Catalent all invoiced amounts outstanding hereunder, [*]; and

C. in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B) or by Catalent pursuant to Section 16.2(C), Client shall pay Catalent for [*].

16.4 Survival. The rights and obligations of the parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 7.4 (Payment Terms), 7.5 (Taxes), 7.6 (Client and Third Party Expenses), 9.2 (Recordkeeping), 9.6 (Recall), 12.3 (Limitations on Warranties), 16.3 (Effect of Termination) and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

ARTICLE 17 NOTICE

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally; (B) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (C) when delivered if sent by express courier service, to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

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To Client: Salix Pharmaceuticals, Inc.
1700 Perimeter Park Drive
Morrisville, NC 27560
USA
Attn: AVP, Pharmaceutical Development and
Manufacturing

With a copy to: Salix Pharmaceuticals, Inc.
1700 Perimeter Park Drive
Morrisville, NC 27560
USA
Attn: General Counsel

To Catalent: Catalent Pharma Solutions, LLC
1100 Enterprise Drive
Winchester, KY 40391
USA
Attn: VP, General Manager
Fax: 859-745-6636

With a copy to: Catalent Pharma Solutions, LLC
14 Schoolhouse Road
Somerset, NJ 08873
USA
Attn: General Counsel (Legal Department)
Fax: 732-537-6491

**ARTICLE 18
MISCELLANEOUS**

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement, as well as that certain Confidentiality Agreement dated June 1, 2004 between the parties, constitutes the entire understanding between the parties, and supersedes any contracts, agreements or understandings (oral or written) of the parties, with respect to the subject matter hereof, including, for avoidance of doubt, that certain quotation letter (QTE-SAL.07.1207.00) dated December 7, 2007, and that certain quotation letter (QTE-SAL.09-2665.01). No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular shall include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but

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not limited to”, “without limitation” or words of similar import, (E) the word “or” shall be, deemed to include the word “and” (e.g., “and/or”) and (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and neither party will incur any debts or make any commitments for the other party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint ventures, co-partners, employer/employee or principal and agent. Neither party shall have any responsibility for the hiring, termination or compensation of the other party’s employees or contractors or for any employee benefits of any such employee or contractor.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party’s consent, assign this Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning party or the assigning party’s business unit responsible for performance under this Agreement.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person or entity other than the parties named herein and their respective successors and permitted assigns.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware, USA excluding its conflicts of law provisions.

18.10 Alternative Dispute Resolution. If any dispute arises between the parties in connection with this Agreement, such dispute shall be presented to the respective presidents or senior executives of Catalent and Client for their consideration and resolution. If such parties cannot reach a resolution of the dispute, then such dispute shall be referred to non-binding mediation. If the parties are unable to resolve their dispute at mediation within 120 days following referral of such dispute, either party shall be free to pursue any and all legal remedies available to such party.

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18.11 Prevailing Party. In any dispute resolution proceeding between the parties in connection with this Agreement, the prevailing party will be entitled to recover its reasonable attorney's fees and costs in such proceeding from the other party.

18.12 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Force Majeure. Except as to payments required under this Agreement, neither party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such party's performance hereunder if such default or delay is caused by events beyond such party's reasonable control, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, public utilities or common carriers; *provided*, that the party seeking relief under this Section shall immediately notify the other party of such cause(s) beyond such party's reasonable control. The party that may invoke this Section shall use commercially reasonable efforts to reinstate its ongoing obligations to the other party as soon as practicable. If the cause(s) shall continue unabated for [*], then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.14 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

[Signature page follows]

* **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

EXECUTION COPY

IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to execute this Agreement effective as of the Effective Date.

Catalent PharmaSolutions, LLC

Salix Pharmaceuticals, Inc.

By: /s/ Ian Muir

By: _____

Name: Ian Muir

Name: _____

Its: VP Modified Release

Its: _____

EXECUTION COPY

IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to execute this Agreement effective as of the Effective Date.

Catalent Pharma Solutions, LLC

Salix Pharmaceuticals, Inc.

By: _____

By: /s/ William P. Forbes

Name: _____

Name: William P. Forbes

Its: _____

Its: VP, R&D and CDO

ATTACHMENT A
VALIDATION SERVICES

See attached.

[*]

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

CERTIFICATION

I, Carolyn J. Logan, certify that:

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

Date: May 6, 2009

By: /s/ Carolyn J. Logan
Carolyn J. Logan
President and Chief Executive Officer

CERTIFICATION

I, Adam C. Derbyshire, certify that:

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

Date: May 6, 2009

By: /s/ Adam C. Derbyshire
Adam C. Derbyshire
Executive Vice President and
Chief Financial Officer

