

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

**FORM 10-Q**

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

For the quarterly period ended September 30, 2008

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 000-23265

**SALIX PHARMACEUTICALS, LTD.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

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

Indicate by check mark whether the Registrant 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 3, 2008 was 48,062,100

**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)

	September 30, 2008 (unaudited)	December 31, 2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 121,881	\$ 111,272
Accounts receivable, net	40,706	52,208
Inventory, net	23,120	17,676
Prepaid and other current assets	8,738	14,219
Total current assets	194,445	195,375
Property and equipment, net	5,301	5,877
Restricted cash	15,000	—
Goodwill	85,157	86,383
Product rights and intangibles, net	98,899	105,713
Deferred tax asset	16,682	—
Other assets	5,343	3,754
Total assets	<u>\$ 420,827</u>	<u>\$ 397,102</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 9,019	\$ 11,889
Accrued liabilities	20,363	20,588
Reserve for product returns, rebates and chargebacks	34,547	52,998
Current portion of capital lease obligations	869	1,009
Total current liabilities	64,798	86,484
Long-term liabilities:		
Convertible senior notes	60,000	—
Borrowings under credit facility	15,000	15,000
Lease incentive obligation	2,193	2,436
Other long term liability	18,412	—
Long term portion of capital lease obligations	821	612
Total long-term liabilities	96,426	18,048
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, issuable in series, none outstanding	—	—
Common stock, \$0.001 par value; 80,000,000 shares authorized, 48,047,807 shares issued and outstanding at September 30, 2008 and 47,708,985 shares issued and outstanding at December 31, 2007	48	47
Additional paid-in capital	400,794	397,261
Accumulated deficit	(141,239)	(104,738)
Total stockholders' equity	259,603	292,570
Total liabilities and stockholders' equity	<u>\$ 420,827</u>	<u>\$ 397,102</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,	
	2008	2007	2008	2007
<b>Revenues:</b>				
Net product revenues	\$42,872	\$67,355	\$118,197	\$193,818
Revenues from collaborative agreements	—	12	—	2,512
<b>Total revenues</b>	<u>42,872</u>	<u>67,367</u>	<u>118,197</u>	<u>196,330</u>
<b>Costs and expenses:</b>				
Cost of products sold (excluding amortization of product rights and intangibles of \$2,271 and \$2,271 for the three-month periods ended September 30, 2008 and 2007, respectively, and \$6,813 and \$6,355 for the nine-month periods ended September 30, 2008 and 2007, respectively)	7,763	13,083	22,133	38,129
Fees and costs related to license agreements	—	200	1,605	1,650
Amortization of product rights and intangible assets	2,271	2,271	6,813	6,355
Research and development	14,442	15,992	55,698	56,805
Selling, general and administrative	23,411	20,891	67,555	64,102
<b>Total cost and expenses</b>	<u>47,887</u>	<u>52,437</u>	<u>153,804</u>	<u>167,041</u>
Income (loss) from operations	(5,015)	14,930	(35,607)	29,289
Interest and other income (expense), net	(512)	1,443	98	2,645
Income (loss) before provision for income tax	(5,527)	16,373	(35,509)	31,934
Provision for income tax	112	(2,200)	(992)	(4,680)
<b>Net income (loss)</b>	<u>\$ (5,415)</u>	<u>\$ 14,173</u>	<u>\$ (36,501)</u>	<u>\$ 27,254</u>
<b>Net income (loss) per share, basic</b>	<u>\$ (0.11)</u>	<u>\$ 0.30</u>	<u>\$ (0.76)</u>	<u>\$ 0.58</u>
<b>Net income (loss) per share, diluted</b>	<u>\$ (0.11)</u>	<u>\$ 0.29</u>	<u>\$ (0.76)</u>	<u>\$ 0.56</u>
Shares used in computing net income (loss) per share, basic	<u>48,040</u>	<u>47,438</u>	<u>47,842</u>	<u>47,237</u>
Shares used in computing net income (loss) per share, diluted	<u>48,040</u>	<u>48,611</u>	<u>47,842</u>	<u>48,624</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)**

	Nine months ended September 30,	
	2008	2007
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ (36,501)	\$ 27,254
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:		
Depreciation and amortization	9,215	7,803
Loss on disposal of property and equipment	—	3
Stock-based compensation expense	3,356	2,564
Excess tax benefits from stock-based compensation	—	(149)
Changes in operating assets and liabilities:		
Accounts receivable, inventory, prepaid expenses and other assets	15,641	(2,852)
Accounts payable and accrued liabilities	(3,338)	(2,817)
Reserve for product returns, rebates and chargebacks	(18,451)	4,214
Net cash provided (used) by operating activities	(30,078)	36,020
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(853)	(2,155)
Increase in other non-current assets	—	(2,012)
Increase in restricted cash	(15,000)	—
Purchase of product rights	—	(55,000)
Net cash used in investing activities	(15,853)	(59,167)
<b>Cash flows from financing activities</b>		
Net proceeds from convertible senior debt offering	57,266	—
Borrowings under credit facility	—	15,000
Principal payments on capital lease obligations	(904)	181
Excess tax benefits from stock-based compensation	—	149
Proceeds from issuance of common stock upon exercise of stock options	178	1,584
Net cash provided by financing activities	56,540	16,914
Net increase (decrease) in cash and cash equivalents	10,609	(6,233)
Cash and cash equivalents at beginning of period	111,272	76,465
Cash and cash equivalents at end of period	\$121,881	\$ 70,232

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

# SALIX PHARMACEUTICALS, LTD.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2008

(Unaudited)

### *1. Organization and Basis of Presentation*

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

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

The accompanying consolidated financial statements include all adjustments that, in the opinion of management, are necessary for a fair presentation of financial position, results of operations and cash flows. The results of operations for interim periods are not necessarily indicative of results to be expected for a full year or any future period. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been omitted in accordance with the SEC’s rules and regulations for interim reporting.

### *2. Revenue Recognition*

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

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

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

The Company establishes allowances for estimated rebates, chargebacks and product returns based on numerous 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 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 that might 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 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 the Company implements a price increase, it generally offers its 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, the Company recognizes the related revenue upon shipment and includes the shipments in estimating its 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 \$5.4 million and \$10.4 million as of September 30, 2008 and 2007, respectively. The balance at September 30, 2008 excludes amounts related to Colazal, which are included in the reserves discussed below. 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

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

chargebacks, 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.

Allowances for product returns were \$6.0 million and \$7.9 million as of September 30, 2008 and 2007, respectively. The balance at September 30, 2008 excludes amounts related to Colazal, which are included in the reserve discussed below. These allowances reflect an estimate of the Company's liability for product that may be returned by the original purchaser in accordance with the Company's stated return policy. The Company estimates its liability for product returns at each reporting period based on historical return rates, the estimated inventory in the channel, and 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 estimates are within a reasonable range and also reviews prior period activity to ensure the Company's methodology is still reasonable.

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, 2008 and 2007 was 6.5% and 9.7% for rebates, chargebacks, and discounts, and 6.0% and 3.2%, for product returns, respectively. The percentages for the nine-month period ended September 30, 2008 exclude data related to Colazal.

Colazal, the Company's balsalazide disodium capsule, historically accounted for a majority of the Company's revenue. 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. In the fourth quarter of 2007, the Company recorded a \$34.6 million reserve, which was 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. At September 30, 2008, this liability was \$23.2 million. The decrease in this reserve is a result of returns, chargebacks and rebates related to Colazal, offset by an increase in the reserve of \$2.0 million and \$2.8 million for the three-month and nine-month periods ended September 30, 2008. 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, actual return activity, estimated chargeback and rebate activity based on price erosion as a result of the generic approvals, 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 and also reviews prior period activity to ensure that the Company's methodology is still reasonable.

### *3. Commitments*

#### *Purchase Order Commitments*

At September 30, 2008, the Company had binding purchase order commitments for inventory purchases expected to be delivered over the next 6 months aggregating approximately \$21.4 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 Dr. Falk Pharma GmbH for mesalamine granules— 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, 2008, the Company had paid \$3.0 million of milestone payments. The Company received marketing approval from the FDA for mesalamine granules on October 31, 2008, and as a result a \$6 million milestone payment became due. The remaining milestone payment is contingent upon an additional regulatory approval.

License and Supply Agreement with Norgine B.V. — In December 2005, the Company entered into a license and supply agreement with Norgine for the rights to sell NRL944, a bowel cleansing product the Company now markets in the United States under the trade name MoviPrep. Pursuant to the terms of this agreement, the Company

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

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, 2008, the Company had paid \$17.0 million of milestone payments. The remaining milestone payments are contingent upon reaching sales thresholds.

License and Supply Agreement with the Debiopharm Group – In September 2006, the Company acquired the exclusive right to sell, market and distribute vapreotide acetate in the United States. Pursuant to the terms of this agreement, the Company is obligated to make upfront and milestone payments to Debiopharm that could total up to \$14.0 million over the term of the agreement. As of September 30, 2008, the Company had paid \$0.5 million of milestone payments. On October 27, 2008, the new drug application for vapreotide acetate was accepted for filing by the FDA, and as a result a \$0.5 million milestone payment became due. The remaining milestone payments are contingent upon achievement of regulatory approval and reaching sales thresholds.

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 Wilmington Pharmaceuticals, LLC – In September 2007 the Company entered into an Exclusive Sublicense Agreement with Wilmington Pharmaceuticals to commercialize Metoclopramide — Zydys® worldwide. 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, 2008, the Company had paid \$1.0 million of these milestone payments. The remaining milestone payments are contingent upon regulatory approval. The Company also loaned Wilmington \$2.0 million, which is due on the earlier of December 31, 2009, or regulatory approval.

License Agreement with Dr. Falk Pharma GmbH for budesonide— In March 2008, the Company entered into a License Agreement with Dr. Falk Pharma GmbH. The agreement provides the Company with an exclusive license to develop and commercialize in the United States Dr. Falk Pharma’s budesonide products. The products covered in the License Agreement include U.S. patent-protected budesonide rectal foam and budesonide gastro-resistant capsule, patents for which expire in 2015 and 2016, respectively. Pursuant to the license agreement the Company is obligated to make an upfront payment and regulatory milestone payments that could total up to \$23.0 million to Dr. Falk Pharma, with the majority contingent upon achievement of U.S. regulatory approval. As of September 30, 2008, the Company had paid \$1.0 million of these milestone payments.

#### *4. Fair Value of Financial Instruments*

The Company adopted SFAS No. 157, “Fair Value Measurements”, as of January 1, 2008. SFAS No. 157 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. SFAS No. 157 applies to all assets and liabilities that are being measured and reported on a fair value basis. SFAS No. 157 requires new disclosure that establishes a framework for measuring fair value in GAAP, and expands disclosure about fair value measurements. This statement enables the reader of the financial statements to assess the inputs used to develop those measurements by establishing a hierarchy for ranking the quality and reliability of the information used to determine fair values. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy under SFAS No. 157 are described below:

##### Basis of Fair Value Measurement

- |         |   |
|---------|---|
| Level 1 | Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.             |
| Level 2 | Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly. |
| Level 3 | Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.                                    |

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

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Cash equivalents are financial instruments that are subject to SFAS No. 157. These instruments are valued based on level 1 measurements. There is no unrealized gain or loss related to these instruments.

The adoption of SFAS No. 157 did not have a material effect on the Company's consolidated financial statements. In February 2008, the FASB issued FASB Staff Position ("FSP") No. FAS 157-2, "Effective Date of FASB Statement No 157", which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on at least an annual basis, to years beginning after November 15, 2008. The Company adopted FSP No. FAS 157-2 and deferred the application of SFAS No. 157 to goodwill and product rights and intangibles, net until January 1, 2009.

*5. Cash and Cash Equivalents*

The Company considers all highly liquid investments with maturities of three months or less from date of purchase 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, 2008, cash and cash equivalents consisted primarily of demand deposits, overnight investments in Eurodollars, and money market funds at reputable financial institutions and did not consist of 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 generic and other competition. Inventory at September 30, 2008 consisted of \$13.4 million of raw materials, \$4.1 million of work-in-process and \$5.6 million of finished goods.

Inventory of \$6.6 million is related to balsalazide disodium tablets which are not currently approved for marketing by the US Food and Drug Administration, or FDA. The Company filed a New Drug Application, or NDA, for this product with the FDA in July 2007, and received an approvable letter from the FDA on May 16, 2008. The Company submitted a response to the approvable letter on June 30, 2008. The FDA has up to six months to review the submission so the Company expects a response from the FDA by December 30, 2008. Inventory of \$1.3 million is related to mesalamine granules which are not currently approved for marketing by the FDA. The Company filed a NDA for this product with the FDA in December 2007. The FDA has up to ten months to review the submission so the Company expects a response from the FDA by October 31, 2008.

Inventory at December 31, 2007 consisted of \$7.5 million of raw materials, \$3.6 million of work-in-process and \$6.6 million of finished goods. As of September 30, 2008, inventory reserves totaling \$0.6 million, compared to \$0.8 million as of December 31, 2007, 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.

When the Company makes product acquisitions that include license agreements, product rights and other identifiable intangible assets, it records the purchase price of those 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

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

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 their estimated economic useful life. In accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long Lived Assets", the Company assesses the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. The Company believes that the following factors could trigger an impairment review: significant underperformance relative to historical or projected future operating results; significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business; and significant negative industry or economic trends.

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

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

In November 2003, the Company acquired from aaiPharma LLC for \$2.0 million the exclusive right to sell 25, 75 and 100 milligram dosage strengths of azathioprine tablets in North America under the name Azasan. The purchase price was fully allocated to product rights and related intangibles and is being amortized over a period of ten years. Although Azasan does not have any patent protection, the Company believes ten years is an appropriate amortization period based on established product sales history and management experience. At September 30, 2008, accumulated amortization for the Azasan intangible was \$1.0 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 experience. At September 30, 2008, accumulated amortization for the King product intangibles was \$5.5 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 decrease in goodwill during the three-month and nine-month periods ended September 30, 2008 and 2007 was a result of the use of net operating income tax loss carryforwards generated by InKine prior to its acquisition by the Company. 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 products' patent protection and the estimated economic lives of the product rights and related intangibles. At September 30, 2008, accumulated amortization for the InKine intangibles was \$9.0 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 patent-protected, liquid PEG bowel cleansing product, NRL944, in the United States. Upon execution of the Agreement, the Company made a \$2.0 million payment to Norgine. In August 2006, the Company received FDA marketing approval for NRL944 under the branded name of MoviPrep and as a result Salix made a \$15.0 million payment to Norgine. The Company is amortizing the payment 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, 2008, accumulated amortization for the MoviPrep intangible was \$1.9 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 any patent protection, the Company believes 15 years is an appropriate amortization period based on established product history and management experience. At September 30, 2008, accumulated amortization for the Merck products was \$6.0 million.

*8. Credit Facility*

In February 2007, the Company entered into a \$100.0 million revolving credit facility that matures in February 2012. On August 4, 2008 the credit facility was amended to waive defaults that may have arisen as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007 and the credit facility was reduced to \$20.0 million. As a result of the execution of the amendment to our credit facility on August 4, 2008, the Company recorded a \$1.1 million non-cash charge to expense a portion of the unamortized costs related to the credit facility under EITF No. 98-14, "Debtor's Accounting for Changes in Line-of-Credit or Revolving-Debt Arrangements". 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, 2008, \$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. 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 the Company's option, either (a) a base rate equal to the higher of (i) the Federal Funds Rate plus  $\frac{1}{2}$  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, 2008, restricted cash of \$15.0 million represents the collateral on deposit with the Administrative Agent related to the credit facility. At September 30, 2008 the Company was in compliance with applicable covenants under the credit facility.

The credit facility contains various representations, warranties and affirmative, negative and financial covenants customary for financings of this type.

*9. Convertible Senior Notes*

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

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

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

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

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

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

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

#### *10. Research and Development*

In accordance with its policy, the Company expenses research and development costs, both internal and externally contracted, as incurred. Effective January 1, 2008 the Company adopted EITF No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities". Adoption of EITF No. 07-3 did not have a material effect on the Company's consolidated financial position, results of operations or cash flows.

#### *11. Comprehensive Income*

SFAS No. 130, "Reporting Comprehensive Income", requires that the Company display an amount representing comprehensive income (loss) for the year in a financial statement, which is displayed with the same prominence as other financial statements. Other comprehensive income (loss) includes foreign currency translation gains and losses, as well as any unrealized gains and losses on investments. For the periods presented, there was no other comprehensive income or loss.

#### *12. Stock-Based Compensation*

At September 30, 2008, the Company had one active share-based compensation plan, the 2005 Stock Plan, allowing for the issuance of stock options and restricted shares. Awards granted from this plan are granted at the fair market value on the date of grant, and vest over periods ranging from one to four years.

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

Starting in 2006, the Company began issuing restricted shares to employees, executive officers and directors of the Company. The restrictions on the restricted stock granted to date to employees and executive officers of the Company, generally lapse 25% annually over four years, or 33% over three years. For board members of the Company, restrictions on annual grants lapse 100% after one year and restrictions on an initial grant made to a new board member lapse 33% annually over 3 years. The Company estimates the fair value of the restricted stock using an assumed forfeiture rate of 7.8% and expenses this fair value on a straight-line basis over the period during which the restrictions lapse. Each quarter, the Company adjusts this fair value based on actual forfeitures. For the nine-month periods ended September 30, 2008 and 2007 the Company recognized \$3.4 million and \$2.6 million, respectively, in share based-compensation expense related to the restricted shares. For the three-month periods ended September 30, 2008 and 2007 the Company recognized \$1.5 million and \$0.6 million, respectively, in share based-compensation expense related to the restricted shares. As of September 30, 2008, the total amount of unrecognized compensation cost related to nonvested restricted stock awards, to be recognized as expense subsequent to September 30, 2008, was approximately \$13.9 million, and the related weighted-average period over which the Company expects to recognize it is approximately 2.53 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, 2007	611,253	5,214,529	\$ 14.03	1,123,199	\$ 12.68	6,337,728	\$ 13.80
Granted	(963,019)	—	—	963,019	\$ 7.05	963,019	\$ 7.05
Exercised	—	(58,189)	\$ 3.06	—	—	(58,189)	\$ 3.06
Vested	—	—	—	(280,633)	\$ 12.70	(280,633)	\$ 12.70
Additional shares authorized	837,311	—	—	—	—	—	—
Cancelled	315,322	(471,492)	\$ 18.42	(129,284)	\$ 12.59	(600,776)	\$ 17.16
Balance at September 30, 2008	<u>800,867</u>	<u>4,684,848</u>	<u>\$ 13.73</u>	<u>1,676,301</u>	<u>\$ 9.45</u>	<u>6,361,149</u>	<u>\$ 12.60</u>

For the nine-month period ended September 30, 2008, 0.1 million shares of the Company's outstanding stock at a value of \$0.4 million were issued upon the exercise of options. The Company recognized no share-based compensation expense for stock options during the nine-month period ended September 30, 2008, nor any income tax benefit. The total intrinsic value of options exercised during the nine-month period ended September 30, 2008 was \$0.2 million. As of September 30, 2008, there was no unrecognized share-based compensation cost as all stock options were fully vested. Cash received from stock option exercises was \$0.2 million during the nine-month period ended September 30, 2008.

### 13. Income Taxes

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

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

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

On January 1, 2007, the Company adopted the provisions of FIN 48. As a result of applying the provisions of FIN 48, the Company recognized an increase of \$2.4 million in the liability for unrecognized tax benefits and a reduction in the valuation allowance as of January 1, 2007, for the same amount. The unrecognized tax benefits as of January 1, 2008 relate to federal tax credit carryforwards. During the third quarter of 2008, the FIN 48 reserve increased by \$18.4 million related to timing items which will be offset by net operating losses upon ultimate settlement. As a result, a corresponding deferred tax asset related to net operating losses was also recognized. It is anticipated that the FIN 48 reserve generated during the third quarter of 2008 will reverse in the fourth quarter of 2008. This reversal is not expected to have a significant impact on the results of operations, cash flows or the financial position of the Company. 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 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 Internal Revenue Service has commenced an examination of the Company's U.S. income tax return for 2005. The Company anticipates that any adjustments as a result of this examination would not be material to its financial position.

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, 2008 and 2007, 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 period and nine-month periods ended September 30, 2008 was 2.0% and (2.8)%, respectively, due to the utilization of acquisition-related deferred tax assets. The Company's effective tax rate for the three-month period and nine-month periods ended September 30, 2007 was 13.4% and 14.7%, respectively, due to the utilization of net operating loss carry-forwards. The Company re-evaluates this estimate each quarter based on the Company's estimated tax expense for the year.

#### *14. Net Income per Share*

The Company computes net income (loss) per share in accordance with SFAS No. 128, "Earnings Per Share" ("SFAS 128"). Under the provisions of SFAS 128, basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares and dilutive common share equivalents then outstanding. Common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and the impact of unvested restricted stock grants. Under the provisions of SFAS 128, the Company will account for the effect of the convertible Notes on diluted net income (loss) per share using the treasury stock method. As a result, the convertible Notes will have no effect on diluted net income (loss) per share until the Company's stock price exceeds the conversion price of \$9.25 per share. For the three-month and nine-month periods ended September 30, 2008, the effect of approximately 6,486,000 shares that may be issued upon conversion of the Notes were excluded from the diluted net income per share calculation.

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

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

	<u>Three months ended</u> <u>September 30,</u>		<u>Nine months ended</u> <u>September 30,</u>	
	<u>2008</u>	<u>2007</u>	<u>2008</u>	<u>2007</u>
<b>Numerator:</b>				
Net income (loss)	\$(5,415)	\$14,173	\$(36,501)	\$27,254
<b>Denominator:</b>				
Weighted average common shares, basic	48,040	47,438	47,842	47,237
Dilutive effect of stock options	—	1,100	—	1,238
Dilutive effect of restricted stock	—	73	—	149
<b>Weighted average common shares, diluted</b>	<b><u>48,040</u></b>	<b><u>48,611</u></b>	<b><u>47,842</u></b>	<b><u>48,624</u></b>

For the three-month and nine-month periods ended September 30, 2008, weighted average common shares, diluted are equal to weighted average common shares, basic, because inclusion of the 704,290 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 nine-month periods ended September 30, 2008 and 2007, there were 4,672,691 and 3,883,644 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 three-month periods ended September 30, 2008 and 2007, there were 4,268,962 and 3,903,595, respectively, potential common shares outstanding that were excluded from the diluted net income per share calculation because their effect would have been anti-dilutive.

*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>2008</u>	<u>2007</u>	<u>2008</u>	<u>2007</u>
Colazal	\$(1,266)	\$31,128	\$ 79	\$ 92,380
Xifaxan	21,373	16,101	56,132	47,277
Purgatives – Moviprep/OsmoPrep/Visicol	15,531	12,120	41,506	34,567
Other – Anusol/Azasan/Diuril/Pepcid/Proctocort	7,234	8,006	20,480	19,594
<b>Net product revenues</b>	<b><u>\$42,872</u></b>	<b><u>\$67,355</u></b>	<b><u>\$118,197</u></b>	<b><u>\$193,818</u></b>

*16. Recently Issued Accounting Pronouncements*

In December 2007, the FASB issued SFAS No. 141 (revised 2007) “Business Combinations” (“SFAS 141R”). SFAS 141R is effective for fiscal years beginning on or after December 15, 2008, which means that the Company will adopt SFAS 141R in our fiscal year 2009. SFAS 141R replaces SFAS 141 “Business Combinations” and requires that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations, as well as for an acquirer to be identified for each business combination. SFAS 141R establishes principles and requirements for how the acquirer: (i) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree; (ii) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and (iii) determines what information to disclose to enable users of financial statements to evaluate the nature and financial effects of the business combination.

In December 2007, the FASB issued SFAS No. 160 “Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51” (“SFAS 160”). SFAS 160 is effective for fiscal years beginning on or after December 15, 2008, which means that the Company will adopt SFAS 160 in our fiscal year 2009. This statement amends ARB 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 changes accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity in the Consolidated Financial Statements. SFAS 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements of SFAS 160 shall be applied prospectively. The Company does not believe the adoption of SFAS 160 will have a material impact on the Company’s consolidated financial position, results of operations and cash flows.

In May 2008, the FASB issued FASB Staff Position (“FSP”) No. APB 14-1, “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (including Partial Cash Settlement)” which is effective for financial statements issued for fiscal years beginning after December 15, 2008, and early adoption is not permitted. Upon adoption, this FSP will be applied retrospectively to all periods presented and the cumulative effect of the change in accounting principle on periods prior to those presented will be recognized as of the beginning of the first period presented. This FSP applies to convertible debt instruments that may be settled in cash and requires separate accounting for the liability and equity components of the convertible debt. The Company is currently evaluating the impact of the adoption of this FSP. The Company’s convertible Notes may be settled in cash, as a result, upon adoption of the FSP on January 1, 2009, the Company will be required to separately account for the liability and equity components of the convertible debt instrument by allocating the proceeds from issuance of the instrument between the liability component and the embedded conversion option, or equity component. This allocation will be done by first determining the fair value of similar Notes that do not include the embedded conversion option, which equals the liability component. The excess of the initial proceeds received from the convertible Notes over the amount allocated to the liability component will be allocated to the embedded conversion option, or equity component. This excess will be 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. This will result in interest expense for periods subsequent to adoption related to the convertible debt in excess of the coupon rate of 5.5%.

*17. Legal Proceedings*

Norgine, B.V. and Norgine Europe, B. V. own U.S. Patent No. 7,169,381. The ‘381 patent is listed with the United States Food and Drug Administration as protecting the Company’s 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 1, 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 and seeking a declaratory judgment confirming the validity of the patent. Novel filed an Answer and Counterclaim on June 20, 2008. No trial date has been set.

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

Net sales of MoviPrep were \$20.1 million in 2007. As of September 30, 2008, the Company had net intangible assets related to MoviPrep of \$13.2 million. If a generic version of MoviPrep enters the market, the Company may have to write off a portion or all of these intangible assets, and the Company's business, financial condition, results of operations and cash flows could be materially adversely affected.

CDC, LLC, owns U.S. Patent No. 5,616,346. The '346 patent is listed with the United States Food and Drug Administration as protecting the Company's OsmoPrep product. CDC licensed OsmoPrep and the '346 patent to the Company for commercialization in the United States. Novel Laboratories, Inc., filed an ANDA with the FDA seeking approval to market a generic version of OsmoPrep in the United States prior to the May 18, 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 and seeking a declaratory judgment confirming the validity of the patent. The lawsuit also joins CDC as a party. No trial date has been set.

Net sales of OsmoPrep were \$25.4 million in 2007. As of September 30, 2008, the Company had net intangible assets related to OsmoPrep of \$28.0 million. If a generic version of OsmoPrep enters the market, the Company may have to write off a portion or all of these intangible assets, and the Company's business, financial condition, results of operations and cash flows could be materially adversely affected.

On or about September 22, 2008, the Company received a product liability lawsuit claiming that OsmoPrep allegedly caused acute renal failure leading to permanent damage and loss of consortium. The lawsuit is currently in the early stages and the Company is unable to predict an outcome. The Company maintains product liability insurance for product liability claims.

*18. Subsequent Events*

The Company received marketing approval from the FDA for mesalamine granules on October 31, 2008.

On October 27, 2008, the NDA for vapreotide acetate was accepted for filing by the FDA.

## 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, 2007, 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 diseases, 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 150-member specialty sales and marketing team focused on high-prescribing U.S. gastroenterologists to sell our products.

Our current products demonstrate our ability to execute this strategy. As of September 30, 2008, our primary products were:

- XIFAXAN® (rifaximin) Tablets 200 mg;
- OSMOPREP® (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets;
- MOVIPREP® (PEG 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate and Ascorbic Acid for Oral Solution);
- VISICOL® (sodium phosphate monobasic monohydrate, USP, and sodium phosphate dibasic anhydrous, USP) Tablets;
- AZASAN® Azathioprine Tablets, USP, <sup>75</sup>/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); and
- COLAZAL® (balsalazide disodium) Capsules 750 mg.

We currently market our products, and intend, if approved by the FDA, to market future products to U.S. gastroenterologists and other physician targets through our own direct sales force. We enter into distribution relationships outside the United States and in certain markets in the United States where a larger sales organization is appropriate. Currently, our sales and marketing staff consists of approximately 150 people.

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. 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. For example, wholesalers made initial stocking purchases of OsmoPrep when it was launched in the second quarter of 2006 and Moviprep when it was launched in the third quarter of 2006.

In December 2000, we established our own field sales force to market Colazal in the United States. Currently, this sales force has approximately 100 sales representatives in the field and markets our currently 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. In addition, we intend to enter into distribution relationships outside the United States and in markets in the United States where a larger sales organization is appropriate.

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

<u>Compound</u>	<u>Indication</u>	<u>Status</u>
Balsalazide disodium tablets	Ulcerative colitis	Approvable Letter Received
Mesalamine granules	Ulcerative colitis	Marketing approval received October 31, 2008
Rifaximin	Hepatic encephalopathy	Phase III
Rifaximin	Irritable bowel syndrome	Phase III
Rifaximin	<i>C. difficile</i> -associated diarrhea	Phase III
Rifaximin	Travelers' diarrhea prevention	Phase III
Vapreotide acetate	Acute esophageal variceal bleeding	NDA filed October 27, 2008
Metaclopramide - Zydys <sup>®</sup>	Gastroparesis and refractory gastroesophageal reflux	NDA filed

On May 16, 2008 we received an approvable letter from the FDA for balsalazide disodium tablets. We submitted a response to the approvable letter on June 30, 2008. The FDA has up to six months to review the submission so we expect a response from the FDA by December 30, 2008.

### **Critical Accounting Policies**

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, 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, chargebacks and coupons, inventory, intangible assets and goodwill, allowance for uncollectible accounts, investments, 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, 2008. We did not make any changes in those policies during the quarter.

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

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

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

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

In our analyses, we use prescription data purchased from a third-party data provider to develop estimates of historical inventory channel pull-through. We utilize an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, we develop an estimate of the quantity of product in the channel that might be subject to various rebate, chargeback and product return exposures. At least quarterly for each product line, we prepare an internal estimate of ending inventory units in the distribution channel by adding estimated inventory in the channel at the beginning of the period, plus net product shipments for the period, less estimated prescriptions written for the period. Based on that analysis, we develop an estimate of the quantity of product in the channel that might be subject to various rebate, chargeback and product return exposures. This is done for each product line by applying a rate of historical activity for rebates, chargebacks and product returns, adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product

estimated to be in the distribution channel. Internal forecasts that are utilized to calculate the estimated number of months in the channel are regularly adjusted based on input from members of our sales, marketing and operations groups. The adjusted forecasts take into account numerous factors including, but not limited to, new product introductions, direct communication with customers and potential product expiry issues.

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

Allowances for estimated rebates and chargebacks were \$5.4 million and \$10.4 million as of September 30, 2008 and 2007, respectively. The balance at September 30, 2008 excludes 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 and also review prior period activity to ensure that our methodology is still reasonable. Had a change in one or more variables in the analyses (utilization rates, contract modifications, etc.) resulted in an additional percentage point change in the trailing average of estimated chargeback and rebate activity in 2007, we would have recorded an adjustment to revenues of approximately \$3.1 million, or 1.0%, for the year.

Allowances for product returns were \$6.0 million and \$7.9 million as of September 30, 2008 and 2007, respectively. The balance at September 30, 2008 excludes amounts related to Colazal, which are included in the reserve discussed below. 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. 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 and also 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, 2007 of approximately \$4.5 million and a corresponding change in 2007 net product revenue of less than 2.0%.

Colazal, our balsalazide disodium capsule, historically accounted for a majority of the Company's revenue. 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. In the fourth quarter of 2007, the Company recorded a \$34.6 million reserve, which is 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. At September 30, 2008 the reserve balance was \$23.2 million. The decrease in this reserve is a result of returns, chargebacks and rebates related to Colazal, offset by an increase in the reserve of \$2.0 million and \$2.8 million for the three-month and nine-month periods ended September 30, 2008. 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 subsequent to the generic approvals;
- our estimate of potential reduction of Colazal demand by our 1100mg balsalazide tablets if approved by the FDA;
- our estimate of chargeback and rebate activity based on price erosion as a result of the generic approvals;
- our estimate of the generic market that will be obtained by Watson, our authorized generic distributor; 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 \$8.2 million and a corresponding change in 2007 net product revenue of approximately 3.5%. A change in assumptions that resulted in a 10% change in the estimated future demand of Colazal would have resulted in a change in the Colazal return reserve of approximately \$2.6 million and a corresponding change in 2007 net product revenue of approximately 1.1%.

For the nine-month periods ended September 30, 2008 and 2007, 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. 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, 2008 and 2007 was 6.5% and 9.7% for rebates, chargebacks and discounts and was 6.0% and 3.2% for product returns, respectively. The percentages for the nine-month period ended September 30, 2008 exclude data related to Colazal.

## Results of Operations

*Three-month and Nine-month Periods Ended September 30, 2008 and 2007*

### Revenues

The following table summarizes net product revenues by product for the three-month and nine-month periods ended September 30, 2008 and 2007:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Colazal	\$ (1,266)	\$31,128	\$ 79	\$ 92,380
<i>% of net product revenues</i>	<i>(3 )%</i>	<i>46 %</i>	<i>— %</i>	<i>48 %</i>
Xifaxan	21,373	16,101	56,132	47,277
<i>% of net product revenues</i>	<i>50 %</i>	<i>24 %</i>	<i>48 %</i>	<i>24 %</i>
Purgatives – Moviprep/OsmoPrep/Visicol	15,531	12,120	41,506	34,567
<i>% of net product revenues</i>	<i>36 %</i>	<i>18 %</i>	<i>35 %</i>	<i>18 %</i>
Other – Anusol/Azasan/Diuril/Pepcid/Proctocort	7,234	8,006	20,480	19,594
<i>% of net product revenues</i>	<i>17 %</i>	<i>12 %</i>	<i>17 %</i>	<i>10 %</i>
Net product revenues	<u>\$42,872</u>	<u>\$67,355</u>	<u>\$118,197</u>	<u>\$193,818</u>

Net product revenues for the three-month period ended September 30, 2008 were \$42.9 million, compared to \$67.4 million for the corresponding three-month period in 2007, a 36% decrease. The net product revenue decrease for the three-month period ended September 30, 2008 compared to the three-month period ended September 30, 2007 was primarily due to a decrease in sales of Colazal as a result of the approval of three generic balsalazide capsule products on December 28, 2007, and slightly lower sales of Pepcid, partially offset by:

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

Prescription growth for the three-month period ended September 30, 2008 compared to the corresponding three-month period in 2007 was 10% for Xifaxan and 13% for our purgatives.

Net product revenues for the nine-month period ended September 30, 2008 were \$118.2 million, compared to \$193.8 million for the corresponding nine-month period in 2007, a 39% decrease. The net product revenue decrease for the nine-month period ended September 30, 2008 compared to the nine-month period ended September 30, 2007 was primarily due to a decrease in sales of Colazal as a result of the approval of three generic balsalazide capsule products on December 28, 2007, and an increase in the return reserve for Visicol as a result of an unexpected large return from a small wholesaler, partially offset by:

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

Prescription growth for the nine-month period ended September 30, 2008 compared to the corresponding nine-month period in 2007 was 8% for Xifaxan and 16% for our purgatives.

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, 2008 was \$23.2 million. This reserve represents an estimate of the Company's liability for Colazal that may be returned by the original purchaser in accordance with the Company's stated return policy as a result of these generic approvals. This estimate was developed based on the following estimates:

- our estimate of the quantity and expiration dates of Colazal inventory in the distribution channel based on historical net product shipments less estimated historical prescriptions written;
- our estimate of future demand for Colazal based on the actual erosion of product demand for several comparable products that were previously genericized, and the most recent demand for Colazal prior to the generic approvals;
- the actual demand for Colazal experienced during 2008 subsequent to the generic approvals;
- our estimate of potential cannibalization of Colazal demand by our 1100mg balsalazide tablet if approved by the FDA;
- our estimate of chargeback and rebate activity based on price erosion as a result of the generic approvals;

- our estimate of the generic market that will be obtained by Watson, our authorized generic partner; 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 \$8.2 million and a corresponding change in 2007 net product revenue of approximately 3.5%. A change in assumptions that resulted in a 10% change in the estimated future demand of Colazal would have resulted in a change in the Colazal return reserve of approximately \$2.6 million and a corresponding change in 2007 net product revenue of approximately 1.1%.

Revenues from collaborative agreements for the nine-month period ended September 30, 2007 consists of an upfront payment of \$1.5 million upon execution of an agreement to license exclusive rights to market DIACOL™ in 28 territories in Europe to Dr. Falk Pharma GmbH of Freiberg, Germany, and a \$1.0 million milestone payment from Zeria Pharmaceutical Co., Ltd. of Tokyo, Japan as a result of their receipt of marketing approval of Visiclear® Tablets for colon cleansing in Japan. Revenues from collaborative agreements for the three-month and nine-month periods ended September 30, 2007 include \$12,000 in royalty income from sales of Visicol under the trade name Visiclear® Zeria. We did not receive any revenues from collaborative agreements during the three-month period or nine-month period ended September 30, 2008.

### **Costs and Expenses**

Costs and expenses for the three-month period ended September, 30, 2008 were \$47.9 million, compared to \$52.4 million for the corresponding three-month period in 2007. Costs and expenses for the nine-month periods ended September 30, 2008 and 2007 were \$153.8 million and \$167.0 million, respectively. Lower operating expenses in absolute terms for the three-month and nine-month periods ended September 30, 2008 compared to the corresponding periods in 2007 were due primarily to decreased cost of products sold related to the corresponding decrease in product revenue.

#### *Cost of Products Sold*

Cost of products sold for the three-month period ended September 30, 2008 was \$7.8 million, compared with \$13.1 million for the corresponding three-month period in 2007. Cost of products sold for the nine-month period ended September 30, 2008 was \$22.1 million, compared with \$38.1 million for the corresponding nine-month period in 2007. The decrease in cost of products sold for the three-month and nine-month periods ended September 30, 2008 compared to the three-month and nine-month periods ended September 30, 2007 was due primarily to decreased sales of Colazal as a result of the approval of three generic balsalazide capsule products on December 28, 2007.

Gross margin on total product revenue, excluding \$2.3 million in amortization of product rights and intangible assets for the three-month periods ended September 30, 2008 and 2007, respectively, was 81.9% for the three-month period ended September 30, 2008 and 80.6% for the three-month period ended September 30, 2007. Gross margin on total product revenue, excluding \$6.8 million and \$6.4 million in amortization of product rights and intangible assets for the nine-month periods ended September 30, 2008 and 2007, respectively, was 81.3% for the nine-month period ended September 30, 2008 and 80.3% for the nine-month period ended September 30, 2007.

#### *Fees and Costs Related to License Agreements*

Fees and costs related to license agreements for the nine-month period ended September 30, 2008 consists of \$105,000 to obtain the Canadian rights to Visicol. In addition, fees and costs related to license agreements for the nine-month period ended September 30, 2008 consists of a \$0.5 million milestone payment to Wilmington Pharmaceuticals, and a \$1.0 million up-front payment to Dr. Falk Pharma for the exclusive license to develop and commercialize Dr. Falk Pharma's budesonide products in the United States. Fees and costs related to license agreements for the three-month period and nine-month period ended September 30, 2007 includes payments made to

Cedars-Sinai Medical Center under the terms of the related license agreement. Fees and costs related to license agreements for the nine-month period ended September 30, 2007 also include payment of \$1.1 million to Clinical Development Capital, the successor licensor of DIACOL™ and Visiclear®, for its share of the milestone revenue of \$2.5 million recognized during the nine-month period ended September 30, 2007.

#### *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 nine-month period ended September 30, 2008 compared to the corresponding periods in 2007 is primarily a result of the acquisition of Pepcid in February 2007.

#### *Research and Development*

Research and development expenses were \$14.4 million for the three-month period ended September 30, 2008, compared to \$16.0 million for the comparable period in 2007. Research and development expenses were \$55.7 million for the nine-month period ended September 30, 2008, compared to \$56.8 million for the comparable period in 2007. The decrease in research and development expenses for the three-month period ended September 30, 2008 compared to the corresponding period in 2007 is due to the substantial completion of our 1100mg balsalazide tablet and mesalamine granules programs during the first quarter of 2008, resulting in decreased spending on these programs in the three-month period ended September 30, 2008 compared to the three-month period ended September 30, 2007, partially offset by increased costs associated with ongoing late-stage studies to expand the Xifaxan label. The decrease for the nine-month period ended September 30, 2008 compared to the corresponding period in 2007 was due primarily to decreased spending in the second and third quarters of 2008 on our 1100mg balsalazide tablet and mesalamine granules programs substantially completed during the first quarter of 2008, partially offset by increased costs associated with ongoing late-stage studies to expand the Xifaxan label. Since inception, we have incurred research and development expenditures of approximately \$66.1 million for balsalazide, \$78.6 million for rifaximin and \$35.4 million for mesalamine granules.

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. Effective January 1, 2008 we adopted EITF No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities". EITF 07-3 states that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. Adoption of EITF No. 07-3 did not have a material effect on our consolidated financial position, results of operations or cash flows. We expect research and development costs to increase in absolute terms for the fourth quarter of 2008 compared to the third quarter of 2008, and for fiscal 2009, as we continue to pursue additional indications and formulations for rifaximin, initiate development for the budesonide product candidates we recently acquired from Dr. Falk, continue to develop mesalamine granules, and if and when we acquire new products.

#### *Selling, General and Administrative*

Selling, general and administrative expenses were \$23.4 million for the three-month period ended September 30, 2008, compared to \$20.9 million in the corresponding three-month period in 2007. Selling, general and administrative expenses were \$67.5 million for the nine-month period ended September 30, 2008, compared to \$64.1 million in the corresponding nine-month period in 2007. These increases were primarily due to an increase in marketing expenses for our purgative products and pre-marketing expenses for our balsalazide disodium tablets and mesalamine granules product, partially offset by a reduction in marketing expenses for Colazal in 2008 compared to 2007.

### **Interest and Other Income (Expense), Net**

Interest and other income (expense), net for the three-month periods ended September 30, 2008 and 2007 was (\$0.5) million and \$1.4 million, respectively. Interest and other income (expense), net for the three-month period ended September 30, 2008 consisted of \$0.1 million of interest expense on our credit facility, \$0.4 million of interest expense on our convertible Notes and a \$1.1 million non-cash charge to expense a portion of the unamortized costs related to the credit facility under EITF No. 98-14, "Debtor's Accounting for Changes in Line-of-Credit or Revolving-Debt Arrangements", offset by \$1.1 million of interest and other income. Interest and other income (expense), net for the three-month period ended September 30, 2007 consisted of \$1.2 million received as final settlement of a legal matter initiated by InKine prior to our acquisition of InKine, and \$0.4 million of interest income, offset by \$0.2 million of interest expense on our credit facility.

Interest and other income (expense), net for the nine-month periods ended September 30, 2008 and 2007 was \$0.1 million and \$2.6 million, respectively. Interest and other income (expense), net for the nine-month period ended September 30, 2008 consisted of \$0.6 million of interest expense on our credit facility, \$0.4 million of interest expense on our convertible Notes and the \$1.1 million non-cash charge to expense a portion of the unamortized costs related to the credit facility, offset by \$2.2 million of interest and other income. Interest and other income (expense), net for the nine-month period ended September 30, 2007 consisted of the \$1.2 million legal matter settlement and \$2.3 million of interest income, offset by \$0.9 million of interest expense on our credit facility.

The decrease in interest income for 2008 compared to 2007 is due primarily to lower interest rates on our investments in 2008, partially offset by higher cash and cash equivalent balances during 2008 as compared to 2007.

### **Provision for Income Tax**

Income tax expense (benefit) was (\$0.1) million for the three-month period ended September 30, 2008, compared to \$2.2 million in the corresponding three-month period in 2007. Income tax expense was \$1.0 million for the nine-month period ended September 30, 2008, compared to \$4.7 million in the corresponding nine-month period in 2007. Our effective tax rate was 2.0% and (2.8%) for the three-month and nine-month periods ended September 30, 2008, and 13.4% and 14.7% for the three-month and nine-month periods ended September 30, 2007. The change in effective rate is primarily due to the increased utilization of acquisition-related deferred tax assets in the three-month and nine-month periods ended September 30, 2008 as compared to the three-month and nine-month periods ended September 30, 2007.

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

Net loss was \$5.4 million for the three-month period ended September 30, 2008, compared to net income of \$14.2 million in the corresponding three-month period in 2007. Net loss was \$36.5 million for the nine-month period ended September 30, 2008, compared to net income of \$27.3 million in the corresponding nine-month period in 2007.

### **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 our first product, Colazal, in January 2001, net product revenue has been a source of cash. On August 22, 2008 we closed an offering of \$60 million in Convertible Senior Notes due 2028. Net proceeds from the offering were \$57.3 million. As of September 30, 2008, we had approximately \$121.9 million in cash and cash equivalents, compared to \$111.3 million as of December 31, 2007.

To date, the recent decline in the stock market, lack of credit availability, and financial institution difficulties have had a limited effect on our business. As a result of the closing of our convertible note offering in August 2008, we believe our cash and cash equivalent balances should be sufficient to satisfy our cash requirements for the foreseeable future. At September 30, 2008, cash and cash equivalents consisted primarily of demand deposits, 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 in any of our investments to date.

However, continued declines in the stock market and deterioration in the overall economy could lead to a decrease in demand for our marketed products, which could have an adverse effect on our business, financial condition and results of operations.

Net cash used by operating activities of \$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 provided by operating activities for the nine-month period ended September 30, 2007 of \$36.0 million was also primarily attributable to our net income for the period.

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 used in investing activities for the nine-month period ended September 30, 2007 of \$59.2 million was primarily related to the acquisition of Pepcid in February 2007.

Net cash provided 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. Net cash provided by financing activities for the nine-month period ended September 30, 2007 of \$16.9 million was primarily a result of borrowings under our credit facility entered into in February 2007, which helped fund our acquisition of Pepcid OS.

As of September 30, 2008, we had non-cancelable purchase order commitments for inventory purchases of approximately \$21.3 million over six months. We anticipate significant expenditures related to our on-going sales, marketing, product launch and development efforts associated with 1100mg balsalazide tablets, Xifaxan, Visicol, Azasan, Anusol-HC, Proctocort, OsmoPrep, MoviPrep, Pepcid Oral Suspension and mesalamine granules. To the extent we acquire rights to additional products or product candidates, we will incur additional expenditures.

Our contractual commitments for non-cancelable purchase commitments of inventory, minimum lease obligations for all non-cancelable operating leases, and minimum capital lease obligations (including interest) as of September 30, 2008 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	\$11,477	\$ 521	\$ 4,279	\$ 3,226	\$ 3,451
Purchase commitments	21,397	21,397	—	—	—
Capital lease obligations	1,770	272	1,364	134	—
Total	<u>\$34,644</u>	<u>\$22,190</u>	<u>\$ 5,643</u>	<u>\$ 3,360</u>	<u>\$ 3,451</u>

In February 2007, we entered into a \$100.0 million revolving credit facility that matures in February 2012. On August 4, 2008 the credit facility was amended to waive defaults that may have arisen as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007 and the credit facility was reduced to \$20.0 million. On August 22, 2008 the credit facility was further amended to allow us to issue the convertible Notes described below. At September 30, 2008, \$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  $\frac{1}{2}$  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, 2008 on our outstanding borrowings was 3.81%. 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 its balance sheet. At September 30, 2008, restricted cash of \$15.0 million represents the collateral on deposit with the Administrative Agent related to the credit facility. At September 30, 2008 we were in compliance with applicable covenants under the credit facility.

The credit facility contains various representations, warranties and affirmative, negative and financial covenants customary for financings of this type.

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

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

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

As of September 30, 2008, we had an accumulated deficit of \$141.2 million and cash and cash equivalent balances of \$121.9 million. We expect to be unprofitable and experience negative cash flow during 2008, due to the approval of three generic balsalazide capsule products on December 28, 2007. 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: FDA and foreign regulatory processes; the status of competitive products, including potential generics; intellectual property risks; the actual amount of Colazal returns we receive compared to our current estimates; our ability to maintain our current credit facility; our success selling products; the results of research and development activities; establishment of and change in collaborative relationships; technological advances by us and other pharmaceutical companies; and whether we acquire rights to additional products. If we incur more debt, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. If we issue additional equity, our stockholders could suffer dilution. We might also enter into additional collaborative arrangements that could provide us with additional funding in the form of equity, debt, licensing,

milestone and/or royalty payments. We might not be able to enter into such arrangements or raise any additional funds on terms favorable to us or at all.

### **Cautionary Statement**

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. The following statement highlights some of these risks. For more detail, see “Part I. Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2007.

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: our need to return to profitability; our dependence on a limited number of products, particularly Xifaxan and our bowel cleansing products; the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties; results of future litigation; intense competition, including potential 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; 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 other risk factors detailed from time to time in our other SEC filings.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

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

### **Item 4. Controls and Procedures**

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

There was no change in our internal control over financial reporting in the quarter ended September 30, 2008 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

Norgine, B.V. and Norgine Europe, B. V. own U.S. Patent No. 7,169,381. The '381 patent is listed with the United States Food and Drug Administration 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 1, 2024 expiration of the '381 patent. On May 14, 2008, we, together with Norgine, filed a lawsuit in the United States District Court for the District of New Jersey against Novel for infringement of the '381 patent and seeking a declaratory judgment confirming the validity of the patent. Novel filed an Answer and Counterclaim on June 20, 2008. No trial date has been set.

CDC, LLC, owns U.S. Patent No. 5,616,346. The '346 patent is listed with the United States Food and Drug Administration as protecting our OsmoPrep product. CDC licensed OsmoPrep and the '346 patent to us for commercialization in the United States. Novel Laboratories, Inc., filed an ANDA, with the FDA seeking approval to market a generic version of OsmoPrep in the United States prior to the May 18, 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 and seeking a declaratory judgment confirming the validity of the patent. The lawsuit also joins CDC as a party. No trial date has been set.

On about September 22, 2008, we received a product liability lawsuit filed in Hamilton County, Tennessee, claiming that OsmoPrep allegedly caused acute renal failure leading to permanent damage and loss of consortium. We are currently in the early stages of the lawsuit and are unable to predict an outcome. The Company maintains product liability insurance for product liability claims.

### 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>
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

**SIGNATURES**

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

SALIX PHARMACEUTICALS, LTD.

Date: November 6, 2008

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

Date: November 6, 2008

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







