

SALIX PHARMACEUTICALS LTD

Form 10-Q

May 10, 2005

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2005

or

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

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

Commission file number: 000-23265

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**SALIX PHARMACEUTICALS, LTD.**

(Exact name of Registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of

94-3267443  
(I.R.S. Employer

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incorporation or organization)

Identification No.)

**8540 Colonnade Center Drive, Suite 501**

**Raleigh, North Carolina 27615**

(Address of principal executive offices, including zip code)

**(919) 862-1000**

(Registrant's telephone number, including area code)

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

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

The number of shares of the Registrant's Common Stock outstanding as of May 5, 2005 was 36,657,721.

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

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

	March 31, 2005	December 31, 2004
	_____	_____
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 30,619	\$ 48,108
Short-term investments	4,000	4,000
Accounts receivable, net	26,756	10,457
Inventory, net	28,453	26,655
Prepaid and other current assets	2,485	1,871
	_____	_____
Total current assets	92,313	91,091
Property and equipment, net	2,215	2,281
Intangible and other assets, net	14,111	14,492
	_____	_____
Total assets	\$ 108,639	\$ 107,864
	_____	_____
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,246	\$ 4,306
Accrued liabilities	15,607	16,871
	_____	_____
Total current liabilities	17,853	21,177
Commitments and contingencies		
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, 36,622,090 shares issued and outstanding at March 31, 2005 and 36,514,648 shares issued and outstanding at December 31, 2004	37	37
Additional paid-in capital	171,954	171,214
Accumulated other comprehensive loss	(676)	(676)
Accumulated deficit	(80,529)	(83,888)
	_____	_____
Total stockholders' equity	90,786	86,687
	_____	_____
Total liabilities and stockholders' equity	\$ 108,639	\$ 107,864
	_____	_____

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



**Table of Contents****SALIX PHARMACEUTICALS, LTD.****CONSOLIDATED STATEMENTS OF OPERATIONS****(unaudited)****(U.S. Dollars, in thousands, except per share data)**

	<b>Three months ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Revenues:</b>		
Net product revenues	\$ 28,810	\$ 19,859
<b>Total revenues</b>	<b>28,810</b>	<b>19,859</b>
<b>Operating costs and expenses:</b>		
Cost of products sold (excluding \$381 of amortization of product rights in 2005)	6,748	4,696
License fees and costs related to collaborative agreements		31
Amortization of intangible assets	381	
Research and development	4,285	4,955
Selling, general and administrative	14,193	12,768
<b>Total operating cost and expenses</b>	<b>25,607</b>	<b>22,450</b>
<b>Income (loss) from operations</b>	<b>3,203</b>	<b>(2,591)</b>
Interest, and other income (expense), net	249	166
<b>Income (loss) before income tax</b>	<b>3,452</b>	<b>(2,425)</b>
Income tax expense	93	
<b>Net income (loss)</b>	<b>\$ 3,359</b>	<b>\$ (2,425)</b>
<b>Net income (loss) per share, basic</b>	<b>\$ 0.09</b>	<b>\$ (0.07)</b>
<b>Net income (loss) per share, diluted</b>	<b>\$ 0.09</b>	<b>\$ (0.07)</b>
<b>Shares used in computing net income (loss) per share, basic</b>	<b>36,551</b>	<b>35,775</b>
<b>Shares used in computing net income (loss) per share, diluted</b>	<b>38,698</b>	<b>35,775</b>

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

**Table of Contents****SALIX PHARMACEUTICALS, LTD.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited)****(U.S. dollars, in thousands)**

	<b>Three months ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ 3,359	\$ (2,425)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	596	187
Changes in operating assets and liabilities:		
Accounts receivable, inventory and other assets	(18,711)	(4,121)
Accounts payable and other current liabilities	(3,324)	2,425
Deferred revenue		95
Net cash used in operating activities	(18,080)	(3,839)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(149)	(118)
Proceeds from maturity of investments		10
Net cash used in investing activities	(149)	(108)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock	740	1,851
Net cash provided by financing activities	740	1,851
Effect of exchange rate changes on cash		(95)
Net decrease in cash and cash equivalents	(17,489)	(2,191)
Cash and cash equivalents at beginning of period	48,108	62,795
Cash and cash equivalents at end of period	\$ 30,619	\$ 60,604

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

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**SALIX PHARMACEUTICALS, LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2005**

**(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 financial statements are stated in United States dollars and are prepared under accounting principles generally accepted in the United States. The accompanying condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All significant intercompany balances and transactions have been eliminated.

The accompanying consolidated financial statements include all adjustments (consisting only of normal recurring items), that in the opinion of management, are necessary for a fair presentation of financial position, results of operations and cash flows. These financial statements should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Quarterly Report and with the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004 filed with the Securities and Exchange Commission. The results of operations for interim periods are not necessarily indicative of results to be expected for a full year or any future period.

Certain amounts in the 2004 financial statements have been reclassified to conform to the 2005 presentation. These reclassifications did not result in any changes to the net loss or stockholders' equity as previously reported.

*2. Commitments*

At March 31, 2005, the Company had binding purchase order commitments for inventory purchases aggregating approximately \$16.3 million over nine months.

*3. Investments*

The Company considers all investments that have a maturity of greater than three months and less than one year to be short-term investments. All securities with maturities beyond one year are considered long-term investments. The Company's investments consist of government agency and high-grade corporate bonds. The Company's existing investments are classified as available-for-sale. All available-for-sale investments are classified as current, as the Company has the ability to use them for current operating and investing purposes.

4. *Inventory*

Inventory at March 31, 2005 consisted of \$18.6 million of raw materials and \$9.9 million of finished goods. Inventory at December 31, 2004 consisted of \$18.0 million of raw materials and \$8.7 million of finished goods. Inventories are stated at the lower of cost (which approximates actual cost on a first-in, first-out cost method) or market. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life, and current and expected market conditions, including levels of competition. As appropriate, provisions are made to reduce inventories to their net realizable value.

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The Company may make scale-up and commercial quantities of products prior to receiving final FDA marketing approval. The production of these pre-launch inventories involves the risk that such products may not be approved for marketing on a timely basis, or ever. Pre-launch inventories are capitalized at a point where the Company believes that marketing approval is likely, a well-characterized manufacturing process is established and anticipated future sales support the carrying value of the inventory. At March 31, 2005, the Company had no inventories of non-FDA approved products.

### *5. Intangible Assets*

When the Company makes product acquisitions that include license agreements, product rights and other identifiable intangible assets, the Company records the aggregate purchase price, along with the value of the product-related liabilities that it assumes, as intangible assets. The Company allocates the purchase price to the fair value of the various intangible assets in order to amortize their cost as an expense in the statement of operations over the estimated economic useful life of the related assets. The Company assesses the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value might not be recoverable. Some factors that the Company considers important which could trigger an impairment review include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of 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, an impairment loss will be recognized in an amount equal to the difference. The Company reviews intangible assets for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

In November 2003, the Company acquired from aaiPharma LLC the exclusive right to sell 25, 75 and 100 milligram dosage strengths of azathioprine tablets in North America under the name Azasan for \$2.0 million. The purchase price 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 history and management experience. At March 31, 2005, accumulated amortization for Azasan was \$0.3 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 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 history and management experience. At March 31, 2005, accumulated amortization for the King products was \$1.0 million.

Amortization expense is calculated on a straight-line basis over the estimated useful life of the asset. Amortization expense for the three-month period ended March 31, 2005 was \$0.4 million. Estimated amortization expense for each of the succeeding five years is \$1.5 million.

### *6. Stock Dividend*

In June 2004, the Board of Directors approved a three-for-two stock split of the Company's common stock, in the form of a stock dividend. As a result, stockholders received one additional common share for every two shares held on the record date of June 30, 2004. Statements or certificates were issued on or about July 12, 2004. All share and per share amounts have been retroactively adjusted to reflect the split for all periods presented.



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The Company's product sales are recorded upon shipment of order and transfer of title. Reported product revenue is net of estimated contractual allowances related to managed care agreements, government rebates, customer returns and other discounts. The Company estimates allowances for revenue reducing items using a combination of relevant information including market data, historical information and internal analyses that the Company performs. Provisions for these estimated costs are recorded at the time of sale and are periodically adjusted to reflect actual experiences. If actual experience were greater than the Company's estimates, the Company would record additional expenses in that period.

In December 1999, the SEC issued Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB 104, *Revenue Recognition*, which clarifies conditions to be met in order to recognize revenue. SAB 101 requires companies to recognize up-front non-refundable fees over the term of the related agreement unless the fee is in exchange for products delivered or services performed that represent the culmination of a separate earnings process.

Due to the uniqueness of each of the Company's licensing arrangements, the Company analyzes each element of each contract, including milestone payments, to determine the appropriate revenue recognition. In accordance with SAB 101 and SAB 104, the Company recognizes revenue upon achievement of contractual milestones only when and to the extent it concludes that a separate earnings process has been culminated or the milestone is representative of the level of effort and progress toward completion of a long-term contract.

**8. Research and Development**

Research and development costs, both internal and externally contracted, are expensed as incurred. These costs include direct expenditures for goods and services, as well as indirect expenditures such as salaries, administrative expenses and various allocated costs.

**9. Comprehensive Income (Loss)**

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes foreign currency translation adjustments.

Comprehensive income (loss) for the three months ended March 31, 2005 and 2004 was as follows:

	<b>Three months ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
Net income (loss)	\$ 3,359	\$ (2,425)
Cumulative foreign currency translation adjustments		(95)
<b>Comprehensive income (loss)</b>	<b>\$ 3,359</b>	<b>\$ (2,520)</b>

*10. Stock-Based Compensation*

The Company accounts for stock-based awards to employees under the intrinsic value method in accordance with Accounting Principles Board Opinion, or APB, No. 25, *Accounting for Stock Issued to Employees* and has adopted the disclosure-only alternative of SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB 25, the Company generally recognizes no compensation expense with respect to such awards.

In December 2002, SFAS No. 148, *Accounting for Stock Based Compensation-Transition and Disclosure* an amendment of FASB Statement No. 123 was issued. This statement amended SFAS Statement No. 123 *Accounting for Stock Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock based employee compensation. In addition, this statement amended the disclosure requirements of SFAS 123 to require prominent disclosures in

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both annual and interim financial statements about the method of accounting for stock based employee compensation and the effects of the method used on reported results (see below). The provisions of SFAS No. 148 have been adopted herein.

Had compensation cost for the Company's stock-based compensation plans been determined based on the fair value at the grant dates for awards under those plans consistent with the method of SFAS No. 123, the Company's net income (loss) and net income (loss) per share would have been adjusted to the pro forma amounts indicated below for the three-month periods ended March 31, 2005 and 2004, respectively.

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
	<u>          </u>	<u>          </u>
<b>Net income (loss):</b>		
As reported	\$ 3,359	\$ (2,425)
Stock-based compensation expense under fair value method	(3,017)	(1,432)
	<u>          </u>	<u>          </u>
<b>Pro forma net income (loss)</b>	<b>\$ 342</b>	<b>\$ (3,857)</b>
	<u>          </u>	<u>          </u>
<b>Net income (loss) per share, basic:</b>		
As reported, basic	\$ 0.09	\$ (0.07)
Stock-based compensation expense under fair value method	(0.08)	(0.04)
	<u>          </u>	<u>          </u>
<b>Pro forma, basic</b>	<b>\$ 0.01</b>	<b>\$ (0.11)</b>
	<u>          </u>	<u>          </u>
<b>Net income (loss) per share, diluted:</b>		
As reported, diluted	\$ 0.09	\$ (0.07)
Stock-based compensation expense under fair value method	(0.08)	(0.04)
	<u>          </u>	<u>          </u>
<b>Pro forma, diluted</b>	<b>\$ 0.01</b>	<b>\$ (0.11)</b>
	<u>          </u>	<u>          </u>

Future pro forma net income (loss) and net income (loss) per share results might be materially different from actual amounts reported.

**11. Income Taxes**

Income taxes are provided 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. A valuation allowance is provided 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.

The provision for income taxes reflects the Company's estimate of the effective tax rate expected to be applicable for the full fiscal year. This estimate is re-evaluated by the Company each quarter based on the Company's estimated tax expense for the year.

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

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

	<b>Three months ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Numerator:</b>		
Net income (loss)	\$ 3,359	\$ (2,425)
<b>Denominator:</b>		
Weighted average common shares, basic	36,551	35,775
Dilutive effect of stock options	2,147	
<b>Weighted average common shares, diluted</b>	<b>38,698</b>	<b>35,775</b>

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For the three-month periods ended March 31, 2005 and 2004, there were 1,855,156 and 4,633,830 respectively, potential common shares outstanding that were excluded from the diluted net income per share calculation because their effect would have been anti-dilutive.

*13. 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 (in thousands):

	Three months ended March 31,	
	2005	2004
Colazal	\$ 23,827	\$ 19,369
Xifaxan	2,608	
Other	2,375	490
Net product revenues	\$ 28,810	\$ 19,859

*14. Recently Issued Accounting Pronouncements*

In December 2004, the FASB issued Statement No. 123R, *Share-Based Payment*, which requires companies to expense the fair value of employee stock options and other forms of stock-based compensation. This requirement represents a significant change because share-based stock option awards, a predominate form of stock compensation for the Company, were not recognized as compensation expense under APB 25. Statement 123R requires the cost of the award, as determined on the date of grant at fair value, to be recognized over the period during which an employee is required to provide service in exchange for the award, usually the vesting period. The grant-date fair value of the award will be estimated using an option-pricing model. The Company is required to adopt Statement 123R beginning January 1, 2006 under one of two transition methods, a modified-prospective method or a modified-retrospective method. The Company is evaluating all of the provisions of Statement 123R and the expected effect on the Company including, among other items, reviewing compensation strategies related to stock-based awards, selecting an option pricing model and determining the transition method.

**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 *Cautionary Statement* included in this *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.*



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### **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 100-member specialty sales and marketing team focused on high-prescribing U.S. gastroenterologists to sell our products. We rely on distribution relationships with third parties to sell our products outside the United States.

We generate revenue primarily by selling our products, prescription drugs, to pharmaceutical wholesalers. These direct customers of ours 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. Revenue could be less than anticipated in subsequent quarters as wholesalers' increased inventory is used up. We believe such increased buying occurred in 2004 and it could again.

In December 2000, we established our own field sales force to market Colazal in the United States. Currently, this sales force has approximately 70 sales representatives in the field. Although the creation of an independent sales organization involved substantial costs, we believe that the financial returns from Colazal, Xifaxan, Azasan and the Anusol-HC/Proctocort lines and other future products, if acquired and approved, will be more favorable to us than those from the indirect sale of products through marketing partners.

### **Critical Accounting Policies**

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, we identified our most critical accounting policies and estimates upon which our financial status depends as those relating to revenue recognition, investments, inventory, intangible assets, allowance for uncollectible accounts, allowance for returns, and allowance for rebates and coupons. We reviewed our policies and determined that those policies remained our most critical accounting policies for the three months ended March 31, 2005. We did not make any changes in those policies during the quarter.

### **Results of Operations**

#### *Three-month Periods Ended March 31, 2005 and 2004*

Net product revenues for the three-month period ended March 31, 2005 were \$28.8 million, compared to \$19.9 million for the corresponding three-month period in 2004. We expect that future revenues will consist solely or primarily of net product revenue. Net product revenue increases for the three-month period ended March 31, 2004 compared to the three-month period ended March 31, 2005 were due primarily to increased sales of Colazal, and the commercial launch of Xifaxan and acquisition of the Anusol-HC and Proctocort products during 2004.

Costs and expenses for the three-month period ended March 31, 2005 were \$25.6 million, compared to \$22.5 million for the corresponding three-month period in 2004. Higher operating expenses in absolute terms were due primarily to Xifaxan market research and commercial development activities, along with increased cost of products sold related to the corresponding increase in product revenue. However, as expected, as we increased revenue using the commercialization infrastructure built with significant investment over the past few years, costs and expenses in 2005 were less, as a percentage of revenue, than in 2004. We expect this trend to continue.

Cost of products sold for the three-month period ended March 31, 2005 was \$6.7 million, compared with \$4.7 million for the corresponding three-month period in 2004. The increase in cost of products sold for the three-month period ended March 31, 2005 compared to the three-month period ended March 31, 2004 was due primarily to increased sales of Colazal, and the commercial launch of Xifaxan and acquisition of the Anusol-HC and Proctocort products during 2004. Cost of products sold does not include amortization of product rights.

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There were no license fees and costs related to collaborative agreements for the three-month period ended March 31, 2005, compared with \$31,000 in the corresponding three-month period ended March 31, 2004.

Research and development expenses were \$4.3 million for the three-month period ended March 31, 2005, compared to \$5.0 for the comparable period in 2004. Our current major research and development projects are for additional potential indications for rifaximin and granulated mesalamine. The decrease in research and development expenses for the three-month period ended March 31, 2005 was due primarily to the timing of development expenses. To date, we have incurred research and development expenditures of approximately \$21.2 million for balsalazide, \$31.9 million for rifaximin and \$9.1 million for granulated mesalamine. Due to the risks and uncertainties of the drug development and regulatory approval process, research and development expenditures are difficult to forecast and subject to unexpected increases. We expect research and development costs to increase in absolute terms as we pursue additional indications and formulations for balsalazide and rifaximin, pursue development of granulated mesalamine, and if and when we acquire new products.

Selling, general and administrative expenses were \$14.2 million for the three-month period ended March 31, 2005, compared to \$12.8 million in the corresponding three-month period in 2004. This increase was primarily due to Xifaxan market research and commercial development activities.

Interest and other income, net was \$0.2 million for each of the three-month periods ended March 31, 2005 and March 31, 2004.

Income tax expense was \$0.1 million for the three-month period ended March 31, 2005. Our effective tax rate for three-month period was 2.7% due to the utilization of net operating loss carryforwards. We recognized no income tax expense during the three-month period ended March 31, 2004.

Net income was \$3.4 million for the three-month period ended March 31, 2005, compared to net losses of \$2.4 million in the corresponding three-month period in 2004.

## **Liquidity and Capital Resources**

Since inception, we have financed product development, operations and capital expenditures primarily from public and private sales of equity securities and from funding arrangements with collaborative partners. Since launching Colazal in January 2001, product revenue has been a growing source of cash, a trend that we expect to continue. As of March 31, 2005, we had approximately \$34.6 million in cash, cash equivalents and investments, compared to \$52.1 million as of December 31, 2004.

Cash used in our operations was \$18.1 million for the three-month period ended March 31, 2005, compared with \$3.8 million in the corresponding three-month period in 2004. Negative operating cash flows during this period were primarily attributable to increased accounts receivable in 2005 associated with increased sales. To date, we have not experienced any material accounts receivable collection issues. Based on a review of specific customer balances, industry experience and the current economic environment, we currently reserve for specific accounts plus 1% of the outstanding accounts receivable balance as an allowance for uncollectible accounts, which at March 31, 2005 was approximately \$1.1 million.

Cash used in investing activities for the three-month periods ended March 31, 2005 and March 31, 2004 was \$0.1million. Cash used for both periods was primarily related to capital expenditures for the purchase of office furniture and equipment.

Cash provided by financing activities during the three-month period ended March 31, 2005 was \$0.7 million compared to \$1.9 million in the corresponding three-month period in 2004. Cash provided by financing activities for both periods was primarily related to the exercise of stock options.

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As of March 31, 2005, we had non-cancelable purchase order commitments for inventory purchases of approximately \$16.3 million over nine months. We anticipate continued significant expenditures in the remainder of 2005 related to our continued sales, marketing, product launch and development efforts associated with Colazal, Xifaxan, Azasan, Anusol-HC and Proctocort. To the extent we acquire rights to additional products, we will incur additional expenditures.

As of March 31, 2005, we had an accumulated deficit of \$80.5 million. We believe our cash, cash equivalent and investment balances should be sufficient to satisfy our cash requirements for the foreseeable future. However, our actual cash needs might vary materially from those now planned because of a number of factors, including our success selling products, the results of research and development activities, FDA and foreign regulatory processes, establishment of and change in collaborative relationships, technological advances by us and other pharmaceutical companies, the status of competitive products and whether we acquire rights to additional products. We might seek additional debt or equity financing or both to fund our operations or acquisitions. If we incur debt, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. If we issued additional equity, our stockholders could suffer dilution. We might also enter into additional collaborative arrangements with corporate partners 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.

Statements contained in this Form 10-Q which 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, we can give no assurance that our expectations will 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 dependence on a limited number of pharmaceutical products, including particularly balsalazide and rifaximin, and the uncertainty of market acceptance of those products; the high cost and uncertainty of the research, clinical trials, regulatory oversight and other development activities involving pharmaceutical products; our limited sales and marketing experience; the uncertainty of obtaining, and our dependence on, third parties to manufacture and sell our products; intense competition; the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties; and results of future litigation and other risk factors detailed from time to time in our other SEC filings.

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

Our purchases of raw materials and product sales to European distribution partners are denominated in Euros. Translation into our reporting currency, the United States dollar, has not historically had a material impact on our financial position. Additionally, our net assets denominated in currencies other than the functional currency have not 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.

Pursuant to our investment policy, we have invested a portion of our available cash in government agency and high-grade corporate bonds. Due to the nature and maturity terms of these investments, we do not believe these investments present significant market risk.

**Item 4. Controls and Procedures**

(a) 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. As of the end of the period

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covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective to provide the reasonable assurance discussed above.

(b) No change in the Company's internal control over financial reporting occurred during the Company's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Table of Contents****PART II. OTHER INFORMATION****Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Registrant s Form</b>	<b>Dated</b>	<b>Exhibit Number</b>	<b>Filed Herewith</b>
10.50*	Co-promotion Agreement dated March 2, 2005 between Salix Pharmaceuticals, Inc. and Altana Pharma US, Inc.				X
31.1	Certification by the Chief Executive Officer pursuant to Section 240.13a-14 or section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
31.2	Certification by the Chief Financial Officer pursuant to Section 240.13a-14 or section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification by the Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

\* Certain portions of this agreement have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the SEC.

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**SIGNATURES**

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

SALIX PHARMACEUTICALS, LTD.

Date: May 10, 2005

By: /s/ Carolyn J. Logan

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Carolyn J. Logan  
President and Chief Executive Officer

Date: May 10, 2005

By: /s/ Adam C. Derbyshire

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Adam C. Derbyshire  
Senior Vice President, Finance & Administration and  
  
Chief Financial Officer