



**2008 Annual Report**

**Included in the 2008 Annual Report:  
Form 10-K filed with the U.S. Securities and Exchange Commission on March 11, 2009**

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

**FORM 10-K**

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

For the Fiscal Year ended December 31, 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)

**Securities Registered Pursuant to Section 12(b) of the Act:**

<u>Title of Each Class</u>	<u>Name of Exchange on which Registered</u>
Common Stock, \$0.001 Par Value	Nasdaq Global Market
Preferred Share Purchase Rights	Nasdaq Global Market

**Securities Registered Pursuant to Section 12(g) of the Act: None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES  NO

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 Act (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  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 aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant on June 30, 2008 (based on the closing sale price of U.S. \$7.03 of the Registrant's common stock, as reported on The Nasdaq Global Market on such date) was approximately U.S. \$141,251,133. Common stock held by each officer and director and by each person known to the Company who owned 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the Registrant's common stock outstanding at March 10, 2009 was 48,119,013.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive Proxy Statement to be filed for its 2009 Annual Meeting of Stockholders currently scheduled to be held June 18, 2009 are incorporated by reference into Part III of this report.

**SALIX PHARMACEUTICALS, LTD.**  
**ANNUAL REPORT ON FORM 10-K**  
**TABLE OF CONTENTS**

		<u>Page</u>
<b>PART I</b>		
Item 1.	Business .....	1
Item 1A.	Risk Factors .....	18
Item 1B.	Unresolved Staff Comments .....	24
Item 2.	Properties .....	24
Item 3.	Legal Proceedings .....	25
Item 4.	Submission of Matters to a Vote of Security Holders .....	25
	Executive Officers of the Registrant .....	25
<b>PART II</b>		
Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities .....	27
Item 6.	Selected Financial Data .....	29
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations .....	30
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk .....	45
Item 8.	Financial Statements and Supplementary Data .....	45
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure .....	45
Item 9A.	Controls and Procedures .....	45
Item 9B.	Other Information .....	46
<b>PART III</b>		
Item 10.	Directors, Executive Officers and Corporate Governance .....	47
Item 11.	Executive Compensation .....	47
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters .....	47
Item 13.	Certain Relationships and Related Transactions, and Director Independence .....	48
Item 14.	Principal Accountant Fees and Services .....	48
<b>PART IV</b>		
Item 15.	Exhibits and Financial Statement Schedule .....	49
	SIGNATURES .....	54

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 “Item 1A. Risk Factors” and “Cautionary Statement” included in “Item 7. 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. Unless otherwise indicated or required by the context, the terms “we,” “our,” “us” and the “Company” refer to Salix Pharmaceuticals, Ltd. and all of its subsidiaries.

## PART I

### Item 1. Business

Salix Pharmaceuticals, Ltd., a Delaware corporation, 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. Our website address is [www.salix.com](http://www.salix.com). Information on our website is not incorporated herein by reference. We make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission.

### OVERVIEW

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

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

Our current products demonstrate our ability to execute this strategy. As of December 31, 2008, our products were:

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

We generate revenue primarily by selling our products, namely prescription drugs, to pharmaceutical wholesalers. These direct customers resell and distribute our products to and through pharmacies to patients who have had our products prescribed by doctors. We currently market our products, and intend to market future products, if approved by the U.S. Food and Drug Administration, or FDA, to U.S. gastroenterologists and other physicians through our own direct sales force. In December 2000, we established our own field sales force to market Colozal in the United States. Currently, this sales force has approximately 100 sales representatives in the field and markets our approved products. Although the creation of an independent sales organization involved substantial costs, we believe that the financial returns from our direct product sales have been and will continue to be more favorable to us than those from the indirect sale of products through marketing partners. We enter into distribution or licensing relationships outside the United States and in certain markets in the U.S. where a larger sales organization is appropriate. Currently, our sales and marketing staff, including our sales representatives, consists of approximately 150 people.

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

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

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

## PRODUCTS

### Xifaxan® (rifaximin) tablets

Xifaxan is a gastrointestinal-specific oral antibiotic that the FDA approved in May 2004 for the treatment of patients 12 years of age and older with travelers' diarrhea caused by noninvasive strains of *E. coli*. According to the Centers for Disease Control, each year between 30% and 50% of international travelers, an estimated 20.0 million people, develop diarrhea, with approximately 80% of the cases caused by bacteria. Approximately 1.4 million people sought treatment in the United States for infectious diarrhea in 2008 and approximately 1.2 million of those patients were prescribed a drug.

We believe the advantages of Xifaxan to treat these infections are two-fold: (1) site-targeted antibiotic delivery; and (2) improved tolerability compared to other treatments. Less than 0.5% of the drug is absorbed into the bloodstream when it is taken orally. In addition, the drug might also cause fewer side effects or discomforts such as nausea, headache or dizziness than observed with currently available, more highly-absorbed antibiotics. We believe Xifaxan is also less likely to cause harmful interaction with other drugs a patient may be taking. We believe Xifaxan is unique because there is no other U.S.-approved oral antibiotic with its potential lack of systemic absorption and safety profile.

We launched Xifaxan in the United States in July 2004 using our own direct sales force. We had net product sales of \$79.9 million, \$64.3 million and \$51.6 million of Xifaxan in the United States in 2008, 2007 and 2006 respectively. We are exploring potential additional indications, formulations, clinical trials and co-promotion arrangements to capitalize on the potential for Xifaxan, including our development programs in hepatic encephalopathy, irritable bowel syndrome, prevention of travelers' diarrhea, and *C. difficile*-associated diarrhea. Based on these potential indications, we believe Xifaxan can potentially compete in an annual U.S. market in excess of approximately \$4 billion, comprised of over 12 million patient visits. While the potential market for Xifaxan is large, we expect to capture only a portion of each market due to competition, ability to capture share in each market, market acceptance and/or other factors.

The patents for the rifaximin composition of matter (also covering a process of making rifaximin and using rifaximin to treat gastrointestinal infectious diseases) expired in May 2001 in the United States and Canada. Rifaximin is a new chemical entity and was granted a five-year new chemical exclusivity by the FDA when it was approved in May 2004. Rifaximin, therefore, has data exclusivity to May 2009. In May 2006, a U.S. patent (composition of matter and process patent that covers several physical states of rifaximin) was issued that we believe extends the patent coverage of the current form of rifaximin until May 2024. Alfa Wasserman S.p.a., the patent owner, has licensed rights to rifaximin in the United States to Salix. In July 2006, Salix entered into an agreement with Cedars-Sinai Medical Center, or CSMC, for the right to use its patent and patent applications relating to methods of diagnosis and treating irritable bowel syndrome and other disorders caused by small intestinal bacterial overgrowth. The CSMC agreement also provides Salix the right to use the U.S. Patent No. 7,452,857, which issued in November 2008 and provides protection relating to rifaximin for treating irritable bowel syndrome, or IBS, caused by small intestinal bacterial overgrowth until August 2019. We have filed applications for patents relating to additional indications using rifaximin and related chemical substances.

#### **MoviPrep® (PEG 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid) oral solution**

In December 2005, we acquired exclusive rights to sell MoviPrep in the United States from Norgine B.V. MoviPrep is a patent-protected, liquid polyethylene glycol-salt, or PEG, bowel cleansing product that was approved by the FDA in August 2006 and competes with a number of liquid PEG bowel cleansing products. MoviPrep is differentiated from other liquid PEG bowel cleansing products by the inclusion of ascorbic acid in its formulation. MoviPrep is indicated for bowel cleansing prior to colonoscopy, intestinal surgery and barium enema X-ray examinations. Net product sales for MoviPrep were \$33.9 million in 2008, \$20.1 million in 2007 and \$5.0 million in 2006. We expect that the voluntary recall of C.B. Fleet's products discussed below could lead to increased future demand for MoviPrep.

Approximately 5.7 million prescriptions for bowel cleansing products were written in 2008, representing a market value of \$218 million. In terms of prescription dollar sales, the market for bowel cleansing products has been growing at a 28% annual compound rate for the last five years. Our bowel cleansing products compete with a number of PEG bowel cleansing products.

Norgine, B.V. and Norgine Europe, B. V. own U.S. Patent No. 7,169,381, or the '381 patent, which is listed with the FDA as protecting our MoviPrep product to 2024. Norgine licensed MoviPrep and the '381 patent to us for commercialization in the United States. In 2008, 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 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. This lawsuit prevents Novel from marketing a generic version of MoviPrep for up to 30 months, unless Novel receives an earlier non-appealable judgment to the contrary. Novel filed an Answer and Counterclaim on June 20, 2008. No trial date has been set.

#### **Visicol® and OsmoPrep® (sodium phosphate monobasic monohydrate, USP, sodium phosphate dibasic anhydrous, USP) tablets**

In September 2005, we acquired Visicol with the completion of the acquisition of InKine Pharmaceutical Company, Inc. Visicol and OsmoPrep tablets are indicated for cleansing of the colon as a preparation for colonoscopy

in adults 18 years of age or older. Visicol was the first, and it and OsmoPrep are the only, tablet bowel cleansing products approved by the FDA and marketed in the United States. OsmoPrep is a patented, second-generation tablet bowel cleansing product approved by the FDA in March 2006. OsmoPrep offers potential benefits compared to Visicol such as its lack of microcrystalline cellulose, smaller tablet size and possible lower dose administration. Net product sales for Visicol were (\$1.4) million, \$2.2 million and \$18.0 million in 2008, 2007 and 2006 respectively. Net product sales for OsmoPrep were \$30.3 million in 2008, \$25.4 million in 2007 and \$22.5 million in 2006.

CDC, LLC, owns U.S. Patent No. 5,616,346, or the '346 patent, for the formulation and use of OsmoPrep, which CDC licensed to us for commercialization in the United States. The '346 patent is listed with the FDA as protecting our OsmoPrep product to 2013. In 2008, 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. This lawsuit prevents Novel from marketing a generic version of OsmoPrep for up to 30 months, unless Novel receives an earlier non-appealable judgment to the contrary. No trial date has been set. An additional U.S. patent application for OsmoPrep is pending that, if issued, could provide patent protection through 2024.

On December 11, 2008, the FDA announced a proposed boxed warning for OsmoPrep and Visicol that addresses the potential risk of acute kidney injury. We are working with the FDA to develop a risk evaluation and mitigation strategy, or REMS, including a medication guide, and we plan to conduct post-marketing clinical trials. In its announcement, the FDA also recommended that consumers not use over the counter Oral Sodium Phosphate, or OSP's, for bowel cleansing. On December 12, 2008, C.B. Fleet Company announced a voluntary complete recall of their over-the-counter products Fleet® Phospho-soda® and Fleet® Phospho-soda® EZ-Prep® Bowel Cleansing System. These products were priced significantly lower than the available prescription bowel cleansing products and we believe accounted for approximately 3 million bowel cleansing procedures during 2008. We expect that this recall will result in an increase in demand for prescription bowel cleansing products in 2009. It is difficult to predict the effect that this combination of events will have on future demand for OsmoPrep and Visicol at this time.

#### **Azasan® (azathioprine) tablets**

In November 2003, we acquired from aaiPharma LLC the exclusive right to sell 25, 75 and 100 milligram dosage strengths of azathioprine tablets in North America under the brand name Azasan. Azasan is an FDA-approved drug that suppresses immune system responses and is indicated for preventing rejection of kidney transplants and treatment of severe arthritis. In February 2004, we launched the 75 and 100 milligram dosage strengths of Azasan in the United States. Net product sales for Azasan were \$3.1 million, \$3.4 million and \$4.8 million in 2008, 2007 and 2006, respectively. The patents and data exclusivity for Azasan have expired.

#### **Anusol-HC® and Proctocort® (hydrocortisone) creams and suppositories**

In June 2004, we acquired the exclusive right to sell Anusol-HC 2.5% (hydrocortisone USP) cream, Anusol-HC 25 mg (hydrocortisone acetate) rectal suppositories, Proctocort 1% (hydrocortisone USP) cream and Proctocort 30 mg (hydrocortisone acetate) rectal suppositories from King Pharmaceuticals, Inc. The two cream products are topical corticosteroids indicated for relief of the inflammatory and pruritic, or itching, manifestations of corticosteroid-responsive dermatoses. The two suppository products are indicated for use in inflamed hemorrhoids and postirradiation proctitis, as well as an adjunct in the treatment of chronic ulcerative colitis and other inflammatory conditions. Combined net product sales for the Anusol-HC and Proctocort product lines were \$3.7 million, \$2.9 million and \$3.0 million in 2008, 2007 and 2006, respectively. The patents and data exclusivity for Anusol-HC and Proctocort have expired.

#### **Pepcid® (famotidine) for Oral Suspension and Oral Suspension Diuril® (Chlorothiazide)**

In February 2007, we purchased the U.S. prescription pharmaceutical product rights to Pepcid Oral Suspension and Diuril Oral Suspension from Merck & Co., Inc. Pepcid Oral Suspension is a widely known prescription pharmaceutical product indicated for several gastrointestinal indications, including the treatment of duodenal ulcer,

benign gastric ulcer and gastro-esophageal reflux disease. Pepcid Oral Suspension and Diuril Oral Suspension, both liquid formulations of their solid dosage form counterparts, compete in a combined market of approximately \$150 million, concentrated in pediatric and hospitalized patient populations. Net product sales for Pepcid were \$18.2 million in 2008 and \$22.2 million in 2007. Net product sales for Diuril were \$0.6 million for 2008 and \$0.2 million for 2007. The patents and data exclusivity for Pepcid Oral Suspension and Diuril Oral Suspension have expired.

#### **Apriso™ (mesalamine) extended-release capsules 0.375g**

In July 2002 we acquired the exclusive development rights in the United States to a granulated mesalamine product from Dr. Falk Pharma GmbH, one of the most recognized gastroenterology companies worldwide. On October 31, 2008, the FDA granted marketing approval for Apriso for the maintenance of remission of ulcerative colitis in adults. Apriso is a locally-acting aminosalicylate and is the first and only mesalamine product approved by the FDA for once-a-day dosing for the maintenance of remission of ulcerative colitis. Apriso is designed to provide for the distribution of the active ingredient beginning in the small bowel and continuing throughout the colon. The product's unique prolonged release mechanism might allow us to expand the range of treatment options for ulcerative colitis. We shipped Apriso to wholesalers in the fourth quarter of 2008 and launched Apriso to physicians in late February 2009.

Ulcerative colitis is a chronic form of inflammatory bowel disease characterized by inflammation of the lining of the colon. Symptoms of active ulcerative colitis include rectal bleeding, abdominal pain, increased stool frequency, loss of appetite, fever and weight loss. The cause of ulcerative colitis is unknown and no known cure exists except for the removal of the colon. It is estimated that as many as 500,000 people in the United States have ulcerative colitis. People are most often diagnosed with the disease in their mid-30's, although the disease can occur at any age.

Apriso is patent protected until 2018.

#### **Colazal® (balsalazide disodium) capsules**

Our first drug, Colazal, was approved by the FDA in 2000 for the treatment of mildly to moderately active ulcerative colitis. We launched Colazal to physicians in the United States in January 2001 using our own sales force. In December 2006, the FDA approved Colazal for use in pediatric patients between 5 to 17 years of age with ulcerative colitis. The pediatric use of Colazal has been granted orphan drug designation. On December 28, 2007, the Office of Generic Drugs, or OGD, approved three generic balsalazide capsule products, and we announced that we had entered into an agreement with Watson Pharma, Inc. to market and sell an authorized generic of Colazal.

We had net product sales of \$1.4 million, \$92.4 million and \$103.5 million of Colazal in the United States in 2008, 2007 and 2006, respectively. Colazal net product revenues for 2007 include a \$34.6 million reduction representing our estimate of Colazal previously sold to wholesalers that may be returned to us under our return policy as a result of the generic approvals discussed above. We do not anticipate significant Colazal sales in 2009 or beyond.

### **DEVELOPMENT PROGRAMS**

#### **Balsalazide Disodium tablets**

We have developed an 1100 mg tablet formulation of balsalazide disodium. We believe the convenience the balsalazide tablet formulation is designed to provide, by means of twice-a-day dosing and a reduced number of pills, demonstrates our ongoing commitment to bring products to market that better serve the needs of gastroenterologists and their patients. On July 17, 2007 we submitted an NDA to the FDA seeking approval to market an 1100 mg tablet formulation of balsalazide disodium. On May 16, 2008 we received an approvable letter from the FDA. We submitted a complete response to the approvable letter on June 30, 2008. On December 22, 2008, the FDA issued a complete response letter. Based on its review, the FDA has determined that the application cannot be approved in its present form and that clinical data from an additional adequate and well-controlled clinical trial will be required in order to conduct further review on the NDA. We have been granted a Type A meeting with the FDA and will meet with the FDA to discuss appropriate next steps and determine if the issues described in the December 22, 2008 complete response letter can be resolved and the product can be approved for marketing. We do not intend to conduct additional clinical investigation of balsalazide tablets in this indication. The patent for balsalazide disodium tablets will expire in 2018.

## **Xifaxan® (rifaximin) tablets**

We are committed to maximizing the commercial potential of our GI-targeted antibiotic, Xifaxan. We have prioritized our development efforts and have budgeted resources to expedite our late-stage trials in hepatic encephalopathy and irritable bowel syndrome. These studies are generating data that should provide the basis for forthcoming New Drug Applications.

### *Hepatic Encephalopathy*

In October 2008, we announced the successful completion and outcome of our pivotal Phase III trial to evaluate the efficacy, safety and tolerability of rifaximin in preventing hepatic encephalopathy, or HE. This study demonstrates that the protocol-specified, intent-to-treat, primary endpoint comparison of a 6-month course of rifaximin at 550 mg dosed twice-a-day provides a highly statistically significant result in preventing HE, compared to placebo. The results seen with the primary endpoint are corroborated by the secondary endpoints. Hepatic encephalopathy, which encompasses a spectrum of reversible neuropsychiatric abnormalities that occur in patients with acute or chronic liver disease, is a serious medical condition that has no FDA-approved drug therapies available. We intend to submit an NDA during 2009.

### *Irritable Bowel Syndrome*

In June 2008 we initiated patient enrollment in the Phase III trials to assess the efficacy and safety of rifaximin (550 mg TID) in the treatment of patients with non-constipation irritable bowel syndrome, or non-C IBS. We are conducting two 600-subject trials, TARGET 1 and TARGET 2, in a total of approximately 190 study centers throughout the U.S. and Canada. We expect to complete patient enrollment by mid-2009.

### *Prevention of Travelers' Diarrhea*

We have completed two Phase III trials to evaluate Xifaxan in the prevention of travelers' diarrhea. In December 2008 we had a pre-NDA meeting with the FDA to discuss these data and potential next steps. We currently plan to submit an NDA for the prevention of travelers' diarrhea in late 2009.

### *C. difficile-associated Diarrhea*

In December 2008, we concluded patient enrollment in our *C. Difficile*-associated diarrhea, or CDAD, trial. Final enrollment into this trial concluded with the enrollment of 238 of the protocol defined 300 patients enrolled. During 2009, we intend to analyze the results of this trial and, data allowing, request a meeting with the FDA to discuss the next appropriate steps for this indication.

## **Vapreotide acetate**

In September 2006 we acquired exclusive marketing rights for vapreotide acetate in the United States from the Debiopharm Group. Patient enrollment in a confirmatory Phase III trial in the United States as a treatment of acute esophageal variceal bleeding was completed during the third quarter of 2008. Debiopharm submitted a complete response to the FDA during the fourth quarter of 2008, and the FDA granted an April 1, 2009 Prescription Drug User Fee Act, or PDUFA, goal date. We believe the FDA is likely to request a review of vapreotide acetate at a future Advisory Committee meeting, and therefore the April 1, 2009 PDUFA date may be extended. If approved by the FDA, vapreotide acetate will be the only approved treatment for esophageal variceal bleeding in the United States. Vapreotide acetate has been granted orphan drug designation in the United States, and as a result, if approved, will have seven years of exclusivity from the approval date.

## **Metozolv™ (metoclopramide) orally disintegrating tablets**

In September 2007, we acquired exclusive, worldwide rights to metoclopramide-Zydis® from Wilmington Pharmaceuticals. Metoclopramide is indicated for short-term (4–12 weeks) therapy for adults with symptomatic documented gastroesophageal reflux who fail to respond to conventional therapy, and for the relief of symptoms associated with acute and recurrent diabetic gastric stasis. Metozolv is a fast-dissolve formulation of metoclopramide that has patent protection until 2017 and additional patent protection pending that, if issued, will provide intellectual property protection until 2023.

Wilmington submitted an NDA seeking approval to market Metozolv and, the FDA originally granted a November 30, 2008 PDUFA goal date. In November 2008, however, the FDA extended the PDUFA goal date three months, to February 27, 2009, to provide time for a full review of the submission. On February 26, 2009, Wilmington received a complete response letter from the FDA, indicating that it requires a REMS for Metozolv prior to approval of the NDA. With the exception of the REMS requirement, all substantive questions and issues surrounding the Metozolv application have been resolved. We intend to submit the REMS by mid March and will work with the FDA to expedite the approval of Metozolv. In a separate action on February 26, 2009, the FDA issued a class-wide requirement for all manufacturers of metoclopramide in the United States to provide a REMS for their products.

### **Crofelemer**

In December 2008 we acquired rights to crofelemer from Napo Pharmaceuticals, Inc. We are investigating crofelemer in a Phase III study as an anti-secretory anti-diarrheal agent for the treatment of chronic diarrhea in people living with HIV, or HIV-associated diarrhea. Patents for crofelemer provide intellectual property protection to 2018. If crofelemer receives marketing approval, it should be eligible for 5 years marketing exclusivity as a new molecular entity. The product also might be entitled to patent term restoration.

### **Budesonide**

In March 2008, we acquired a license from Dr. Falk Pharma GmbH to a family of budesonide products, including a budesonide rectal foam and a budesonide gastro-resistant capsule, in the United States. The rectal foam product and the gastro-resistant capsule products have patent coverage in the U.S. until 2015 and 2016, respectively. We expect to initiate Phase III studies on the budesonide rectal foam product during 2009.

## **COLLABORATIVE AND PRODUCT ACQUISITION AGREEMENTS**

We have and will continue to enter into various collaborations and product acquisition agreements with licensors, licensees and others. To date, we have entered into the following agreements:

### **Product Acquisitions and In-License Agreements**

#### *aaiPharma LLC*

In November 2003, we 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. In addition, the agreement provides that Salix is to pay aaiPharma, on a quarterly basis, a percentage royalty payment based on Salix's net sales of Azasan in exchange for aaiPharma supplying us with drug product. Because the amount of the royalty payment is based on net sales during a quarter, with no minimum royalty amount, Salix is unable to prospectively disclose the absolute amount of such royalty payments. Royalties are only incurred if there is associated revenue, and then are included in "Cost of products sold" in the Statements of Operations.

#### *Alfa Wassermann S.P.A.*

In June 1996, Salix entered into a license agreement with Alfa Wassermann S.p.A, a privately held pharmaceutical company headquartered in Italy, pursuant to which Alfa Wassermann licensed to Salix the exclusive rights to make, use and sell rifaximin (Xifaxan) in the United States and Canada for the treatment of gastrointestinal and respiratory tract diseases. Pursuant to the license agreement, we agreed to pay Alfa Wassermann a net sales-based royalty, as well as milestone payments. Salix made annual milestone payments in varying amounts to Alfa Wassermann until the commercial launch of Xifaxan in July 2004. No more milestone payments remain under this agreement. Our obligation to pay royalties commenced upon the commercial launch of the product and continues until the later of (1) the expiration of the period in which the manufacture, use or sale of the products by an unlicensed third party would constitute an infringement on the patent covering the product or (2) 10 years from commercial launch. Thereafter, the licenses granted to us shall continue as irrevocable royalty-free paid-up licenses. However, we would remain obligated to pay a net sales based royalty for use of the product trademark if we choose to continue using it after the other licenses expired. Because the amount of the royalty payment is based on net sales during a quarter, with

no minimum royalty amount, Salix is unable to prospectively disclose the absolute amount of such royalty payments. Royalties are only incurred if there is associated revenue, and then are included in “Cost of products sold” in the Statements of Operations.

Alfa Wassermann has agreed separately to supply us with bulk active ingredient rifaximin at a fixed price. Salix is committed to purchase a percentage of its rolling 12-month forecast that is updated monthly, and these amounts are included in the “Purchase Commitments” line of its contractual commitments table in its Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The license agreement does not have a set term and continues until terminated in accordance with its terms. Either party to the agreement may terminate it following a material breach by the other party and the failure of the breaching party to remedy the breach within 60 days. In addition, Alfa Wassermann has the right to terminate the agreement on three months’ written notice in the event that we fail to sell the product for a period of six consecutive months after commercial launch. In addition, Alfa Wassermann may terminate the agreement if we become involved in bankruptcy, liquidation or similar proceedings. We may terminate the agreement in respect of any indication or any part of the territory covered on 90 days’ notice, at which point our rights with respect to that indication or territory shall cease.

#### *Biorex Laboratories Limited*

Pursuant to an agreement entered into between us and Biorex in 1992, Biorex granted us the exclusive worldwide right (other than Japan, Taiwan, Korea and the United States) to develop, manufacture and sell balsalazide for all disease indications for a period of 15 years from the date of commercial launch, subject to early termination in certain circumstances, including upon the material breach by either party and, in the case of Biorex, in the event of our bankruptcy or if a sub-licensee of ours terminates or becomes entitled to terminate its sublicense as a result of actions by us. Pursuant to this agreement, Salix must pay to Biorex a percentage of any gross profits realized by Salix, plus a percentage of fees payable to Salix in connection with any sublicense by Salix of the rights under the agreement. Under a separate agreement, Biorex granted us the exclusive right to develop, manufacture and sell balsalazide for all disease indications in the United States for a period of nine years from the date of commercial launch or the term of the applicable patent, whichever is longer. Under these agreements, we paid Biorex fees upon entering into the agreements and are obligated to make additional milestone and royalty payments for the drug. The royalty payments to be made by us pursuant to the agreement governing the United States are based on net sales, subject to minimum royalty payments for the first five years following commercial launch. Under the agreement governing territories other than the United States, we are obligated to pay to Biorex a portion of any gross profit on sales of balsalazide outside the United States. Under these agreements, we undertook to complete preclinical testing, perform clinical trials and obtain regulatory approvals for balsalazide. During 2001, we acquired from Biorex the exclusive right and license to develop, manufacture and sell balsalazide in Japan, Korea and Taiwan. We did not have to pay any fees to Biorex upon entering into this agreement, but we are obligated to pay Biorex a portion of any upfront payments, milestone payments and gross profit on sales of balsalazide in Japan, Korea and Taiwan as well. Because the amount of the royalty payment is based on net sales during a quarter, with no minimum royalty amount, Salix is unable to prospectively disclose the absolute amount of such royalty payments. Royalties are only incurred if there is associated revenue, and then are included in “Cost of products sold” in the Statements of Operations.

#### *Cedars — Sinai Medical Center*

On June 28, 2006, Salix entered into a license agreement with Cedars-Sinai Medical Center, or CSMC, for the right to use a patent and a patent application relating to methods of diagnosing and treating irritable bowel syndrome and other disorders caused by small intestinal bacterial overgrowth. Under the agreement, CSMC grants Salix the right to use its patent and patent application relating to methods of diagnosis and treating irritable bowel syndrome and other disorders caused by small intestinal bacterial overgrowth. CSMC also grants Salix a nonexclusive license to use any unpublished research and development information, know-how and technical data of CSMC as necessary to exploit all rights granted to Salix with respect to rifaximin, with a right to sublicense. In November 2008, the U.S. Patent and Trademark Office issued a patent to Cedars-Sinai Medical Center providing protection relating to rifaximin for treating irritable bowel syndrome caused by small intestinal bacterial overgrowth which provides protection until August 2019. Salix has an exclusive license to this patent from Cedars–Sinai Medical Center to make, have made, use, sell and have sold and import licensed products related to the use of rifaximin.

As of December 31, 2007, the aggregate \$1.2 million license fee had been paid. A portion of the \$1.2 million was considered an up-front, non-refundable and irrevocable licensing fee. The balance was considered a prepaid, non-refundable and irrevocable royalty applicable as credit towards royalty amounts due and payable to CSMC, if any, under the agreement. At such time as the use of rifaximin is approved by the FDA as a treatment for irritable bowel syndrome, Salix will be required to pay CSMC low single digit percentage royalties on net sales of licensed products. An additional term of the license agreement with CSMC provides that Salix will expend a minimum amount per calendar year to seek and obtain regulatory approval and develop and commercialize licensed products. Because the license agreement provides the ability for Salix to terminate the agreement upon giving written notice of not less than 90 days, Salix does not include amounts payable under the license agreement as a purchase obligation in its contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations.

#### *Clinical Development Capital Partnership*

In connection with Salix's acquisition of InKine in September 2005, Salix assumed a license agreement with ALW Partnership for the worldwide rights, in perpetuity, to develop, use, market, sell, manufacture, have manufactured and sub-license Visicol and improvements, including OsmoPrep, in the field of colonic purgatives, along with ALW Partnership's body of proprietary technical information, trade secrets and related know-how. Pursuant to this license agreement, Salix pays to Clinical Development Capital, or CDC, ALW's successor, on a quarterly basis, a percentage royalty payment based on Salix's net sales of these products. Because the amounts of the royalty payments are based on net sales during a quarter Salix is unable to prospectively disclose the amount of such royalty payments. The agreement requires a minimum annual royalty payment of \$0.1 million. Additional royalties are only incurred if there is associated revenue, and then are included in "Cost of products sold" in the Statements of Operations.

#### *Debiopharm Group*

The Debiopharm Group is a global biopharmaceutical development company headquartered in Lausanne, Switzerland. Debiopharm developed vapreotide acetate for the treatment of acute esophageal variceal bleeding. In September 2006 we acquired the exclusive right to sell, market and distribute vapreotide acetate in the United States. The agreement provides that Salix make an upfront payment and milestone payments of up to \$8.0 million to Debiopharm contingent upon achievement of regulatory milestones, up to an additional \$6.0 million in milestone payments contingent on reaching sales thresholds, and quarterly royalty payments on net sales of vapreotide acetate, if approved. As of December 31, 2008, \$1.0 million of the upfront and milestone payments had been made. The remaining milestone payments are contingent upon achievement of regulatory approval and sales thresholds. Because the milestone payments are conditioned upon events that might never occur, we do not consider the potential milestone payment as a purchase obligation nor a commitment to be reported in our contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations.

#### *Dr. Falk Pharma GmbH*

Pursuant to Salix's license agreement, as amended, with Dr. Falk Pharma GmbH, Salix acquired the rights to develop and market a granulated formulation of mesalamine. The agreement provides that Salix make milestone payments in an aggregate amount of up to \$11.0 million to Dr. Falk upon certain events prior to the commercial launch of the product, and quarterly royalty payments thereafter. As of December 31, 2008, \$9.0 million of milestone payments had been made. The remaining milestone payment is contingent upon achievement of additional regulatory approval. Because this milestone payments are conditioned upon events that might never occur, we do not consider the potential milestone payments as purchase obligations nor a commitment to be reported in our contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations. Royalties are only incurred if there is associated revenue, and then are included in "Cost of products sold" in the Statements of Operations.

In March 2008 we acquired a license from Dr. Falk Pharma GmbH to a family of budesonide products, including a budesonide rectal foam and a budesonide gastro-resistant capsule, in the United States. The rectal foam product and the gastro-resistant capsule products have patent coverage in the U.S. until 2015 and 2016, respectively. The agreement

requires Salix 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. At such time as the use of either of these products is approved by the FDA, Salix will be required to pay Dr. Falk royalties on net sales of licensed products. As of December 31, 2008, \$1.0 million of upfront and milestone payments had been made. The remaining milestone payments are contingent upon filing NDA's and achievement of regulatory approvals. Because these milestone payments are conditioned upon events that might never occur, we do not consider the potential milestone payments as purchase obligations nor a commitment to be reported in our contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations.

*King Pharmaceuticals, Inc.*

In June 2004, we acquired the exclusive right to sell Anusol-HC<sup>®</sup> 2.5% (hydrocortisone USP) cream, Anusol-HC<sup>®</sup> 25 mg (hydrocortisone acetate) rectal suppositories, Proctocort<sup>®</sup> 1% (hydrocortisone USP) cream and Proctocort<sup>®</sup> 30 mg (hydrocortisone acetate) rectal suppositories from King Pharmaceuticals, Inc. We paid \$13.0 million cash for the four products, and entered into a supply agreement for the suppository products and the Anusol-HC cream product with King Pharmaceuticals; we established an alternate supply arrangement with a contract manufacturer for the Proctocort cream product. Once payment amounts under this and other supply agreements are known and are non-cancelable, Salix includes them in its contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations.

*Merck & Co., Inc.*

In February 2007, we 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. Pursuant to the Agreement, Salix paid Merck \$55.0 million at the closing of the transaction. In addition, Salix will make additional payments to Merck up to an aggregate of \$6.0 million upon the achievement of certain annual gross sales targets for the acquired products during any of the five calendar years beginning in 2007 and ending in 2011. Because these payments are conditioned upon events that might never occur, we do not consider these payments as purchase obligations nor a commitment to be reported in our contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations.

In return for these payments, Salix obtained (1) all rights to the United States regulatory approvals and related data, open purchase orders, inventory and customer lists related to the acquired oral suspension products, (2) an exclusive license to the Pepcid Oral Suspension and Diuril Oral Suspension trademarks for the use of prescription sale of the acquired oral suspension products in the United States, and (3) an exclusive license to certain know-how related to the manufacture of the acquired oral suspension products in the United States. Merck also agreed to manufacture and supply the acquired oral suspension products to Salix through December 31, 2008. In the event that Salix is acquired by another party or if Salix sells all or substantially all of the rights to the acquired products, and Merck determines in its reasonable judgment that such transaction will result in material harm to the Pepcid Oral Suspension name or the licensed trademark, Merck has the right to terminate one or more of the above licenses and the supply obligation.

*Napo Pharmaceuticals, Inc.*

In December 2008 we acquired rights to crofelemer from Napo Pharmaceuticals, Inc. Patents for crofelemer provide intellectual property protection to 2018. Crofelemer currently is being investigated in a Phase III study as an anti-secretory anti-diarrheal agent for the treatment of chronic diarrhea in people living with HIV, or HIV-associated diarrhea. We made an initial payment of \$5 million, consisting of \$4.5 million in an upfront license fee, and a \$500,000 equity investment. In addition, we will make up to \$50.0 million in milestone payments to Napo contingent on regulatory approvals and up to \$250.0 million in milestone payments contingent on reaching certain sales thresholds. We will be responsible for development costs of crofelemer, but costs exceeding \$12.0 million for development of crofelemer used for the HIV-associated diarrhea indication will be credited towards regulatory milestones and thereafter against sales milestones. Additionally, Salix will pay royalties on net sales of crofelemer, if approved. Because these milestone payments are conditioned upon events that might never occur, we do not consider the potential milestone payments as purchase obligations nor a commitment to be reported in our contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations.

### *Norgine B.V.*

In December 2005, we acquired from Norgine B.V. the exclusive rights to sell NRL944 (now marketed by us under the trade name MoviPrep), a proprietary, liquid PEG bowel cleansing product in the United States. The agreement provides that Salix make an upfront payment and milestone payments to Norgine that could total up to \$37.0 million. As of December 31, 2008, \$22.0 million of upfront and milestone payments had been made. The remaining milestone payments are contingent upon reaching sales thresholds. Because these milestone payments are conditioned upon events that might never occur, we do not consider the potential milestone payments as purchase obligations nor a commitment to be reported in our contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations.

### *Wilmington Pharmaceuticals, LLC*

In September 2007, we acquired the exclusive, worldwide right to sell metoclopramide-Zydis® (trade name Metozolv) from Wilmington Pharmaceuticals, LLC. The agreement provides that Salix make an upfront payment and milestone payments that could total up to \$8.0 million. As of December 31, 2008, we had paid \$1.0 million of these upfront and milestone payments. The remaining milestone payment is contingent upon regulatory approval. Additionally, Salix will pay royalties on net sales of Metozolv, if approved. Because these milestone payments are conditioned upon events that might never occur, we do not consider the potential milestone payments as purchase obligations nor a commitment to be reported in our contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations. We also loaned Wilmington \$2.0 million which is due December 31, 2009, or earlier, based on regulatory approval.

## **Product Out-License Collaborations**

### *Dr. Falk Pharma GmbH*

In April 2007, we licensed to Dr. Falk exclusive rights to market DIACOL™ 1500 mg Tablets in 28 territories in Europe. We sell DIACOL, or, sodium phosphate monobasic monohydrate, USP, and sodium phosphate dibasic anhydrous, tablets, USP, in the United States under the trade name OSMOPREP™ Tablets. As part of the agreement, Dr. Falk also has a non-exclusive option to market DIACOL in Italy and France. Under the terms of the agreement, we could receive up to \$4 million in milestone payments, as well as royalty payments based on product sales. Dr. Falk made the first milestone payment of \$1.5 million upon execution of the agreement. Dr. Falk is obligated to use all reasonable efforts to obtain Marketing Authorization by means of the Mutual Recognition Procedure in the territories and option countries.

In December 2008, Falk terminated this agreement pursuant to its terms. Falk will transfer all marketing authorizations for Diacol back to Salix or its designee at Falk's expense. Salix will retain the \$1.5 million non-refundable and non-creditable sum Falk paid Salix upon execution of the License Agreement. Otherwise, there are no other early termination penalties or other financial ramifications to Falk or Salix as a result of the termination.

### *Menarini Pharmaceutical Industries S.R.L.*

Menarini, headquartered in Italy, is the largest manufacturer and distributor of pharmaceuticals in Southern Europe. Menarini also has extensive experience developing and marketing therapies for gastrointestinal disease in its markets. Under our agreements with Menarini, we granted Menarini certain manufacturing rights and exclusive distribution rights with respect to balsalazide in Italy, Spain, Portugal and Greece. The agreement calls for additional milestone revenues to be paid to us relating to additional European marketing approvals, if any, in the Menarini territories. Under the terms of the agreements, we will sell the bulk active ingredient balsalazide to Menarini for marketing and distribution in its territories at cost plus a sales-based royalty. Menarini did not purchase any bulk active ingredient balsalazide from us during 2003, 2005, 2006, 2007 or 2008. During 2004 and 2008, Menarini paid us approximately \$0.1 million and \$0.4 million related to balsalazide purchases, respectively.

Unless terminated sooner in accordance with its terms, the agreement with Menarini continues until the earlier of the expiration of (1) the patents relating to the product or (2) 15 years from the date of the agreement, provided however

that in any case the agreement shall continue for a period of 10 years from the date of first launch. Either party may terminate the agreement upon a material breach by the other party and the failure to remedy such breach within 30 days in the case of a payment breach or 90 days in the case of any other material breach or if a party enters liquidation, bankruptcy or similar proceedings.

*Mayoly-Spindler S.A.S.*

In October 2007, we licensed exclusive rights to market OSMOPREP™ (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets in France to Mayoly–Spindler S.A.S of Chatou, France. Under the terms of the agreement, we may receive up to \$1.0 million in milestone payments, as well as royalty payments based on product sales.

*Pharmatel PTY Limited.*

In June 2004, we granted Pharmatel certain manufacturing rights and exclusive distribution rights with respect to balsalazide in Australia and New Zealand. Under the terms of the agreements, Pharmatel pays us royalty payments based on product sales.

*Zeria Pharmaceutical Co. Ltd.*

In August 2001, InKine licensed exclusive commercial rights in Japan to Visiclear® Tablets for colon cleansing to Zeria Pharmaceutical Co., Ltd. of Tokyo, Japan. Zeria launched Visiclear in June 2007. Visiclear, or sodium phosphate monobasic monohydrate and sodium phosphate dibasic anhydrous, tablets are marketed in the United States under the trade name VISICOL®. Under the terms of the agreements, Zeria pays us royalty payments based on product sales.

**Supply and Distribution Agreement with Watson Pharma, Inc.**

On December 28, 2007, we announced that we entered into a Supply and Distribution Agreement with Watson Pharma, Inc., pursuant to which Watson will be Salix's exclusive distributor to market and sell an authorized generic of Colazal (balsalazide disodium) Capsules 750 mg, Salix's anti-inflammatory drug approved for the treatment of mildly to moderately active ulcerative colitis, in the United States. Watson agrees to use commercially reasonable efforts to sell authorized generic Colazal, and has sole discretion to establish prices and terms. Watson will pay Salix a portion of its profits for sales under the agreement, and Salix will supply Watson with all its requirements for the product. The agreement terminates in October 2011, provided that either party may terminate immediately upon bankruptcy of the other, or for uncured breaches of the other party. Salix may also terminate on 30 days notice if the agreement has become commercially unviable, if it obtains the right to prohibit other generics from being sold or if it ceases distribution of branded Colazal.

**MANUFACTURING**

We own no manufacturing facilities. We have in the past used and plan to continue to use third-party manufacturers to produce material for use in clinical trials and for commercial product. This manufacturing strategy enables us to direct our financial resources to product in-licensing and acquisition, product development, and sales and marketing efforts, without devoting resources to the time and cost associated with building and maintaining manufacturing facilities.

Under our supply agreement with Alfa Wassermann, Alfa Wassermann is obligated to supply us with bulk rifaximin drug substance, the active pharmaceutical ingredient in Xifaxan tablets, until July 2014 or introduction of a generic product, whichever occurs first. Our supply of rifaximin drug substance is manufactured by ZaCh Systems (formerly Zambon) in Lonigo, Italy, and Aventis in Brindisi, Italy. Under a long-term supply agreement, rifaximin is converted into Xifaxan drug product for us by Patheon, Inc. in Whitby, Ontario. Bulk Xifaxan tablets are packaged into finished Xifaxan commercial bottles by Patheon and packaged into Xifaxan commercial blister packs by Carton Service Inc. in Norris, Tennessee.

Under our long-term supply agreement with aaiPharma, aaiPharma produces our commercial supply of 75 mg and 100 mg Azasan finished product.

Under our long-term supply agreement with Paddock Laboratories, Inc. in Minneapolis, Minnesota, Paddock produces our commercial supply of finished product of Anusol-HC Cream, Anusol-HC Suppositories and Proctocort Suppositories. In addition, through prior supply arrangements between King Pharmaceuticals and Crown Laboratories, Inc. in Johnson City, Tennessee, Crown continues to produce our commercial supply of Proctocort Cream finished product.

Under our long-term supply agreement with WellSpring Pharmaceutical Corporation in Oakville, Ontario, WellSpring produces our commercial supply of OsmoPrep finished product.

Under our long-term supply agreement with Norgine in Hengoed, Wales, Norgine produces our commercial supply of MoviPrep pouches. For secondary packaging of MoviPrep into commercial finished kits, we have two vendors qualified: Norgine, at its Hengoed, Wales facility; and Carton Service in Norris, Tennessee.

Merck manufactured our commercial supply of Pepcid Oral Suspension and Diuril Oral Suspension through December 2008. Under a long-term supply agreement beginning in 2009, Paddock Laboratories in Minneapolis, Minnesota, now produces our commercial supply of Pepcid Oral Suspension and Diuril Oral Suspension.

Bayer AG in Wuppertal, Germany supplies us with bulk mesalamine active ingredient. Under a long-term supply agreement with Catalent Pharma Solutions in Winchester, Kentucky, Catalent converts this mesalamine into our commercial supply of bulk Apriso, 375mg mesalamine capsules. The bulk Apriso capsules are then packaged into finished Apriso commercial bottles by Carton Service in Norris, Tennessee.

Cosma S.P.A. in Bergamo, Italy supplies us with bulk metoclopramide active ingredient. Under a long-term supply agreement with Catalent in Swindon, United Kingdom, Catalent converts this metoclopramide into our commercial supply of Metozolv, 5mg and 10mg tablets in blister packaging. The Metozolv blister packs are then packaged into finished cartons by Carton Service in Norris, Tennessee.

Currently, under long-term supply agreements, we use balsalazide drug substance (the active pharmaceutical ingredient in Colazal capsules) manufactured by OmniChem s.a., a subsidiary of Ajinomoto in Belgium, and PharmaZell (formerly Noveon Pharma, GmbH) in Raubling, Germany. Also, under long-term supply agreements, balsalazide is encapsulated into Colazal drug product for us by Nexgen Pharma, Inc. (formerly Anabolic Laboratories) in Irvine, California. Bulk Colazal capsules are packaged into finished Colazal commercial bottles by Nexgen and Carton Service in Norris, Tennessee.

With respect to our 1100 mg balsalazide tablet formulation and our 550 mg rifaximin tablet formulation, which are currently under development, we plan to negotiate commercial supply agreements with the same manufacturers who supplied the drug substance and drug product for the supplies of the Phase III clinical trial material, if approved. Under our manufacturing and supply agreement with Glenmark Pharmaceuticals, Ltd. in Mumbai, India, Glenmark supplies us with crofelemer, which we are currently investigating in a Phase III study, and will supply us with commercial supplies of crofelemer, if approved.

## **SALES AND MARKETING**

We currently market our products and intend, if approved by the FDA, to market future products to U.S. gastroenterologists through our own direct sales force. We enter into distribution relationships outside the United States and in markets where a larger sales organization is appropriate. Currently, our sales and marketing staff consists of approximately 150 people, which we believe should also position us to sell additional products, if and when acquired and/or approved for U.S. marketing. Because there are a relatively small number of gastroenterologists that write a majority of the prescriptions in our indications, we believe that the size of our sales force is appropriate to reach our target physicians. Our sales force consists of approximately 100 employees who regularly call on approximately 16,000 healthcare professionals. We also have approximately ten national account managers who regularly call on major drug

wholesalers, managed care organizations, large retail chains, formularies and related organizations. We believe we have created an attractive incentive program for our sales force that is based upon goals in prescription growth, market share achievement and customer service.

We cultivate relationships of trust and confidence with the high prescribing gastroenterologists in the United States. We use a variety of marketing techniques to promote our products including sampling, journal advertising, promotional materials, specialty publications, coupons, money-back or product replacement guarantees, educational conferences and informational websites.

## **PATENTS AND PROPRIETARY RIGHTS**

### **General**

The patents for the rifaximin composition of matter (also covering a process of making rifaximin and using rifaximin to treat gastrointestinal infectious diseases) expired in May 2001 in the United States and Canada. In May 2006, a U.S. patent (composition of matter and process patent that covers several physical states of rifaximin) was issued that extends the patent coverage of the currently marketed form of rifaximin to May 22, 2024. Alfa Wasserman S.p.a., the patent owner, has licensed rights to rifaximin in the United States to Salix. In July 2006, Salix entered into an agreement with Cedars-Sinai Medical Center, or CSMC, for the right to use its patent and patent applications relating to methods of diagnosis and treating irritable bowel syndrome and other disorders caused by small intestinal bacterial overgrowth. The CSMC agreement also provides Salix the right to use the U.S. Patent No. 7,452,857 which issued in November 2008, and provides protection relating to rifaximin for treating irritable bowel syndrome, or IBS, caused by small intestinal bacterial overgrowth until August 2019. We have filed applications for patents relating to additional indications using rifaximin and related chemical substances.

The patent for the treatment of the intestinal tract with Apriso, the granulated mesalamine product, provides patent coverage to 2018.

The patent for balsalazide 1100 mg tablets provides patent coverage to 2018.

The patent for balsalazide 1100 mg tablets relating to the increase of bioavailability provides coverage until November 2027.

The patent for Visicol provides patent coverage to 2013.

The patent for OsmoPrep provides patent coverage to 2013. Additional patent protection is being sought on OsmoPrep that, if approved, will provide patent coverage to 2024.

The patent for MoviPrep provides patent coverage to 2024. This patent was issued by the USPTO in January 2007 and it contains composition of matter and kit claims.

The patent for vapreotide acetate expired in 2006; however, we will be applying for Patent Term Restoration.

The patents for crofelemer provide protection to 2018. We are seeking applications for patents relating to additional indications using crofelemer and related chemical substances.

The budesonide rectal foam product and the gastro-resistant capsule product have patent coverage in the U.S. until 2015 and 2016, respectively.

The patents for the balsalazide composition of matter and method of treating ulcerative colitis with balsalazide expired in July 2001 in the United States; however, we were granted five years of new chemical entity data exclusivity for balsalazide until July 2005 and an extension of such patent under the Waxman-Hatch Act through July 2006. We also obtained patent extensions for the composition of balsalazide in Italy and the United Kingdom until July 2006. We have filed applications for patents relating to additional indications using balsalazide and related chemical substances. In November of 2008, the United States Patent and Trademark Office issued a patent covering methods for increasing the bioavailability of balsalazide.

## **Data Exclusivity**

Rifaximin was a new chemical entity, therefore, the FDA granted us five-year new chemical entity exclusivity when it was approved in May 2004. Therefore, rifaximin has data exclusivity through May 2009.

Apriso, the granulated mesalamine product, is not a new chemical entity, but is entitled to three years of exclusivity from its approval based on the new clinical investigations that have been required during the approval process. The exclusivity prevents the FDA from approving an NDA for a granulated mesalamine product which relied upon the new clinical investigation in our NDA for three years from October 31, 2008. The patent for the granulated mesalamine protects the product until April 2018.

Metoclopramide, which is not a new chemical entity, might be entitled to three years of data exclusivity from the date of its approval based on the new clinical investigations that have been required during the approval process. Such exclusivity would have the effect of preventing the FDA from approving an NDA for a metoclopramide product which relied upon the new clinical investigation in our NDA for three years from the date of approval. Our metoclopramide product is a fast-dissolve formulation that has patent protection until 2017 and additional patent protection pending that, if issued, will provide intellectual property protection until 2023.

Vapreotide acetate is a new chemical entity and will be entitled to data exclusivity for five years beginning from the date of the approval of our NDA, if approved. Vapreotide acetate is also an orphan drug, therefore, the product will be entitled to orphan exclusivity for seven years beginning from the date of the approval of our NDA, if approved.

Azasan and the Anusol-HC and Proctocort product lines are mature products, thus, there are no available patent or exclusivity rights.

The Pepsid product line is a mature product line, thus, there are no available patent or exclusivity rights.

Crofelemer, which is a new chemical entity, should be eligible for market exclusivity for five years in the United States. As a new molecular entity, we believe crofelemer may be entitled to patent term restoration. The patents for crofelemer provide protection until 2018.

## **GOVERNMENT REGULATION**

The research, testing, manufacture, marketing and distribution of drug products are extensively regulated by governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous regulation by the FDA. The Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, record keeping, labeling, promotion and marketing and distribution of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject a company to administrative sanctions or judicially imposed sanctions such as civil penalties, criminal prosecution, injunctions, product seizure or detention, product recalls, and total or partial suspension of product marketing and/or approvals. In addition, non-compliance may result in the FDA's refusal to approve pending NDAs or supplements to approved NDAs or in the withdrawal of an NDA. Any such sanction could result in adverse publicity, which could have a material adverse effect on our business, financial conditions, and results of operation.

The steps ordinarily required before a new pharmaceutical product containing a new chemical entity may be marketed in the United States include: (1) preclinical laboratory tests, preclinical studies in animals and formulation studies; (2) the submission to the FDA of a notice of claimed investigational exemption for a new drug or antibiotic, which must become effective before clinical testing may commence; (3) adequate and well-controlled clinical human trials to establish the safety and efficacy of the drug for each indication; (4) the submission of an NDA to the FDA; and (5) FDA review and approval of the NDA prior to any commercial sale or shipment of the drug. Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety and efficacy of the product. Preclinical tests must be conducted in compliance with Good Laboratory Practice regulations. The results of preclinical testing are submitted to the FDA as part of an IND. A 30-day waiting period after the filing of each IND is required prior to the commencement of clinical testing in humans. In addition, the FDA may, at any time during this 30-day period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical

trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

Clinical trials to support NDAs are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics and pharmacological actions and safety, including side effects associated with increasing doses. Phase II usually involves studies in a limited patient population to (1) assess the efficacy of the drug in specific, targeted indications, (2) assess dosage tolerance and optimal dosage and (3) identify possible adverse effects and safety risks. If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further demonstrate clinical efficacy and to further test for safety within an expanded patient population at geographically dispersed clinical study sites. There can be no assurance that Phase I, Phase II or Phase III testing will be completed successfully within any specified time period, if at all, with respect to any of our products subject to such testing.

After successful completion of the required clinical testing, generally an NDA is submitted. FDA approval of the NDA is required before marketing may begin in the United States. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. In such an event, the NDA must be resubmitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The FDA generally has 10 months in which to review the NDA and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter, outlining the deficiencies in the submission and often requiring additional testing or information. If FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or a complete response letter, which usually contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. Furthermore, approval may entail ongoing requirements for post-marketing studies, and marketed products, manufacturers and manufacturing facilities are subject to continual review and periodic inspections. In addition, identification of certain side effects after a drug is on the market or the occurrence of manufacturing problems could cause subsequent withdrawal of approval, reformulation of the drug, additional preclinical testing or clinical trials and changes in labeling of the product.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a disease or condition that affects populations of fewer than 200,000 individuals in the United States or a disease whose incidence rates number more than 200,000 where the sponsor establishes that it does not realistically anticipate that its product sales will be sufficient to recover its costs. The sponsor that obtains the first marketing approval for a designated orphan drug for a given rare disease is eligible to receive marketing exclusivity for use of that drug for the orphan indication for a period of seven years. Vapreotide acetate, rifaximin for the treatment of hepatic encephalopathy and Colazal for the treatment of mildly to moderately active ulcerative colitis in pediatric patients between 5 to 17 years of age have been granted orphan drug status.

### **Regulation of Drug Compounds Outside of the United States**

Outside the United States, the ability to market a drug is contingent upon receiving marketing authorizations from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country. Currently, foreign marketing authorizations are applied for at a national level, although within the European Union procedures are available to companies wishing to market a product in more than one European Union member state. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above.

If and when necessary, we will choose the appropriate route of European regulatory filing to accomplish the most rapid regulatory approvals. However, the chosen regulatory strategy might not secure regulatory approvals or approvals of our chosen product indications. Furthermore, we must obtain pricing approval in addition to regulatory approval prior to launching the product in the approving country. Failure to obtain pricing approval in a timely manner or approval of pricing which would support an adequate return on investment or generate a sufficient margin to justify the economic risk might delay or prohibit the commercial launch of the product in those countries.

## **COMPETITION**

Competition in our business is intense and characterized by extensive research efforts, rapid technological progress and an increasing rate of generic product approvals. Technological developments by competitors, earlier regulatory approval for marketing competitive products, including generic versions of our products, or superior marketing capabilities possessed by competitors could adversely affect the commercial potential of our products and could have a material adverse effect on our revenue and results of operations. We believe that there are numerous pharmaceutical and biotechnology companies, including large well known pharmaceutical companies and generic manufacturers, as well as academic research groups throughout the world, engaged in research and development efforts with respect to pharmaceutical products targeted at gastrointestinal diseases and conditions addressed by our current and potential products. In particular, we are aware of products in research or development by competitors that address the diseases being targeted by our products. Developments by others might render our current and potential products obsolete or non-competitive. Competitors might be able to complete the development and regulatory approval process sooner and, therefore, market their products earlier than us. Many of our competitors have substantially greater financial, marketing and personnel resources and development capabilities than we do.

For example, many large, well capitalized companies already offer products in the United States and Europe that target the indications for balsalazide and our mesalamine extended-release capsule product, including mesalamine (GlaxoSmithKline plc, Giuliani S.p.A., Axcan Pharma, Inc., Solvay S.A., The Procter & Gamble Company and Shire Pharmaceuticals Group plc), sulfasalazine (Pharmacia & Upjohn, Inc.), and olsalazine (Alaven Pharmaceutical LLC). Asacol, marketed by Procter & Gamble, is currently the most prescribed product for the treatment of ulcerative colitis in the United States, and Shire introduced once-a-day Lialda in 2007. In addition, on December 28, 2007, the Office of Generic Drugs approved three generic balsalazide capsule products.

Several prescription, liquid PEG products compete with Visicol, OsmoPrep and MoviPrep in the bowel cleansing market. These prescription products include Colyte, Golytely, Halflytely, and Nulytely (Braintree) and Trilyte (Alaven Pharmaceutical LLC). Generic prescription, liquid PEG products are also available.

The most frequently prescribed product for treatment of travelers' diarrhea in the United States currently is ciprofloxacin, commonly known as "Cipro®" and marketed by Bayer AG. The most frequently prescribed products that compete with Azasan are Imuran®, marketed by Prometheus Laboratories, Inc., and its various generics and Purinethol®, marketed by GATE Pharmaceuticals, and its various generics. The most frequently prescribed products that compete with Anusol-HC and Proctocort are AnaMantle HC, marketed by Bradley Pharmaceuticals; Analpram HC, marketed by Ferndale Laboratories; Proctofoam-HC and Proctocream-HC, marketed by Alaven Pharmaceutical LLC; Procto-Kit, marketed by Ranbaxy Pharmaceuticals; and various generics.

## **EMPLOYEES**

As of December 31, 2008, we had approximately 280 full-time employees. We believe that our future success will depend in part on our continued ability to attract, hire, and retain qualified personnel, including sales and marketing personnel in particular. Competition for such personnel is intense, and there can be no assurance that we will be able to identify, attract, and retain such personnel in the future. None of our employees are represented by a labor union. We have not experienced any work stoppages and consider our relations with our employees to be good.

## Item 1A. Risk Factors

*This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this report and in any documents incorporated in this report by reference.*

*If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.*

### **We expect to be unprofitable and experience negative cash flow during 2009, and we may need additional capital.**

We will be unprofitable and have negative cash flow during 2009. We believe that our current cash and cash equivalents together with cash generated from the sale of our products will be sufficient to fund our operations for 2009. Our future capital requirements will depend on many factors, including but not limited to:

- any impact on us of current conditions and uncertainties in the economy generally and the financial markets;
- patient and physician demand for our products;
- the status of competitive products, including current and potential generics;
- the results, costs and timing of our research and development activities, regulatory approvals and product launches;
- our ability to reduce our costs in the event product demand is less than expected, or regulatory approvals are delayed or more expensive than expected;
- the number of products we acquire or in-license;
- the actual amount of Colazal returns we receive compared to our current estimates; and
- our ability to maintain our current credit facility.

We believe that we will be able to return to a positive cash flow position without requiring additional capital based on our current projections. However these projections may change due to changes in the factors discussed above, or other factors. If we need additional capital, we might seek additional debt or equity financing or both to fund our operations or acquisitions. 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 issued 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, especially in the current economic environment. Our common stock is likely to decrease in value if the market believes that we will be unable to return to profitability, or that we will be required to raise additional capital.

Our credit facility, as amended, contains various representations, warranties and affirmative, negative and financial covenants customary for financings of this type. For example, as long as we maintain an amount equal to the amount outstanding under the credit facility on deposit with the Administrative Agent of the credit facility and maintain a minimum of \$23.0 million in cash on our balance sheet, the leverage test and fixed charge test are suspended under the credit facility. We were in compliance with all applicable covenants under the credit facility, as amended, at December 31, 2008. If we fall out of compliance with the financial covenants in the future, we would need to obtain a waiver or amendment, or the amount outstanding on the credit facility would be immediately due.

### **Future sales of Xifaxan and our other marketed products might be less than expected.**

We currently market and sell eleven primary products, with a majority of our historical revenue derived from sales of Colazal prior to 2008. We expect Xifaxan, which was launched in mid-2004, Moviprep, which we acquired from Norgine in December 2005, and OsmoPrep, which we acquired in connection with our acquisition of InKine in September 2005, to be growing and significant sources of revenue in the future. If sales of our marketed products decline or if we experience product returns significantly in excess of estimated amounts recorded, particularly with respect to Xifaxan, Moviprep and OsmoPrep, it would have a material adverse effect on our business, financial condition and results of operations.

The degree of market acceptance of our products among physicians, patients, healthcare payors and the medical community will depend upon a number of factors including:

- the timing of regulatory approvals and product launches by us or competitors, such as the launch of Lialda, and including any generic or over-the-counter competitors;
- perceptions by physicians and other members of the healthcare community regarding the safety and efficacy of the products;
- price increases, and the price of our products relative to other drugs or competing treatments;
- patient and physician demand;
- adverse side effects or unfavorable publicity concerning our products or other drugs in our class;
- the results of product development efforts for new indications;
- the scope and timing of additional marketing approvals and favorable reimbursement programs for expanded uses;
- availability of sufficient commercial quantities of the products; and
- our success in getting other companies to distribute our products outside of the U.S. gastroenterology market.

### **Regulatory approval of our product candidates is time-consuming, expensive and uncertain, and could result in unexpectedly high expenses and delay our ability to sell our products.**

Development of our products are subject to extensive regulation by governmental authorities in the United States and other countries. This regulation could require us to incur significant unexpected expenses or delay or limit our ability to sell our product candidates, including specifically metoclopramide, balsalazide disodium tablets, rifaximin for hepatic encephalopathy, or HE, and vaptotide acetate, our product candidates that are farthest along in the regulatory approval process. In early 2008, the FDA announced that because of its large workload it might not meet its target dates to respond to NDA submissions, and in November 2008 it extended the metoclopramide-Zydis review until February 2009. In addition, in 2008 we received two “approvable” or “complete response” letters from the FDA for balsalazide tablets and Wilmington Pharmaceuticals received one in February 2009 for metoclopramide, each requesting additional information or further studies, rather than regulatory approval.

Our clinical studies might be delayed or halted, or additional studies might be required, for various reasons, including:

- the drug is not effective;
- patients experience severe side effects during treatment;
- appropriate patients do not enroll in the studies at the rate expected, as has been the case with our Xifaxan Phase III trial in Thailand for the prevention of travelers’ diarrhea;
- drug supplies are not sufficient to treat the patients in the studies; or
- we decide to modify the drug during testing.

If regulatory approval of any product is granted, it will be limited to those indications for which the product has been shown to be safe and effective, as demonstrated to the FDA's satisfaction through clinical studies. For example, Xifaxan has been approved for treatment of travelers' diarrhea, but we are developing Xifaxan for HE and other indications. The FDA may never approve any of our compounds in the indications we are pursuing, which would mean we cannot market these compounds for use in these indications.

**Our ability to increase revenue in the future will depend in part on our success in in-licensing or acquiring additional pharmaceutical products.**

We currently intend to in-license or acquire additional pharmaceutical products, as we did with vopreotide acetate and crofelemer, that have been developed beyond the initial discovery phase and for which late-stage human clinical data is already available, or as we did with Pepcid Oral Suspension, that has already received regulatory approval. These kinds of pharmaceutical products might not be available to us on attractive terms or at all. To the extent we acquire rights to additional products, we might incur significant additional expense in connection with the development and, if approved by the FDA, marketing of these products.

**Regulatory approval, even if granted, might entail ongoing requirements or restrictions on marketing that could increase our expenses and limit revenue.**

Approval might entail ongoing requirements for post-marketing studies, or limit how or to whom we can sell our products. Even if regulatory approval is obtained, labeling and promotional activities are subject to continual scrutiny by the FDA and state regulatory agencies and, in some circumstances, the Federal Trade Commission. For example, in 2008 the FDA required us to put a "black box" warning on the OsmoPrep and Visicol labels regarding potential kidney damage that could result from their use, which could limit future sales of those products. In addition, FDA enforcement policy prohibits the marketing of approved products for unapproved, or off-label, uses. These regulations and the FDA's interpretation of them might increase our expenses, impair our ability to effectively market our products, and limit our revenue.

**Failure to comply with manufacturing regulation could harm us financially and could hurt our reputation.**

We and our third-party manufacturers such as Glenmark Pharmaceuticals Ltd. that produces crofelemer are also required to comply with the applicable FDA current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our products, and they are subject to additional FDA inspection. Manufacturing regulations can increase our expenses and delay production, either of which could reduce our margins. In addition, if we fail to comply with any of the FDA's continuing regulations, we could be subject to reputational harm and sanctions, including:

- delays, warning letters and fines;
- product recalls or seizures and injunctions on sales;
- refusal of the FDA to review pending applications;
- total or partial suspension of production;
- withdrawals of previously approved marketing applications; and
- civil penalties and criminal prosecutions.

In addition, the occurrence of manufacturing problems could cause subsequent withdrawal of approval, reformulation of the drug, additional testing or changes in labeling of the product.

**Our intellectual property rights might not afford us with meaningful protection.**

The intellectual property rights protecting our products might not afford us with meaningful protection from generic and other competition. In addition, because our strategy is to in-license or acquire pharmaceutical products

which typically have been discovered and initially researched by others, future products might have limited or no remaining patent protection due to the time elapsed since their discovery. Competitors could also design around any of our intellectual property or otherwise design competitive products that do not infringe our intellectual property.

Any litigation that we become involved in to enforce intellectual property rights could result in substantial cost to us. In addition, claims by others that we infringe their intellectual property could be costly. Our patent or other proprietary rights related to our products might conflict with the current or future intellectual property rights of others. Litigation or patent interference proceedings, either of which could result in substantial cost to us, might be necessary to defend any patents to which we have rights and our other proprietary rights or to determine the scope and validity of other parties' proprietary rights. The defense of patent and intellectual property claims is both costly and time-consuming, even if the outcome is favorable. Any adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to cease selling one or more of our products. We might not be able to obtain a license to any third-party technology that we require to conduct our business, or, if obtainable, that technology might not be available at a reasonable cost.

Upon patent expiration, our drugs could be subject to generic competition, which could negatively affect our pricing and sales volume. As previously disclosed, this has already happened to Colazal, which had been our largest selling drug prior to 2008.

Patent applications relating to rifaximin compositions and related chemical substances were filed together with Alfa Wasserman and issued in May 2006. This patent extends patent coverage to 2024. In November of 2008, the United States Patent and Trademark Office issued a patent covering the use of rifaximin for treating irritable bowel syndrome (IBS) caused by small intestinal bacterial overgrowth. In January 2007, the United States Patent and Trademark Office issued a patent covering composition of matter and kit claims for MoviPrep. The MoviPrep patent provides coverage to September 2024. The patent for Visicol and OsmoPrep will expire in 2013. Additional patent protection is being sought for OsmoPrep that, if approved, will provide patent coverage to 2024. The patent for the treatment of the intestinal tract with the Apriso will provide patent coverage to 2018. The patent application relating to the dosage form for metoclopramide protects the product until July 2017. The patent for vaporeotide acetate expired in 2006; however, we will be applying for patent Term Restoration. The patent for crofelemer, relating to enteric formulations and uses thereof provide protection until 2018 and should be entitled to patent term restoration as a new molecular entity. There is no assurance that these patents or the patent term restorations will be issued or granted, respectively. Patent expiration dates listed herein, unless otherwise noted, are for U.S. patents and assume there are no patent term adjustments, extensions or other adverse events that could affect the term or scope of a patent.

Rifaximin is a new chemical entity and was granted five-year new chemical entity exclusivity by the FDA when it was approved in May 2004. Rifaximin, therefore, has data exclusivity only until May 2009. Accordingly, the Office of Generic Drugs would have been able to accept an ANDA for Xifaxan tablets on or any time subsequent to May 2008, if the applicant certified that its generic rifaximin does not infringe Salix's patent. If this occurred, a Paragraph IV notification would have to be provided to us by the applicant. Although we do not possess any specific knowledge of any such filing at the current time, the expiration of data exclusivity could result in a challenge to the related intellectual property rights of Xifaxan 200mg tablets at any time in the future. In May 2008 we submitted a Citizen Petition, requesting the director of the Office of Generic Drugs of the Food and Drug Administration impose scientifically appropriate standards for the demonstration of bioequivalence for abbreviated new drug applications citing Xifaxan as the reference listed drug.

Vaporeotide acetate is a new chemical entity and will be entitled to data exclusivity for five years beginning from the date of the approval of our NDA, if approved. Vaporeotide acetate is also an orphan drug, therefore the product will be entitled to orphan exclusivity for seven years beginning from the date of the approval of the NDA, if approved.

Because Azasan, Anusol-HC and Proctocort are mature products there are no patents or data exclusivity rights available, which subjects us to greater risk of generic competition for those products.

We also rely on trade secrets, proprietary know-how and technological advances, which we seek to protect, in part, through confidentiality agreements with collaborative partners, employees and consultants. These agreements might be breached and we might not have adequate remedies for any such breach. In addition, our trade secrets and proprietary know-how might otherwise become known or be independently developed by others.

**Intense competition might render our products noncompetitive or obsolete.**

Competition in our business is intense and characterized by extensive research efforts and rapid technological progress. Technological developments by competitors, regulatory approval for marketing competitive products, including potential generic or over-the-counter products, or superior marketing resources possessed by competitors could adversely affect the commercial potential of our products and could have a material adverse effect on our revenue and results of operations. We believe that there are numerous pharmaceutical and biotechnology companies, including large well-known pharmaceutical companies, as well as academic research groups throughout the world, engaged in research and development efforts with respect to pharmaceutical products targeted at gastrointestinal diseases and conditions addressed by our current and potential products. In particular, we are aware of products in research or development by competitors that address the diseases being targeted by our products. Developments by others might render our current and potential products obsolete or noncompetitive. Competitors might be able to complete the development and regulatory approval process sooner and, therefore, market their products earlier than we can.

Many of our competitors have substantially greater financial, marketing and personnel resources and development capabilities than we do. For example, many large, well-capitalized companies already offer products in the United States and Europe that target the indications for:

- Xifaxan as approved (travelers' diarrhea), including ciprofloxacin, commonly known as Cipro (Bayer AG);
- Visicol, OsmoPrep and MoviPrep, including Colyte, Golytely, Halflytely, and Nulytely (Braintree) and Trilyte (Alaven Pharmaceutical LLC) and Fleets Phospho-Soda;
- Apriso, including Asacol (Proctor & Gamble), sulfasalazine (Pfizer), Dipentum (Alaven Pharmaceutical LLC), Pentasa (Shire Pharmaceuticals Group, plc), once-a-day Lialda (Shire), and three generic balsalazide capsule products; and
- Xifaxan under development, including Lotronex<sup>®</sup> (Prometheus), and Zelnorm<sup>®</sup> (Novartis), which is no longer available on the market in the US, for IBS.

In addition, other products are in research or development by competitors that address the diseases and diagnostic procedures being targeted by these and our other products.

**We could be exposed to significant product liability claims that could prevent or interfere with our product commercialization efforts.**

We have been in the past and might continue to be subjected to product liability claims that arise through the testing, manufacturing, marketing and sale of our products. These claims could expose us to significant liabilities that could prevent or interfere with our product commercialization efforts. Product liability claims could require us to spend significant time and money in litigation or to pay significant damages. Although we currently maintain liability coverage for both clinical trials and the commercialization of our products, it is possible that this coverage will be insufficient to satisfy any liabilities that may arise. In the future, we might not be able to obtain adequate coverage at an acceptable cost or might be unable to obtain adequate coverage at all.

**If third-party payors do not provide coverage or reimburse patients for our products, our ability to derive revenues will suffer.**

Our success will depend in part on the extent to which government and health administration authorities, private health insurers and other third-party payors will pay for our products. Reimbursement for newly approved healthcare products is uncertain. In the United States and elsewhere, third-party payors, such as Medicaid, are increasingly challenging the prices charged for medical products and services. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products. In the United States, a number of legislative and regulatory proposals aimed at changing the healthcare system have been proposed in recent years, and the Obama administration has indicated it would like to address this. In addition, an increasing emphasis on managed care in the United States has and will continue to increase pressure on pharmaceutical pricing. While we cannot predict whether legislative or regulatory proposals will be

adopted or what effect those proposals or managed care efforts, including those relating to Medicaid payments, might have on our business, the announcement and/or adoption of such proposals or efforts could increase costs and reduce or eliminate profit margins. Third-party insurance coverage might not be available to patients for our products. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our products, the market acceptance of these products might be reduced.

**We are dependent on third parties to manufacture our products.**

We have limited experience and capabilities in manufacturing pharmaceutical products. We do not generally expect to engage directly in the manufacturing of products, but instead contract with others for these services. A limited number of manufacturers exist which are capable of manufacturing our marketed products and our product candidates. We might fail to contract with the necessary manufacturers or might contract with manufacturers on terms that may not be entirely acceptable to us. Our manufacturing strategy presents the following risks:

- the manufacture of products might be difficult to scale up when required and result in delays, inefficiencies and poor or low yields of quality products;
- some of our contracts contain purchase commitments that require us to make minimum purchases that might exceed needs or limit the ability to negotiate with other manufacturers, which might increase costs;
- the cost of manufacturing certain products might make them prohibitively expensive;
- delays in scale-up to commercial quantities and any change in manufacturers could delay clinical studies, regulatory submissions and commercialization of our products;
- manufacturers are subject to the FDA's cGMP regulations and similar foreign standards, and we do not have control over compliance with these regulations by the third-party manufacturers; and
- if we need to change manufacturers, FDA and comparable foreign regulators would require new testing and compliance inspections and the new manufacturers would have to be educated in the processes necessary for the production of our products.

**We are dependent on third parties to supply us with products.**

We rely entirely on third parties to supply us with our commercially marketed products and our products under development. For example, Glenmark Pharmaceuticals Ltd., a corporation organized and located in India, manufactures and supplies us with crofelemer, an anti-secretory agent that we are developing for the treatment of HIV-associated diarrhea. The raw material for crofelemer grows in parts of South America. Glenmark obtains it from select countries in South America. The amount of resources Glenmark devotes to these activities and its ability to successfully obtain raw material is not within our control. Failure of Glenmark to manufacture and supply us with crofelemer, whether due to international political or economic conditions or otherwise, could delay development, increase expenses and delay or prevent us from generating revenue from crofelemer, if approved, any of which could have a material adverse effect on our business. Likewise, interruption of supply of any of our other products could have a material adverse effect on our business.

**Our results of operations might fluctuate from period to period, and a failure to meet the expectations of investors or the financial community at large could result in a decline in our stock price.**

Our results of operations might fluctuate significantly on a quarterly and annual basis due to, among other factors:

- the timing of regulatory approvals and product launches by us or competitors, including potential generic or over-the-counter competitors;
- the level of revenue generated by commercialized products, including potential increased purchases of inventory by wholesalers in anticipation of potential price increases or introductions of new dosages or bottle sizes, and subsequent lower than expected revenue as the inventory is used;
- the timing of any up-front payments that might be required in connection with any future acquisition of product rights;

- the timing of milestone payments that might be required to our current or future licensors;
- fluctuations in our development and other costs in connection with ongoing product development programs;
- the level of marketing and other expenses required in connection with product launches and ongoing product growth;
- the timing of the acquisition and integration of businesses, assets, products and technologies; and
- general and industry-specific business and economic conditions.

### **Our stock price is volatile.**

Our stock price has been extremely volatile and might continue to be, making owning our stock risky. Between January 1, 2005 and March 10, 2009, the price of a share of our common stock varied from a low of \$5.07 to a high of \$22.79, as adjusted for the 3-for-2 stock split effected in July 2004.

The securities markets have experienced significant price and volume fluctuations unrelated to the performance of particular companies, including as a result of the current credit and economic crisis. In addition, the market prices of the common stock of many publicly traded pharmaceutical and biotechnology companies have in the past been and can in the future be expected to be especially volatile. Announcements of prescription trends, technological innovations or new products by us or our competitors, generic approvals, developments or disputes concerning proprietary rights, publicity regarding actual or potential medical results relating to products under development by us or our competitors, regulatory developments in both the United States and other countries, public concern as to the safety of pharmaceutical products, and economic and other external factors, as well as period-to-period fluctuations in financial results, might have a significant impact on the market price of our common stock.

### **Antitakeover provisions could discourage a takeover that stockholders consider to be in their best interests or prevent the removal of our current directors and management.**

We have adopted a number of provisions that could have antitakeover effects or prevent the removal of our current directors and management. We have adopted a stockholder protection rights plan, commonly referred to as a poison pill. The rights plan is intended to deter an attempt to acquire us in a manner or on terms not approved by our board of directors. The rights plan will not prevent an acquisition that is approved by our board of directors. We believe our rights plan assisted in our successful defense against a hostile takeover bid earlier in 2003. Our charter authorizes our board of directors to determine the terms of up to 5,000,000 shares of undesignated preferred stock and issue them without stockholder approval. The issuance of preferred stock could make it more difficult for a third party to acquire, or discourage a third party from acquiring, voting control in order to remove our current directors and management. Our bylaws also eliminate the ability of the stockholders to act by written consent without a meeting or make proposals at stockholder meetings without giving us advance written notice, which could hinder the ability of stockholders to quickly take action that might be opposed by management. These provisions could make more difficult the removal of current directors and management or a takeover of Salix, even if these events could be beneficial to stockholders. These provisions could also limit the price that investors might be willing to pay for our common stock.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

In mid-2005, we moved our corporate headquarters to Morrisville, North Carolina, where we occupy approximately 77,000 square feet of office space under a lease expiring in 2015. We sub-leased our former corporate headquarters located in Raleigh, North Carolina, of approximately 26,000 square feet of office space under a lease expiring in 2011. We also lease a small amount of additional space in Palo Alto, California. We believe our existing facilities are adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms as needed.

### Item 3. Legal Proceedings

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

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

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

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

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

### Item 4. Submission of Matters to a Vote of Security Holders

No matter was submitted to a vote of our stockholders during the fourth quarter of the year ended December 31, 2008.

### Executive Officers of the Registrant

The following table sets forth information concerning our executive officers as of March 1, 2008:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Carolyn J. Logan . . . . .	60	President, Chief Executive Officer, and Director
Adam C. Derbyshire . . . . .	43	Senior Vice President, Finance and Administration, and Chief Financial Officer
William P. Forbes . . . . .	47	Vice President, Research and Development and Chief Development Officer

Carolyn J. Logan has served as President and Chief Executive Officer and as a member of the Board of Directors since July 2002. She previously served as Senior Vice President, Sales and Marketing from June 2000 to July 2002. Prior to joining us, Ms. Logan served as Vice President, Sales and Marketing of the Oclassen Dermatologics division of Watson Pharmaceuticals, Inc. from May 1997 to June 2000, and as Vice President, Sales from February 1997 to May 1997. Prior to that date, she served as Director, Sales of Oclassen Pharmaceuticals, Inc. from January 1993 to February 1997. Prior to joining Oclassen, Ms. Logan held various sales and marketing positions with Galderma Laboratories, Ulmer Pharmacal and Westwood Pharmaceuticals. Ms. Logan received a B.S. degree in Biology and Dental Hygiene from the University of North Carolina at Chapel Hill.

Adam C. Derbyshire has served as Senior Vice President, Finance and Administration and Chief Financial Officer since June 2003. Mr. Derbyshire previously served as Vice President, Finance and Administration and Chief Financial Officer from June 2000 to June 2003. From June 1999 to June 2000, Mr. Derbyshire was Vice President, Corporate Controller and Secretary of Medco Research, Inc., acquired by King Pharmaceuticals, Inc. in February 2000, Corporate Controller and Secretary of Medco from September 1995 to June 1999 and Assistant Controller of Medco from October 1993 to September 1995. Mr. Derbyshire received his B.S. degree from the University of North Carolina at Wilmington and his MBA from the University of North Carolina at Charlotte.

William P. Forbes joined Salix in January 2005 as Vice President, Research and Development, and Chief Medical Officer. From 2002 through 2004, Dr. Forbes was Vice President, Clinical Development and Regulatory Affairs of Metabasis Therapeutics, Inc. He has also worked for Otsuka America Pharmaceutical, Inc. in a variety of roles of increasing responsibility from 1991 to 2002 and Glaxo, Inc. from 1989 through 1991. He has extensive experience in clinical development, regulatory affairs and project management. Dr. Forbes received his Doctor of Pharmacy degree from Creighton University.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the Nasdaq Global Market under the symbol "SLXP". The following table sets forth the high and low sales prices of our common stock, as reported on the Nasdaq Global Market for the eight quarters ended December 31, 2008.

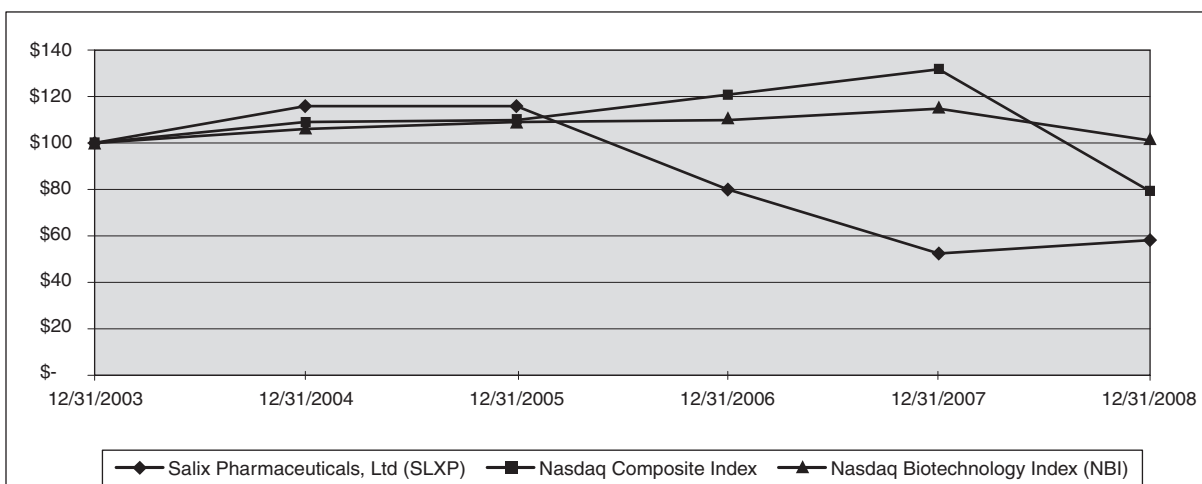
	<u>High</u>	<u>Low</u>
Fiscal year ended December 31, 2007		
First quarter . . . . .	\$16.38	\$11.63
Second quarter . . . . .	14.49	12.24
Third quarter . . . . .	14.26	10.75
Fourth quarter . . . . .	13.33	7.50
Fiscal year ended December 31, 2008		
First quarter . . . . .	\$ 8.18	\$ 5.40
Second quarter . . . . .	7.86	6.06
Third quarter . . . . .	9.10	5.34
Fourth quarter . . . . .	10.47	5.07

On March 10, 2009 the closing price for the common stock as reported on the Nasdaq Global Market was \$6.87. As of March 10, 2009 there were 234 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

The securities markets have from time to time experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. Our stock has been particularly volatile, including for example the approximate 21.8% single-day drop on December 28, 2007, when three generic versions of our drug Colazal were approved. The market prices of the common stock of Salix and many publicly traded pharmaceutical and biotechnology companies have in the past and can in the future be expected to be especially volatile. Announcements of technological innovations or new products by us or our competitors, developments or disputes concerning proprietary rights, publicity regarding actual or potential medical results relating to products under development by us or our competitors, regulatory developments in both the United States and other countries, public concern as to the safety of pharmaceutical products and economic and other external factors, as well as period-to-period fluctuations in our financial results, might have a significant impact on the market price of our common stock.

## Performance Graph

The following graph compares our cumulative total stockholder return from December 31, 2003 with those of the Nasdaq Composite Index and the Nasdaq Biotech Index and that all dividends were reinvested. The graph assumes that U.S. \$100 was invested on December 31, 2003 in (1) our common stock, (2) the Nasdaq Composite Index and (3) the Nasdaq Biotech Index. The measurement points utilized in the graph consist of the last trading day in each calendar year, which closely approximates the last day of the respective fiscal year of the Company. The historical stock performance presented below is not intended to and may not be indicative of future stock performance.



	<u>12/31/03</u>	<u>12/31/04</u>	<u>12/31/05</u>	<u>12/31/06</u>	<u>12/31/07</u>	<u>12/31/08</u>
SLXP .....	\$100	\$116	\$116	\$ 80	\$ 52	\$ 58
Nasdaq Composite Index .....	\$100	\$109	\$110	\$121	\$132	\$ 79
Nasdaq Biotech Index .....	\$100	\$106	\$109	\$110	\$115	\$101

In July 2004, we effected a three-for-two stock split of our common stock. As a result of the stock split, stockholders as of the record date of June 30, 2004 received one additional common share for every two shares held on the record date. The payment date for the additional shares was July 13, 2004.

## Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of business and do not anticipate paying any cash dividends in the foreseeable future.

## Item 6. Selected Financial Data

The following selected consolidated financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the Consolidated Financial Statements and the Notes thereto included elsewhere in this report.

### Consolidated Statements of Operations Data:

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(U.S. dollars, in thousands, except per share data)				
Revenues:					
Net product revenues	\$178,766	\$232,880	\$208,533	\$154,703	\$101,697
Revenues from collaborative agreements	—	2,912	—	200	3,799
Total revenues	178,766	235,792	208,533	154,903	105,496
Costs and expenses:					
Cost of products sold	36,710	55,024	41,443	34,222	21,754
Fees and costs related to license agreements	7,105	1,850	1,296	100	1,837
Amortization of product rights and intangible assets	9,891	8,627	4,907	2,279	762
Research and development	76,630	71,947	47,917	34,547	20,366
Selling, general and administrative	95,088	86,492	82,636	70,823	54,128
In-process research and development	—	—	—	74,000	—
Total costs and expenses	225,424	223,940	178,199	215,971	98,847
Income (loss) from operations	(46,658)	11,852	30,334	(61,068)	6,649
Interest and other income (expense), net	(495)	3,326	2,552	1,222	598
Income (loss) before income tax expense	(47,153)	15,178	32,886	(59,846)	7,247
Income tax (expense) benefit	116	(6,953)	(1,376)	(739)	(408)
Net income (loss)	<u>\$ (47,037)</u>	<u>\$ 8,225</u>	<u>\$ 31,510</u>	<u>\$ (60,585)</u>	<u>\$ 6,839</u>
Net income (loss) per share, basic(1)	<u>\$ (0.98)</u>	<u>\$ 0.17</u>	<u>\$ 0.68</u>	<u>\$ (1.55)</u>	<u>\$ 0.19</u>
Net income (loss) per share, diluted(1)	<u>\$ (0.98)</u>	<u>\$ 0.17</u>	<u>\$ 0.65</u>	<u>\$ (1.55)</u>	<u>\$ 0.18</u>
Shares used in computing net income (loss) per share, basic(1)	<u>47,898</u>	<u>47,329</u>	<u>46,634</u>	<u>39,129</u>	<u>36,112</u>
Shares used in computing net income (loss) per share, diluted(1)	<u>47,898</u>	<u>48,678</u>	<u>48,369</u>	<u>39,129</u>	<u>38,930</u>

### Consolidated Balance Sheet Data:

	As of December 31,				
	2008	2007	2006	2005	2004
Cash and cash equivalents	\$ 120,153	\$ 111,272	\$ 76,465	\$ 67,184	\$ 48,108
Short-term investments	—	—	—	998	4,000
Working capital	113,795	108,891	126,216	94,520	69,914
Total assets	401,147	397,102	323,123	282,472	107,864
Borrowings under credit facility	15,000	15,000	—	—	—
Convertible senior notes	60,000	—	—	—	—
Long term portion of capital lease obligations	791	612	—	—	—
Accumulated deficit	(151,775)	(104,738)	(112,963)	(144,473)	(83,888)
Stockholders’ equity	250,823	292,570	277,551	239,853	86,687

(1) See Note 2 of Notes to Consolidated Financial Statements for an explanation of shares used in computing net income (loss) per share.

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

### OVERVIEW

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

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

Our current products demonstrate our ability to execute this strategy. As of December 31, 2008, our products were:

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

We generate revenue primarily by selling our products, namely prescription drugs, to pharmaceutical wholesalers. These direct customers resell and distribute our products to and through pharmacies to patients who have had our products prescribed by doctors. We currently market our products, and intend to market future products, if approved by the U.S. Food and Drug Administration, or FDA, to U.S. gastroenterologists and other physicians through our own direct sales force. In December 2000, we established our own field sales force to market Colazal in the United States. Currently, this sales force has approximately 100 sales representatives in the field and markets our approved products. Although the creation of an independent sales organization involved substantial costs, we believe that the financial returns from our direct product sales have been and will continue to be more favorable to us than those from the indirect sale of products through marketing partners. We enter into distribution or licensing relationships outside the United States and in certain markets in the U.S. where a larger sales organization is appropriate. Currently, our sales and marketing staff, including our sales representatives, consists of approximately 150 people.

Because demand for our products originates with doctors, our sales force calls on high-prescribing specialists, primarily gastroenterologists, and we monitor new and total prescriptions for our products as key performance indicators for our business. Prescriptions result in our products being used by patients, requiring our direct customers to

purchase more products to replenish their inventory. However, our revenue might fluctuate from quarter to quarter due to other factors, such as increased buying by wholesalers in anticipation of a price increase or because of the introduction of new products. Revenue could be less than anticipated in subsequent quarters as wholesalers' increased inventory is used up.

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

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

## CRITICAL ACCOUNTING POLICIES

### General

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to sales of our products, bad debts, inventories, investments, intangible assets and legal issues. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results might differ materially from these estimates under different assumptions or conditions.

Methodologies used and assumptions selected by management in making these estimates, as well as the related disclosures, have been reviewed by and discussed with the Audit Committee of our Board of Directors.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

### Revenue Recognition

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 \$7.4 million and \$9.7 million as of December 31, 2008 and 2007, respectively. The balances exclude amounts related to Colazal, which are included in the reserve discussed below. These allowances reflect an estimate of our liability for items such as rebates due to various governmental organizations under the Medicare/Medicaid regulations, rebates due to managed care organizations under specific contracts and chargebacks due to various organizations purchasing certain of our products through federal contracts and/or group purchasing agreements. We estimate our liability for rebates and chargebacks at each reporting period based on a methodology of applying the relevant quantitative and qualitative assumptions discussed above. Due to the subjectivity of our accrual estimates for rebates and chargebacks, we prepare various sensitivity analyses to ensure our final estimate is within a reasonable range as well as review prior period activity to ensure that our methodology is still reasonable. Had a change in one or more variables in the analyses (utilization rates, contract modifications, etc.) resulted in an additional percentage point change in the trailing average of estimated chargeback and rebate activity in 2008, we would have recorded an adjustment to revenues of approximately \$2.1 million, or 1.0%, for the year.

Allowances for product returns were \$26.6 million and \$43.0 million as of December 31, 2008 and 2007, respectively. These allowances reflect an estimate of our liability for product that may be returned by the original purchaser in accordance with our stated return policy. These balances include \$18.1 million and \$34.6 million at December 31, 2008 and 2007, respectively, reflecting our estimate of Colazal that may be returned to us under our return policy as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007. We estimate our liability for product returns at each reporting period based on historical return rates, the estimated inventory in the channel, and the other factors discussed above. Due to the subjectivity of our accrual estimates for product returns, we prepare various sensitivity analyses to ensure our final estimate is within a reasonable range as well as review prior period activity to ensure that our methodology is still reasonable. A change in assumptions that resulted in a 10% change in forecasted return rates for all products other than Colazal would have resulted in a change in total product returns liability at December 31, 2008 of approximately \$1.5 million and a corresponding change in 2008 net product revenue of less than 1.0%.

Colazal, our balsalazide disodium capsule, accounted for a majority of the Company's revenue prior to 2008. On December 28, 2007, the Office of Generic Drugs, or OGD, approved three generic balsalazide capsule products. As a result of these generic approvals, the Company expects the future sales of Colazal to be significantly less than historical sales of Colazal. At December 31, 2008 and 2007, respectively, \$18.1 million and \$34.6 million were recorded as a liability to reflect the Company's estimate of the Company's liability for Colazal that may be returned by the original purchaser in accordance with the Company's stated return policy as a result of these generic approvals. This estimate was developed based on the following estimates:

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

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

For the years ended December 31, 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, and also as a result of the approval of generic balsalazide capsule products. Accordingly, reductions to revenue and corresponding increases to allowance accounts have likewise increased. The estimated exposure to these revenue-reducing items as a percentage of gross product revenue in the year ended December 31, 2008 and 2007 was 6.3% and 9.7% for rebates, chargebacks and discounts and was 7.2% and 3.3% for product returns excluding the Colazal return reserve, respectively. The differences between 2007 and 2008 were primarily due to the mix of products sold. Increases to the Colazal return reserve was 11.2% of gross product revenue in 2007.

During the fourth quarter of 2008 we recognized \$9.1 million of net product revenue related to shipments to wholesalers of Apriso, which was approved by the FDA on October 31, 2008, and launched to physicians in late February 2009. We evaluated the “Criteria for Recognizing Revenue When Right of Return Exits” under paragraphs 6 and 8 of SFAS No. 48, and “other factors” conditions provided by the Staff within Staff Accounting Bulletin Topic 13(A)(4)(9). Based on our historical experience with Colazal, which has the same indication, is distributed through the same distribution channels and prescribed by the same physicians as Apriso, we have the ability to estimate returns for Apriso and therefore recognized revenue.

### **Inventories**

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. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life, and current and expected market conditions, including levels of competition, including generic competition.

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

Inventory at December 31, 2008 consisted of \$8.5 million of raw materials, \$6.5 million of work-in-process and \$2.3 million of finished goods. 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 December 31, 2008, we had recorded inventory reserves totaling \$3.8 million, compared to \$0.8 million as of December 31, 2007, to reduce inventories to their net realizable value. The increase in inventory reserves during 2008 is due to a reserve for inventory related to balsalazide tablets. In December 2008 we received a complete response letter from the FDA on the balsalazide tablet NDA, which indicated that based on its review, the FDA has determined that the application cannot be approved in its present form and that clinical data from an additional adequate and well-controlled clinical trial will be required in order to conduct further review of the NDA. We do not intend to conduct additional clinical investigation of balsalazide tablets in this indication, as a result we reserved the inventory related to balsalazide tablets.

### **Intangible Assets and Goodwill**

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

When the Company makes product acquisitions that include license agreements, product rights and other identifiable intangible assets, it records the purchase price of such intangibles, along with the value of the product-related liabilities that we assume, as intangible assets. The Company allocates the aggregate purchase price to the fair value of the various tangible and intangible assets in order to determine the appropriate carrying value of the acquired assets and then amortizes the cost of the intangible assets as an expense in the consolidated statements of operations over the estimated economic useful life of the related assets. In accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long Lived Assets", the Company assesses the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value might not be recoverable. The Company believes the following factors could trigger an impairment review: significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of use of the acquired assets or the strategy for our 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 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 history and management's experience. At December 31, 2008 and 2007, accumulated amortization for the Azasan intangible was \$1.0 million and \$0.8 million, respectively.

In June 2004, the Company acquired the exclusive U.S. rights to Anusol-HC 2.5% (hydrocortisone Cream USP), Anusol-HC 25 mg Suppository (Hydrocortisone Acetate), Proctocort Cream (Hydrocortisone Cream USP) 1% and Proctocort Suppositories (Hydrocortisone Acetate Rectal Suppositories, 30 mg) from King Pharmaceuticals, Inc. for \$13.0 million. The purchase price was fully allocated to product rights and related intangibles and is being amortized over a period of ten years. Although Anusol-HC and Proctocort do not have any patent protection, the Company believes ten years is an appropriate amortization period based on established product sales history and management's experience. At December 31, 2008 and 2007, accumulated amortization for the King product intangibles was \$5.9 million and \$4.6 million, respectively.

In September 2005, the Company acquired InKine Pharmaceutical Company, Inc. for \$210.0 million. We 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 us. The Company allocated the remaining \$89.7 million to goodwill, which is not being amortized. The InKine product rights and related intangibles are being amortized over an average period of 14 years, which the Company believes is an appropriate amortization period due to the product's patent protections and the estimated economic lives of the product rights and related intangibles. At December 31, 2008 and 2007, accumulated amortization for the InKine intangibles was \$9.8 million and \$6.8 million, respectively. There is no future research or development planned for the products purchased from InKine.

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, NRL 944, in the United States. In August 2006, the Company received Food and Drug Administration marketing approval for NRL 944 under the branded name of MoviPrep. In January 2007 the United States Patent Office issued a patent providing coverage to

September 1, 2024. In August 2006, pursuant to the terms of the Agreement, Salix made a \$15.0 million payment to Norgine. In December 2008, pursuant to the terms of the Agreement, Salix made a \$5.0 million payment to Norgine. The Company is amortizing these milestone payments over a period of 17.3 years, which the Company believes is an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. At December 31, 2008 and 2007, accumulated amortization for the MoviPrep intangible was \$2.8 million and \$1.2 million, respectively.

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 the 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 December 31, 2008 and 2007, accumulated amortization for the Merck products was \$6.9 million and \$3.2 million, respectively.

In July 2002, the Company acquired the rights to develop and market a granulated formulation of mesalamine from Dr. Falk Pharma GmbH. On October 31, 2008, the FDA granted marketing approval for Apriso for the maintenance of remission of ulcerative colitis in adults. In November 2008, the Company made a \$6.0 million milestone payment to Dr. Falk. The Company is amortizing this milestone payment over a period of 9.5 years, which the Company believes is an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. At December 31, 2008, accumulated amortization for the Apriso intangible was \$0.1 million.

#### **Allowance for Uncollectible Accounts**

Based on a review of specific customer balances, industry experience and the current economic environment, we currently reserve for specific past due accounts that may represent collection concerns plus a percentage of our outstanding trade accounts receivable balance as an allowance for uncollectible accounts, which at December 31, 2008 and 2007 was approximately \$0.6 million and \$3.1 million, respectively. Refer to "Schedule II—Valuation and Qualifying Accounts" for a roll-forward of the allowance for uncollectible accounts.

#### **Cash and Cash Equivalents**

The Company considers all highly liquid investments with maturities from date of purchase of three months or less to be cash equivalents. The Company maintains its cash and cash equivalents in several different financial instruments with various banks and brokerage houses. This diversification of risk is consistent with Company policy to maintain liquidity and ensure the safety of principal. At December 31, 2008, cash and cash equivalents consisted primarily of demand deposits, overnight investments in Eurodollars, certificates of deposit and money market funds at reputable financial institutions and did not include any auction rate securities. The Company has not experienced any loss of principal or liquidity in any of its cash and cash equivalents subsequent to year-end through March 10, 2009.

#### **Research and Development**

The Company expenses research and development costs, both internal and externally contracted, as incurred. For nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities, the Company initially capitalizes the advance payment. Such amounts are then recognized as an expense as the related goods are delivered or the related services are performed. At December 31, 2007, the net asset related to on-going research and development activities to be charged to expense in future periods was \$8.9 million and at December 31, 2008, the net liability related to on-going research and development activities was \$12.7 million.

## RESULTS OF OPERATIONS

Years Ended December 31, 2008, 2007 and 2006

### Revenues

The following table summarizes net product revenues for the years ended December 31, 2008, 2007 and 2006:

	Year ended December 31,		
	2008	2007	2006
Colazal .....	\$ 1,422	\$ 92,401	\$103,478
% of net product revenues .....	1%	40%	49%
Xifaxan .....	79,928	64,260	51,628
% of net product revenues .....	45%	28%	25%
Purgatives—MoviPrep/OsmoPrep/Visicol .....	62,862	47,693	45,502
% of net product revenues .....	35%	20%	22%
Apriso .....	9,123	—	—
% of net product revenues .....	5%	—	—
Other—Anusol/Azasan/Diuril/Pepcid/Proctocort .....	25,431	28,526	7,925
% of net product revenues .....	14%	12%	4%
Net product revenues .....	<u>\$178,766</u>	<u>\$232,880</u>	<u>\$208,533</u>

Revenues totaled \$178.8 million, \$235.8 million and \$208.5 million for 2008, 2007 and 2006, respectively. Revenues for the years ended December 31, 2008 and 2006 consisted solely of net product revenues. Revenues for the year ended December 31, 2007 included net product revenues of \$232.9 million and revenues from collaborative agreements of \$2.9 million.

Net product revenues for 2008 were \$178.8 million, compared to \$232.9 million for 2007. The net product revenue decrease from 2007 to 2008 was primarily due to:

- decreased Colazal sales in 2008 as a result of the approval of three generic balsalazide capsule products on December 28, 2007;
- no additional sales to Watson Pharma, Inc. during 2008, compared to \$2.2 million in sales to Watson Pharma, Inc. during the fourth quarter of 2007 in connection with their launch of the authorized generic;
- decreased net sales of Visicol due to an increase in the return reserve for a return from a small wholesaler; and
- decreased unit sales of Pepcid.

These decreases in net product revenue were partially offset by increases in net product revenues due to:

- price increases on our products;
- increased unit sales of Xifaxan, OsmoPrep and MoviPrep; and
- the sale of \$9.1 million of Apriso in 2008 after FDA approval was received in October 2008.

Total estimated prescription growth from 2007 to 2008 was 9% 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. At December 31, 2008 and 2007, respectively, \$18.1 million and \$34.6 million were recorded as a liability to reflect the Company's estimate of the Company's liability for Colazal that may be returned by the original purchaser in accordance with the Company's stated return policy as a result of these generic approvals. This estimate was developed based on the following estimates:

- our estimate of the quantity and expiration dates of Colazal inventory in the distribution channel based on historical net product shipments less estimated historical prescriptions written;

- our estimate of future demand for Colazal based on the actual erosion of product demand for several comparable products that were previously genericized, and the actual demand for Colazal experienced during 2008 subsequent to the generic approvals;
- our estimate of chargeback and rebate activity based on actual chargeback and rebate activity during 2008 subsequent to the generic approvals; and
- other relevant factors.

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

Net product revenues for 2007 were \$232.9 million, compared to \$208.5 million for 2006. The net product revenue increase from 2006 to 2007 was primarily due to:

- price increases on our products;
- increased unit sales of Xifaxan;
- 41 weeks of sales for Pepcid, which we acquired during February 2007;
- increased unit sales of Colazal, offset by the Colazal return reserve recorded as a result of the approval of three generic balsalazide capsule products on December 28, 2007;
- \$2.2 million in sales to Watson Pharma, Inc. during the fourth quarter of 2007 in connection with their launch of the authorized generic; and
- a full year of sales for OsmoPrep and MoviPrep, which were launched during the second and fourth quarters of 2006, respectively;
- partially offset by reduced unit sales of Visicol.

Total estimated prescription growth from 2006 to 2007 was 1% for Colazal, 35% for Xifaxan, and 98% for our purgatives.

Revenues from collaborative agreements for 2007 consists of an upfront payment of \$1.5 million upon execution of an agreement to license exclusive rights to market OsmoPrep, under the name DIACOL™, in 28 territories in Europe to Dr. Falk Pharma GmbH of Freiberg, Germany; 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; and \$0.4 million upon execution of an agreement to license exclusive rights to market OSMOPREP™ in France to Mayoly — Spindler S.A.S of Chatou, France. Revenues from collaborative agreements for 2007 also include \$12,000 in royalty income from sales of Visiclear® by Zeria. We did not receive any revenues from collaborative agreements during 2006.

### **Costs and Expenses**

Total costs and expenses were \$225.4 million, \$223.9 million and \$178.2 million for 2008, 2007 and 2006, respectively. Higher operating expenses in absolute terms for 2008 compared to 2007 were due primarily to increased research and development activities; and increased selling, general and administrative expenses, offset by decreased cost of products sold related to the corresponding decrease in product revenue. Higher operating expenses in absolute terms for 2007 compared to 2006 were due primarily to increased research and development activities, increased cost of products sold related to the corresponding increase in product revenue, increased selling, general and administrative expenses due to the expansion of our infrastructure, marketing costs related to our launches of OsmoPrep in the second quarter of 2006 and MoviPrep in the fourth quarters of 2006, and the acquisition of Pepcid during February 2007.

### *Cost of Products Sold*

Cost of products sold were \$36.7 million, \$55.0 million and \$41.4 million for 2008, 2007 and 2006, respectively. Gross margin on total product revenue, excluding \$9.9 million, \$8.6 million and \$4.9 million in amortization of product rights and intangible assets for 2008, 2007 and 2006, was 79%, 76% and 80% in 2008, 2007 and 2006, respectively. The decrease in cost of products sold in absolute dollars from 2007 to 2008 was primarily due to decreased sales of Colazal, partially offset by increased sales of Xifaxan, Moviprep, OsmoPrep and Apriso. The lower gross margin in 2007 compared to 2008 is a result of the return reserve recorded in the fourth quarter of 2007 for Colazal as a result of the approval of three generic balsalazide capsule products.

The increase in cost of products sold in absolute dollars from 2006 to 2007 was primarily due to increased sales of Colazal and Xifaxan, a full year of sales for OsmoPrep and Moviprep and the acquisition of Pepcid during February 2007. Cost of products sold does not include amortization of product rights and intangibles. Refer to “Critical Accounting Policies — Intangible Assets and Goodwill” above.

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

Fees and costs related to license agreements were \$7.1 million, \$1.9 million and \$1.3 million in 2008, 2007 and 2006, respectively, and relate primarily to payments made to Debiovision, Cedars-Sinai, Biorex and Alfa Wassermann under the terms of their respective license agreements. The amount for 2008 includes \$5.0 in upfront payments to Napo Pharmaceuticals in connection with the acquisition of the rights to crofelemer. The amount for 2007 also includes payments of \$1.5 million to Clinical Development Capital, the successor licensor of Visicol<sup>®</sup> and OsmoPrep, for its share of the German, Japanese and French milestone revenue of \$2.9 million recognized during 2007.

### *Research and Development*

Research and development expense was \$76.6 million, \$71.9 million and \$47.9 million for 2008, 2007 and 2006, respectively. The increase in research and development expenses from 2007 to 2008 was due primarily to:

- initiation of our Phase III IBS studies of Xifaxan;
- continuation of our Phase III HE study of Xifaxan; and
- increased headcount costs;
- partially offset by reduced expenses related to development of our 1100mg balsalazide tablet submission completed in July 2007.

The increase in research and development expenses from 2006 to 2007 was due primarily to:

- the expansion of our Colazal life cycle management program through initiatives to strengthen and support our 1100mg balsalazide tablet submission;
- our development program for granulated mesalamine; and
- the costs associated with ongoing late-stage studies of Xifaxan.

Through December 31, 2008, we had incurred research and development expense of approximately \$64.4 million for balsalazide, \$73.9 million for rifaximin and \$28.6 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 changes. 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 as we pursue

additional indications and formulations for rifaximin, initiate development for the budesonide product candidates we recently acquired from Dr. Falk, continue the clinical development of crofelemer, which we recently acquired from Napo, and if and when we acquire new products.

#### *Selling, General and Administrative*

Selling, general and administrative expenses were \$95.1 million, \$86.5 million and \$82.6 million for 2008, 2007 and 2006, respectively. The increase from 2007 to 2008 was primarily due to:

- increased headcount costs;
- increased sales and marketing costs related to our purgative franchise;
- pre-marketing expenses related to Apriso, balsalazide tablets and metoclopramide-Zydis; and
- increased legal costs for to the patent litigation related to MoviPrep and OsmoPrep;
- partially offset by decreased marketing costs related to Colazal and Xifaxan.

The slight increase in absolute dollars from 2006 to 2007 was primarily due to:

- the expansion of our infrastructure related to OsmoPrep and MoviPrep;
- the acquisition of Pepcid; and
- the write-off of Colazal samples;
- partially offset by reduced spending on the launch of OsmoPrep.

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

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

Interest and other income (expense), net was (\$0.5) million, \$3.3 million and \$2.6 million in 2008, 2007 and 2006, respectively. Interest and other income (expense), net for 2008 consisted of:

- \$1.1 million of interest expense on our credit facility;
- \$1.4 million of interest expense on our convertible notes issued in August 2008; 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";
- partially offset by \$3.1 million of interest and other income.

Interest and other income (expense), net for 2007 consisted of:

- \$1.2 million received as final settlement of a legal matter initiated by InKine prior to our acquisition of InKine; and
- \$3.4 million of interest income;
- partially offset by \$1.3 million of interest expense on our credit facility which was closed in February 2007.

Interest and other income (expense), net for 2006 consisted of \$2.6 million of interest income.

The increase in interest income from 2006 to 2007 was primarily due to higher average daily cash balances and increased short-term interest rates. Due to the current economic climate, future interest rates on our cash and cash equivalents, and as a result, interest income, will be lower than we experienced during 2008.

### **Provision for Income Tax**

Income tax (benefit) expense was (\$0.1) million, \$7.0 million and \$1.4 million in 2008, 2007 and 2006, respectively. Our effective tax rate was (0.2%), 45.8% and 4.2% in 2008, 2007 and 2006, respectively, due to utilization of net operating loss carryforwards. The higher than expected rate in 2007 was due to an increase in the valuation allowance for deferred taxes related to the \$34.6 million reserve related to Colazal recorded in the fourth quarter.

At December 31, 2008, 2007 and 2006, we had U.S. federal net operating loss carryforwards of approximately \$108.7 million, \$37.0 million and \$111.1 million, respectively. These carryforwards will expire on various dates beginning in 2020 through 2024 if not utilized. Utilization of the federal net operating loss and credit carryforwards may be subject to a substantial annual limitation due to the “change in ownership” provisions of the Internal Revenue Code. The annual limitation might result in the expiration of net operating losses and credits before utilization.

### **Quarterly Results of Operations**

See Note 13 of Notes to Consolidated Financial Statements for a presentation of our quarterly results of operations for the years ended December 31, 2008 and 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 Colazal in January 2001, net product revenue has been a growing source of cash. On August 22, 2008 we closed an offering of \$60.0 million in convertible senior notes due 2028. Net proceeds from the offering were \$57.3 million. As of December 31, 2008, we had \$120.2 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 December 31, 2008, cash and cash equivalents consisted primarily of demand deposits, certificates of deposit, overnight investments in Eurodollars and money market funds at reputable financial institutions, and did not include any auction rate securities. We have not realized any material loss in principal or liquidity in any of our investments to date. However, continued 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 was \$20.9 million in 2008 and 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 2007 and 2006 was \$76.1 million and \$17.9 million in 2007 and 2006, respectively. Positive operating cash flows in 2007 was primarily attributable to increased earnings before the Colazal return reserve noncash charge, and reduced accounts receivable and inventory balances in 2007. Positive operating cash flows in 2006 was primarily attributable to increased earnings, partially offset by increased accounts receivable balances due to increased sales in December 2006 and decreased accounts payable and accrued liability balances.

Net cash used in investing activities was \$26.9 million in 2008 and was primarily attributable to the transfer of \$15.0 million of cash to restricted cash as a result of the amendment of our credit facility, a \$6.0 million milestone payment to Dr. Falk in connection with the approval of Apriso, and a \$5.0 million sales milestone payment to Norgine for MoviPrep. Net cash used in investing activities was \$59.4 million in 2007 and was primarily attributable to the acquisition of Pepcid for \$55.0 million and the purchase of property and equipment. Net cash used in investing activities was \$12.8 million in 2006 and was primarily attributable to the acquisition of MoviPrep and the purchase of property and equipment, partially offset by \$1.0 million of investments that matured or were called by the issuers.

Net cash provided by financing activities of \$56.6 million in 2008 consisted primarily of the proceeds of our convertible debt offering closed in August 2008. Net cash provided by financing activities of \$18.1 million in 2007 consisted primarily of \$15.0 million of borrowings under our credit facility entered into in February 2007, and the exercise of stock options. Net cash provided by financing activities of \$4.2 million in 2006 consisted primarily of the exercise of stock options.

As of December 31, 2008, we had non-cancelable purchase order commitments for inventory purchases of approximately \$28.3 million. We anticipate significant expenditures related to our on-going sales, marketing, product launch efforts and our on-going development efforts for rifaximin, our budesonide product candidates and crofelemer. To the extent we acquire rights to additional products, we will incur additional expenditures.

Our contractual commitments for non-cancelable purchase commitments of inventory, minimum lease obligations for all non-cancelable operating leases, debt and minimum capital lease obligations (including interest) as of December 31, 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 . . . . .	\$ 10,956	\$ 2,116	\$ 5,388	\$ 2,952	\$ 500
Purchase commitments . . . . .	28,294	28,294	—	—	—
Convertible senior notes(1) . . . . .	124,900	3,300	6,600	6,600	108,400
Borrowings under credit facility(2) . . . . .	16,496	472	945	15,079	—
Capital lease obligations . . . . .	1,717	901	813	3	—
Total . . . . .	<u>\$182,363</u>	<u>\$35,083</u>	<u>\$13,746</u>	<u>\$24,634</u>	<u>\$108,900</u>

- (1) Contractual interest obligations related to our convertible senior notes total \$64.9 million at December 31, 2008, including \$3.3 million, \$6.6 million, \$6.6 million and \$48.4 million due in one year or less, two to three years, four to five years, and greater than five years, respectively.
- (2) Contractual interest obligations related to our credit facility total \$1.5 million based on the interest rate at December 31, 2008, including \$0.5 million, \$0.9 million, and \$0.1 million due in one year or less, two to three years, and four to five years, respectively.

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

In February 2007, we entered into a \$100.0 million revolving credit facility that matures in February 2012. On August 4, 2008 we amended the credit facility to waive defaults that may have arisen as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007 and reduced the credit facility to \$20.0 million. On August 22, 2008 we further amended the credit facility to allow us to issue the convertible notes described below. At December 31, 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 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 December 31, 2008 on our outstanding borrowings was 3.15%. We must maintain an amount equal to the amount outstanding under the credit facility on deposit with the Administrative Agent of the credit facility and maintain a minimum of \$23.0 million in cash on our balance sheet. At December 31, 2008, restricted cash of \$15.0 million represents the collateral on deposit with the Administrative Agent related to the credit facility. At December 31, 2008 we were in compliance with applicable covenants under the credit facility.

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

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

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

As of December 31, 2008, we had an accumulated deficit of \$151.6 million, and cash and cash equivalent balances of \$120.2 million. We expect to be unprofitable and experience negative cash flow during 2009. We believe our cash and cash equivalent balances should be sufficient to satisfy our cash requirements for the foreseeable future. Based on our current projections, we believe that we will be able to return to a positive cash flow position without requiring additional capital. However, we might seek additional debt or equity financing or both to fund our operations or acquisitions, and our actual cash needs might vary materially from those now planned because of a number of factors including: general economic conditions; FDA and foreign regulatory processes; the status of competitive products, including potential generics; intellectual property risks; the actual amount of Colazal returns we receive compared to our current estimates; our ability to maintain our current credit facility; our success selling products; the results of research and development activities; establishment of and change in collaborative relationships; technological advances by us and other pharmaceutical companies; and whether we acquire rights to additional products. If we incur more debt, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. If we issue additional equity, our stockholders could suffer dilution. We might also enter into additional collaborative arrangements that could provide us with additional funding in the form of equity, debt, licensing, milestone and/or royalty payments. We might not be able to enter into such arrangements or raise any additional funds on terms favorable to us or at all.

## 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 we 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. We do not believe the adoption of SFAS 141R will have a material impact on our consolidated financial position, results of operations and cash flows; however, our accounting for acquisitions after the adoption of SFAS 141R may produce materially different results than accounting under the current guidance.

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 we 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. We do not believe the adoption of SFAS 160 will have a material impact on our 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. We are currently evaluating the impact of the adoption of this FSP. Our convertible Notes may be settled in cash, as a result, upon adoption of the FSP on January 1, 2009, we 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%. We currently believe approximately 25% of the initial proceeds will be allocated to the equity component, and the effective interest rate, including the amortization of the debt discount, on the liability component will be approximately 12%.

## 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 “Item 1A . Risk Factors”.

Statements contained in this Form 10-K that are not historical facts are or might constitute forward-looking statements under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Although we believe the expectations reflected in such forward-looking statements are based on reasonable assumptions, our expectations might not be attained. Forward-looking statements involve known and unknown risks that could cause

actual results to differ materially from expected results. Factors that could cause actual results to differ materially from our expectations expressed in the report include, among others: general economic conditions; our need to return to profitability; intense competition, including from generics; the high cost and uncertainty of the research, clinical trials and other development activities involving pharmaceutical products; the unpredictability of the duration and results of regulatory review of New Drug Applications and Investigational New Drug Applications; the possible impairment of, or inability to obtain intellectual property rights and the costs of obtaining such rights from third parties; our dependence on our first nine pharmaceutical products, particularly Colazal and Xifaxan, and the uncertainty of market acceptance of our products; the uncertainty of obtaining, and our dependence on, third parties to manufacture and sell our products; and results of future litigation and other risk factors detailed from time to time in our other SEC filings.

#### **Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

Our purchases of raw materials are denominated primarily 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 might change.

#### **Item 8. Financial Statements and Supplementary Data**

The information required by this Item is set forth in the Consolidated Financial Statements and Notes thereto beginning at page F-1 of this Report.

#### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

#### **Item 9A. Control and Procedures**

##### **Conclusion Regarding the Effectiveness of Disclosure 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. As of the end of the period 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 President and Chief Executive Officer and Senior VP, Finance and Administration and Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(e). Based upon this evaluation, the Company's 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.

##### **Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met and must reflect the fact that there are resource constraints that require management to consider the benefits of internal controls relative to their costs. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all error and all fraud. Under the supervision and with the participation of our management, including our CEO and our Senior VP, Finance and Administration and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control — Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

The effectiveness of our internal control over financial reporting as of December 31, 2008, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included on page F-2 herein.

**Changes in Internal Control over Financial Reporting**

There was no change in our internal controls over financial reporting during the fourth quarter of the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

**Item 9B. Other Information**

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item concerning our directors is incorporated by reference from the section captioned “Proposal One—Election of Directors” contained in our proxy statement related to the 2009 Annual Meeting of Stockholders scheduled to be held on June 18, 2009, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

The Board of Directors has determined that the members of the Audit Committee are independent as defined in Rule 4200(a)(15) of the National Association of Securities Dealers’ listing standards. The Board of Directors has also determined that John F. Chappell, Thomas W. D’Alonzo, William Harral III and William P. Keane are “audit committee financial experts” as defined in Item 401(h) of Regulation S-K.

Our Board of Directors adopted a code of conduct that applies to all of our directors and employees. Our Board also adopted a separate code of ethics for our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and Controller, or persons performing similar functions. We will provide copies of our code of conduct and code of ethics without charge upon request. To obtain a copy of our code of conduct and code of ethics, please send your written request to Salix Pharmaceuticals, Ltd., 1700 Perimeter Park Drive, Morrisville, NC 27560, Attn: General Counsel. In addition, you can find those codes on our website at [www.salix.com/pdf/Salix\\_Code\\_Bus\\_Cond.pdf](http://www.salix.com/pdf/Salix_Code_Bus_Cond.pdf).

The information required by this Item concerning executive officers of the Registrant is set forth at the end of Part I of this report.

The information required by this Item concerning compliance with Section 16(a) of the United States Securities Exchange Act of 1934, as amended, is incorporated by reference from the section of the proxy statement captioned “—Section 16(a) Beneficial Ownership Reporting Compliance.”

### Item 11. Executive Compensation

The information required by this Item is incorporated by reference to the information under the sections captioned “—Grant of Plan Based Awards for 2008,” “—Outstanding Equity Awards at 2008 Fiscal Year End,” “—Option Exercises and Stock Vested in 2008,” “—Director Compensation For 2008,” “—Compensation Discussion and Analysis,” “—Summary Compensation Table,” “—Compensation Committee Report,” and “—Compensation Committee Interlocks and Insider Participation” contained in the proxy statement.

### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth the indicated information as of December 31, 2008 with respect to our equity compensation plans:

<u>Plan Category</u>	<u>(a) Number of Securities to be issued Upon Exercise of Outstanding Options, Warrants and Rights, or Vesting of Restricted Shares</u>	<u>(b) Weighted Average Exercise Price of Outstanding Options, Warrants, Rights and Restricted Shares</u>	<u>(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Related in Column (a))</u>
Equity Compensation Plans Approved by Security Holders .....	6,266,688	\$12.55	836,622
Equity Compensation Plans Not Approved by Security Holders .....	—	—	—
Total .....	<u>6,266,688</u>	<u>\$12.55</u>	<u>836,622</u>

The other information required by this Item is incorporated by reference to the information under the section captioned “—Security Ownership of Management and Certain Beneficial Owners.”

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this Item is incorporated by reference to the information under the section captioned “—Transactions with Related Persons” and “Proposal One—Election of Directors—Corporate Governance Matters” contained in the proxy statement.

**Item 14. Principal Accountant Fees and Services**

The information required by this Item is incorporated by reference to the information under the section captioned “—Audit Committee Report” contained in the proxy statement.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

#### (a) 1. Financial Statements

The following statements are filed as part of this report:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm .....	F-2
Report of Independent Registered Public Accounting Firm on Financial Statements .....	F-3
Consolidated Balance Sheets .....	F-4
Consolidated Statements of Operations .....	F-5
Consolidated Statements of Stockholders' Equity .....	F-6
Consolidated Statements of Cash Flows .....	F-7
Notes to Consolidated Financial Statements .....	F-8

#### 2. Financial Statement Schedules

Schedule II—Valuation and Qualifying Accounts .....	F-30
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Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

#### 3. 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>
1.1	Purchase Agreement dated August 18, 2008 by and between Salix Pharmaceuticals, Ltd. and Banc of America Securities LLC.	8-K	8/22/08	1.1	
2.1	Agreement and Plan of Merger dated June 23, 2005 among Salix Pharmaceuticals, Ltd., InKine Pharmaceutical Company, Inc. and Metal Acquisition Corp.	8-K	6/24/05	2.1	
2.2	Certificate of Domestication.	S-3	02/12/02	2.1	
2.3*	Asset Purchase Agreement dated June 30, 2004 between King Pharmaceuticals, Inc., Monarch Pharmaceuticals, Inc., Parkedale Pharmaceuticals, Inc., Salix Pharmaceuticals, Inc. and Salix Pharmaceuticals, Ltd.	10-Q	08/09/04	2.2	
3.1	Certificate of Incorporation, as amended.	10-Q	05/10/06	3.1	
3.2	Amended and Restated Bylaws.	8-K	09/02/03	3.2	
4.1	Indenture dated August 22, 2008 by and between Salix Pharmaceuticals, Ltd. and U.S Bank, National Association.	8-K	08/22/08	4.1	
4.2	Form of 5.5% Convertible Senior Note due 2028 (included in Exhibit 4.1).	8-K	08/22/08	4.2	
10.3	Form of 1996 Stock Plan for Salix Holdings, Ltd., as amended September 2000 and form of Notice of Stock Option Grant and Stock Option Agreement thereunder, as amended March 12, 2001.	10-Q	08/09/04	10.3	

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
10.4*	Amendment Agreement effective as of September 17, 1992 by and among Glycyx Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc. and Biorex.	S-1	08/15/97	10.4	
10.5*	License Agreement, dated September 17, 1992 between Biorex Laboratories Limited and Glycyx Pharmaceuticals, Ltd. and letter agreement amendments thereto.	S-1	08/15/97	10.5	
10.6*	Research and Development Agreement dated September 21, 1992 between Glycyx Pharmaceuticals, Ltd. and AB Astra and letter agreement amendments thereto.	S-1	08/15/97	10.6	
10.7*	Distribution Agreement dated September 21, 1992 between Glycyx Pharmaceuticals, Ltd. and AB Astra.	S-1	08/15/97	10.7	
10.8*	Amended and Restated License Agreement by and between Salix Pharmaceuticals, Inc. and Biorex Laboratories, Limited, dated April 16, 1993.	S-1	08/15/97	10.8	
10.9*	Co-Participation Agreement, dated April 30, 1993 between Salix Pharmaceuticals, Inc. and AB Astra as amended by Amendment No. 1 thereto effective September 30, 1993.	S-1	08/15/97	10.9	
10.9.1	Letter Agreement dated October 16, 1998 to Co-Participation Agreement dated April 30, 1993 by and between Salix Pharmaceuticals, Inc. and AB Astra.	10-Q	11/16/98	10.9.1	
10.11*	Distribution Agreement, dated September 23, 1994 between Glycyx Pharmaceuticals, Ltd. and Menarini International Operations Luxembourg SA and amendments thereto.	S-1	08/15/97	10.11	
10.12*	License Agreement, dated June 24, 1996, between Alfa Wassermann S.p.A. and Salix Pharmaceuticals, Ltd.	S-1	08/15/97	10.12	
10.13*	Supply Agreement, dated June 24, 1996, between Alfa Wassermann S.p.A. and Salix Pharmaceuticals, Ltd.	S-1	08/15/97	10.13	
10.22	Termination and Settlement Agreement dated as of December 22, 1999, by and between Astra AB and Salix Pharmaceuticals Inc. (a wholly owned subsidiary of Salix Pharmaceuticals, Ltd.).	8-K	12/28/99	10.22	
10.23	Agreement dated December 22, 1999, between Glycyx Pharmaceuticals, Ltd. and Astra AB.	8-K	12/28/99	10.23	
10.25*	Agreement dated May 17, 2000 between Glycyx Pharmaceuticals, Ltd. and Shire Pharmaceuticals Group plc.	10-Q	08/14/00	10.25	
10.26*	Agreement dated May 17, 2000 between Biorex Laboratories Limited and Glycyx Pharmaceuticals, Ltd.	10-Q	08/14/00	10.26	
10.29	Lease Agreement dated June 30, 2000 by and between Colonnade Development, LLC and Salix Pharmaceuticals, Inc.	10-Q	08/14/01	10.29	
10.30*	License Agreement between Biorex Laboratories Limited and Glycyx Pharmaceuticals, Ltd. dated August 22, 2001.	10-Q	11/14/01	10.30	

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
10.31	Form of Employment Agreement for executive officers.	10-Q	11/14/01	10.31	
10.32*	License Agreement by and between Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH dated July 15, 2002.	10-Q	11/14/02	10.32	
10.36	Rights Agreement, dated as of January 10, 2003, between Salix Pharmaceuticals, Ltd. and Computershare Investor Services LLC, as Rights Agent.	8-K	01/10/03	10.36	
10.37	Common Stock Purchase Agreement dated November 6, 2003 among Salix Pharmaceuticals, Ltd. and the investors listed therein.	8-K	11/10/03	10.37	
10.39*	License Agreement dated October 17, 2003, between Glycyx Pharmaceuticals, Ltd (a wholly owned subsidiary of Salix Pharmaceuticals, Ltd.) and Chong Kun Dang Pharmaceutical Corporation.	10-Q	11/14/03	10.39	
10.40*	Amendment Agreement dated November 24, 2003 between Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH.	10-K	03/12/04	10.40	
10.41*	License Agreement dated October 31, 2003 between aaiPharma LLC, aaiPharma Inc. and Salix Pharmaceuticals, Ltd.	10-K	03/12/04	10.41	
10.44*	Supply Agreement dated June 30, 2004 between King Pharmaceuticals, Inc., Parkedale Pharmaceuticals, Inc., Salix Pharmaceuticals, Inc. and Salix Pharmaceuticals, Ltd.	10-Q	08/09/04	10.44	
10.45	License Assignment and Consent Agreement dated June 30, 2004 between Parkedale Pharmaceuticals, Inc., King Pharmaceuticals, Inc., Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Warner-Lambert Company LLC and Parke, Davis & Company LLC.	10-Q	08/09/04	10.45	
10.46	Assignment of Trademarks Agreement dated June 30, 2004 between Parkedale Pharmaceuticals, Inc. and Salix Pharmaceuticals, Inc.	10-Q	08/09/04	10.46	
10.47	License Agreement dated June 30, 2004 between Monarch Pharmaceuticals, Inc., Parkedale Pharmaceuticals, Inc., King Pharmaceuticals, Inc., Salix Pharmaceuticals, Inc. and Salix Pharmaceuticals, Ltd.	10-Q	08/09/04	10.47	
10.48	Office lease dated as of November 24, 2004 between Salix Pharmaceuticals, Ltd. And Duke Realty Limited Partnership.	8-K	12/13/04	10.48	
10.49	Co-Promotion Agreement dated March 2, 2005 between Salix Pharmaceuticals, Inc. and Altana Pharma US, Inc.	10-Q/A	08/23/05	10.49	
10.50	2005 Stock Plan and forms of Notice of Option Grant and Stock Option Agreement.	S-8	06/30/05	10.50	
10.51	Termination Agreement dated August 19, 2005 between Salix Pharmaceuticals, Inc. and Altana Pharma US, Inc.	8-K	08/22/05	10.51	

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
10.53	License and Supply Agreement dated as of December 7, 2005 between Salix Pharmaceuticals, Inc. and Norgine B.V.	8-K	12/13/05	10.53	
10.54	Form of Restricted Stock Grant to be granted pursuant to the 2005 Stock Plan.	10-K	03/16/06	10.54	
10.55	License Agreement entered into on June 18, 2006 between Cedars-Sinai Medical Center and Salix Pharmaceuticals, Inc.	8-K	07/05/06	10.55	
10.56	Development and License Agreement, dated September 5, 2006 with Debiovision Inc.	10-Q	11/09/06	10.56	
10.57	\$100.0 million Credit Facility by and among Salix Pharmaceuticals, Ltd., Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, Wachovia Bank, National Association, as Syndication Agent, and RBC Centura Bank, as Documentation Agent, and the Other Lenders Party thereto, and Banc of America Securities LLC, as Sole Lead Arranger and Sole Book Manager, dated February 22, 2007.	8-K	02/28/06	10.57	
10.58*	Master Purchase and Sale and License Agreement dated February 22, 2007 between Merck & Co., Inc. and Salix Pharmaceuticals, Ltd.	10-Q	5/10/07	10.58	
10.59*	License Agreement dated April 16, 2007 between Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH.	10-Q	5/10/07	10.59	
10.60*	Co-Promotion Agreement dated September 4, 2007, with Eisai Inc.	10-Q	8/09/07	10.60	
10.61**	Supply and Distribution Agreement between Salix Pharmaceuticals, Inc. and Watson Pharma, Inc.	10-K	3/14/08	10.61	
10.62*	License Agreement dated March 13, 2008 between Dr. Falk Pharma GmbH and Salix Pharmaceuticals, Inc.	10-Q	5/07/08	10.62	
10.63	Waiver and First Amendment to Credit Agreement, by and among Salix Pharmaceuticals, Ltd., Bank of America, N.A., as Administrative Agent, and the lender parties thereto, dated as of August 4, 2008	10-Q	8/05/08	10.63	
10.64**	Collaboration Agreement between Napo Pharmaceuticals, Inc. and Salix Pharmaceuticals, Inc.				X
10.65**	Manufacturing and Supply Agreement between Salix Pharmaceuticals, Inc. and Glenmark Pharmaceuticals Ltd.				X
21.1	Subsidiaries of the Registrant.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
23.2	Consent of Independent Registered Public Accounting Firm.				X

<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

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

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

(b) Exhibits

See Item 15(a)(3) above.

(c) Financial Statement Schedules

See Item 15(a)(1) above.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

### SALIX PHARMACEUTICALS, LTD.

/s/ CAROLYN J. LOGAN

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Carolyn J. Logan  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Form 10-K has been signed below by the following persons on behalf of the Registrant and on the dates indicated.

Date: March 11, 2009

/s/ CAROLYN J. LOGAN

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Carolyn J. Logan  
President, Chief Executive Officer  
(Principal Executive Officer) and Director

Date: March 11, 2009

/s/ ADAM C. DERBYSHIRE

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Adam C. Derbyshire  
Senior Vice President, Finance & Administration and  
Chief Financial Officer (Principal  
Financial and Accounting Officer)

Date: March 11, 2009

/s/ JOHN F. CHAPPELL

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John F. Chappell  
Chairman of the Board

Date: March 11, 2009

/s/ THOMAS W. D'ALONZO

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Thomas W. D'Alonzo  
Director

Date: March 11, 2009

/s/ RICHARD A. FRANCO

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Richard A. Franco  
Director

Date: March 11, 2009

/s/ WILLIAM P. KEANE

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William P. Keane  
Director

Date: March 11, 2009

/s/ WILLIAM HARRAL III

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William Harral III  
Director

Date: March 11, 2009

/s/ MARK A. SIRGO

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Mark A. Sirgo  
Director

**SALIX PHARMACEUTICALS, LTD.**  
**Index to Consolidated Financial Statements**

	<u>PAGE</u>
AUDITED CONSOLIDATED FINANCIAL STATEMENTS	
Report of Independent Registered Public Accounting Firm .....	F-2
Report of Independent Registered Public Accounting Firm on Financial Statements .....	F-3
Consolidated Balance Sheets .....	F-4
Consolidated Statements of Operations .....	F-5
Consolidated Statements of Stockholders' Equity .....	F-6
Consolidated Statements of Cash Flows .....	F-7
Notes to Consolidated Financial Statements .....	F-8
CONSOLIDATED FINANCIAL STATEMENT SCHEDULE	
Schedule II—Valuation and Qualifying Accounts .....	F-30

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To Board of Directors and Stockholders of  
Salix Pharmaceuticals, Ltd.

In our opinion, the accompanying consolidated balance sheet and the related consolidated statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Salix Pharmaceuticals, Ltd. at December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing in Item 9A. Our responsibility is to express opinions on these financial statements, on the financial statement schedule and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for uncertain tax positions in 2007.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina  
March 11, 2009

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON FINANCIAL STATEMENTS**

The Board of Directors and Stockholders of  
Salix Pharmaceuticals, Ltd.

We have audited the accompanying consolidated statements of operations, stockholders' equity, and cash flows of Salix Pharmaceuticals, Ltd. for the year ended December 31, 2006. Our audit also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of Salix Pharmaceuticals, Ltd.'s operations and its cash flows for the year ended December 31, 2006, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

Raleigh, North Carolina  
March 9, 2007

**SALIX PHARMACEUTICALS, LTD.**

**Consolidated Balance Sheets**

	December 31,	
	2008	2007
	(U.S. dollars, in thousands, except share and per share amounts)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 120,153	\$ 111,272
Accounts receivable, net .....	40,461	52,208
Inventory, net .....	17,311	17,676
Prepaid and other current assets .....	8,295	14,219
Total current assets .....	186,220	195,375
Property and equipment, net .....	4,849	5,877
Restricted cash .....	15,000	—
Goodwill .....	85,257	86,383
Product rights and intangibles, net .....	106,822	105,713
Other assets .....	2,999	3,754
Total assets .....	\$ 401,147	\$ 397,102
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 10,099	\$ 11,889
Accrued liabilities .....	27,443	20,929
Reserve for product returns, rebates and chargebacks .....	34,034	52,657
Current portion of capital lease obligations .....	849	1,009
Total current liabilities .....	72,425	86,484
Long-term liabilities:		
Convertible senior notes .....	60,000	—
Borrowings under credit facility .....	15,000	15,000
Lease incentive obligation .....	2,108	2,436
Long term portion of capital lease obligations .....	791	612
Total long-term liabilities .....	77,899	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, 48,078,200 and 47,708,985 shares issued and outstanding at December 31, 2008 and 2007, respectively .....	48	47
Additional paid-in-capital .....	402,550	397,261
Accumulated deficit .....	(151,775)	(104,738)
Total stockholders' equity .....	250,823	292,570
Total liabilities and stockholders' equity .....	\$ 401,147	\$ 397,102

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

**SALIX PHARMACEUTICALS, LTD.**  
**Consolidated Statements of Operations**

	Year Ended December 31,		
	2008	2007	2006
	(U.S. dollars, in thousands, except per share data)		
<b>Revenues:</b>			
Net product revenues	\$178,766	\$232,880	\$208,533
Revenues from collaborative agreements	—	2,912	—
Total revenues	178,766	235,792	208,533
<b>Costs and expenses:</b>			
Cost of products sold (excluding \$9,891, \$8,627 and \$4,907 in amortization of product rights and intangible assets for the years ended December 31, 2008, 2007 and 2006, respectively)	36,710	55,024	41,443
Fees and costs related to license agreements	7,105	1,850	1,296
Amortization of product rights and intangible assets	9,891	8,627	4,907
Research and development	76,630	71,947	47,917
Selling, general and administrative	95,088	86,492	82,636
Total costs and expenses	225,424	223,940	178,199
Income (loss) from operations	(46,658)	11,852	30,334
Interest and other income (expense), net	(495)	3,326	2,552
Income (loss) before income tax	(47,153)	15,178	32,886
Income tax (expense) benefit	116	(6,953)	(1,376)
Net income (loss)	\$ (47,037)	\$ 8,225	\$ 31,510
Net income (loss) per share, basic	\$ (0.98)	\$ 0.17	\$ 0.68
Net income (loss) per share, diluted	\$ (0.98)	\$ 0.17	\$ 0.65
Shares used in computing net income (loss) per share, basic	47,898	47,329	46,634
Shares used in computing net income (loss) per share, diluted	47,898	48,678	48,369

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

**SALIX PHARMACEUTICALS, LTD.**  
**Consolidated Statements of Stockholders' Equity**

	Common Stock		Additional Paid-in- capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	(U.S. dollars, in thousands, except share amounts)					
Balance at December 31, 2005	46,307,394	\$ 46	\$384,959	\$(679)	\$(144,473)	\$239,853
Issuance of common stock upon exercise of stock options	726,323	1	4,213	—	—	4,214
Income tax benefit from non-qualified stock option exercises	—	—	90	—	—	90
Compensation expense related to restricted stock awards	—	—	1,205	—	—	1,205
Realized loss on foreign currency translation	—	—	—	679	—	679
Net income	—	—	—	—	31,510	31,510
Balance at December 31, 2006	47,033,717	47	390,467	—	(112,963)	277,551
Issuance of common stock upon exercise of stock options	382,115	—	2,053	—	—	2,053
Income tax benefit from non-qualified stock option exercises	—	—	118	—	—	118
Issuance of common stock upon vesting of restricted stock	204,425	—	—	—	—	—
Issuance of common stock upon exercise of warrants	88,728	—	945	—	—	945
Compensation expense related to restricted stock awards	—	—	3,678	—	—	3,678
Net income	—	—	—	—	8,225	8,225
Balance at December 31, 2007	47,708,985	47	397,261	—	(104,738)	292,570
Issuance of common stock upon exercise of stock options	67,713	—	248	—	—	248
Issuance of common stock upon vesting of restricted stock	301,502	1	—	—	—	1
Income tax benefit from non-qualified stock option exercises	—	—	285	—	—	285
Compensation expense related to restricted stock awards	—	—	4,756	—	—	4,756
Net loss	—	—	—	—	(47,037)	(47,037)
Balance at December 31, 2008	48,078,200	\$ 48	\$402,550	\$ —	\$(151,775)	\$250,823

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

**SALIX PHARMACEUTICALS, LTD.**

**Consolidated Statements of Cash Flows**

	<b>Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>(U.S. dollars, in thousands)</b>			
<b>Cash Flows from Operating Activities</b>			
Net income (loss) .....	\$ (47,037)	\$ 8,225	\$ 31,510
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:			
Loss on disposal of property and equipment .....	—	3	47
Reduction in income taxes payable from stock option exercises .....	—	—	90
Depreciation and amortization .....	12,973	10,642	6,472
Realized loss on foreign currency translation .....	—	—	679
Stock-based compensation expense .....	4,757	3,678	1,205
Changes in assets and liabilities:			
Accounts receivable, inventory, prepaid expenses and other assets .....	22,651	11,266	(25,063)
Accounts payable and accrued liabilities .....	4,396	5,129	(1,077)
Reserve for product returns, rebates and chargebacks .....	(18,623)	37,210	4,031
Net cash provided (used) by operating activities .....	(20,883)	76,153	17,894
<b>Cash Flows from Investing Activities</b>			
Purchases of property and equipment .....	(856)	(2,368)	(1,700)
Purchase of product rights, intangibles and other assets .....	(11,000)	(55,000)	(12,124)
Increase in restricted cash .....	(15,000)	—	—
Increase in other non-current assets .....	—	(2,054)	—
Proceeds from maturity of investments .....	—	—	998
Net cash used in investing activities .....	(26,856)	(59,422)	(12,826)
<b>Cash Flows from Financing Activities</b>			
Borrowing under credit facility .....	—	15,000	—
Net proceeds from convertible senior note offering .....	57,266	—	—
Principal payments on capital lease obligations .....	(1,179)	(40)	—
Excess tax benefit from stock-based compensation .....	285	118	—
Proceeds from issuance of common stock upon exercise of stock options .....	248	2,998	4,213
Net cash provided by financing activities .....	56,620	18,076	4,213
Net increase in cash and cash equivalents .....	8,881	34,807	9,281
Cash and cash equivalents at beginning of year .....	111,272	76,465	67,184
Cash and cash equivalents at end of year .....	<u>\$120,153</u>	<u>\$111,272</u>	<u>\$ 76,465</u>
<b>Supplemental Disclosure of Cash Flow Information</b>			
Cash paid for income taxes .....	<u>\$ 591</u>	<u>\$ 3,385</u>	<u>\$ 1,023</u>
Cash paid for interest .....	<u>\$ 875</u>	<u>\$ 862</u>	<u>\$ —</u>

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

**SALIX PHARMACEUTICALS, LTD.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2008**

**(1) ORGANIZATION AND BASIS OF PRESENTATION**

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

These consolidated financial statements are stated in U.S. dollars and are prepared under accounting principles generally accepted in the United States. The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant inter-company 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.

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Use of Estimates**

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

**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.

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

- the number of and specific contractual terms of agreements with customers;
- estimated levels of inventory in the distribution channel;
- historical rebates, chargebacks and returns of products;

## SALIX PHARMACEUTICALS, LTD.

### Notes to Consolidated Financial Statements — Continued

- direct communication with customers;
- anticipated introduction of competitive products or generics;
- anticipated pricing strategy changes by the Company and/or its competitors;
- analysis of prescription data gathered by a third-party prescription data provider;
- the impact of changes in state and federal regulations; and
- estimated remaining shelf life of products.

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

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

Allowances for estimated rebates and chargebacks were \$7.4 million and \$9.7 million as of December 31, 2008 and 2007, respectively. The balance at December 31, 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 chargebacks, the Company prepares various sensitivity analyses to ensure the Company's final estimate is within a reasonable range as well as review prior period activity to ensure that the Company's methodology continues to be appropriate.

Allowances for product returns were \$26.6 million and \$43.0 million as of December 31, 2008 and 2007, respectively. 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. These balances include \$18.1 million and \$34.6 million at December 31, 2008 and 2007, respectively, reflecting the Company's estimate of Colazal that may be

## **SALIX PHARMACEUTICALS, LTD.**

### **Notes to Consolidated Financial Statements — Continued**

returned to us under our return policy as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007. The Company estimates its liability for product returns at each reporting period based on historical return rates, estimated inventory in the channel and the other factors discussed above. Due to the subjectivity of the Company's accrual estimates for product returns, the Company prepares various sensitivity analyses to ensure the Company's final estimate is within a reasonable range and also reviews prior period activity to ensure that the Company's methodology is still reasonable.

Colazal, the Company's balsalazide disodium capsule, has historically accounted for a majority of the Company's revenue prior to 2008. On December 28, 2007, the Office of Generic Drugs, or OGD, approved three generic balsalazide capsule products. As a result of these generic approvals, the Company expects the future sales of Colazal to be significantly less than historical sales of Colazal. At December 31, 2008 and 2007, respectively, \$18.1 million and \$34.6 million were recorded as a liability to reflect an estimate of the Company's liability for Colazal that may be returned by the original purchaser in accordance with the Company's stated return policy as a result of these generic approvals. This estimate is based on an estimate of Colazal inventory in the channel and related expiration dates of this inventory, estimated erosion of Colazal demand based on the generic approvals and the resulting estimated pull-through of Colazal, and other factors. Due to the subjectivity of this estimate, the Company prepares various sensitivity analyses to ensure the Company's final estimate is within a reasonable range.

The Company's provision for revenue-reducing items such as rebates, chargebacks, and product returns as a percentage of gross product revenue in the twelve-month periods ended December 31, 2008 and 2007 was 6.3% and 9.7% for rebates, chargebacks and discounts and was 7.2% and 3.3% for product returns, respectively, excluding the Colazal return reserve. Increase to the Colazal return reserve were 11.2% of gross product revenue in 2007.

During the fourth quarter of 2008 we recognized \$9.1 million of net product revenue related to shipments to wholesalers of Apriso, which was approved by the FDA on October 31, 2008, and will be launched to physicians in late February 2009. We evaluated the "Criteria for Recognizing Revenue When Right of Return Exits" under paragraphs 6 and 8 of SFAS No. 48, and "other factors" conditions provided by the Staff within Staff Accounting Bulletin Topic 13(A)(4)(9). Based on our historical experience with Colazal, which has the same indication, is distributed through the same distribution channels and prescribed by the same physicians as Apriso, we have the ability to estimate returns for Apriso and therefore recognized revenue.

### **Research and Development**

The Company expenses research and development costs, both internal and externally contracted, as incurred. For nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities, the Company initially capitalizes the advance payment. Such amounts are then recognized as an expense as the related goods are delivered or the related services are performed. At December 31, 2007, the net asset related to on-going research and development activities to be charged to expense in future periods was \$8.9 million and at December 31, 2008, the net liability related to on-going research and development activities was \$12.7 million.

### **Cash and Cash Equivalents**

The Company considers all highly liquid investments with maturities from date of purchase of three months or less to be cash equivalents. The Company maintains its cash and cash equivalents in several different financial instruments with various banks and brokerage houses. This diversification of risk is consistent with Company policy to maintain liquidity and ensure the safety of principal. At December 31, 2008, cash and cash equivalents consisted primarily of demand deposits, overnight investments in Eurodollars, certificates of deposit and money market funds at reputable financial institutions and did not include any auction rate securities.

## **SALIX PHARMACEUTICALS, LTD.**

### **Notes to Consolidated Financial Statements — Continued**

#### **Accounts Receivable**

The Company extends credit on an uncollateralized basis primarily to wholesale drug distributors and retail pharmacy chains throughout the United States. The Company is required to estimate the level of accounts receivable which ultimately will be uncollectible. The Company calculates this estimate based on a review of specific customer balances, industry experience and the current economic environment. Currently, the Company reserves for specific accounts plus a percentage of the Company's outstanding trade accounts receivable balance as an allowance for uncollectible accounts. Our allowance for uncollectible accounts at December 31, 2008 and 2007 was \$0.6 million and \$3.1 million, respectively.

#### **Fair Value of Financial Instruments**

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, and capital lease obligations approximated their fair values as of December 31, 2008 and 2007 due to the short-term nature of these financial instruments. The carrying amount of the Company's credit facility approximated its fair value at December 31, 2007 and 2008 due to the fact that interest rate was determined based on prevalent market rates.

#### **Property and Equipment**

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets, generally three to five years, using the straight-line method.

#### **Inventories**

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

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

Inventory at December 31, 2008 consisted of \$8.5 million of raw materials, \$6.5 million of work-in-process, and \$2.3 million of finished goods. 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 December 31, 2008, inventory reserves totaling \$3.8

**SALIX PHARMACEUTICALS, LTD.**

**Notes to Consolidated Financial Statements — Continued**

million, compared to \$0.8 million as of December 31, 2007, have been recorded to reduce inventories to their net realizable value. The increase in inventory reserves during 2008 is due to a reserve for inventory related to balsalazide tablets. In December 2008 the Company received a complete response letter from the FDA on the balsalazide tablet NDA, which indicated that based on its review, the FDA has determined that the application cannot be approved in its present form and that clinical data from an additional adequate and well-controlled clinical trial will be required in order to conduct further review on the NDA. The Company does not intend to conduct additional clinical investigation of balsalazide tablets in this indication, as a result the Company reserved the inventory related to balsalazide tablets.

**Intangible Assets and Goodwill**

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

When the Company makes product acquisitions that include license agreements, product rights and other identifiable intangible assets, it records the purchase price of such intangibles, along with the value of the product related liabilities that it assumes, as intangible assets. The Company allocates the aggregate purchase price to the fair value of the various tangible and intangible assets in order to determine the appropriate carrying value of the acquired assets and then amortizes the cost of the intangible assets as an expense in its consolidated statement of operations over the estimated economic useful life of the related assets. In accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", the Company assesses the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. The Company believes that the following factors could trigger an impairment review: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business; and significant negative industry or economic trends.

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

The Company assesses impairment of goodwill on an annual basis in accordance with Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets". At December 31, 2008 there is no impairment to goodwill.

The following table reflects the components of all specifically identifiable intangible assets as of December 31 (in thousands):

	<u>Gross Amount</u>	<u>Accumulated Amortization</u>	<u>Net Carrying Amount</u>	<u>Average Life</u>
2008 .....	\$133,388	\$26,566	\$106,822	10 years
2007 .....	\$122,388	\$16,675	\$105,713	13 years

Amortization expense is calculated on a straight-line basis over the estimated useful life of the asset. Amortization expense for the years ended December 31, 2008, 2007 and 2006 was \$9.9 million, \$8.6 million and \$4.9 million, respectively. Estimated amortization expense related to intangible assets existing as of December 31, 2008 is \$10.0 million annually for each of the succeeding five years.

## SALIX PHARMACEUTICALS, LTD.

### Notes to Consolidated Financial Statements — Continued

In November 2003, the Company acquired from aaiPharma LLC for \$2.0 million the exclusive right to sell 25, 75 and 100 milligram dosage strengths of azathioprine tablets in North America under the name Azasan. The purchase price was fully allocated to product rights and related intangibles and is being amortized over a period of ten years. Although Azasan does not have any patent protection, the Company believes ten years is an appropriate amortization period based on established product sales history and management's experience. At December 31, 2008 and 2007, accumulated amortization for the Azasan intangible was \$1.0 million and \$0.8 million, respectively.

In June 2004, the Company acquired the exclusive U.S. rights to Anusol-HC 2.5% (hydrocortisone Cream USP), Anusol-HC 25 mg Suppository (Hydrocortisone Acetate), Proctocort Cream (Hydrocortisone Cream USP) 1% and Proctocort Suppositories (Hydrocortisone Acetate Rectal Suppositories, 30 mg) from King Pharmaceuticals, Inc. for \$13.0 million. The purchase price was fully allocated to product rights and related intangibles and is being amortized over a period of ten years. Although Anusol-HC and Proctocort do not have any patent protection, the Company believes ten years is an appropriate amortization period based on established product sales history and management's experience. At December 31, 2008 and 2007, accumulated amortization for the King product intangibles was \$5.9 million and \$4.6 million, respectively.

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 over the twelve-month period ended December 31, 2008 was a result of the use of net operating income tax loss carryforwards generated by InKine prior to its acquisition by the Company in 2005. The InKine product rights and related intangibles are being amortized over an average period of 14 years, which the Company believes is an appropriate amortization period due to the product's patent protection and the estimated economic lives of the product rights and related intangibles. At December 31, 2008 and 2007, accumulated amortization for the InKine intangibles was \$9.8 million and \$6.8 million, respectively.

In December 2005, the Company entered into a License and Supply Agreement with Norgine B.V., granting Salix the exclusive right to sell a patented-protected, liquid PEG bowel cleansing product, NRL 944, in the United States. In August 2006, the Company received Food and Drug Administration marketing approval for NRL 944 under the branded name of MoviPrep. In January 2007 the United States Patent Office issued a patent providing coverage to September 1, 2024. In August 2006, pursuant to the terms of the Agreement, Salix made a \$15.0 million payment to Norgine. In December 2008, pursuant to the terms of the Agreement, the Company made a \$5.0 million payment to Norgine. The Company is amortizing these milestone payments over a period of 17.3 years, which the Company believes is an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. At December 31, 2008 and 2007, accumulated amortization for the MoviPrep intangible was \$2.8 and \$1.2 million, respectively.

In February 2007, the Company entered into a Master Purchase and Sale and License Agreement with Merck & Co. Inc., to purchase the U.S prescription pharmaceutical product rights to Pepcid Oral Suspension and Diuril Oral Suspension from Merck. The Company paid Merck \$55.0 million at the closing of this transaction. The purchase price was fully allocated to product rights and related intangibles, and is being amortized over a period of 15 years. Although Pepcid and Diuril do not have patent protection, the Company believes 15 years is an appropriate amortization period based on established product history and management experience. At December 31, 2008 and 2007, accumulated amortization for the Merck products was \$6.9 million and \$3.2 million, respectively.

In July 2002, the Company acquired the rights to develop and market a granulated formulation of mesalamine from Dr. Falk Pharma GmbH. On October 31, 2008, the FDA granted marketing approval for Apriso for the maintenance of remission of ulcerative colitis in adults. In November 2008, the Company made a \$6.0 million milestone payment to Dr. Falk. The Company is amortizing this milestone payment over a period of 9.5 years, which

**SALIX PHARMACEUTICALS, LTD.**

**Notes to Consolidated Financial Statements — Continued**

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 December 31, 2008, accumulated amortization for the Apriso intangible was \$0.1 million.

**Asset Impairment**

The Company reviews the value and remaining useful lives of its long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable to determine if an impairment has occurred. If this review indicates that the assets will not be recoverable, based on an analysis of undiscounted cash flows over the remaining amortization period, the Company will reduce the carrying value of its long-lived assets accordingly, in accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets."

The approval of three generic balsalazide capsule products on December 28, 2007 was a change in circumstance that caused us to review the carrying amount of our long-lived assets. Based on this review there was no impairment to our long-lived assets and no reduction to their carrying value is required.

**Restricted Cash**

At December 31, 2008, restricted cash of \$15.0 million represents the collateral on deposit with the Administrative Agent related to the Company's credit facility.

**Shipping and Handling Costs**

The Company does not charge its customers for freight costs. The amounts of such costs are included in selling, general and administrative expenses and are not material.

**Advertising Costs**

The Company charges advertising costs to expense as incurred. Advertising expenses were approximately \$8.3 million, \$5.7 million and \$2.3 million for the years ended December 31, 2008, 2007 and 2006, respectively.

**Segment Reporting**

The Company operates in a single industry and segment 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):

	<b>Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Colazal .....	\$ 1,422	\$ 92,401	\$103,478
Xifaxan .....	79,928	64,260	51,628
Purgatives – Visicol/OsmoPrep/MoviPrep .....	62,862	47,693	45,502
Pepcid .....	18,225	22,191	—
Apriso .....	9,123	—	—
Other .....	7,206	6,335	7,925
Net product revenues .....	<u>\$178,766</u>	<u>\$232,880</u>	<u>\$208,533</u>

## SALIX PHARMACEUTICALS, LTD.

### Notes to Consolidated Financial Statements — Continued

Colazal net product revenues for 2007 includes a \$34.6 million reduction representing the Company's estimate of Colazal previously sold to wholesalers that may be returned to the Company under its return policy as a result of the approval of three generic balsalazide capsule products on December 28, 2007.

#### Comprehensive Income (Loss)

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

#### Stock-Based Compensation

At December 31, 2008, the Company had one active share-based compensation plan, the 2005 Stock Plan, allowing for the issuance of stock options and restricted stock. The Company accounts for share-based compensation under SFAS No 123R, "Share-Based Payment," which requires that companies estimate the fair value of share-based payment awards on the date of the grant. The cost is to be recognized over the period during which an employee is required to provide service in exchange for the award. The valuation provisions of SFAS 123R apply to new grants and grants modified after the adoption date that were outstanding as of the effective date.

#### Income Taxes

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

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

On January 1, 2007, the Company adopted the provisions of FIN 48. As a result of applying the provisions of FIN 48, the Company recognized an increase of \$2.4 million in the liability for unrecognized tax benefits and a reduction in the valuation allowance as of January 1, 2007 for the same amount. The unrecognized tax benefits as December 31, 2008 relate to federal tax credit carryforwards. The Company does not expect the unrecognized tax benefits to change significantly over the next 12 months.

The Company continues to fully recognize its tax benefits which are offset by a valuation allowance to the extent that it is more likely than not that the deferred tax assets will not be realized. The Company does not expect any significant changes in its unrecognized tax benefits for the next twelve months.

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

**SALIX PHARMACEUTICALS, LTD.**

**Notes to Consolidated Financial Statements — Continued**

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

**Net Income (Loss) Per Share**

The Company computes net income (loss) per share in accordance with SFAS No. 128, “Earnings Per Share” (“SFAS 128”). Under the provisions of SFAS 128, basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares and dilutive common share equivalents then outstanding. Common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and the impact of vested restricted stock grants. Under the provisions of SFAS 128, the Company will account for the effect of the convertible Notes on diluted net income (loss) per share using the treasury stock method. As a result, the convertible Notes will have no effect on diluted net income (loss) per share until the Company’s stock price exceeds the conversion price of \$9.25 per share. For the year ended December 31, 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.

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

	Year ended December 31,		
	2008	2007	2006
Numerator:			
Net income (loss) .....	\$(47,037)	\$ 8,225	\$31,510
Denominator:			
Weighted average common shares, basic .....	47,898	47,329	46,634
Dilutive effect of stock options and restricted stock awards .....	—	1,349	1,735
Weighted average common shares, diluted .....	47,898	48,678	48,369

For the year ended December 31, 2008, weighted average common shares, diluted are equal to weighted average common shares, basic, because inclusion of the 133,053 and 578,386 shares of restricted stock and stock options, respectively, would have an anti-dilutive effect due to the net loss during that period. For the years ended 2008, 2007, and 2006, there were 4,434,835, 3,731,150, and 4,027,149, respectively, potential common shares outstanding that were excluded from the diluted net income (loss) per share calculation because their effect would have been anti-dilutive.

**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 we 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 affects of the business combination. The Company does not believe the adoption of SFAS 141R will have a material impact on the Company’s consolidated financial position, results of operations and cash flows; however, the Company’s accounting for acquisitions after the adoption of SFAS 141R may produce materially different results than accounting under the current guidance.

## SALIX PHARMACEUTICALS, LTD.

### Notes to Consolidated Financial Statements — Continued

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 we 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. We are currently evaluating the impact of the adoption of this FSP. Our convertible Notes may be settled in cash, as a result, upon adoption of the FSP on January 1, 2009, we 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%. The Company currently believes approximately 25% of the initial proceeds will be allocated to the equity component, and the effective interest rate, including the amortization of the debt discount, on the liability component will be approximately 12%.

### (3) PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31 (in thousands):

	2008	2007
Cost:		
Furniture and equipment . . . . .	\$ 6,228	\$ 5,383
Computer equipment . . . . .	4,801	4,940
Assets under capital lease . . . . .	2,860	1,661
	13,889	11,984
Accumulated depreciation:		
Furniture and equipment . . . . .	(4,124)	(3,230)
Computer equipment . . . . .	(3,696)	(2,837)
Assets under capital lease . . . . .	(1,220)	(40)
	(9,040)	(6,107)
Net property and equipment . . . . .	\$ 4,849	\$ 5,877

Depreciation expense was approximately \$3.1 million, \$2.0 million and \$1.6 million in 2008, 2007 and 2006, respectively.

## SALIX PHARMACEUTICALS, LTD.

### Notes to Consolidated Financial Statements — Continued

#### (4) ACCRUED LIABILITIES

Accrued liabilities consisted of the following at December 31 (in thousands):

	<u>2008</u>	<u>2007</u>
Accrued expenses .....	\$23,831	\$13,278
Accrued royalties .....	3,612	7,651
Total accrued liabilities .....	<u>\$27,443</u>	<u>\$20,929</u>

#### (5) CREDIT FACILITY

In February 2007, the Company entered into a \$100.0 million revolving credit facility that matures in February 2012. On August 4, 2008 the credit facility was amended to waive defaults that may have arisen as a result of the approval of three generic balsalazide capsule products by the Office of Generic Drugs on December 28, 2007 and the credit facility was reduced to \$20.0 million. On August 22, 2008 the credit facility was further amended to allow the Company to issue the convertible Notes described in Note 6 below. 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”. At December 31, 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. Borrowings under the credit facility may be used for working capital, capital expenditures, acquisitions and other general corporate purposes.

The credit facility bears interest at a rate per annum equal to, at the Company’s option, either (a) a base rate equal to the higher of (i) the Federal Funds Rate plus 1/2 of 1% and (ii) the Bank of America prime rate, or (b) a Eurodollar rate (based on LIBOR), plus 0.00% for base rate borrowings and 1.00% for Eurodollar rate borrowings. The Company must maintain an amount equal to the amount outstanding under the credit facility on deposit with the Administrative Agent of the credit facility and maintain a minimum of \$23.0 million in cash on its balance sheet. At December 31, 2008, restricted cash of \$15.0 million represents the collateral on deposit with the Administrative Agent related to the credit facility. At December 31, 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.

#### (6) 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.

## **SALIX PHARMACEUTICALS, LTD.**

### **Notes to Consolidated Financial Statements — Continued**

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

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

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

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

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

### **(7) STOCKHOLDERS’ EQUITY**

#### **Preferred Stock**

A total of 5,000,000 shares of preferred stock are authorized and issuable. No shares of preferred stock were issued or outstanding as of December 31, 2008.

#### **Common Stock**

As of December 31, 2008 the Company was authorized to issue up to 80,000,000 shares of \$0.001 par value common stock. As of December 31, 2008 and 2007, there were 48,078,200 and 47,708,985 shares of common stock issued and outstanding, respectively.

#### **Stockholder Rights Plan**

On January 9, 2003, the Company’s Board of Directors adopted an updated stockholder rights plan. Consequently, the Board authorized the redemption, effective on January 20, 2003, of rights under its existing stockholder rights plan

## SALIX PHARMACEUTICALS, LTD.

### Notes to Consolidated Financial Statements — Continued

for \$0.0001 per right. Pursuant to the updated plan, stock purchase rights were distributed to stockholders at the rate of one right with respect to each share of common stock held of record as of January 20, 2003. The rights plan is designed to enhance the Board's ability to prevent an acquirer from depriving stockholders of the long-term value of their investment and to protect stockholders against attempts to acquire the Company by means of unfair or abusive takeover tactics. The rights become exercisable based upon certain limited conditions related to acquisitions of stock, tender offers and business combinations involving the Company.

#### Stock Plans

The Company's 1994 Stock Plan (the "1994 Plan") was adopted by the Board of Directors in March 1994 and approved by the stockholders in March 1995. The Company's 1996 Stock Plan (the "1996 Plan") was adopted by the Board of Directors and approved by the Company's stockholders in February 1996. The Company's 2005 Stock Plan (the "2005 Plan") was adopted by the Board of Directors in April 2005 and approved by the stockholders in June 2005. The stock granted under the 1994 Plan, the 1996 Plan and the 2005 Plan may be either stock options or restricted shares. Stock options expire no later than ten years from the date of grant.

Option prices shall be at least 100% of the fair market value on the date of grant for incentive stock options, and no less than 85% of the fair market value for nonqualified stock options. If, at the time the Company grants an option, the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the exercise price for an incentive stock option shall be at least 110% of the fair market value and the option shall not be exercisable more than five years after the date of grant. The options generally become exercisable in increments of 1/48th per month over a period of 48 months from the date of grant. Options may be granted with different vesting terms as determined by the board of directors. Since inception of the Company's 1994 Plan, 1996 Plan and 2005 Plan the Company's stock option grants were all at fair market value. Starting in 2006, the Company began issuing restricted shares to employees, executives and directors of the Company.

#### Stock-Based Compensation

At December 31, 2008, the Company had one active share-based compensation plan, the 2005 Stock Plan, allowing for the issuance of stock options and restricted stock. The Company accounts for share-based compensation under SFAS No 123R, "Share-Based Payment," which requires that companies estimate the fair value of share-based payment awards on the date of the grant. The cost is to be recognized over the period during which an employee is required to provide service in exchange for the award. The valuation provisions of SFAS 123R apply to new grants and grants modified after the adoption date that were outstanding as of the effective date.

Starting in 2006, the Company began issuing restricted shares to employees, executives and directors of the Company. The restrictions on the restricted stock lapse according to one of two schedules. For employees and executives of the Company, restrictions lapse 25% annually over four years or 33% over 3 years. For board members of the company, restrictions lapse 100% after one year. The fair value of the restricted stock was estimated using an assumed forfeiture rate of 8.1% and is being expensed on a straight-line basis over the period during which the restrictions lapse. For the year ended December 31, 2008, the Company recognized \$4.8 million in share based compensation expense related to the restricted shares. As of December 31, 2008, the total amount of unrecognized compensation cost related to nonvested restricted stock awards, to be recognized as expense subsequent to December 31, 2008, was approximately \$12.4 million, and the related weighted-average period over which it is expected to be recognized is approximately 2.34 years.

**SALIX PHARMACEUTICALS, LTD.**

**Notes to Consolidated Financial Statements — Continued**

Aggregate stock plan activity is as follows:

	Total Shares Available For Grant	Stock Options		Restricted Shares		Stock Options and Restricted Shares	
		Number	Weighted Average Price	Number Subject to Issuance	Weighted Average Price	Number	Weighted Average Price
Balance at December 31, 2005 . . . .	54,925	7,336,606	\$13.58	—	—	7,336,606	\$13.58
Additional shares authorized . .	1,500,000	—	—	—	—	—	—
Granted . . . . .	(711,826)	—	—	711,826	\$12.13	711,826	\$12.13
Exercised . . . . .	—	(726,280)	\$ 5.81	—	—	(726,280)	\$ 5.81
Canceled/forfeited . . . . .	143,612	(283,789)	\$18.75	(29,920)	\$12.02	(313,709)	\$18.11
Balance at December 31, 2006 . . . .	986,711	6,326,537	\$14.24	681,906	\$12.52	7,008,443	\$14.07
Granted . . . . .	(758,407)	—	—	758,407	\$12.81	758,407	\$12.81
Vested . . . . .	—	—	—	(204,425)	\$12.45	(204,425)	\$12.45
Exercised . . . . .	—	(382,115)	\$ 5.37	—	—	(382,115)	\$ 5.37
Canceled/forfeited . . . . .	382,949	(729,893)	\$20.33	(112,689)	\$13.06	(842,582)	\$19.36
Balance at December 31, 2007 . . . .	611,253	5,214,529	\$14.03	1,123,199	\$12.68	6,337,728	\$13.80
Additional shares authorized . .	837,311	—	—	—	—	—	—
Granted . . . . .	(1,009,597)	—	—	1,009,597	\$ 7.10	1,009,597	\$ 7.10
Exercised . . . . .	—	(67,713)	\$ 3.66	—	—	(67,713)	\$ 3.66
Vested . . . . .	—	—	—	(301,502)	\$12.65	(301,502)	\$12.65
Canceled/forfeited . . . . .	397,655	(528,983)	\$18.55	(182,439)	\$11.54	(711,422)	\$16.75
Balance at December 31, 2008 . . . .	836,622	4,617,833	\$13.67	1,648,855	\$ 9.39	6,266,688	\$12.55

Exercise prices for options outstanding as of December 31, 2008 ranged from \$1.13 to \$48.58 per share.

Exercise Price	Options Outstanding and Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life (Yrs)	Weighted Average Exercise Price
\$ 1.13 – 4.92 . . . . .	1,034,690	2.61	\$ 3.39
\$ 5.40 – 14.46 . . . . .	1,003,797	4.30	9.57
\$15.02 – 17.94 . . . . .	1,161,139	5.91	17.35
\$18.14 – 20.89 . . . . .	894,478	5.56	19.09
\$21.07 – 48.58 . . . . .	523,729	5.61	24.43
	<u>4,617,833</u>	4.72	\$13.67

At December 31, 2008, there were 4,617,833 exercisable options with a weighted average exercise price of \$13.67. At December 31, 2007, there were 5,214,529 exercisable options with a weighted average exercise price of \$14.03.

For the year ended December 31, 2008, 0.1 million shares of the Company's outstanding stock with a market value of \$0.5 million were issued upon the exercise of stock options. The Company recognized no share-based compensation expense related to stock options for the year ended December 31, 2008 or 2007, nor any income tax benefit. The total intrinsic value of options exercised for the years ended December 31, 2008, 2007 and 2006 was \$0.3 million, \$3.0 million, and \$5.8 million, respectively. As of December 31, 2008, there was no unrecognized compensation cost for stock options due to the fact that all stock options were fully vested as noted above. For the year ended December 31, 2008, the Company received \$0.2 million in cash from stock option exercises.

**SALIX PHARMACEUTICALS, LTD.**

**Notes to Consolidated Financial Statements — Continued**

**(8) INCOME TAXES**

As of December 31, 2008, the Company had U.S. federal net operating loss carryforwards of \$116.0 million. Of this amount, approximately \$21.7 million is limited by section 382 of the Internal Revenue Code. The Company's remaining net operating loss carryforwards of approximately \$16.6 million relates to excess stock option benefit which, if and when realized, will credit additional paid-in capital. The Company also has gross North Carolina net operating loss carryforwards in the amount of \$51.7 million.

The provision for income taxes in the accompanying consolidated statements of operations for the years ended December 31, 2008, 2007 and 2006 consisted of the following (in thousands):

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Current:			
Federal .....	\$ (541)	\$1,424	\$ 522
State .....	(701)	2,224	854
Total current taxes .....	<u>(1,242)</u>	<u>3,648</u>	<u>1,376</u>
Deferred:			
Federal .....	1,126	3,305	—
State .....	—	—	—
Total deferred taxes .....	<u>1,126</u>	<u>3,305</u>	<u>—</u>
Total current taxes .....	<u>\$ (116)</u>	<u>\$6,953</u>	<u>\$1,376</u>

The tax effects of temporary differences that give rise to significant portions of the deferred tax asset at December 31, 2008 and 2007 are as follows (in thousands):

	<u>2008</u>	<u>2007</u>
Net operating loss carryforwards .....	\$ 35,420	\$ 15,270
Capitalized research and development expenses .....	2,244	3,583
Research and development credits .....	18,131	7,505
Other credits .....	1,760	1,105
Timing differences, including reserves, accruals, and writeoffs .....	9,858	26,949
Total deferred tax assets .....	67,413	54,412
Valuation allowance .....	<u>(60,378)</u>	<u>(42,345)</u>
Net deferred tax assets .....	<u>7,035</u>	<u>12,067</u>
Intangible assets .....	(4,825)	(11,930)
Property, plant and equipment .....	—	(2)
Accrued return allowance .....	(2,209)	—
Allowance for third parties .....	(1)	(135)
Net deferred tax liabilities .....	<u>(7,035)</u>	<u>(12,067)</u>
Net deferred taxes .....	<u>\$ —</u>	<u>\$ —</u>

The Company has provided a valuation allowance for the gross deferred tax asset due to the uncertainty regarding the Company's ability to realize the entire asset. The valuation allowance has increased by approximately \$18.0 million and decreased by approximately \$8.5 million during the years ended December 31, 2008 and 2007, respectively.

**SALIX PHARMACEUTICALS, LTD.**

**Notes to Consolidated Financial Statements — Continued**

The deferred tax assets include deferred tax assets and liabilities acquired from InKine which were fully reserved in the amount of \$14.5 million. In the current year, \$1.1 million of these deferred tax assets were realized, resulting in a reduction to goodwill.

Utilization of the federal net operating loss carryforwards may be subject to a substantial annual limitation due to the change in ownership provisions of the Internal Revenue Code of 1986. If this limitation applies, the ultimate ability for the Company to use existing net operating loss carryovers and tax credit carryovers to offset future income may be limited. The Company's net operating loss carryforwards begin to expire at the end of the taxable year ending December 31, 2021.

A reconciliation of the statutory income tax rate to the effective income tax rate is as follows:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Federal statutory income tax rate . . . . .	35.0%	35.0%	35.0%
State income taxes, net of federal income tax benefit . . . . .	(0.5)%	1.4%	2.4%
Change in valuation allowance . . . . .	(40.6)%	55.7%	(30.7)%
Tax credit, non-deductible expenses and other . . . . .	5.9%	(46.3)%	(2.5)%
	(0.2)%	45.8%	4.2%

In June 2006, 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 derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

On January 1, 2007, the Company adopted the provisions of FIN 48. As a result of applying the provisions of FIN 48, the Company recorded an increase of \$2.4 million in its unrecognized tax benefits. The unrecognized tax benefits as of December 31, 2008 relate to federal tax credit carryforwards. The Company does not expect our unrecognized tax benefits to change significantly over the next 12 months.

The following table summarizes the activity related to our unrecognized tax benefits for the years ended December 31, 2008 and 2007 (in thousands):

	<b>2008</b>	<b>2007</b>
Balance at January 1 . . . . .	\$ 2,448	\$2,448
Increases related to prior year tax positions . . . . .	18,413	—
Decreases related to prior year tax positions . . . . .	(18,413)	—
Balance at December 31 . . . . .	\$ 2,448	\$2,448

If these unrecognized tax benefits of \$2.4 million at December 31, 2008 were recognized, they would have decreased the Company's annual effective tax rate. No expense has been recorded for interest and penalties related to these tax positions.

The 1993 through 2008 tax years remain subject to examination by federal and state taxing authorities. The audit of the 2005 tax year by the Internal Revenue Service was closed during 2008.

**(9) SIGNIFICANT CONCENTRATIONS**

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. The Company's

**SALIX PHARMACEUTICALS, LTD.**

**Notes to Consolidated Financial Statements — Continued**

principal financial instruments subject to potential concentration of credit risk are accounts receivable, which are unsecured, and cash equivalents. The Company's cash equivalents consist primarily of money market funds. The amount of certain bank deposits may at times exceed the FDIC insurance limits.

The Company's primary customers are wholesale pharmaceutical distributors and retail pharmacy chains in the United States.

Total revenues from customers representing 10% or more of total revenues for the respective years, are summarized as follows:

	<b>Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Customer 1 .....	42%	41%	42%
Customer 2 .....	24%	23%	22%
Customer 3 .....	12%	9%	9%

Additionally, 74% and 72% of the Company's accounts receivable balances were due from these three customers at December 31, 2008 and 2007, respectively.

Under the Company's supply agreement with Alfa Wassermann, Alfa Wassermann is obligated to supply the Company with bulk rifaximin drug substance (the active pharmaceutical ingredient in Xifaxan tablets) until July 2014 or introduction of a generic product, whichever occurs first. The Company's supply of rifaximin drug substance is manufactured by ZaCh Systems (formerly Zambon) in Lonigo, Italy, and Aventis in Brindisi, Italy. Under a long-term supply agreement, rifaximin is converted into Xifaxan drug product by Patheon, Inc. in Whitby, Ontario. Bulk Xifaxan tablets are packaged into finished Xifaxan commercial bottles by Pathoen and packaged into Xifaxan commercial blister packs by Carton Service in Norris, Tennessee.

Under the Company's long-term supply agreement with aaiPharma, aaiPharma produces the Company's commercial supply of 25 mg, 75 mg and 100 mg Azasan finished product.

Under the Company's long-term supply agreement with Paddock Laboratories in Minneapolis, Minnesota, Paddock produces the Company's commercial supply of finished product of Anusol-HC Cream, Anusol-HC Suppositories and Proctocort Suppositories. In addition, through prior supply arrangements between King Pharmaceuticals and Crown Laboratories in Johnson City, Tennessee, Crown continues to produce the Company's commercial supply of Proctocort Cream finished product.

Under the Company's long-term supply agreement with WellSpring Pharmaceuticals in Oakville, Ontario, WellSpring produces commercial supply of OsmoPrep finished product.

Under the Company's long-term supply agreement with Norgine in Hengoed, Wales, Norgine produces commercial supply of Moviprep pouches. For secondary packaging of Moviprep into commercial finished kits, we have two vendors qualified: Norgine, at its Hengoed, Wales facility, and Carton Service in Norris, Tennessee.

Merck manufactured the Company's commercial supply of Pepcid Oral Suspension and Diuril Oral Suspension through December 2008. Under a long-term supply agreement beginning in 2009, Paddock Laboratories in Minneapolis, Minnesota, will produce the Company's commercial supply of Pepcid Oral Suspension and Diuril Oral Suspension

Bayer AG in Wuppertal, Germany supplies the Company with bulk mesalamine active ingredient. Under a long-term supply agreement with Catalent Pharma Solutions in Winchester, Kentucky, Catalent converts this mesalamine into the Company's commercial supply of bulk Apriso, 375mg mesalamine capsules. The bulk Apriso capsules are then packaged into finished Apriso commercial bottles by Carton Service in Norris, Tennessee.

## SALIX PHARMACEUTICALS, LTD.

### Notes to Consolidated Financial Statements — Continued

Cosma S.P.A. in Bergamo, Italy supplies the Company with bulk metoclopramide active ingredient. Under a long-term supply agreement with Catalent in Swindon, United Kingdom, Catalent converts this metoclopramide into the Company's commercial supply of Metozolv, 5mg and 10mg tablets in blister packaging. The Metozolv blister packs are then packaged into finished cartons by Carton Service in Norris, Tennessee.

Currently, under long-term supply agreements, the Company uses balsalazide drug substance (the active pharmaceutical ingredient in Colazal capsules) manufactured by Omnicem s.a., a subsidiary of Ajinomoto in Belgium, and Pharmazell (formerly Noveon Pharma, GmbH) in Raubling, Germany. Also, under long-term supply agreements, balsalazide is encapsulated into Colazal drug product by Nexgen Pharma, inc. (formerly Anabolic Laboratories) in Irvine, California. Bulk Colazal capsules are packaged into finished Colazal commercial bottles by Nexgen and Carton Service in Norris, Tennessee.

With respect to the Company's products currently under development, namely the Company's 1100 mg balsalazide tablet formulation and 550 mg rifaximin tablet formulation, the Company plans to negotiate commercial supply agreements with the same manufacturers who supplied the drug substance and drug product for the supplies of the Phase III clinical trial material.

#### (10) 401(K) PLAN

In 1996, the Company adopted the Salix Pharmaceuticals, Inc. 401(k) Retirement Plan. Eligible participants may elect to defer a percentage of their compensation. From inception through June 2006, the Company matched up to 50% of participant deferrals up to 6% of the participant's compensation. Effective July 2006, the Company matches up to 75% of participant deferrals up to 6% of the participant's compensation. The Company's total matching contributions for all participants were approximately \$1.1 million, \$1.0 million and \$0.7 million in 2008, 2007 and 2006, respectively. Additional discretionary employer contributions may be made on an annual basis.

#### (11) COMMITMENTS

At December 31, 2008, the Company had binding purchase order commitments for inventory purchases aggregating approximately \$28.3 million over the next five months.

##### *Lease Agreements*

During 2007, the Company entered into a three-year agreement to lease computer equipment. The equipment was capitalized at \$0.2 million, which approximates the present value of the minimum lease payments.

The Company leases fleet vehicles for its domestic sales force under a four-year lease agreement. The vehicles were capitalized at \$1.5 million, which approximates the present value of the minimum lease payments.

The Company leases office facilities under various non-cancelable operating leases, the last of which expires on April 30, 2015. Certain of these leases contain future payment obligations that escalate over time. Rent expense was approximately \$1.5 million, \$1.9 million and \$1.6 million for the years ended December 31, 2008, 2007 and 2006, respectively. The Company sub-leased its former corporate headquarters of approximately 26,000 square feet of office space under a lease expiring in 2011, total future minimum sublease payments due under this sublease were \$1.1 million as of December 31, 2008.

**SALIX PHARMACEUTICALS, LTD.**

**Notes to Consolidated Financial Statements — Continued**

As of December 31, 2008, future minimum payments for leases were as follows (in thousands):

<u>Years ending December 31,</u>	<u>Operating Leases</u>	<u>Capital Leases</u>
2009 .....	\$ 2,116	\$ 901
2010 .....	2,163	611
2011 .....	1,735	202
2012 .....	1,490	3
2013 .....	1,461	—
Thereafter .....	<u>1,991</u>	<u>—</u>
Total future minimum payments required .....	<u>\$10,956</u>	1,717
Less: Amount representing interest .....		<u>77</u>
Present value of net minimum lease payments .....		1,640
Less: Current portion of capital lease obligations .....		<u>849</u>
Long term portion of capital lease obligations .....		<u>\$ 791</u>

*Potential Milestone Payments*

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

License Agreement with Cedars-Sinai Medical Center — In June 2006, the Company entered into a license agreement with Cedars-Sinai for the right to use a patent and a patent application relating to methods of diagnosing and treating irritable bowel syndrome and other disorders caused by small intestinal bacterial overgrowth. Pursuant to the license agreement, the Company is obligated to pay Cedars-Sinai a license fee of \$1.2 million over time. As of December 31, 2008, the Company had paid this license fee in full. The Company may terminate the license agreement upon written notice of not less than 90 days.

License and Supply Agreement with the Debiopharm Group — In September 2006, the Company acquired the exclusive right to sell, market and distribute Sanvar in the United States. Pursuant to the terms of this agreement, the Company is obligated to make an upfront and milestone payments to Debiopharm that could total up to \$8.0 million contingent upon achievement of certain regulatory milestones, and an additional \$6.0 million in milestone payments contingent on reaching certain sales thresholds over the term of the agreement. As of December 31, 2008, the Company had paid \$1.0 million of milestone payments. The remaining milestone payments are contingent upon achievement of regulatory approval and certain sales thresholds.

License Agreement with Dr. Falk Pharma GmbH for granulated mesalamine — In July 2002, the Company and Dr. Falk entered into a license agreement which they amended in November 2003 and February 2005. Pursuant 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 December 31, 2008, the Company had paid \$9.0 million of milestone payments. The remaining milestone payment is contingent upon achievement of additional regulatory approval.

License Agreement with Dr. Falk Pharma GmbH for budesonide — In March 2008, the Company entered into a License Agreement with Dr. Falk Pharma GmbH. The agreement provides the Company with an exclusive license to develop and commercialize in the United States Dr. Falk Pharma's budesonide products. The products covered in the

## SALIX PHARMACEUTICALS, LTD.

### Notes to Consolidated Financial Statements — Continued

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 December 31, 2008, the Company had paid \$1.0 million of these milestone payments.

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

License Agreement with Napo Pharmaceuticals, Inc. — In December 2008 the Company entered into a Collaboration Agreement with Napo. Pursuant to the agreement, the Company has an exclusive, royalty-bearing license to crofelemer for the treatment of HIV-associated diarrhea and additional indications of pediatric diarrhea and acute infectious diarrhea in a certain territory. The Company also has a non-exclusive, worldwide, royalty-bearing license to use Napo-controlled trademarks associated with crofelemer. The Company has made an initial payment of \$5.0 million to Napo and will make up to \$50 million in milestone payments to Nap contingent on regulatory approvals and up to \$250.0 million in milestone payments contingent on reaching certain sales thresholds. The Company is responsible for development costs of crofelemer, but costs exceeding \$12.0 million for development of crofelemer used for the HIV-associated diarrhea indication will be credited towards regulatory milestones and thereafter against sales milestones.

License and Supply Agreement with Norgine B.V. — In December 2005, the Company entered into a license and supply agreement with Norgine for the rights to sell NRL944, a bowel cleansing product the Company now markets in the United States under the trade name MoviPrep. Pursuant to the terms of this agreement, the Company is obligated to make upfront and milestone payments to Norgine that could total up to \$37.0 million over the term of the agreement. As of December 31, 2008, the Company had paid \$22.0 million of milestone payments. The remaining milestone payments are contingent upon reaching sales thresholds.

License Agreement with Wilmington Pharmaceuticals, LLC — In September 2007, the Company entered into an Exclusive Sublicense Agreement with Wilmington Pharmaceuticals. The agreement provides that the Company is obligated to make upfront and milestone payments up to an aggregate amount of \$8.0 million to Wilmington. As of December 31, 2008, the Company had paid \$1.0 million of these milestone payments. The remaining milestone payment is contingent upon regulatory approval. The Company also loaned Wilmington \$2.0 million which is due December 31, 2009, or earlier based on regulatory approval.

**SALIX PHARMACEUTICALS, LTD.**

**Notes to Consolidated Financial Statements — Continued**

**(12) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)**

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2008 and 2007:

	<u>Mar 31</u>	<u>June 30</u>	<u>Sept 30</u>	<u>Dec 31 (2)</u>
<i>(in thousands, except per share amounts)</i>			<i>(unaudited)</i>	
<b>2008</b>				
Net product revenue . . . . .	\$ 34,254	\$41,071	\$42,872	\$ 60,569
Cost of products sold, excluding amortization of product rights and intangible assets . . . . .	7,256	7,114	7,763	14,577
Net loss . . . . .	(23,997)	(7,089)	(5,415)	(10,536)
Net loss per share, basic (1) . . . . .	(0.50)	(0.15)	(0.11)	(0.22)
Net loss per share, diluted (1) . . . . .	(0.50)	(0.15)	(0.11)	(0.22)
<b>2007</b>				
Net product revenue . . . . .	\$ 59,785	\$66,678	\$67,355	\$ 39,062
Cost of products sold, excluding amortization of product rights and intangible assets . . . . .	12,005	13,041	13,083	16,895
Net income (loss) . . . . .	2,844	10,237	14,173	(19,029)
Net income (loss) per share, basic (1) . . . . .	0.06	0.22	0.30	(0.40)
Net income (loss) per share, diluted (1) . . . . .	0.06	0.21	0.29	(0.40)

- (1) The sum of per share earnings by quarter may not equal earnings per share for the year due to the changes in average share calculations. This is in accordance with prescribed reporting requirements.
- (2) The quarter ended December 31, 2007 includes a \$34.6 million charge as a reduction of net product revenues as a result of the approval of three generic balsalazide capsule products on December 28, 2007.

**(13) LEGAL PROCEEDINGS**

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

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

The Company is also involved in a lawsuit against Novel because it is seeking FDA approval to market a generic version of the Company's OsmoPrep product. CDC, LLC, owns U.S. Patent No. 5,616,346 (the '346 patent). The '346 patent is listed with the FDA as protecting the Company's OsmoPrep product. CDC, by its predecessor, licensed OsmoPrep and the '346 patent to the Company for commercialization in the United States. Novel 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 2013 expiration of the '346 patent. On September 8, 2008, the Company filed a lawsuit in the United States

## **SALIX PHARMACEUTICALS, LTD.**

### **Notes to Consolidated Financial Statements — Continued**

District Court for the District of New Jersey against Novel for the infringement of the '346 patent. The lawsuit also joins CDC as a party. Novel filed an Answer and Counterclaims on December 16, 2008. Novel denied infringement and asserted defenses of patent invalidity. No trial date has been set. The Company intend to vigorously defend the patent rights for OsmoPrep.

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

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

#### **(14) SUBSEQUENT EVENTS**

On February 26, 2009, Wilmington received a complete response letter from the FDA, indicating that it requires a risk evaluation and mitigation strategy, or REMS, for Metozolv prior to approval of the NDA. With the exception of the REMS requirement, all substantive questions and issues surrounding the Metozolv application have been resolved. The Company intends to submit the REMS by mid March and will work with the FDA to expedite the approval of Metozolv.

## SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS

### Allowance for Rebates, Chargebacks and Coupons

	<u>Year ended December 31,</u>	<u>Beginning Balance</u>	<u>Additions</u>	<u>Deductions</u>		<u>Ending Balance</u>
			<u>Provision Related to Current Period Sales</u>	<u>Rebates, Chargebacks and Discounts or Credits Related to Current Period Sales</u>	<u>Rebates, Chargebacks and Discounts or Credits Related to Prior Period Sales</u>	
(in thousands)						
2008 .....		\$9,676	\$13,576	\$10,333	\$5,482	\$7,437
2007 .....		\$7,986	\$29,369	\$22,241	\$5,438	\$9,676
2006 .....		\$7,301	\$21,577	\$15,104	\$5,788	\$7,986

### Allowance for Returns

	<u>Year ended December 31,</u>	<u>Beginning Balance</u>	<u>Additions</u>	<u>Deductions</u>		<u>Ending Balance</u>
			<u>Provision Related to Current Period Sales</u>	<u>Returns or Credits Related to Prior Period Sales</u>		
(in thousands)						
2008 .....		\$43,322	\$ 4,074	\$20,799		\$26,597
2007 .....		\$ 6,112	\$46,562	\$ 9,352		\$43,322
2006 .....		\$ 2,081	\$ 8,317	\$ 4,286		\$ 6,112

### Allowance for Uncollectible Accounts

	<u>Year ended December 31,</u>	<u>Beginning Balance</u>	<u>Additions</u>	<u>Deductions</u>		<u>Ending Balance</u>
			<u>Charged to Costs and Expenses</u>	<u>Accounts Written Off During Period</u>		
(in thousands)						
2008 .....		\$3,112	—	\$2,547		\$ 565
2007 .....		\$2,683	\$429	—		\$3,112
2006 .....		\$1,988	\$695	—		\$2,683

### Inventory Allowance

	<u>Year ended December 31,</u>	<u>Beginning Balance</u>	<u>Additions</u>	<u>Deductions</u>		<u>Ending Balance</u>
			<u>Charged to Costs and Expenses</u>	<u>Amounts Recovered During Period</u>		
(in thousands)						
2008 .....		\$ 789	\$3,297	\$ 318		\$3,768
2007 .....		\$ 684	\$ 297	\$ 192		\$ 789
2006 .....		\$2,841	\$1,152	\$3,309		\$ 684

### Valuation Allowance on Deferred Tax Assets

	<u>Year ended December 31,</u>	<u>Beginning Balance</u>	<u>Additions</u>	<u>Deductions</u>		<u>Ending Balance</u>
			<u>Provisions for Valuation Allowance</u>	<u>Release of Valuation Allowance/Other</u>		
(in thousands)						
2008 .....		\$42,345	\$18,033	—		\$60,378
2007 .....		\$50,842	—	\$8,497		\$42,345
2006 .....		\$55,651	—	\$4,809		\$50,842

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-110942) and Form S-8 (Nos. 333-126685, 333-126290, 333-116675, 333-96771, 333-63604, 333-61497, 333-135268, 333-47586 and 333-151658) of Salix Pharmaceuticals, Ltd. of our report dated March 11, 2009 relating to the financial statements, financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina  
March 11, 2009

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 No. 333-110942) of Salix Pharmaceuticals, Ltd.,
- (2) Registration Statement (Form S-8 No. 333-126685) pertaining to the InKine Pharmaceutical Company, Inc. 1993 Stock Option Plan, the InKine Pharmaceutical Company, Inc. 1997 Consultant Stock Option Plan, the InKine Pharmaceutical Company, Inc. 1999 Equity Compensation Plan, and the InKine Pharmaceutical Company, Inc. 2004 Equity Compensation Plan,
- (3) Registration Statements (Form S-8 Nos. 333-126290, 333-135268 and 333-151658) pertaining to the 2005 Stock Plan of Salix Pharmaceuticals, Ltd., and
- (4) Registration Statements (Form S-8 Nos. 333-116675, 333-96771, 333-63604, 333-61497, and 333-47586) pertaining to the 1996 Stock Option Plan, as amended;

of our report dated March 9, 2007, with respect to the consolidated financial statements and schedule of Salix Pharmaceuticals, Ltd., included in this Annual Report (Form 10-K) of Salix Pharmaceuticals, Ltd.

/s/ Ernst & Young LLP

Raleigh, North Carolina  
March 11, 2009





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

In connection with the Annual Report on Form 10-K of Salix Pharmaceuticals, Ltd. (the "Company") for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Carolyn J. Logan, President and Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

/s/ Carolyn J. Logan

Carolyn J. Logan  
President and Chief Executive Officer

March 11, 2009

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

In connection with the Annual Report on Form 10-K of Salix Pharmaceuticals, Ltd. (the "Company") for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Adam C. Derbyshire, Senior Vice President, Finance and Administration and Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

/s/ Adam C. Derbyshire

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

March 11, 2009



**Salix Pharmaceuticals, Ltd.**  
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