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

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**FORM 10-Q**

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

For the quarterly period ended September 30, 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

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**SALIX PHARMACEUTICALS, LTD.**

(Exact name of Registrant as specified in its charter)

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**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)

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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 November 6, 2009 was 49,344,406.

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## 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>September 30,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 69,102	\$ 120,153
Accounts receivable, net	75,458	40,461
Inventory, net	22,326	17,311
Prepaid and other current assets	9,628	8,295
Total current assets	<u>176,514</u>	<u>186,220</u>
Property and equipment, net	5,430	4,849
Restricted cash	15,000	15,000
Goodwill	85,257	85,257
Product rights and intangibles, net	106,522	106,822
Other assets	1,944	2,336
Total assets	<u>\$ 390,667</u>	<u>\$ 400,484</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 15,834	\$ 10,099
Accrued liabilities	45,060	27,443
Reserve for product returns, rebates and chargebacks	27,416	34,034
Current portion of capital lease obligations	840	849
Total current liabilities	<u>89,150</u>	<u>72,425</u>
Long-term liabilities:		
Convertible senior notes	46,639	44,759
Borrowings under credit facility	15,000	15,000
Lease incentive obligations	1,832	2,108
Long term portion of capital lease obligations	631	791
Total long-term liabilities	<u>64,102</u>	<u>62,658</u>
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, 49,191,431 shares issued and outstanding at September 30, 2009 and 48,078,200 shares issued and outstanding at December 31, 2008	49	48
Additional paid-in capital	426,309	417,698
Accumulated deficit	<u>(188,943)</u>	<u>(152,345)</u>
Total stockholders' equity	<u>237,415</u>	<u>265,401</u>
Total liabilities and stockholders' equity	<u>\$ 390,667</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 September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
<b>Revenues:</b>				
Net product revenues	<u>\$65,658</u>	<u>\$42,872</u>	<u>\$162,666</u>	<u>\$118,197</u>
<b>Costs and expenses:</b>				
Cost of products sold (excluding amortization of product rights and intangibles of \$2,562 and \$2,271 for the three-month periods ended September 30, 2009 and 2008, and \$7,565 and \$6,813 for the nine-month periods ended September 30, 2009 and 2008, respectively)	13,207	7,763	34,523	22,133
Amortization of product rights and intangible assets	2,562	2,271	7,565	6,813
Research and development	26,143	14,442	69,554	57,303
Selling, general and administrative	<u>29,622</u>	<u>23,411</u>	<u>83,632</u>	<u>67,555</u>
Total cost and expenses	<u>71,534</u>	<u>47,887</u>	<u>195,274</u>	<u>153,804</u>
Income (loss) from operations	(5,876)	(5,015)	(32,608)	(35,607)
Interest income (expense) and other income, net	<u>(1,417)</u>	<u>(541)</u>	<u>(4,062)</u>	<u>69</u>
Income (loss) before provision for income tax	(7,293)	(5,556)	(36,670)	(35,538)
Income tax (expense) benefit	<u>(22)</u>	<u>112</u>	<u>72</u>	<u>(992)</u>
Net income (loss)	<u>\$ (7,315)</u>	<u>\$ (5,444)</u>	<u>\$ (36,598)</u>	<u>\$ (36,530)</u>
Net income (loss) per share, basic	<u>\$ (0.15)</u>	<u>\$ (0.11)</u>	<u>\$ (0.76)</u>	<u>\$ (0.76)</u>
Net income (loss) per share, diluted	<u>\$ (0.15)</u>	<u>\$ (0.11)</u>	<u>\$ (0.76)</u>	<u>\$ (0.76)</u>
Shares used in computing net income (loss) per share, basic	<u>48,878</u>	<u>48,040</u>	<u>48,410</u>	<u>47,842</u>
Shares used in computing net income (loss) per share, diluted	<u>48,878</u>	<u>48,040</u>	<u>48,410</u>	<u>47,842</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)**

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (36,598)	\$ (36,530)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	9,683	9,215
Amortization of debt discount	1,880	47
Loss (gain) on disposal of property and equipment	(4)	—
Stock-based compensation expense	4,919	3,356
Changes in operating assets and liabilities:		
Accounts receivable, inventory, prepaid expenses and other assets	(43,218)	15,623
Accounts payable, accrued and other liabilities	18,076	(3,338)
Reserve for product returns, rebates and chargebacks	(6,618)	(18,451)
Net cash used by operating activities	(51,880)	(30,078)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(2,115)	(853)
Increase in restricted cash	—	(15,000)
Net cash used by investing activities	(2,115)	(15,853)
<b>Cash flows from financing activities</b>		
Principal payments on capital lease obligations	(749)	(904)
Net proceeds from convertible senior debt offering	—	57,266
Proceeds from issuance of common stock upon exercise of stock options	3,693	178
Net cash provided by financing activities	2,944	56,540
Net increase (decrease) in cash and cash equivalents	(51,051)	10,609
Cash and cash equivalents at beginning of period	120,153	111,272
Cash and cash equivalents at end of period	<u>\$ 69,102</u>	<u>\$121,881</u>

Supplemental Non-Cash Disclosure

At September 30, 2009, \$4.2 million is included as an accrued liability that was paid to Wilmington Pharmaceuticals in October 2009. This related to the milestone payment for the September 8, 2009 approval of Metozolv by the FDA.

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

**SALIX PHARMACEUTICALS, LTD.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 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 U. S. 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 when 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.

The Company recognizes revenue from sales transactions where the buyer has the right to return the product 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 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 \$15.9 million and \$7.4 million as of September 30, 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 \$8.9 million and \$8.5 million as of September 30, 2009 and December 31, 2008, respectively. These allowances reflect an estimate of the Company's liability for product that may be

## SALIX PHARMACEUTICALS, LTD.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued

returned by the original purchaser in accordance with the Company's stated return policy. These balances do not include \$2.6 million and \$18.1 million at September 30, 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 in December 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 September 30, 2009 and December 31, 2008, respectively, \$2.6 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. The decrease in the liability from December 31, 2008 to September 30, 2009 is a result of actual Colazal returns, rebates and chargebacks. 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 nine-month periods ended September 30, 2009 and 2008 was 9.7% and 6.5% for rebates, chargebacks and discounts and was 5.6% and 6.0% for product returns, respectively, excluding the Colazal return reserve.

### 3. Commitments

#### *Purchase Order Commitments*

At September 30, 2009, the Company had binding purchase order commitments for inventory purchases expected to be delivered over the next three months aggregating approximately \$23.8 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 was obligated to pay Cedars-Sinai a license fee of \$1.2 million over time. As of September 30, 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. Under the terms of the agreement, on August 4, 2009, the Company provided a 30-day notice to DebioPharm of termination of the agreement because the FDA did not approve Sanvar. As of September 30, 2009, the Company had paid \$1.0 million of milestone payments.

## SALIX PHARMACEUTICALS, LTD.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued

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 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 September 30, 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. The agreement provides the Company with an exclusive license to develop and commercialize in the United States Dr. Falk'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, with the majority contingent upon achievement of U.S. regulatory approval. As of September 30, 2009, the Company had paid \$1.5 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 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 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 September 30, 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 for Metozolv. 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 September 30, 2009, the Company had recorded \$8.0 million of these milestone payments. The Company also loaned Wilmington \$2.8 million which was netted against the payment of the approval milestone as a result of FDA approval on September 8, 2009.

License Agreement with Lupin Ltd. — In September 2009, the Company entered into a Development, Commercialization and License Agreement with Lupin Ltd for Lupin's proprietary drug delivery technology for rifaximin. The agreement provides that the Company is obligated to make upfront and milestone payments to Lupin that could total up to \$55.0 million over the term of the agreement. As of September 30, 2009, the Company had paid \$5.0 million of milestone payments. The remaining milestone payments are contingent upon achievement of certain clinical and regulatory milestones.

## SALIX PHARMACEUTICALS, LTD.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued

#### 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 September 30, 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 September 30, 2009 and December 31, 2008 due to the fact that interest rate was determined based on prevalent market rates.

#### 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 September 30, 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 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 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 September 30, 2009 consisted of \$10.6 million of raw materials, \$8.8 million of work-in-process, and \$2.9 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 September 30, 2009, inventory reserves totaling \$3.1 million, compared to \$3.8 million as of December 31, 2008, were 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.

## SALIX PHARMACEUTICALS, LTD.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued

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. The Company assesses the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value might 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 might not be recoverable.

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 September 30, 2009 accumulated amortization for the Azasan intangible was \$1.2 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 September 30, 2009 accumulated amortization for the King product intangibles was \$6.8 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 September 30, 2009 accumulated amortization for the InKine intangibles was \$12.1 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 in the United States. In August 2006, the Company received Food and Drug Administration marketing approval for this product under the branded name of MoviPrep. In January 2007, the U. S. 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 September 30, 2009 accumulated amortization for the MoviPrep intangible was \$3.7 million.

## **SALIX PHARMACEUTICALS, LTD.**

### **NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued**

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 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 September 30, 2009 accumulated amortization for the Merck products was \$9.6 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 the product under the name 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 10 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 September 30, 2009, accumulated amortization for the Apriso intangible was \$0.6 million.

In September 2007, the Company entered into an Exclusive Sublicense Agreement with Wilmington Pharmaceuticals. On September 8, 2009, the FDA granted marketing approval for the product under the name Metozolv, for relief of symptomatic gastroesophageal reflux and for the relief of symptoms associated with diabetic gastroparesis. In September 2009, the Company recorded a \$7.3 million milestone payment to Wilmington. The Company is amortizing this milestone payment over a period of 8 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 September 30, 2009, accumulated amortization for the Metozolv intangible was \$0.1 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 might have resulted from 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 September 30, 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 September 30, 2009, restricted cash of \$15.0 million represents the collateral on deposit with the Administrative Agent related to the credit facility. At September 30, 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.

## SALIX PHARMACEUTICALS, LTD.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued

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.

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 first of these conditions was met as of September 30, 2009. 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.

Effective January 1, 2009, the Company is required 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 separately accounting for the liability and equity components of the convertible debt. 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

## SALIX PHARMACEUTICALS, LTD.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued

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 related to the issuance costs related to the equity component. The consolidated statement of operations for the three-month period and nine-month period ended September 30, 2008 have been adjusted to reflect the amortization of the debt discount of \$47,000 less \$18,000 related to issuances costs related to the equity component.

The carrying value of the equity component at September 30, 2009 and December 31, 2008 was \$15.2 million. The effective interest rate on the liability component for the three-month and nine-month periods ended September 30, 2008 was 12.6%. Total interest cost of \$1.5 million and \$4.4 million was recognized during the three-month and nine-month periods ended September 30, 2009, respectively including \$0.6 million and \$1.9 million of amortization of debt discount, respectively. Total interest cost of \$0.4 million was recognized during the three-month and nine-month periods ended September 30, 2008, respectively, including \$47,000 of amortization of debt discount, respectively.

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

	<u>September 30,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
Principal amount of the liability component	\$ 60,000	\$ 60,000
Unamortized discount	<u>(13,361)</u>	<u>(15,241)</u>
Net carrying amount	<u>\$ 46,639</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. The Company recognizes these amounts as an expense as the vendor delivers the related goods or performs the related services.

#### 11. Comprehensive Income

The Company is required to 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 September 30, 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 estimates 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.

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 33.3% over three 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 9.0% and is being expensed on a straight-line basis over the period during which the restrictions lapse. For the nine-month periods ended September 30, 2009 and 2008, the Company recognized \$4.9 million and \$3.4 million in share-based compensation expense related to the restricted shares, respectively. For the three-month periods ended September 30, 2009 and 2008, the Company recognized

**SALIX PHARMACEUTICALS, LTD.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued**

\$2.0 million and \$1.5 million in share-based compensation expense related to the restricted shares, respectively. As of September 30, 2009, the total amount of unrecognized compensation cost related to nonvested restricted stock awards, to be recognized as expense subsequent to September 30, 2009, was approximately \$15.9 million, and the related weighted-average period over which it is expected to be recognized is approximately 2.7 years.

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	2,000,000	—	—	—	—	—	—
Granted	(1,190,971)	—	—	1,190,971	\$ 10.29	1,190,971	\$ 10.29
Exercised	—	(584,286)	\$ 7.29	—	—	(584,286)	\$ 7.29
Vested	—	—	—	(583,199)	\$ 9.36	(583,199)	\$ 9.36
Forfeited or cancelled	120,851	(150,040)	\$ 18.11	(55,135)	\$ 9.93	(205,175)	\$ 15.91
Balance at September 30, 2009	<u>1,766,502</u>	<u>3,883,507</u>	<u>\$ 14.46</u>	<u>2,201,492</u>	<u>\$ 9.87</u>	<u>6,084,999</u>	<u>\$ 12.81</u>

For the nine-month period ended September 30, 2009, the Company issued 584,286 shares of stock with a market value of \$9.3 million upon the exercise of stock options. The Company recognized no share-based compensation expense related to stock options for the nine-month period ended September 30, 2009, nor any income tax benefit. The total intrinsic value of options exercised for the nine-month period ended September 30, 2009 was \$5.0 million. As of September 30, 2009, there was no unrecognized compensation cost for stock options because all stock options were fully vested. For the nine-month period ended September 30, 2009, the Company received net proceeds of \$4.3 million in cash from the issuance of common stock upon the exercise of stock options.

### 13. Income Taxes

The Company provides for income taxes under the liability method. 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. At September 30, 2009 the Company has provided a valuation allowance for the gross deferred tax asset due to uncertainty regarding the Company's ability to realize the entire asset.

On January 1, 2007, 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 September 30, 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 nine-month periods ended September 30, 2009 and 2008, there was no such interest or penalties.

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 and nine-month periods ended September 30, 2009 were (0.3)% and 0.2%, respectively. The Company's effective tax rate for the three-month and nine-month periods ended September 30, 2008 were 2.0% and (2.8)%, respectively. The Company re-evaluates this estimate each quarter based on the Company's estimated tax expense for the year. The Company's

**SALIX PHARMACEUTICALS, LTD.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued**

effective tax rates differ from the statutory rate of 35% primarily due to changes in the valuation allowance for deferred tax assets.

**14. Net Income (Loss) per Share**

The Company computes basic net income (loss) per share 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. 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 and nine-month periods ended September 30, 2009, the effect of approximately 6,486,000 shares issuable upon conversion of the Notes were excluded from the diluted net income per share calculation, because their inclusion would have an anti-dilutive effect due to the net loss during those periods.

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

	<u>Three months ended</u> <u>September 30,</u>		<u>Nine months ended</u> <u>September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
<b>Numerator:</b>				
Net income (loss)	\$(7,315)	\$(5,444)	\$(36,598)	\$(36,530)
<b>Denominator:</b>				
Weighted average common shares, basic	48,878	48,040	48,410	47,842
Dilutive effect of stock options	—	—	—	—
Dilutive effect of restricted stock	—	—	—	—
<b>Weighted average common shares, diluted</b>	<b><u>48,878</u></b>	<b><u>48,040</u></b>	<b><u>48,410</u></b>	<b><u>47,842</u></b>

For the three-month ended September 30, 2009 and 2008, weighted average common shares, diluted are equal to weighted average common shares, basic, because inclusion of the effect of 1,629,682 and 704,290 shares of restricted stock and stock options, respectively, would have an anti-dilutive effect due to the net loss during those periods. For the nine-month periods ended September 30, 2009 and 2008, weighted average common shares, diluted are equal to weighted average common shares, basic, because inclusion of the effect of 1,349,172 and 640,533 shares of restricted stock and stock options, respectively, would have an anti-dilutive effect due to the net loss during that period. For the three-month periods ended September 30, 2009 and 2008, there were 1,082,018 and 4,268,962, respectively, potential common shares outstanding that were excluded from the diluted net income per share calculation because their effect would have been anti-dilutive. For the nine-month periods ended September 30, 2009 and 2008, there were 2,323,309 and 4,672,691, 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):

	<u>Three months ended</u> <u>September 30,</u>		<u>Nine months ended</u> <u>September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Inflammatory Bowel Disease – Colazal/Apriso	\$ (2,379)	\$ (1,266)	\$ (1,521)	\$ 79
Xifaxan	42,668	21,373	93,027	56,132
Purgatives – Visicol/OsmoPrep/MoviPrep	16,638	15,531	45,806	41,506
Other – Anusol/Azasan/Diuril/Pepcid/Proctocort	<u>8,731</u>	<u>7,234</u>	<u>25,354</u>	<u>20,480</u>
Net product revenues	<u>\$65,658</u>	<u>\$42,872</u>	<u>\$162,666</u>	<u>\$118,197</u>

**16. Recently Issued Accounting Pronouncements**

In August 2009, the FASB issued authoritative guidance regarding measuring liabilities at fair value. The authoritative guidance sets forth the types of valuation techniques to be used to value a liability when a quoted price in an active market for the identical liability is not available. It also clarifies transfer restrictions on the fair value of a liability and the ability to use the fair value of a liability that is traded as an asset as an input to the valuation of the underlying liability. The authoritative guidance is effective for interim and annual periods beginning after August 26, 2009. The Company is assessing the impact of this new guidance and expects no material impact to its financial statements upon adoption.

In May 2009, the FASB issued authoritative guidance regarding subsequent events. The authoritative guidance establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The authoritative guidance requires disclosure of the date through which subsequent events have been evaluated and whether that date represents the date the financial statements were issued or were available to be issued. The authoritative guidance is effective for interim and annual periods ending after June 15, 2009. The Company has evaluated subsequent events through November 9, 2009, the date of the issuance of the accompanying condensed consolidated financial statements.

In April 2009, the FASB issued authoritative guidance to aid in determining fair value when the volume and level of activity for the assets or liabilities have significantly decreased and when identifying transactions are not orderly, such as a forced liquidation or distressed sale. The authoritative guidance became effective for the Company on April 1, 2009, and the adoption of the guidance did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued authoritative guidance on the recognition and presentation of other-than-temporary impairments. The authoritative guidance incorporates impairment guidance for debt securities from various sources of authoritative literature and clarifies the interaction of the factors that should be considered when determining whether a debt security is other than temporarily impaired. The authoritative guidance became effective for the Company on April 1, 2009 and the adoption of the guidance did not have a material impact on the Company's consolidated financial statements.

## SALIX PHARMACEUTICALS, LTD.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued

In October 2009, the FASB issued authoritative guidance regarding revenue arrangements with multiple deliverables. The guidance requires entities to allocate revenue in an arrangement using estimated selling prices of the delivered goods and services based on a selling price hierarchy. The guidance further eliminates the residual method of revenue allocation and requires revenue to be allocated using the relative selling price method. The new guidance should be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with early adoption permitted. The Company is currently assessing the impact of adopting this new guidance.

#### 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. On June 25, 2009 the Company and Norgine amended the complaint to add a claim for correction of inventorship for the '381 patent. Novel filed an Answer and Counterclaims to the first Amended Complaint on July 10, 2009. Novel has denied infringement and asserted various affirmative defenses, including 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 a defense of patent invalidity. No trial date has been set. The Company intends 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 as suitable 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 ended 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 know 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.

**SALIX PHARMACEUTICALS, LTD.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—Continued**

The Company is currently and might continue to be subject to product liability claims that arise through the testing, manufacturing, marketing and sale of its products, including a number of claims relating to OsmoPrep and Visicol in connection with their “box” label warning. The Company intends to defend these claims vigorously but is currently unable to predict the outcome or to reasonably estimate the range of potential expenses or loss, if any. The Company currently maintains liability coverage for its products but it is possible that this coverage, and any future coverage, will be insufficient to satisfy any liabilities that arise. The Company would have to assume defense of the lawsuits and be responsible for damages, fees and expenses, if any, that are awarded against it or for amounts in excess of the Company’s product liability coverage.

**18. Subsequent Events**

The Company has performed an evaluation of subsequent events through November 9, 2009, which is the date the financial statements were issued. There were no events requiring disclosure.

## 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 245-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 September 30, 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;
- METOZOLV™ ODT (metoclopramide HCl) 5mg and 10mg orally disintegrating tablets, which we plan to begin selling in the fourth quarter of 2009; 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 160 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 245 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:

<b>Compound</b>	<b>Indication</b>	<b>Status</b>
Rifaximin	Hepatic encephalopathy	NDA submitted June 24, 2009
Rifaximin	Irritable bowel syndrome	Phase III
Rifaximin	Travelers' diarrhea prevention	Phase III
Rifaximin	<i>C. difficile</i> — associated diarrhea	Phase III
Crofelemer	HIV-associated diarrhea	Phase III
Balsalazide disodium tablet	Ulcerative colitis	Complete response submitted to FDA October 26, 2009

### **Critical Accounting Policies**

In our Annual Report on Form 10-K for the 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 nine-month period ended September 30, 2009. We did not make any changes in those policies during the quarter.

We recognize revenue when 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.

We recognize revenue from sales transactions where the buyer has the right to return the product 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, 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 \$15.9 million and \$5.4 million as of September 30, 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 continues to be appropriate. 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 \$8.9 million and \$6.0 million as of September 30, 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 \$2.6 million and \$23.2 million at September 30, 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 in December 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 September 30, 2009 and 2008, respectively, \$2.6 million and \$23.2 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. The decrease in the liability from December 31, 2008 to September 30, 2009 is a result of actual Colazal returns, rebates and chargebacks. 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 nine-month periods ended September 30, 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 nine-month periods ended September 30, 2009 and 2008 was 9.7% and 6.5% for rebates, chargebacks and discounts and was 5.6% and 6.0% for product returns excluding the Colazal return reserve, respectively.

## Results of Operations

Three-month and Nine-month Periods Ended September 30, 2009 and 2008

### Revenues

The following table summarizes net product revenues for the three-month and nine-month periods ended September 30 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Inflammatory Bowel Disease – Colazal/Apriso	\$ (2,379)	\$ (1,266)	\$ (1,521)	\$ 79
<i>% of net product revenues</i>	<i>(3 )%</i>	<i>(3 )%</i>	<i>(1 )%</i>	<i>— %</i>
Xifaxan	42,668	21,373	93,027	56,132
<i>% of net product revenues</i>	<i>65 %</i>	<i>50 %</i>	<i>57 %</i>	<i>48 %</i>
Purgatives – Visicol/OsmoPrep/ MoviPrep	16,638	15,531	45,806	41,506
<i>% of net product revenues</i>	<i>25 %</i>	<i>36 %</i>	<i>28 %</i>	<i>35 %</i>
Other – Anusol/Azasan/Diuril/Pepcid/Proctocort	8,731	7,234	25,354	20,480
<i>% of net product revenues</i>	<i>13 %</i>	<i>17 %</i>	<i>16 %</i>	<i>17 %</i>
Net product revenues	<u>\$65,658</u>	<u>\$42,872</u>	<u>\$162,666</u>	<u>\$118,197</u>

Net product revenues for the three-month period ended September 30, 2009 were \$65.7 million, compared to \$42.9 million for the corresponding three-month period in 2008, a 53% increase. The net product revenue increase for the three-month period ended September 30, 2009 compared to the three-month period ended September 30, 2008 was primarily due to:

- increased unit sales of Xifaxan;
- increased unit sales of MoviPrep;
- increased unit sales of Pepcid ; and
- price increases on our products.

These increases were partially offset by decreased unit sales of OsmoPrep and an adjustment in the reserve for Colazal returns.

Prescription growth for the three-month period ended September 30, 2009 compared to the corresponding three-month period in 2008 was 15% for Xifaxan and 11% for our purgative franchise. Prescriptions for MoviPrep increased 66% for the three-month period ended September 30, 2009 compared to prescriptions for the three-month period ended September 30, 2008. Prescriptions for OsmoPrep for the three-month period ended September 30, 2009 declined 45% compared to prescriptions for the three-month period ended September 30, 2008 due to the boxed label warning announced by the FDA on December 11, 2008.

Net product revenues for the nine-month period ended September 30, 2009 were \$162.7 million, compared to \$118.2 million for the corresponding nine-month period in 2008, a 38% increase. The net product revenue increase for the nine-month period ended September 30, 2009 compared to the nine-month period ended September 30, 2008 was primarily due to:

- increased unit sales of Xifaxan;
- increased unit sales of MoviPrep;
- sales of Apriso, which the FDA approved in October 2008 and we launched in February 2009;
- increased unit sales of Pepcid; and
- price increases on our products.

These increases were partially offset by decreased unit sales of OsmoPrep and an adjustment in the reserve for Colazal returns.

Prescription growth for the nine-month period ended September 30, 2009 compared to the corresponding nine-month period in 2008 was 13% for Xifaxan and 19% for our purgatives. Prescriptions for MoviPrep for the nine-month period ended September 30, 2009 increased 79% compared to prescriptions for the nine-month period ended September 30, 2008. Prescriptions for OsmoPrep for the nine-month period ended September 30, 2009 declined 37% compared to prescriptions for the nine-month period ended September 30, 2008 due to the boxed label warning announced by the FDA on December 11, 2008.

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 September 30, 2009 and 2008 was \$2.6 million and \$23.2 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. The decrease in the liability from December 31, 2008 to September 30, 2009 is a result of actual Colazal returns. We developed this estimate based on the following:

- 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 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 September 30, 2009 were \$71.5 million, compared to \$47.9 million for the corresponding three-month period in 2008, and \$195.3 million for the nine-month period ended September 30, 2009, compared to \$153.8 million for the corresponding nine-month period in 2008. Higher operating expenses in absolute terms were due primarily to increased research and development costs, general and

administrative expenses, and increased cost of products sold related to the corresponding increase in product revenue.

#### *Cost of Products Sold*

Cost of products sold for the three-month period ended September 30, 2009 was \$13.2 million, compared with \$7.8 million for the corresponding three-month period in 2008. Cost of products sold for the nine-month period ended September 30, 2009 was \$34.5 million, compared with \$22.1 million for the corresponding nine-month period in 2008. The increase in cost of products sold in absolute terms for the three-month and nine-month periods ended September 30, 2009 compared to the three-month and nine-month periods ended September 30, 2008 was primarily due to the increase in net product revenues discussed above.

Gross margin on total product revenue, excluding \$2.6 million and \$2.3 million in amortization of product rights and intangible assets for the three-month periods ended September 30, 2009 and 2008, respectively, was 79.9% for the three-month period ended September 30, 2009 and 81.9% for the three-month period ended September 30, 2008. Gross margin on total product revenue, excluding \$7.6 million and \$6.8 million in amortization of product rights and intangible assets for the nine-month periods ended September 30, 2009 and 2008, respectively, was 78.8% for the nine-month period ended September 30, 2009 and 81.3% for the nine-month period ended September 30, 2008. Lower gross margins for the three-month and nine-month periods ended September 30, 2009 compared to the corresponding periods in 2008 were primarily due to the product revenue mix in the respective periods.

#### *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 and nine-month periods ended September 30, 2009 compared to the corresponding periods 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 \$26.1 million for the three-month period ended September 30, 2009, compared to \$14.4 million for the comparable period in 2008. The increase in research and development expenses for the three-month period ended September 30, 2009 compared to the corresponding period in 2008 was due primarily to:

- increased expenses related to the continuation of our development program for crofelemer, which we acquired from Napo in December 2008;
- increased expenses related to our development program for budesonide;
- increased expenses related to investigator initiated studies;
- a \$5.0 million upfront payment in connection with our collaboration with Lupin; and
- increased headcount costs.

These increases were partially offset by:

- reduced expenses related to our development program for granulated mesalamine, or Apriso, which the FDA approved in October 2008;
- reduced expenses related to our IBS development program for rifaximin, because our Phase III trials

were completed in mid 2009; and

- reduced expenses related to our hepatic encephalopathy development program for rifaximin, because our Phase III trials were completed in mid 2009.

Research and development expenses were \$69.6 million for the nine-month period ended September 30, 2009, compared to \$57.3 million for the comparable period in 2008. The increase in research and development expenses for the nine-month period ended September 30, 2009 compared to the corresponding period in 2008 was due primarily to:

- 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;
- increased expenses related to our development program for budesonide;
- a \$5.0 million upfront payment in connection with our collaboration with Lupin;
- increased expenses related to investigator initiated studies; and
- increased headcount costs.

These increases were partially offset by:

- reduced expenses related to our development program for our 1100mg balsalazide tablet;
- reduced expenses related to our development program for granulated mesalamine, or Apriso, which the FDA approved in October 2008; and
- reduced expenses related to our hepatic encephalopathy development program for rifaximin, because our Phase III trials were completed in mid 2009.

From inception through September 30, 2009, we had incurred research and development expenditures of approximately \$72.5 million for balsalazide, \$131.3 million for rifaximin, \$8.9 million for crofelemer and \$37.7 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 generally 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 \$29.6 million for the three-month period ended September 30, 2009, compared to \$23.4 million in the corresponding three-month period in 2008. This increase was primarily due to:

- increased costs related to the expansion of our sales force from 96 sales representatives to 160 sales representatives during the three-month period ended September 30, 2009;
- expenses related to the launch of Apriso;

- increased legal costs for the patent litigation related to Moviprep and Osmoprep; and
- increased headcount costs.

These increases were partially offset by decreased pre-marketing costs for our 1100mg balsalazide tablet and decreased marketing costs for Osmoprep.

Selling, general and administrative expenses were \$83.6 million for the nine-month period ended September 30, 2009, compared to \$67.6 million in the corresponding nine-month period in 2008. This increase was primarily due to:

- increased costs related to the expansion of our sales force from 96 sales representatives to 160 sales representatives during the three-month period ended September 30, 2009;
- expenses related to the launch of Apriso;
- increased legal costs for the patent litigation related to Moviprep and Osmoprep; and
- increased headcount costs.

These increases were partially offset by decreased pre-marketing costs for our 1100mg balsalazide tablet, and decreased marketing costs for Osmoprep.

We expect selling, general and administrative expenses to increase in absolute terms as we expand our sales and marketing team and efforts for our current products, the anticipated fourth quarter 2009 launch of Metozolv, and other indications for rifaximin, if approved.

#### ***Interest and Other Income, Net***

Interest income (expense) and other income, net was \$1.4 million in expense for the three-month period ended September 30, 2009, compared to \$0.5 million in expense in the corresponding three-month period in 2008. Interest and other income, net for the three-month period ended September 30, 2009 consisted of:

- \$0.1 million of interest expense on our credit facility; and
- \$1.6 million of interest expense on our convertible notes issued in August 2008, including \$0.6 million of amortization of debt discount; partially offset by \$0.3 of interest income.

Interest and other income, net for the three-month period ended September 30, 2008 consisted of:

- \$1.1 million of interest income;
- offset by \$0.4 million of interest expense on our convertible notes issued in August 2008; and
- \$0.1 million of interest expense on our credit facility and a \$1.1 million non-cash charge to expense a portion of the unamortized costs related to the credit facility.

Interest income (expense) and other income, net was \$4.1 million in expense for the nine-month period ended September 30, 2009, compared to \$0.1 million in income in the corresponding nine-month period in 2008. Interest and other income, net for the nine-month period ended September 30, 2009 consisted of:

- \$0.4 million of interest expense on our credit facility; and
- \$4.6 million of interest expense on our convertible notes issued in August 2008, including \$1.8 million of amortization of debt discount; partially offset by \$1.0 million of interest income.

Interest and other income, net for the nine-month period ended September 30, 2008 consisted of:

- \$2.2 million of interest income;
- offset by \$0.4 million of interest expense on our convertible notes issued in August 2008, including \$0.1 million of amortization of debt discount; and
- \$0.6 million of interest expense on our credit facility and the \$1.1 million non-cash charge to expense a portion of the unamortized costs related to the credit facility.

The decrease in interest income for the three-month and nine-month periods ended September 30, 2009 compared to the corresponding periods in 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 expense was \$22,000 for the three-month period ended September 30, 2009, compared to \$112,000 in benefit for the corresponding three-month period in 2008. Income tax benefit was \$72,000 for the nine-month period ended September 30, 2009, compared to \$1.0 million in expense for the corresponding nine-month period in 2008. Our effective tax rate was (0.3) % for the three-month period ended September 30, 2009, and 2.0% in the corresponding three-month period in 2008. Our effective tax rate was 0.2% for the nine-month period ended September 30, 2009, and (2.8) % in the corresponding nine-month period in 2008. Our effective tax rates differ from the statutory rate of 35% primarily due to changes in the valuation allowance for deferred tax assets.

#### ***Net Income (Loss)***

Net loss was \$7.3 million for the three-month period ended September 30, 2009, compared to \$5.4 million in the corresponding three-month period in 2008. Net loss was \$36.6 million for the nine-month period ended September 30, 2009, compared to \$36.5 million in the corresponding nine-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 September 30, 2009, we had \$69.1 million in cash and cash equivalents compared to \$120.2 million as of December 31, 2008. 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. We believe our cash and cash equivalent balances should be sufficient to satisfy our cash requirements for the foreseeable future. At September 30, 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 impair our liquidity and/or 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 \$51.9 million for the nine-month period ended September 30, 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 used by operating activities of \$30.1 million for the nine-month period ended September 30, 2008 was primarily attributable to our net loss for the period, and product returns

and chargebacks for Colazal, partially offset by collection of accounts receivable for product revenue recognized in the fourth quarter of 2007.

Net cash used in investing activities for the nine-month period ended September 30, 2009 of \$2.1 million was primarily for the approval milestone payment to Wilmington Pharmaceuticals for Metozolv, and purchases of property and equipment. Net cash used in investing activities for the nine-month period ended September 30, 2008 of \$15.9 million was for the purchases of property and equipment and the transfer of \$15.0 million of cash to restricted cash as a result of the amendment of our credit facility.

Net cash provided by financing activities for the nine-month period ended September 30, 2009 was \$2.9 million consisting primarily of proceeds from the exercise of stock options. Net cash used by financing activities for the nine-month period ended September 30, 2008 was \$56.5 million consisting primarily of the proceeds of our convertible debt offering closed in August 2008.

As of September 30, 2009, we had non-cancelable purchase order commitments for inventory purchases of approximately \$23.8 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 September 30, 2009 were as follows (in thousands):

	<u>Total</u>	<u>&lt; 1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>&gt; 5 years</u>
Operating leases	\$ 9,372	\$ 533	\$ 5,388	\$ 2,951	\$ 500
Purchase commitments	23,776	23,776	—	—	—
Convertible senior notes(1)	122,425	3,300	6,600	6,600	105,925
Borrowings under credit facility(2)	15,512	159	15,353	—	—
Capital lease obligations	1,522	243	1,279	— 3	—
Total	<u>\$172,607</u>	<u>\$28,011</u>	<u>\$28,620</u>	<u>\$9,551</u>	<u>\$106,425</u>

- (1) Contractual interest obligations related to our convertible senior notes total \$62.4 million at September 30, 2009, including \$3.3 million, \$6.6 million, \$6.6 million and \$45.9 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 \$1.2 million based on the interest rate at September 30, 2009, including \$0.5 million and \$0.7 million due in one year or less and two to three years, respectively.

We enter into license agreements with third parties that require us to make royalty, milestone or other payments contingent upon certain future events linked to the successful development and commercialization of pharmaceutical products. Certain of the payments are contingent upon the successful achievement of an important event in the development life cycle of these pharmaceutical products, which might not occur. If required by the agreements, we will 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 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 might have resulted from 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 September 30, 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 September 30, 2009 on our outstanding borrowings was 1.41%. 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 September 30, 2009, restricted cash of \$15.0 million represents the collateral on deposit with the Administrative Agent related to the credit facility. At September 30, 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 first of these conditions was met as of September 30, 2009. 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 September 30, 2009, we had an accumulated deficit of \$188.9 million, and cash and cash equivalent balances of \$69.1 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; litigation and 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 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. In addition, our limited amount of floating interest rate debt under our credit facility results in immaterial risk as a result of interest rate fluctuations.

#### **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 Executive 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 September 30, 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. On June 25, 2009 we and Norgine amended the complaint to add a claim for correction of inventorship for the '381 patent. Novel filed an Answer and Counterclaims to the first Amended Complaint on July 10, 2009. Novel has denied infringement and asserted various affirmative defenses, including 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 a defense 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 as suitable 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 ended 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 know 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.

We are currently and might continue to be subject to product liability claims that arise through the testing, manufacturing, marketing and sale of our products, including a number of claims relating to OsmoPrep and Visicol in connection with their "box" label warning. We intend to defend these claims vigorously but are currently unable to predict the outcome or to reasonably estimate the range of potential expenses or loss, if any. We currently maintain liability coverage for our products but it is possible that this coverage, and any future coverage, will be insufficient to satisfy any liabilities that arise. We would have to assume defense of the lawsuits and be responsible for damages, fees and expenses, if any, that are awarded against us or for amounts in excess of our product liability coverage. Lawsuits can also be time-consuming and harm our reputation and business, even if we are successful in defending them.

**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>
10.67*	Development, Commercialization and License Agreement Between Lupin Ltd. and Salix Pharmaceuticals, Inc.				X
10.68*	Rifaximin Manufacturing and Supply Agreement Between Salix Pharmaceuticals, Inc. and Lupin Ltd.				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.



## 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: November 9, 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: November 9, 2009

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

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Salix Pharmaceuticals, Ltd. (the "Company") for the period ended September 30, 2009 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Carolyn J. Logan, President and Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

Date: November 9, 2009

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

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Salix Pharmaceuticals, Ltd. (the "Company") for the period ended September 30, 2009 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Adam C. Derbyshire, Executive Vice President, Finance and Administration, and Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

Date: November 9, 2009

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