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, 2012 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	**94-3267443**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

8510 Colonnade Center Drive
Raleigh, North Carolina 27615
(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:

Title of Each Class	Name of Exchange on which Registered
Common Stock, $0.001 Par Value	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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☒ NO ☐

Indicate by check mark 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, 2012 (based on the closing sale price of U.S. $54.44 of the Registrant's common stock, as reported on The Nasdaq Global Market on such date) was approximately U.S. $2,604,110,452. Common stock held by each officer and director and by each person known to the Company who owned 10% 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 February 24, 2013 was 61,149,571.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement to be filed for its 2013 Annual Meeting of Stockholders currently scheduled to be held June 13, 2013 are incorporated by reference into Part III of this report.

SALIX PHARMACEUTICALS, LTD.

ANNUAL REPORT ON FORM 10-K

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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 and medical devices used in the treatment of a variety of gastrointestinal disorders, which are those affecting the digestive tract. Our website address is www.salix.com. Information on our website, Twitter feed and Facebook page are not incorporated herein by reference. We make available free of charge through our website our press releases, Annual Reports 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 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 and medical devices 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
- market our products through our approximately 335-member specialty sales and marketing team primarily focused on high-prescribing U.S. physicians in the following specialties: gastroenterologists, who are doctors who specialize in gastrointestinal disorders; hepatologists, who are doctors who specialize in liver disease; and colorectal surgeons, who are doctors who specialize in disorders of the colon and rectum.

Our current products demonstrate our ability to execute this strategy. As of December 31, 2012, our products were:

- XIFAXAN® (rifaximin) Tablets 200 mg, indicated for travelers' diarrhea;
- XIFAXAN®550mg (rifaximin) Tablets 550 mg, indicated for overt hepatic encephalopathy, or HE;
- MOVIPREP® (PEG 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate and Ascorbic Acid for Oral Solution), indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older;
- APRISO™ (mesalamine) extended-release capsules, indicated for the maintenance of remission of ulcerative colitis;
- RELISTOR® (methylnaltrexone bromide) subcutaneous injection (SI) indicated for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient;
- OSMOPREP™ (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets, indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older;

- SOLESTA®, a biocompatible tissue-bulking agent indicated for the treatment of fecal incontinence, acquired in our purchase of Oceana in December 2011;
- DEFLUX®, a biocompatible tissue-bulking agent indicated for the treatment of vesicoureteral reflux (VUR), acquired in in our purchase of Oceana in December 2011;
- FULYZAQ™, (crofelemer) delayed-release tablets, indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy, which the U.S. Food and Drug Administration, or FDA, approved on December 31, 2012;
- GIAZO™, (balsalazide disodium) tablets, indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older;
- METOZOLV™ ODT (metoclopramide hydrochloride) 5mg and 10mg orally disintegrating tablets, indicated for short-term (4 to 12 weeks) use in adults for treatment of refractory GERD, which is symptomatic, documented gastroesophageal reflux disease that fails to respond to conventional therapy, and for relief of symptoms of acute and recurrent diabetic gastroparesis;
- AZASAN® Azathioprine Tablets, USP, 75mg and 100 mg, indicated as an adjunct for the prevention of rejection in renal homotransplantations and to reduce signs and symptoms of severe active rheumatoid arthritis;
- ANUSOL-HC® 2.5% (Hydrocortisone Cream, USP), ANUSOL-HC® 25 mg Suppository (Hydrocortisone Acetate), indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses;
- PROCTOCORT® Cream (Hydrocortisone Cream, USP) 1% and PROCTOCORT® Suppository (Hydrocortisone Acetate Rectal Suppositories) 30 mg, indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses;
- PEPCID® (famotidine) for Oral Suspension, indicated for the short-term treatment of gastroesophageal reflux disease (GERD), active duodenal ulcer, active benign gastric ulcer, erosive esophagitis due to GERD, and peptic ulcer disease;
- DIURIL® (Chlorothiazide), indicated for the treatment of hypertension and also as adjunctive therapy in edema associated with congestive heart failure, cirrhosis of the liver, corticosteroid and estrogen therapy, and kidney disease; and
- COLAZAL® (balsalazide disodium) Capsules 750 mg, indicated for the treatment of mildly to moderately active ulcerative colitis (UC) in patients 5 years of age and older.

We generate revenue primarily by selling our products 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 FDA, to U.S. gastroenterologists, hepatologists, colorectal surgeons 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. As of December 31, 2012, this sales force had approximately 235 sales representatives in the field marketing our approved products in the United States. 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 generally 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. As a result of our acquisition of Oceana Therapeutics, Inc. in December 2011, we have approximately ten sales representatives based in Europe who sell Solesta and Deflux there. We also sell Deflux through distributors in approximately 20 countries outside the United States and Europe. As of December 31, 2012, our sales and marketing staff, including our sales representatives, consisted of approximately 335 people.

Because demand for our products originates with doctors, our sales force calls on high-prescribing specialists, primarily gastroenterologists, hepatologists and colorectal surgeons, 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 consumed.

Our primary product candidates currently in human clinical trials and their status are as follows:

Compound	Indication	Status
Rifaximin	Irritable bowel syndrome, or IBS	Supplemental New Drug Application, or sNDA, submitted June 7, 2010; Complete Response Letter, or CRL, received on March 7, 2011; FDA meeting held on June 20, 2011; Advisory Committee held on November 16, 2011; currently in Phase 3 retreatment study
Methylnaltrexone bromide oral	Opioid induced constipation in patients with chronic non-malignant pain; oral	Phase 3
Budesonide foam	Ulcerative proctitis	Phase 3
Rifaximin EIR	Crohn's disease	Phase 2

PRODUCTS

Xifaxan® (rifaximin) tablets

Xifaxan is a gastrointestinal-specific oral antibiotic. The FDA approved Xifaxan 200mg in May 2004 for the treatment of patients 12 years of age and older with travelers' diarrhea caused by noninvasive strains of *E coli*.

Xifaxan 550mg was approved by the FDA in March 2010 for reduction in risk of overt hepatic encephalopathy, or HE, recurrence in patients 18 years of age or older. According to the U.S. Department of Health and Human Services' Healthcare Utilization Project, there are approximately 380,000 patients in the United States who suffer from episodic overt HE.

We launched Xifaxan 200mg in the United States in July 2004 and Xifaxan 550mg in May 2010 using our own direct sales force. We are exploring potential additional indications, formulations, clinical trials and co-promotion arrangements to capitalize on the potential for Xifaxan, including our development program in irritable bowel syndrome.

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 was 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, had data exclusivity to May 2009. The FDA granted rifaximin 550mg, which is approved for the reduction in risk of HE recurrence in patients greater than 18 years of age, orphan exclusivity through March 2017. The table below lists patents covering several physical states, or polymorphic forms, of rifaximin that provide protection for all indications we are currently marketing and assessing. Alfa Wasserman S.p.a., the owner of the indicated patents, has licensed the rights to Salix in the United States. 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 provides Salix the right to use the patents listed below, as well as other members of the patent family indicated as licensed from CSMC. On April 19, 2011, the United States Patent and Trademark Office, or the USPTO, issued the method of treatment patent U.S. 7,928,115 to Salix directed to the use of rifaximin in Travelers'

Diarrhea, which should provide protection until July 2029. In November 2012, the USPTO issued an additional patent covering methods of using rifaximin to treat IBS, which should provide protection until July 2029.

U.S. Patent No.	Issue Date	Expiration	Subject
7,045,620*	May-06	Jun-24	Composition of matter and process patent covering several physical states of rifaximin
7,612,199*	Nov-09	Jun-24	Covers several physical states, or polymorphous forms of rifaximin
7,906,542*	May-11	Jun-25	Covers several physical states, or polymorphous forms of rifaximin in pharmaceutical formulations
7,902,206*	Mar-11	Jun-24	Covers several physical states, or polymorphous forms of rifaximin
7,452,857**	Nov-08	Aug-19	Use of rifaximin for treating irritable bowel syndrome
7,605,240**	Oct-09	Aug-19	Treatment of bloating caused by small intestinal bacterial overgrowth associated with irritable bowel syndrome
7,718,608**	May-10	Aug-19	Use of rifaximin for treating irritable bowel syndrome
7,935,799**	May-11	Aug-19	Use of rifaximin for treating diarrhea
7,928,115	Apr-11	Jul-29	Use of rifaximin for treating travelers' diarrhea
8,158,781*	Apr-12	Jun-24	Covers physical states, or polymorphous forms of rifaximin
8,158,644*	Apr-12	Jun-24	Covers physical states, or polymorphous forms of rifaximin
8,193,196*	Jun-12	Sept-27	Covers physical states, or polymorphous forms of rifaximin
8,309,569	Nov-12	Jul-29	Use of rifaximin for treating IBS

* Licensed from Alfa Wasserman S.p.a.

** Licensed from Cedars-Sinai Medical Center

In addition, we have filed applications for patents relating to additional indications using rifaximin and related chemical substances. In September 2009, Lupin Ltd. granted Salix the exclusive right in the United States to its bioadhesive drug delivery technology for use with rifaximin. In March 2011, Lupin granted Salix exclusive worldwide rights (except for India) to exploit Lupin technology and technology jointly developed by Lupin and Salix for all rifaximin products for human use. In October 2009, Cipla, Limited granted Salix the exclusive rights in the United States to its amorphous rifaximin application PCT Patent Application No. PCT/GB2007/003629; WO 2008/035109. In October 2012, the USPTO declared an interference action to determine the priority of invention between Cipla's application related to amorphous rifaximin and Solmag SpA's application directed to amorphous rifaximin.

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, had data exclusivity until May 2009. Accordingly, the Office of Generic Drugs of the U.S. Food and Drug Administration, or OGD, would have been able to accept an Abbreviated New Drug Application, or ANDA, for Xifaxan tablets on or any time subsequent to May 2008, if the applicant made certifications of patent non-infringement or invalidity. 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's Petition, requesting the director of OGD impose scientifically appropriate standards for the demonstration of bioequivalence for abbreviated new drug applications citing Xifaxan as the reference listed drug. Rifaximin 550mg, which is approved for the reduction in risk of HE recurrence in patients 18 years of age and older, was granted orphan exclusivity through March 2017. Accordingly OGD would have been able to accept an ANDA for Xifaxan 550mg tablets on or any time subsequent to March 2010, if the applicant made certifications of patent non-infringement or invalidity. 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 orphan exclusivity period does not prohibit the filing of an ANDA and thus, an ANDA filing could result in a challenge to the related intellectual property rights of Xifaxan 550mg tablets at any time in the future. The OGD would be unable to finally approve an ANDA until the expiration of the orphan exclusivity in March 2017. On November 29, 2011 the FDA posted draft bioequivalence guidance for rifaximin 200mg

tablets for the treatment of travelers' diarrhea. This guidance recommends successful completion of a randomized, double blind, parallel placebo controlled clinical trial in humans with clinical endpoints in order to file an ANDA for approval of a generic rifaximin 200mg tablet for the treatment of travelers' diarrhea. In February 2012, the FDA posted draft bioequivalence guidance for rifaximin 550 mg tablets. The draft guidance for rifaximin 550 mg tablets recommends that in addition to conducting the program outlined in the FDA posted draft guidance document for rifaximin 200 mg tablets discussed above, a single-dose, three-way crossover in-vivo study of fasting bioequivalence with pharmacokinetic endpoints in both fasting and fed states be performed in the 550mg tablets. Additionally, the guidance stipulated that the formulation of the 550 mg strength should be proportionally similar to that of the 200 mg strength in order to file an ANDA for approval of a generic rifaximin 550 mg tablet for the treatment of hepatic encephalopathy.

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 the FDA approved in August 2006. MoviPrep competes with a number of liquid PEG bowel cleansing products, but is differentiated from these 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.

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 September 2024. Norgine licensed MoviPrep and the '381 patent to us for commercialization in the United States. On February 9, 2010 U.S. Patent No. 7,658,914 was issued and listed in the Orange Book for MoviPrep. In August 2010 we entered into a Sublicense Agreement that granted Novel Laboratories, Inc., or Novel, a license to the patents covering MoviPrep permitting Novel to launch a generic MoviPrep on September 24, 2018.

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 this product, under the trade name Apriso, for the maintenance of remission of ulcerative colitis in adults. Apriso is a locally-acting aminosalicylate and is the first and only delayed and extended release 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 March 2009. Apriso should be patent-protected until 2018. In December 2012 the USPTO issued US Patent No. 8,337,886, which should provide further protection for the Apriso formulation as well as methods of using Apriso until 2018.

On September 7, 2012, Salix and Dr. Falk Pharma filed a patent infringement complaint against Lupin Ltd. and Lupin Pharmaceuticals, Inc. in the U.S. District Court for the District of Delaware. The Complaint alleges infringement of U. S. Patent No. 6,551,620, or the '620 patent, based on Lupin's filing of an ANDA seeking approval to market and sell a generic version of Apriso before the expiration of the 620 patent. The filing of this suit within the 45-day response period provided by the Hatch Waxman Act imposes an automatic 30-month stay of approval of Lupin's ANDA. We continue to evaluate our intellectual property protecting Apriso, in which we have full confidence. We intend to vigorously enforce our intellectual property rights.

Relistor® (methylnaltrexone bromide)

In February 2011, we acquired an exclusive license to develop and commercialize the products containing methylnaltrexone bromide, or the MNTX Compound, marketed under the name Relistor®, from Progenics

Pharmaceuticals, Inc. and a non-exclusive license to manufacture the MNTX Compound and products containing that compound. These licenses are worldwide, except in Japan, where Ono Pharmaceutical Co. Ltd. has previously licensed the subcutaneous formulation of the drug from Progenics. Relistor Subcutaneous Injection is currently indicated for the treatment of opioid-induced constipation, or OIC, in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Relistor was approved in the United States in 2008, and currently the drug is approved for use in over 55 countries worldwide. In 2010, Relistor single–use, pre–filled syringes were approved for use in the United States, Canada and the European Union. The methylnaltrexone license includes intellectual property from the University of Chicago, Progenics and Wyeth Pharmaceuticals, including patents and applications with expiration dates that range from 2017 through 2031, if all are approved. In August 2012, the USPTO issued US Patent No. 8,247,425 which should provide further protection for the prefilled syringe Relistor® product until December 2030.

OsmoPrep® and Visicol® (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 that the FDA approved 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.

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. U.S. Patent 7,687,075, which issued in March 2010, should provide protection until June 2028. In September 2010 we entered into a Sublicense Agreement which granted Novel Laboratories, Inc. a license under the patents covering OsmoPrep such that Novel is permitted to launch a generic OsmoPrep on November 16, 2019.

On December 11, 2008, the FDA announced a proposed boxed warning for OsmoPrep and Visicol that addresses the potential risk of acute kidney injury. During 2009, working with the FDA, we revised the labels to include the boxed warning, and developed a risk evaluation and mitigation strategy, or REMS, including a medication guide. We are conducting post–marketing clinical trials as part of this strategy. In December 2011 the FDA agreed that a REMS is no longer required for OsmoPrep or Visicol.

Solesta®

In December 2011, we acquired an exclusive worldwide license to Solesta with the completion of our acquisition of Oceana Therapeutics, Inc. Solesta is a biocompatible tissue bulking agent, consisting of dextranomer microspheres and stabilized sodium hyaluronate. Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy, such as diet, fiber therapy and/or anti-motility medications. It is the only injectable gel for this indication to be administered in an outpatient setting without the need for surgery or anesthesia. The FDA approved Solesta through the premarket approval process as a Class III Medical Device in May 2011 and Oceana launched it in September 2011. Solesta also is CE Mark-approved and marketed in Europe. Solesta should be protected to May 2014 by a composition and method claims patent, and to July 2015 by a methods of manufacturing patent.

Deflux®

In December 2011, we also acquired an exclusive worldwide license to Deflux with the completion of our acquisition of Oceana. Deflux is a medical device indicated for children affected by Grades II-IV vesicoureteral reflux, a malformation of the urinary bladder that can result in severe infections of the kidneys and irreversible kidney damage. Deflux was granted premarket approval application, or PMA, approval, and has been on the market in the United States since, 2001. Deflux should be protected to May 2014 by a composition and method claims patent, and to July 2015 by a methods of manufacturing patent.

Fulyzaq™ (crofelemer) delayed-release tablets

In December 2008, we acquired rights to crofelemer from Napo Pharmaceuticals, Inc. On December 31, 2012, the FDA granted marketing approval for this product, under the trade name Fulyzaq. Fulyzaq is indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. Patents for Fulyzaq should provide intellectual property protection to 2018. Fulyzaq should also be eligible for five years of marketing exclusivity from the date of FDA approval, and the product might be entitled to patent term restoration.

We expect to begin promoting Fulyzaq in the first quarter of 2013.

Giazo (balsalazide disodium) tablets

On February 3, 2012, the FDA granted marketing approval for this product under the trade name Giazo. Giazo is indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older. We shipped Giazo to wholesalers in the fourth quarter of 2012 and expect to launch Giazo to physicians in the first quarter of 2013. The patent for balsalazide disodium tablets will expire in 2018.

Metozolv®™ ODT (metoclopramide hydrochloride) 5mg and 10mg orally disintegrating tablets

In September 2007, we acquired exclusive, worldwide rights to metoclopramide-Zydis® from Wilmington Pharmaceuticals LLC. Wilmington submitted an NDA seeking approval to market Metozolv ODT and 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. 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. On September 8, 2009 the FDA granted marketing approval for METOZOLV™ ODT (metoclopramide HCl) 5 mg and 10 mg orally disintegrating tablets. METOZOLV ODT is indicated for the relief of symptomatic gastroesophageal reflux or short-term (4-12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy and diabetic gastroparesis or the relief of symptoms in adults associated with acute and recurrent diabetic gastroparesis. In August 2011 the FDA agreed that a REMS is no longer required for Metozolv ODT. On November 3, 2010, we received a paragraph IV notification from Novel Laboratories, Inc. stating that Novel had filed an Abbreviated New Drug Application, or ANDA, to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of U.S. Patent No. 6,413,549, or the ‘549 patent. Upon examination of the relevant sections of the ANDA, we concluded that the ‘549 patent would not be enforced against Novel Laboratories. On March 15, 2010 we received a paragraph IV notification from Zydus Pharmaceuticals, or Zydus, stating that Zydus had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of the ‘549 patent. Upon examination of the relevant sections of the ANDA, we concluded that the ‘549 patent would not be enforced against Zydus.

Azasan® (azathioprine) tablets

In November 2003, we acquired from aaiPharma LLC the exclusive right to sell 25, 75 and 100 mg 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 mg dosage strengths of Azasan in the United States. 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. The patents and data exclusivity for Anusol-HC and Proctocort have expired.

Pepcid® (famotidine) for Oral Suspension and 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 annual U.S. market of approximately $180 million, concentrated in pediatric and hospitalized patient populations. The patents and data exclusivity for Pepcid Oral Suspension and Diuril Oral Suspension have expired. In May 2010, the FDA approved a generic famotidine oral suspension product, and we launched an authorized generic famotidine product. In June 2010 the FDA approved another generic famotidine oral suspension product.

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. 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. We do not anticipate significant Colazal sales in future periods.

DEVELOPMENT PROGRAMS

Xifaxan® (rifaximin) tablets

Irritable bowel syndrome, characterized by abdominal pain, bloating and altered bowel habits, is one of the most common chronic medical conditions and is associated with substantial medical costs. In September 2009, we announced the successful completion and outcome of our two identical pivotal Phase 3 trials to evaluate the efficacy and safety of rifaximin 550 mg dosed three times a day in the treatment of non-constipation irritable bowel syndrome, or non-C IBS. In each trial rifaximin versus placebo treated patients demonstrated a statistically significant improvement for the primary endpoint of the adequate relief of IBS symptoms as assessed over a one-month period (weeks 3, 4, 5 and 6) following completion of a 14-day course of therapy (weeks 1 and 2). Consistent with the primary endpoint in each trial, the key secondary endpoint of relief of IBS-related bloating also demonstrated statistical significance of rifaximin versus placebo in each trial. We received a Complete Response Letter, or CRL, to our NDA on March 7, 2011. The FDA issues a CRL to indicate that the review cycle for an application is complete and that the application is not ready for approval. The FDA deemed that the Xifaxan 550 mg sNDA is not ready for approval primarily due to a newly expressed need for retreatment information. On November 16, 2011 the Gastrointestinal Drugs Advisory Committee of the FDA held a meeting where they supported the Salix/FDA-developed proposed design of a clinical trial to evaluate the safety, efficacy and durability of response with repeat treatment cycles of Xifaxan 550 mg for irritable bowel syndrome with diarrhea. We initiated enrollment in this trial in the first quarter of 2012.

Relistor (methylnaltrexone bromide)

We currently have two development programs for methylnaltrexone bromide: (1) for OIC in patients with chronic non-malignant pain administered via subcutaneous injection, or OIC Chronic Pain; and (2) for OIC in patients with chronic non-malignant pain administered orally, or OIC Oral.

OIC Chronic Pain

On August 30, 2011 we announced that the FDA accepted for filing our supplemental New Drug Application, or

sNDA, for Relistor (methylnaltrexone bromide) Subcutaneous Injection to treat opioid–induced constipation in patients with chronic, non–cancer pain. The FDA issued a PDUFA action date of April 27, 2012 and subsequently extended the date to July 27, 2012. On July 27, 2012, the FDA issued a CRL following the FDA's review of the sNDA. The CRL requests additional clinical data. In October 2012 Salix and Progenics held an End-of-Review meeting with the Division of Gastroenterology and Inborn Errors Products to better understand the contents of the CRL. The Division has expressed a concern that there might be a risk associated with the chronic use of mu-opioid antagonists in patients that are taking opioids for chronic pain. In order to understand this potential risk, the Division has communicated that a very large, well-controlled, chronic administration trial will have to be conducted to assess the safety of any mu-opioid antagonist prior to market approval for the treatment of patients with OIC who are taking opioids for chronic, non-cancer pain. We have held discussions with the Division and have expressed the view that the post-marketing, clinical and preclinical data currently available adequately demonstrate an appropriate and expected safety profile sufficient to permit the approval of the current sNDA. We plan to continue to work with the FDA to generate a reasonable path forward that can be agreed upon by both parties for the further development and regulatory review of this sNDA. While it is not possible to definitively determine the duration of our discussion with the FDA regarding this matter, at this time we anticipate a path forward could be reached with the FDA during 2013. Based on the results of the October 2012 meeting, we believe we might terminate our development program for methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in chronic non-cancer pain.

OIC Oral

On December 20, 2011 we announced the successful outcome of the Phase 3 trial to evaluate the efficacy and safety of oral methylnaltrexone for the treatment of opioid–induced constipation in subjects with chronic, non–cancer pain. This trial, evaluating three once–daily oral methylnaltrexone dosing regimens (150, 300 and 450mg), demonstrated highly statistically significant results for the primary endpoint in two of the three treatment arms when compared to the placebo treatment arm. Both the 300 and 450 mg treatment arms demonstrated highly statistically significant improvements in rescue–free bowel movement, or RFBM, within 4 hours of administration over 28 days of dosing when compared to placebo treatment. In addition, the 300 and 450 mg treatment arms demonstrated highly statistically significant improvements in RFBM within 4 hours of administration following the first dose when compared to placebo treatment. Statistically significant efficacy was also seen in both the 300 and 450 mg treatment groups for the two key secondary efficacy endpoints, including one assessing response (responder/non–responder) to study drug during Weeks 1 to 4 where "responder" is defined as having 3 or more RFBMs per week, with an increase of at least one RFBM per week over baseline, for at least 3 out of the first 4 weeks. Overall, efficacy of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic, non–cancer pain. The overall observed safety profile seen in patients treated with oral methylnaltrexone was comparable to placebo in this study. Based on the CRL discussed above for OIC Chronic Pain, we are currently evaluating the oral OIC development program and currently believe we will continue this program. However, additional information and additional guidance from the FDA could result in the termination of the oral OIC development program.

Budesonide

In March 2008, we acquired a license from Dr. Falk Pharma GmbH to a family of budesonide products, including a budesonide rectal foam, in the United States. In November 2009, we initiated two Phase 3 trials to evaluate the effectiveness and safety of budesonide rectal foam for the treatment of mild to moderate ulcerative proctitis or proctosigmoiditis. The rectal foam product should have patent coverage in the United States until 2015.

Rifaximin EIR

In August 2012 we acquired from Alfa Wassermann an exclusive license in the United States and Canada to develop an extended intestinal release (EIR) formulation of rifaximin for gastrointestinal and respiratory indications, including Crohn's disease. The EIR formulation of rifaximin has been designed to release the active drug following passage through the stomach and provide a homogeneous distribution of rifaximin in the intestinal tract. The EIR formulation of rifaximin was designed to provide an efficient delivery of rifaximin and will be studied for its potential to target difficult to treat diseases of the intestinal tract such as Crohn's disease. We plan to initiate Phase 3 trials in Crohn's disease in 2013. The EIR product should have patent coverage in the United States until 2024.

COLLABORATIVE AND PRODUCT ACQUISITION AGREEMENTS

We have and plan to 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 low double-digit 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. The license agreement and royalty obligations do not have a fixed expiration date, but may be terminated by either party if the other materially breaches the agreement and fails to cure the breach after notice. In addition, aaiPharma has the right to terminate the agreement if Salix is adjudged bankrupt, and Salix has the right to terminate the agreement at any time upon six months' written notice to aaiPharma.

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, the 1996 Agreement. Pursuant to the 1996 Agreement, we agreed to pay Alfa Wassermann a net sales-based single-digit percentage 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 1996 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. The last patent is currently scheduled to expire in 2024. 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, until July 2014 or introduction of a generic product, whichever occurs first, 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.

In August 2012 we entered into an agreement that amended and replaced our 1996 License Agreement with Alfa Wassermann to develop rifaximin, the Amended Agreement, which replaced the 1996 Agreement. The Amended Agreement does not alter any of the terms for any compounds developed under the 1996 Agreement. The Amended Agreement provides us with an exclusive license to develop and commercialize rifaximin products for travelers' diarrhea (TD), hepatic encephalopathy (HE) or irritable bowel syndrome (IBS) in the United States and Canada. We are obligated to pay AlfaWassermann royalties, at the same range of rates as under the 1996 Agreement, on net sales of such products. In addition, the Amended Agreement provides us with an exclusive license to develop and commercialize rifaximin products for Crohn's disease in the United States and Canada and a non-exclusive license to develop such products worldwide. We paid Alfa a non-refundable upfront fee of $10.0 million in August 2012, and are

obligated to make a $25.0 million milestone payment upon receipt of marketing authorization in the United States for an extended intestinal release, or EIR, formulation product for Crohn's disease, and additional milestones based on net sales of EIR formulation products for Crohn's disease of up to $200.0 million. In addition, we are required to pay Alfa royalties on sales of rifaximin products for Crohn's at percentage rates ranging in the low double digits. Our obligation to pay royalties would commence upon the commercial launch of the product and continue 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.

The Amended Agreement does not have a fixed expiration date, but continues until the earlier of 10 years from the commercial launch of the first non-orphan indication or the launch of a generic rifaximin product. After the occurrence of the earlier of those two events, the Amended Agreement may continue year to year at the option of both parties, with six months' notice required to cancel. Either party may terminate following a material breach by the other party that is not cured within 60 days. Alfa Wassermann has the right to terminate 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 can also terminate if we become involved in bankruptcy, liquidation or similar proceedings. We may terminate the Amended Agreement in respect of any indication or any part of the territory covered on 60 days' notice, at which point our rights to that indication or territory shall cease.

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 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, or USPTO, issued a patent to Cedars-Sinai Medical Center providing protection relating to rifaximin for treating irritable bowel syndrome caused by small intestinal bacterial overgrowth until August 2019. In October 2009, the USPTO issued a patent to Cedars-Sinai Medical Center providing protection relating to rifaximin for treating bloating caused by small intestinal overgrowth related to IBS. In May 2010, the USPTO issued a patent to Cedars-Sinai Medical Center providing protection relating to rifaximin for treating irritable bowel syndrome until August 2019. Salix has an exclusive license to these patents 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, 2012, Salix had paid the aggregate $1.2 million license fee. 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 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. The license agreement does not have a fixed expiration date, but continues until terminated in accordance with its terms or until the last patent expires, which is currently in 2019. Royalty obligations terminate with the related patents on a country-by-country basis and when the license agreement terminates. The agreement will terminate automatically if Salix is declared insolvent. The agreement and royalty obligations may be terminated by CSMC if Salix materially breaches the agreement and fails to cure the breach after notice.

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 single-digit 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. The license agreement does not have a fixed expiration date, but continues until terminated in accordance with its terms or until the last patent expires, which is currently in 2028. The agreement and royalty obligations may be terminated by either party if the other materially breaches the agreement and fails to cure the breach after notice. Salix may terminate the agreement with 60 days' written notice to CDC. CDC has the right to terminate the agreement in the event Salix is declared insolvent.

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 Pharma upon certain events prior to the commercial launch of the product, and quarterly low double-digit percentage royalty payments thereafter. As of December 31, 2012 Salix had made all of these milestone payments. Royalties are only incurred if there is associated revenue, and then are included in "Cost of products sold" in the Statements of Operations. The agreement and our obligation to pay royalties continue until the later of expiration of the last patent, which is currently scheduled in 2018, or 15 years from commercial launch, which would be December 2023 because we launched the product in December 2008. The agreement and royalty obligations may be terminated by either party if the other materially breaches the agreement and fails to cure the breach after notice. Dr. Falk Pharma may terminate the agreement if Salix sells all or substantially all of its assets or stock without notifying Dr. Falk Pharma and making a non-termination payment to Dr. Falk Pharma.

In March 2008 we acquired a license from Dr. Falk Pharma to a family of budesonide products, including a budesonide rectal foam in the United States. The rectal foam product has patent coverage in the U.S. until 2015. The agreement requires Salix to make an upfront payment and regulatory milestone payments that could total up to $9.5 million to Dr. Falk Pharma, with the majority contingent upon achievement of U.S. regulatory approval. At such time as the use of this product is approved by the FDA, Salix will be required to pay Dr. Falk Pharma low double-digit percentage royalties on net sales of licensed products. As of December 31, 2012, $1.5 million of upfront and milestone payments had been made. The remaining milestone payments are contingent upon filing an NDA 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. The agreement term continues until the later of expiration of the last patent or 17 years from commercial launch. The last patent is currently scheduled to expire in 2015, and we have yet to launch this product. The agreement may be terminated if either party materially breaches the agreement and fails to cure the breach after notice. Salix may terminate the agreement if development milestones are not achieved. Dr. Falk Pharma may terminate the agreement if development milestones are not achieved or if Salix sells all or substantially all of its assets or stock without notifying Dr. Falk Pharma and making a non-termination payment to Dr. Falk Pharma.

King Pharmaceuticals, Inc.

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. 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.

Lupin, Ltd.

In September 2009, we entered into a Development, Commercialization and License Agreement with Lupin Ltd for Lupin's proprietary drug delivery technology for rifaximin. We made an up-front payment of $5.0 million to Lupin upon execution of this agreement. In March 2011, we entered into an Amended and Restated Development, Commercialization and License Agreement with Lupin, and further amended it in February 2013 (as so amended, the "Amended License Agreement"). The Amended License Agreement replaces in its entirety the September 2009 agreement. The Amended License Agreement provides that we are obligated to make additional upfront payments of $10.0 million, milestone payments to Lupin that could total up to $53.0 million over the term of the agreement, and low double digit royalties in connection with commercialization of relevant products. As of December 31, 2012, we had paid $15.0 million of upfront payments related to the two agreements. In addition, during the portion of the term of the Amended License Agreement ending on September 30, 2019, we must pay Lupin a minimum quarterly payment unless specified payments by us to Lupin during that quarter exceed that amount. Beginning January 1, 2012, we are permitted to charge against such minimum quarterly payments the purchase price for certain rifaximin to be supplied to us by Lupin pursuant to a Rifaximin Manufacturing and Supply Agreement that we and Lupin entered into in September 2009 and subsequently amended. In the event we exercise our right to terminate the Amended License Agreement for convenience, we must pay Lupin an early termination fee equal to a specified portion of the minimum quarterly payments payable by us to Lupin through September 30, 2019, that we have not paid or otherwise satisfied as of the date of termination. The remaining milestone payments are contingent upon achievement of certain clinical and regulatory milestones. Because these milestone payments are conditioned upon events that might never occur, we do not consider the potential milestone payments as purchase obligations nor as a commitment to be reported in our contractual commitments table in Management's Discussion and Analysis of Financial Condition and Results of Operations. The term of the Amended License Agreement continues until the later of the expiration of our obligations to pay royalties in respect of specified products (which is triggered by certain events relating to the introduction by third parties of competitive products, the loss of patent or regulatory exclusivity, and the lapse of time since commercial launch, depending the specified product) and March 31, 2021. Currently, if issued, the last patent would be scheduled to expire in June 2028, or later if patent term adjustments are granted. The agreement may be terminated by either party if the other materially breaches the agreement and fails to cure the breach after notice or if the other party is declared insolvent. We may terminate the agreement if any regulatory authority in the United States requires or causes the withdrawal of one of our prescription rifaximin products, in the event of a generic product entry, for convenience (subject to payment of the early termination fee described above in relevant situations), or if we determine that it is not feasible or desirable to pursue development or commercialization of products licensed under the agreement for reasons relating to the identity of any Lupin successor or our relations with any such successor. In our February 2013 amendment of the agreement, we agreed that if, after good faith negotiation by Lupin, we and Lupin fail by April 12, 2013, to enter into an agreement pursuant to which Lupin will serve as a distributor of authorized generic versions of certain of our products, we will relinquish the right to terminate the agreement in connection with a generic product entry. Lupin may terminate the agreement if the Supply Agreement described below is terminated for any reason other than Lupin's breach.

In September 2009, we also entered into a Rifaximin Manufacturing and Supply Agreement and amended it in February 2013 (as so amended, the "Supply Agreement"). Under the Supply Agreement, Lupin agrees to manufacture and supply us with rifaximin at a set price pursuant to rolling monthly forecasts and quarterly firm forecasts. We must take or pay for rifaximin in an amount equal to not less than 50% of our requirements of rifaximin for the manufacture of our current Xifaxan® product or new immediate release forms thereof or generic forms of the foregoing for sale in the United States, subject to certain minimum purchase requirements, and these amounts are included in the "Purchase Commitments" line of our contractual commitments table in our Management's Discussion and Analysis of Financial Condition and Results of Operations. The agreement terminates 10 years from the date we first required supply from Lupin thereunder, unless we extend it for additional periods. We may terminate the agreement if any regulatory authority in the United States requires or causes the withdrawal of one of our rifaximin products covered by the agreement. We may also terminate the agreement after the commercial sale or distribution in the United States of a generic version of a product covered by the agreement by a third party, or at our convenience after September 30, 2019. The agreement may be terminated by either party if the other materially breaches the agreement and fails to cure the breach after notice or if the other party is declared insolvent. In the February 2013 amendment of the agreement, we agreed that if, after good faith negotiation by Lupin, we and Lupin fail by April 12, 2013, to enter into an agreement

pursuant to which Lupin will serve as a distributor of authorized generic versions of certain of our products we will relinquish the right to terminate the agreement as a result of the sale or distribution of a generic version of a product covered by the agreement by a third party.

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 U. S. 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. 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. In May 2010, the FDA approved a generic famotidine oral suspension product, and we launched an authorized generic famotidine product. In June 2010 the FDA approved another generic famotidine oral suspension product.

Napo Pharmaceuticals, Inc.

In December 2008 we acquired rights to crofelemer from Napo Pharmaceuticals, Inc. Patents for crofelemer provide intellectual property protection to 2018. On December 31, 2012, the FDA granted marketing approval for this product, under the trade name Fulyzaq. We made an initial payment of $5.0 million, consisting of $4.5 million in an upfront license fee, and a $0.5 million equity investment in Napo. 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 for the HIV-associated diarrhea indication will be credited towards regulatory milestones and thereafter against sales milestones. Through December 31, 2012 development costs exceeded $12.0 million by more than the amount of the milestone payment due upon the FDA approval received on December 31, 2012, therefore no payment was made. Additionally, Salix will pay tiered royalties, ranging from lower double-digits to 20 percent, depending on annual sales levels, 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. The license agreement and royalty obligations do not have a fixed expiration date, but continue until terminated in accordance with its terms or until the last patent expires. The last patent is currently scheduled to expire in 2018. The agreement and royalty obligations may be terminated by either party if the other materially breaches the agreement and fails to cure the breach after notice or is declared insolvent. Salix may terminate the agreement if we determine development of the product is not commercially feasible.

On May 5, 2011, Napo Pharmaceuticals, Inc. filed a lawsuit against us in the Supreme Court of the State of New York, County of New York, alleging that we had engaged in fraudulent conduct, breached our Collaboration Agreement with Napo and breached our duty of good faith and fair dealing. We believe that Napo's allegations continue to be without merit and their lawsuit baseless. For more details, see Part I. Item 3 Legal Proceedings. We are moving forward with our development plan for crofelemer in accordance with the existing Collaboration Agreement.

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, 2012, Salix had made $27.0 million of upfront and milestone payments. The remaining milestone payment is contingent upon reaching a sales threshold. Because this milestone payment is conditioned upon an event 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. We pay Norgine a royalty in the teens as a percentage of net sales, and we purchase finished product from Norgine. The royalty obligations terminate upon the earlier of expiration of the last patent or approval of an Abbreviated New Drug Application for the product. The last patent is currently scheduled to expire in 2024. The license agreement does not have a fixed expiration date, but continues until terminated in accordance with its terms. The agreement may be terminated by either party if the other materially breaches the agreement and fails to cure the breach after notice or becomes insolvent. Salix may terminate the agreement with 12 months' written notice. In August 2010 we entered into the First Amendment to License and Supply Agreement in which we and Norgine agreed to modify effective as of October 1, 2010, our obligation to source from Norgine, and Norgine's obligation to supply, our requirements for MoviPrep. We and Norgine also agreed to a reduction in our royalty obligations to Norgine. The First Amendment to License and Supply Agreement also provides for Norgine to reimburse us for one-half of the facilities improvement and expansion payments that we are to make to Novel, up to a specified amount.

Photocure ASA

In October 2010, we acquired from Photocure ASA the worldwide exclusive rights, excluding the Nordic region, to develop and commercialize Lumacan™ for diagnosing, staging or monitoring gastrointestinal dysplasia or cancer. We made an initial payment of $4.0 million to Photocure. We will be responsible for development costs of Lumacan, but Photocure will reimburse us up to $3.0 million for certain out-of-pocket costs incurred by Salix. In December 2012 we made a $4.5 million milestone payment. In addition, we will make up to $72.0 million in milestone payments to Photocure contingent on development and regulatory milestones, and up to $50.0 million in milestone payments contingent on reaching certain sales thresholds. Additionally, Salix will pay tiered royalties, ranging from lower to middle double-digits, depending on annual sales levels, on net sales of Lumacan, 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. Salix may terminate the License Agreement at any time at its sole discretion after the completion of screening procedures sufficient to develop adequate information to allow Salix to reach an informed judgment as to the scientific, regulatory and commercial potential of Lumacan products. Either party may terminate the License Agreement due to the insolvency of, or a material breach of the agreement by, the other party. Photocure may terminate the entire License Agreement if Salix or its sublicensees institutes or participates in a challenge of any of the patents licensed by Photocure to Salix under the License Agreement or if Salix fails to meet a specified clinical milestone. Photocure may also terminate the License Agreement in respect of either or both of Europe or Asia if in respect of the relevant region Salix fails to meet a specified commercialization milestone. If termination of the License Agreement occurs after initial marketing approval of a Lumacan product, Salix is entitled to royalties at a rate in the low-to-mid single digits on net sales by Photocure and its licensees of Lumacan products. If termination of the License Agreement in respect of Europe or Asia occurs after initial marketing approval of a Lumacan product in a specified major market country in the relevant region, then Salix is entitled to royalties at a rate in the low single digits on net sales by Photocure and its licensees of the Lumacan products in the region in respect of which the termination has occurred.

Progenics Pharmaceuticals, Inc.

In February 2011, we acquired an exclusive worldwide license to develop and commercialize the products containing methylnaltrexone bromide, or the MNTX Compound, marketed under the name Relistor®, from Progenics Pharmaceuticals, Inc. We paid Progenics an up-front license fee payment of $60.0 million. In addition, we are obligated to

pay Progenics up to $90.0 million contingent upon achieving specified regulatory approvals and up to $200.0 million contingent upon achieving specified targets for net sales over the term of the agreement. None of the milestones had been achieved, and therefore none of these payments had been made, as of December 31, 2012. 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 must pay Progenics 60% of any revenue received from sublicensees in respect of any country outside the United States. Additionally, we must pay Progenics royalties based on a percentage ranging from the mid- to high-teens of net sales of any product containing the MNTX Compound. We are responsible for the future costs of the development programs for MNTX compounds. The royalty period generally runs until the later of (i) the expiration of the last valid relevant patent claim, (ii) the date on which there is no marketing exclusivity right with respect to the product, and (iii) the 15th anniversary of the first commercial sale subject, in the case of clause (iii), to earlier termination if unauthorized generic competition exceeds specified thresholds. Either party may terminate the License Agreement upon an uncured material branch or specified bankruptcy events. In addition, we may terminate the agreement for safety or efficiency issues, or upon specified prior notice at any time on or after the first anniversary of the agreement, subject to Progenics' right to postpone such latter termination in certain circumstances. Upon the termination of the agreement, all licenses granted to Salix by Progenics will terminate other than respecting any product the royalty period for which has expired in a particular country.

Q-MED AB

In connection with our acquisition of Oceana Therapeutics, Inc. in December 2011, we acquired two license agreements with Q-MED AB, which provide us the worldwide right to commercialize Deflux and Solesta. Under the license agreements and a related stock purchase agreement with Q-Med that we have assumed, we are obligated to pay up to $45.0 million contingent upon achieving specified targets for net sales of Solesta over the term of the agreement. No milestone payments had been made as of December 31, 2012. 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. Additionally, we must pay Q-Med royalties based on a percentage in the low double-digits of net sales of Deflux and Solesta. The royalty obligations continue until the agreements are terminated, but may be reduced if certain conditions are met. Unless previously terminated, the license agreements will expire June 30, 2030, although they may be extended if certain conditions are met. Q-Med may terminate the agreements for our material breach if not cured within 90 days of notice. In addition, we have supply agreements under which we purchase our entire requirements of Deflux and Solesta from Q-Med.

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. The Company also loaned Wilmington $2.8 million, which we netted against the payment of the approval milestone as a result of FDA approval on September 8, 2009. As of December 31, 2012, we had paid all upfront and milestone payments under this agreement. Additionally, Salix will pay mid-teen percentage royalties on net sales of Metozolv. Royalties are only incurred if there is associated revenue, and then are included in "Cost of products sold" in the Statements of Operations. The agreement terminates upon the termination of the royalty obligations, which is the earlier of expiration of the last patent or 10 years from commercial launch. We launched this product in 2009, but the last patent is currently scheduled to expire in June 2017. Salix may terminate the agreement at any time with 180 days' written notice to Wilmington. Wilmington has the right to terminate the agreement in the event Salix opposes the grant of a patent on any patent application, or disputes or directly assists a third party to dispute the validity of any patent covered by the agreement. The agreement may be terminated by either party if the other materially breaches the agreement and fails to cure the breach after notice or if either party is declared insolvent.

MANUFACTURING

We own no manufacturing facilities. We have in the past used and plan to continue to use third-party vendors 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 or packaging 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 200mg rifaximin tablets and Xifaxan 550mg rifaximin tablets, until July 2014 or introduction of a generic product, whichever occurs first. Our supply of rifaximin drug substance supplied by Alfa Wassermann is manufactured by ZaCh Systems in Lonigo, Italy, and Sanofi-Aventis in Brindisi, Italy. Under our supply agreement with Lupin, we are obligated to purchase 50% of our annual requirements of bulk rifaximin drug substance from Lupin, subject to certain minimum purchase requirements. 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 Pharma Packaging Solutions in Norris, Tennessee.

Under our long-term supply agreement with aaiPharma in Wilmington, North Carolina, aaiPharma manufactures and packages our commercial supply of 75mg and 100mg Azasan finished product.

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

Under our supply agreement with Novel Laboratories, Inc. in Somerset, New Jersey, Novel produces our commercial supply of bulk OsmoPrep tablets, which are then packaged into finished OsmoPrep commercial bottles by Pharma Packaging Solutions in Norris, Tennessee.

Under our supply agreement with Actavis, Inc. and Novel Laboratories, Inc., Novel produces our commercial supply of finished MoviPrep kits.

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. Bulk Apriso capsules are then packaged into finished Apriso commercial bottles by Pharma Packaging Solutions 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 which covers the Somerset, New Jersey facility or the Swindon, United Kingdom facility, Catalent converts this metoclopramide into our commercial supply of Metozolv, 5 mg tablets in blister packaging. The Metozolv blister packs are then packaged into finished cartons by Pharma Packaging Solutions in Norris, Tennessee.

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 by PharmaZell in Raubling, Germany. Also, under a long-term supply agreement, balsalazide is encapsulated into Colazal drug product for us by Nexgen Pharma, Inc. in Irvine, California; balsalazide drug substance from OmniChem s.a. is also converted into Giazo 100mg tablets by Nexgen Pharma. Bulk Colazal capsules and bulk Giazo tablets are packaged into finished commercial bottles by both Nexgen and Pharma Packaging Solutions in Norris, Tennessee.

Relistor subcutaneous injection in a vial presentation is produced in bulk by DSM Pharmaceutical Products in Greenville, North Carolina and then packaged into finished Relistor single vials or vial kits by Packaging Coordinators, Inc. in Philadelphia, Pennsylvania. Relistor subcutaneous injection in a pre-filled syringe presentation is produced and packaged into finished Relistor kits by Vetter Pharma International GmbH in Ravensburg, Germany. The drug substance for these Relistor subcutaneous injection presentations is supplied by Mallinckrodt, a subsidiary of Covidien, in St. Louis, Missouri.

Both Deflux and Solesta are produced and packaged into finished Deflux and Solesta kits, respectively, by Q-MED AB in Uppsala, Sweden.

Under our supply agreement with Glenmark Pharmaceuticals, Ltd. in Mumbai, India, Glenmark supplies us with crofelemer drug substance. With respect to our budesonide foam formulation, our methylnaltrexone bromide tablet formulation, and our methylnaltrexone bromide multi-dose pen subcutaneous injection formulation, all of which are currently under development, we plan to negotiate commercial supply agreements with the manufacturers who produced the drug substance and drug product for the Phase 3 clinical trial material, or the manufacturers who produced the pivotal registration batches, if these products receive FDA approval. We are currently negotiating a commercial supply agreement for the manufacture of crofelemer tablets.

SALES AND MARKETING

We currently market our products, and intend, if approved by the FDA, to market future products, to U.S. gastroenterologists, hepatologists, colorectal surgeons and other physicians 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. As of December 31, 2012, our sales and marketing staff consisted of approximately 335 people, and we plan to hire additional people to sell our products for additional indications or sell additional products, if and when acquired and/or approved for U.S. marketing. Because there are a relatively small number of gastroenterologists, hepatologists and colorectal surgeons 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. As of December 31, 2012, our sales force consisted of approximately 235 employees who regularly call on approximately 25,000 healthcare professionals. We also had approximately ten national account managers who regularly call on major drug wholesalers, managed care organizations, large retail chains, formularies and related organizations in the United States. As a result of our acquisition of Oceana in December 2011, we have approximately ten sales representatives based in Europe who sell Solesta and Deflux in Europe. We also sell Deflux through distributors in approximately 20 countries outside the United States and Europe. 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 physicians we call on 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. Rifaximin was 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, had data exclusivity to May 2009. Xifaxan 550mg, which is approved for the reduction in risk of HE recurrence in patients greater than 18 years of age was granted orphan exclusivity through March 2017. Patents covering several physical states, or polymorphic forms, of rifaximin that provide protection for all indications currently marketed and being assessed are listed below in the table. Alfa Wasserman S.p.a., the owner of the indicated patents, has licensed the rights to Salix in the United States. 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 provides Salix the right to use the patents listed below as well as other members of the patent family indicated as licensed from CSMC. On April 19, 2011, the USPTO issued the method of treatment patent U.S. 7,928,115 to Salix directed to the use of rifaximin in Travelers' Diarrhea, which should provide protection until July 2029. In November 2012, the USPTO issued an additional patent coving methods of using rifaximin to treat IBS, which should provide protection until July 2029.

U.S. Patent No.	Issue Date	Expiration	Subject
7,045,620*	May-06	Jun-24	Composition of matter and process patent covering several physical states of rifaximin
7,612,199*	Nov-09	Jun-24	Covers several physical states, or polymorphous forms of rifaximin
7,906,542*	May-11	Jun-25	Covers several physical states, or polymorphous forms of rifaximin in pharmaceutical formulations
7,902,206*	Mar-11	Jun-24	Covers several physical states, or polymorphous forms of rifaximin
7,452,857**	Nov-08	Aug-19	Use of rifaximin for treating irritable bowel syndrome
7,605,240**	Oct-09	Aug-19	Treatment of bloating caused by small intestinal bacterial overgrowth associated with irritable bowel syndrome
7,718,608**	May-10	Aug-19	Use of rifaximin for treating irritable bowel syndrome
7,935,799**	May-11	Aug-19	Use of rifaximin for treating diarrhea
7,928,115	Apr-11	Jul-29	Use of rifaximin for treating travelers' diarrhea
8,158,781*	Apr-12	Jun-24	Covers physical states, or polymorphous forms of rifaximin
8,158,644*	Apr-12	Jun-24	Covers physical states, or polymorphous forms of rifaximin
8,193,196*	Jun-12	Sept-27	Covers physical states, or polymorphous forms of rifaximin
8,309,569	Nov-12	Jul-29	Use of rifaximin for treating IBS

* Licensed from Alfa Wasserman S.p.a.

** Licensed from Cedars-Sinai Medical Center

In addition, we have filed applications for patents relating to additional indications using rifaximin and related chemical substances. In September 2009, Lupin Ltd. granted Salix the exclusive right in the United States to its bioadhesive drug delivery technology for use with rifaximin. In March 2011, Lupin granted Salix an exclusive license to exploit any product containing rifaximin and covered by the Lupin Technology or Joint Technology for all uses in humans worldwide except India. In October 2009, Cipla, Limited granted Salix the exclusive rights in the United States to its amorphous rifaximin application PCT Patent Application No. PCT/GB2007/003629; WO 2008/035109. In October 2012, the USPTO declared in interference to determine the priority of invention between Cipla's application related to amorphous rifaximin and Solmag SpA's application directed to amorphous rifaximin.

The patent for the EIR rifaximin product provides patent coverage to 2024.

The patent for the treatment of the intestinal tract with Apriso provides patent coverage to 2018. In June 2009, U.S. Patent No. 7,547,451 issued, which relates to methods of producing Apriso and provides further protection. In December 2012 the USPTO issued US Patent No. 8,337,886, which will provide further protection for the Apriso formulation as well as methods of using Apriso until 2018.

The patent for Giazo provides patent coverage to 2018.

U.S. Patent Nos. 7,452,872 and 7,625,884,which relate to the use of balsalazide tablets to increase the bioavailability provide coverage for balsalazide 1100 mg tablets until August 2026.

One patent for OsmoPrep provides patent coverage to 2013. Another patent, U.S. Patent No. 7,687,075, which issued March 30, 2010, provides coverage to June 2028. In September 2010 we entered into a sublicense agreement which granted Novel Laboratories, Inc. a license under the patents covering OsmoPrep permitting Novel to launch a generic OsmoPrep on November 16, 2019.

Two patents for MoviPrep provide patent coverage to 2024. The patents were issued by the USPTO in January 2007 and February 2010, respectively and contain composition of matter and kit claims. In August 2010 we entered into a sublicense agreement that granted Novel Laboratories, Inc. a license to the patents covering MoviPrep permitting Novel to launch a generic MoviPrep on September 24, 2018.

The patent for Metozolv is a formulation patent for its 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. On November 3, 2010, we received a paragraph IV notification from Novel stating that Novel had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of U.S. Patent No. 6,413,549, or the ‘549 patent. Upon examination of the relevant sections of the ANDA, we concluded that the ‘549 patent would not be enforced against Novel Laboratories. On March 15, 2010 we received a paragraph IV notification from Zydus Pharmaceuticals, or Zydus, stating that Zydus had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of the ‘549 patent. Upon examination of the relevant sections of the ANDA, we concluded that the ‘549 patent would not be enforced against Zydus.

The patents for Fulyzaq 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 has patent coverage in the U.S. until 2015.

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 2008 and December 2009, the United States Patent and Trademark Office issued patents covering methods for increasing the bioavailability of balsalazide, which will provide coverage for balsalazide until August 2026.

The patents for Lumacan including, U.S. 6,034,267 and U.S. 7,247,655 provide protection until March 2016.

In January 2011 Salix licensed exclusive worldwide (except Japan) rights to Relistor (methylnaltrexone bromide). The Relistor subcutaneous injection product was granted five year new chemical entity exclusivity until April 24, 2013. The exclusivity prevents the FDA from approving an ANDA until April 24, 2013; however, an ANDA may be filed after April 24, 2012. The Relistor subcutaneous injection has patent protection to November 2017. In August of 2012, the USPTO issued US Patent No. 8,247,425; which will provide further protection for the prefilled syringe Relistor product until December 2030. There are other patents pending on the formulation that if issued will provide protection to April 2024. Patent applications for an oral version of Relistor, if issued, should provide protection to March 2031.

In December 2011, Salix acquired licensed rights to Solesta and Deflux through the acquisition of Oceana. Deflux and Solesta are protected by U.S. Patent No. 5,633,001, which is directed to composition and method claims and provides protection to May 2014, and U.S. Patent No. 5,827,937, which is directed to methods of manufacturing and provides protection to July 2015.

Data Exclusivity

Rifaximin was a new chemical entity, therefore, the FDA granted us five-year new chemical entity exclusivity when it was approved for the treatment of travelers' diarrhea in May 2004. Therefore, rifaximin had data exclusivity for the travelers' diarrhea indication through May 2009. Rifaximin 550mg, which is approved for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients > 18 years of age was granted orphan exclusivity through March 2017.

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 ANDA for a granulated mesalamine product which relied upon the new clinical investigation in our NDA for three years from October 31, 2008. The patents for the granulated mesalamine protect the product until April 2018.

In January 2011 Salix licensed exclusive worldwide (except Japan) rights to Relistor (methylnaltrexone bromide). The Relistor subcutaneous injection product was granted five-year new chemical entity exclusivity by the FDA until April 24, 2013. The exclusivity prevents the FDA from approving an ANDA until April 24, 2013; however, an ANDA may be filed after April 24, 2012.

In December 2011, Salix acquired licensed rights to Solesta and Deflux through the acquisition of Oceana. Deflux was granted premarket approval application, or PMA, approval on September 24, 2001. Solesta was granted PMA approval on May 27, 2011 and should receive six years of data exclusivity from the date of approval.

Metoclopramide, which is not a new chemical entity, was not entitled to three years of data exclusivity from the date of its 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. On November 3, 2010, we received a paragraph IV notification from Novel stating that Novel had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of U.S. Patent No. 6,413,549, or the '549 patent. Upon examination of the relevant sections of the ANDA, we concluded that the '549 patent would not be enforced against Novel Laboratories. On March 15, 2001 we received a paragraph IV notification from Zydus Pharmaceuticals stating that Zydus had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of the '549 patent. Upon examination of the relevant sections of the ANDA, we concluded that the '549 patent would not be enforced against Zydus.

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

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

Fulyzaq, or crofelemer, which is a new chemical entity, should be eligible for market exclusivity for five years in the United States from December 31, 2012 when it was approved by the FDA. As a new molecular entity, we believe crofelemer may be entitled to patent term restoration. The patents for crofelemer provide protection until 2018.

Lumacan, which is not a new chemical entity, will only be eligible for three years of data exclusivity. The patents that may cover a Lumacan product provide protection until March 2016.

GOVERNMENT REGULATION

Regulation of Drug Compounds – United States

All of our products are regulated as drug products, other than Solesta and Deflux, which are regulated as medical devices. 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, 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 3 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 3 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. In the last few years, FDA review times have lengthened. 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 an 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. 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.

Regulation of Medical Devices – United States

The medical devices that we manufacture and market, Solesta and Deflux, are subject to regulation by numerous regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation be conducted before a device receives approval for commercial distribution. All medical devices in the United States are subject to General Controls, which include:

- Establishment Registration by manufacturers, distributors, repackages and re-labelers;
- Medical Device Listing with FDA of devices to be marketed;
- Good Manufacturing Practices;
- Labeling regulations; and
- Reporting of adverse events identified by the user, manufacturer and/or distributor.

There are three FDA regulatory classifications of medical devices: Class I; Class II; and Class III. The classifications are assigned by the risk the medical device presents to the patient and the level of regulatory control the

FDA determines is needed to legally market the device. Class I medical devices have the least amount of regulatory control. Class I devices are typically simple in design, manufacture and have a history of safe use. Examples of Class I devices include tongue depressors, arm slings and hand-held surgical instruments. Most Class I devices are exempt from the premarket notification and may be exempt from compliance with the good manufacturing practices regulation.

Class II medical devices are devices where General Controls are not sufficient to assure safety and effectiveness and existing methods/standards/guidance documents are available to provide assurances of safety and effectiveness. In addition to compliance with General Controls, Class II devices are required to comply with Special Controls, including:

- Special labeling requirements;
- Mandatory performance standards;
- Postmarket surveillance; and
- FDA medical device specific guidance.

Class II devices typically require pre-market notification by submission and FDA review of a 510(k) clearance to market submission. A few Class II devices are exempt from the premarket notification. Examples of Class II devices include physiologic monitors, x-ray systems, gas analyzers, pumps and surgical drapes.

Class III medical devices have the most stringent regulatory controls. For Class III medical devices, sufficient information is not available to assure safety and effectiveness through the application of General Controls and Special Controls. Class III devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient. Typically a Pre-Market Approval, or PMA, submission to the FDA is required to allow marketing of a Class III medical device. In this case, two steps of FDA approval are generally required before marketing in the U.S. can begin. First, we must comply with the applicable Investigational Device Exemption regulations in connection with any human clinical investigation of the device in the U.S. Second, the FDA must review our PMA application, which contains, among other things, clinical information acquired under the IDE. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose. Examples of Class III devices that require a PMA are: replacement heart valves; silicone gel-filled breast implants; and implanted brain lobe stimulators. Our current medical devices, Solesta and Deflux, are Class III devices and were approved under PMAs.

The FDA can ban certain medical devices; detain or seize adulterated or misbranded medical devices; order repair, replacement or refund of these devices; and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act pertaining to medical devices, or initiate action for criminal prosecution of such violations. International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements.

Regulation of Medical Devices Outside of the United States

Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

In the European Union, we are required to comply with applicable medical device directives (including the Medical Devices Directive and the Active Implantable Medical Devices Directive) and obtain CE Mark certification in

order to market medical devices. The CE Mark certification, granted following approval from an independent notified body, is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. We are also required to comply with other foreign regulations such as the requirement that we obtain approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) before we can launch new products in Japan. The time required to obtain these foreign approvals to market our products may vary from U.S. approvals, and requirements for these approvals may differ from those required by the FDA.

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, such as those launched against Colazal in December 2007 and Pepcid in 2010, 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 greater financial, marketing and personnel resources and development capabilities than we do.

For example, lactulose, a drug that is used to treat hepatic encephalopathy and competes with Xifaxan 550mg, is offered by various generic manufacturers. 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., Abbott Laboratories, Warner Chilcott plc and Shire Pharmaceuticals Group plc), sulfasalazine (Pharmacia & Upjohn, Inc.), and olsalazine (Alaven Pharmaceutical LLC). Asacol, marketed by Warner Chilcott, 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 and various over-the-counter, or OTC, products compete with Visicol, OsmoPrep and MoviPrep in the bowel cleansing market. These prescription products include Colyte, Golytely, Halflytely, SuPrep and Nulytely (Braintree), Trilyte (Alaven Pharmaceutical LLC) and Prepopik (Ferring Pharmaceuticals, Inc.). 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 it's various generics. The most frequently prescribed products that compete with Anusol-HC and Proctocort are AnaMantle HC, marketed by Nycomed; 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. The most frequently prescribed products that compete with Metozolv are Reglan®, marketed by Alaven Pharmaceuticals LLC, and various generics.

Relistor competes with several branded prescription and OTC products in the OIC market in advanced illness/ palliative care. The OTC products, although not indicated for this condition, are the most frequently prescribed first line for this condition, and include but are not limited to: Kondremul, a lubricant laxative; Miralax, an osmotic laxative; Fleets Phosphosoda and Milk of Magnesia saline laxatives; Dulcolax and Senokot, stimulant laxatives; and Colace, a stool softener. Prescription product competitors, although not indicated for this condition, include, but are not limited to the following products: Amitiza, a chloride channel blocker marketed by Takeda Pharmaceutical Company Limited; Kristalose, an osmotic laxative marketed by Cumberland Pharmaceuticals, Inc.; and Entereg, a mu opioid receptor antagonist marketed by Cubist Pharmaceuticals, Inc.

Fecal incontinence management is still an emerging market, with Solesta being the most recent innovative treatment. Solesta competes in a market with a wide range of treatment approaches, including manipulating diet, OTC therapies such as antidiarrheals, fiber, stool softeners and laxatives, biofeedback, sacral nerve stimulation using a device called Inter Stim marketed by Medtronic, Inc., and finally, sphincteroplasty surgery. Diet changes and OTC medications followed by biofeedback are usually first used before more invasive approaches are taken.

EMPLOYEES

As of December 31, 2012, we had approximately 525 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 might lose all or part of their investment.

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

We currently actively market and sell seven primary products. We expect Xifaxan, which was launched in mid-2004 for the treatment of traveler's diarrhea, and approved and launched in March 2010 for the treatment of hepatic encephalopathy, or HE, to continue to be our most significant source 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, 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, 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, hepatology and colorectal surgery markets.

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 is subject to extensive regulation by governmental authorities in the United States and other countries. 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 since then we have experienced delays in FDA review of Metozolv, balsalazide tablets, crofelemer, rifaximin for HE and Relistor for chronic pain. This regulation and workload could require us to incur significant unexpected expenses or delay or limit our ability to sell our product candidates, including specifically rifaximin for irritable bowel syndrome, or IBS. In August 2010, the FDA accepted our NDA for rifaximin for IBS, and gave us an action date of December 7, 2010. In October 2010 the FDA informed us they were extending the action date by three months to provide for a full review and extended our action date to March 7, 2011. We received a Complete Response Letter, or CRL, on March 7, 2011. The FDA issues a CRL to indicate that the review cycle for an application is complete and that the application is not ready for approval. The FDA deems that the Xifaxan 550 mg sNDA is not ready for approval, primarily due to a newly expressed need for retreatment information. We initiated enrollment in a retreatment trial in the first quarter of 2012, but there is no assurance that the FDA will approve rifaximin for IBS in a timely manner, or at all. On July 27, 2012, the FDA issued a CRL following the FDA's review of a Supplemental New Drug Application for Relistor injection for subcutaneous use for the treatment of opioid-induced constipation in adult patients with chronic, non-cancer pain. The CRL requests additional clinical data. In October 2012 Salix and Progenics held an End-of-Review meeting with the Division of Gastroenterology and Inborn Errors Products to better understand the contents of the CRL. Based on the results of this meeting, we believe we might terminate our development program for methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in chronic non-cancer pain. We are currently evaluating the oral OIC development program and currently believe we will continue this program. However, additional information and additional guidance from the FDA could result in the termination of the oral OIC development program. There is no assurance the FDA will approve Relistor injection for oral use for the treatment of opioid-induced constipation in adult patients with chronic, non-cancer pain in a timely manner, or at all.

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;
- patients do not enroll in the studies at the rate expected, as was the case with our Xifaxan Phase 3 trial in Thailand for the prevention of travelers' diarrhea, and might be the case with our Xifaxan irritable bowel syndrome retreatment study;
- 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, rifaximin has been approved for treatment of travelers' diarrhea and HE, but we are developing rifaximin for IBS and other indications. The FDA might not ever approve any of our compounds in the indications we are pursuing, which would mean we cannot market these compounds for use in these indications.

Regulatory approvals, even if granted, might entail ongoing requirements or restrictions on marketing. These requirements or restrictions, or inquiries into our marketing practices, could increase our expenses and limit revenue.

Regulatory approvals might entail ongoing requirements for post-marketing studies or limit how or to whom we can sell our products. Even if we obtain regulatory approvals, labeling and promotional activities are subject to continual scrutiny by the FDA and other federal and state authorities. 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, and a "black box" warning for Metozolv regarding tardive dyskensia which could result from its use. We believe these warnings contributed to reduced sales of those products, and they could limit future sales of those products.

In addition, we periodically receive inquiries from authorities, including specifically the Office of Prescription Drug Promotion of the FDA, or OPDP, formerly known as the Division of Drug Marketing, Advertising, and Communications of the FDA, or DDMAC, regarding compliance with marketing and other regulations. Responding to inquiries from authorities can be costly and divert the time and attention of our senior management away from our business operations and result in increased legal expenses. On February 1, 2013, our wholly owned subsidiary Salix Pharmaceuticals, Inc. received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents regarding our sales and promotional practices for Xifaxan® (rifaximin), Relistor® (methyinaltrexone bromide) and Apriso® (mesalamine). The Company is in the process of responding to the subpoena and intends to cooperate fully with the subpoena and related government investigation. Currently, we cannot predict or determine the timing or outcome of this inquiry or its impact on financial condition or results of operations. The laws and regulations regarding off-label promotion and the authorities' interpretation of them might increase our expenses, impair our ability to effectively market our products, and limit our revenue.

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 in which we become involved 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.

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 was 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, had data exclusivity to May 2009. Rifaximin 550mg, which is approved for the reduction in risk of HE recurrence in patients greater than 18 years of age was granted orphan exclusivity through March 2017. Patents covering several physical states, or polymorphic forms, of rifaximin that provide protection for all indications currently marketed and being assessed are listed below in the table. Alfa Wasserman S.p.a., the owner of the indicated patents, has licensed the rights to Salix in the United States. 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 provides Salix the right to use the patents listed below as well as other members of the patent family indicated as licensed from CSMC. On April 19, 2011, the USPTO issued the method of treatment patent U.S. 7,928,115 to Salix directed to the use of rifaximin in Travelers' Diarrhea, which should provide protection until July 2029. In November 2012, the USPTO issued an additional patent coving methods of using rifaximin to treat IBS, which should provide protection until July 2029.

U.S. Patent No.	Issue Date	Expiration	Subject
7,045,620*	May-06	Jun-24	Composition of matter and process patent covering several physical states of rifaximin
7,612,199*	Nov-09	Jun-24	Covers several physical states, or polymorphous forms of rifaximin
7,906,542*	May-11	Jun-25	Covers several physical states, or polymorphous forms of rifaximin in pharmaceutical formulations
7,902,206*	Mar-11	Jun-24	Covers several physical states, or polymorphous forms of rifaximin
7,452,857**	Nov-08	Aug-19	Use of rifaximin for treating irritable bowel syndrome
7,605,240**	Oct-09	Aug-19	Treatment of bloating caused by small intestinal bacterial overgrowth associated with irritable bowel syndrome
7,718,608**	May-10	Aug-19	Use of rifaximin for treating irritable bowel syndrome
7,935,799**	May-11	Aug-19	Use of rifaximin for treating diarrhea
7,928,115	Apr-11	Jul-29	Use of rifaximin for treating travelers' diarrhea
8,158,781*	Apr-12	Jun-24	Covers physical states, or polymorphous forms of rifaximin
8,158,644*	Apr-12	Jun-24	Covers physical states, or polymorphous forms of rifaximin
8,193,196*	Jun-12	Sept-27	Covers physical states, or polymorphous forms of rifaximin
8,309,569	Nov-12	Jul-29	Use of rifaximin for treating IBS

* Licensed from Alfa Wasserman S.p.a.

** Licensed from Cedars-Sinai Medical Center

The patent for the treatment of the intestinal tract with Apriso, the granulated mesalamine product, provides patent coverage to 2018. In June 2009, U.S. Patent No. 7,547,451 issued, which relates to methods of producing Apriso and provides further protection. In September 2012 the FDA posted draft guidance on mesalamine. The guidance recommends conducting fed and fasted pK studies measuring mesalamine in the plasma of normal healthy subjects as well as an in vitro comparative dissolution study. On September 7, 2012, we and Dr. Falk Pharma filed a patent infringement complaint against Lupin Ltd. and Lupin Pharmaceuticals, Inc. in the District of Delaware. The Complaint alleges infringement of U. S. Patent No. 6,551,620, or the 620 patent, based on Lupin's filing of an Abbreviated New Drug Application, or ANDA, seeking approval to market and sell a generic version of Apriso before the expiration of the 620 patent. The filing of this suit within the 45 day response period provided by the Hatch Waxman Act imposes an automatic 30 month stay of approval of Lupin's ANDA. We continue to evaluate our intellectual property protecting Apriso in which we have full confidence. We intend to vigorously enforce its intellectual property rights. In December 2012 the USPTO issued US Patent No. 8,337,886, or the '886 patent, which will provide further protection for the Apriso formulation as well as methods of using Apriso until 2018. In February 2013 we received a certification letter to the '886 patent from Lupin. We intend to vigorously enforce our rights in the '886 patent.

The patent application relating to the dosage form for metoclopramide protects the product until July 2017. 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.

The patent for balsalazide 1100 mg tablets provides patent coverage to 2018. U.S. Patent Nos. 7,452,872 and 7,625,884, which relate to the use of balsalazide tablets to increase the bioavailability provide coverage for balsalazide 1100 mg tablets until August 2026.

The budesonide rectal foam product has patent coverage in the U.S. until 2015.

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. Dates provided herein for the expiration of patent applications are merely estimates based on knowledge at this time and could be altered, for example, by terminal disclaimer or if patent term extensions or adjustments are available. The patents for Lumacan including, U.S. 6,034,267 and U.S. 7,247,655 provide protection until March 2016.

In January 2007, the USPTO issued a patent covering composition of matter and kit claims for MoviPrep. The MoviPrep patent provides coverage to September 2024. Norgine, B.V. and Norgine Europe, B.V., which we refer to collectively as Norgine, own U.S. Patent No. 7,169,381, or 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 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. Upon entry by the court on August 30, 2010 of a Consent Judgment included as an exhibit to the Settlement Agreement among the parties and Actavis, Inc., the settlement will resolve all of the parties’ outstanding claims and defenses in the lawsuit. The Consent Judgment provides that Novel’s proposed generic product, absent a license as granted to Novel under the settlement, would infringe the ‘381 patent and further provides that Novel acknowledges and agrees not to contest the validity and enforceability of the ‘381 patent. In addition to the Settlement Agreement, we have entered into a Sublicense Agreement with Norgine and Novel, as well as a Supply Agreement with Novel and Actavis and a First Amendment to License and Supply Agreement with Norgine. Under the terms of the Sublicense Agreement, we and Norgine have granted Novel a fully paid up license under the MoviPrep patents such that it is permitted to launch a generic MoviPrep product on September 24, 2018.

The patent for Visicol and OsmoPrep will expire in 2013. U.S. 7,687,075 issued 30 March 2010 and provides protection for OsmoPrep until June 2028. CDC III, LLC, owns U.S. Patent No. 5,616,346, or the ‘346 patent. The ‘346 patent is listed with the FDA as protecting our OsmoPrep product. CDC licensed OsmoPrep and the ‘346 patent to us for commercialization in the United States. In addition, we own U.S. Patent No. 7,687,075, or the ‘075 patent, protecting OsmoPrep. 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 and the 2028 expiration of the ‘075 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 joined CDC as a party. With the entry by the court of a Consent Judgment, the settlement will resolve all of the parties’ outstanding claims and defenses in the lawsuit. The Consent Judgment provides that Novel’s proposed generic product, absent a license as granted to Novel under the Sublicense Agreement described below, would infringe the ‘346 patent and further provides that Novel acknowledges and agrees not to contest the validity and enforceability of the ‘346 patent. In connection with the settlement, we entered into: a Settlement Agreement with CDC, Novel, Actavis Inc. and the general partnership of Craig Aronchick, William H. Lipshutz and Scott H. Wright (the “General Partnership”) that was the initial licensor of the ‘346 patent to Salix; a Sublicense Agreement with CDC, the General Partnership and Novel; a Supply Agreement with Novel; and, a Second Amendment to Supply Agreement with CDC and the General Partnership. Under the terms of the Sublicense Agreement, we, CDC and the General Partnership have granted Novel a fully paid up, non-exclusive license under the OsmoPrep patents such that it is permitted to launch a generic OsmoPrep product on November 16, 2019.

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, had data exclusivity until May 2009. Accordingly, the Office of Generic Drugs of the U.S. Food and Drug Administration, or OGD, would have been able to accept an ANDA for Xifaxan tablets on or any time subsequent to May 2008, if the applicant made certifications of patent non-infringement or invalidity. 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 OGD impose scientifically appropriate standards for the demonstration of bioequivalence for abbreviated new drug applications citing Xifaxan as the reference listed drug. Rifaximin 550mg, which is approved for the reduction in risk of HE recurrence in patients 18 years of age and older, was granted orphan exclusivity through March 2017. Accordingly OGD would have been able to accept an ANDA for Xifaxan 550mg tablets on or any time subsequent to March 2010, if the applicant made certifications of patent non-infringement or invalidity. 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 orphan exclusivity period does not prohibit the filing of an ANDA and thus, an ANDA filing could result in a challenge to the related intellectual property rights of Xifaxan 550mg tablets at any time in the future. The OGD would be unable to finally approve an ANDA until the expiration of the orphan exclusivity in March 2017. On November 29, 2011 the FDA posted draft bioequivalence guidance for rifaximin 200mg tablets for the treatment of travelers' diarrhea. This guidance recommends successful completion of a randomized, double blind, parallel placebo controlled clinical trial in humans with clinical endpoints in order to file an ANDA for approval of a generic rifaximin 200mg tablet for the treatment of travelers' diarrhea. In February 2012, the FDA posted draft bioequivalence guidance for rifaximin 550 mg tablets. The draft guidance for rifaximin 550 mg tablets recommends that in addition to conducting the program outlined in the FDA posted draft guidance document for rifaximin 200 mg tablets discussed above, a single-dose, three-way crossover in-vivo study of fasting bioequivalence with pharmacokinetic endpoints in both fasting and fed states be performed in the 500mg tablets. Additionally, the guidance stipulated that the formulation of the 550 mg strength should be proportionally similar to that of the 200 mg strength in order to file an ANDA for approval of a generic rifaximin 550 mg tablet for the treatment of hepatic encephalopathy.

On November 3, 2010, we received a paragraph IV notification from Novel Laboratories, Inc. stating that Novel had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of U.S. Patent No. 6,413,549, or the '549 patent. Upon examination of the relevant sections of the ANDA, we concluded that the '549 patent would not be enforced against Novel Laboratories. On March 15, 2001 we received a paragraph IV notification from Zydus Pharmaceuticals stating that Zydus had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of the '549 patent. Upon examination of the relevant sections of the ANDA, we concluded that the '549 patent would not be enforced against Zydus.

In February 2011, Salix licensed exclusive worldwide (except Japan) rights to Relistor (methylnaltrexone bromide). The Relistor subcutaneous injection product was granted five year regulatory new chemical entity exclusivity until April 24, 2013. The exclusivity prevents the FDA from approving an ANDA until April 24, 2013; however, an ANDA may be filed after April 24, 2012. The Relistor subcutaneous injection has patent protection to November 2017. In August 2012 the USPTO issued U.S. Patent No. 8,247,425 covering Relistor subcutaneous injection in a prefilled syringe. The patent provides coverage until December 2030. There are other patents pending on the formulation, that if issued will provide protection to April 2024. Patent application for an oral version of Relistor, if issued, should provide protection to March 2031.

In December 2011, Salix acquired licensed rights to Solesta and Deflux through the acquisition of Oceana Therapeutics, Inc. Deflux and Solesta are protected by U.S. Patent No. 5,633,001, which is directed to composition and method claims and provides protection to May 2014 and U.S. Patent No. 5,827,937, which is directed to methods of manufacturing and provides protection to July 2015.

Because Azasan, Anusol-HC, Pepcid 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. Generic competition is an increasing risk, as we have experienced with Colazal and Pepcid, and with challenges to our bowel-cleansing products' intellectual property noted above. 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 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 for HE, including lactulose (various manufacturers);
- Xifaxan for travelers' diarrhea, including ciprofloxacin, commonly known as Cipro (Bayer AG);
- OsmoPrep and MoviPrep, including Colyte, Golytely, Halflytely, SuPrep, and Nulytely (Braintree), Trilyte (Alaven Pharmaceutical LLC) and Prepopik (Ferring Pharmaceuticals, Inc., as well as potential generics from Novel Laboratories or others;
- Apriso, including Asacol (Warner Chilcott), sulfasalazine (Pfizer), Dipentum (Alaven Pharmaceutical LLC), Pentasa (Shire Pharmaceuticals Group, plc), once-a-day Lialda (Shire), and three generic balsalazide capsule products;
- Relistor for OIC, including OTC laxatives (various manufacturers), Amitiza (Sucampo Pharmaceuticals, Inc.), Kristalose (Cumberland) and Entereg (Cubist);
- Solesta, including various OTC antidiarrheals, fiber, stool softeners and laxatives (various manufacturers), biofeedback, the medical device Inter Stim (Medtronic) and sphincteroplasty surgery;
- Xifaxan under development, including Lotronex® (Nestle S.A.) and Amitiza (Sucampo Pharmaceuticals, Inc.) for IBS; and
- Metozolv ODT, including Reglan• (Alaven Pharmaceutical LLC), and various generics.

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. For example, we are currently and might continue to be subject to a number of product liability claims relating to OsmoPrep and Visicol in connection with their "box" label warning. We intend to defend these claims vigorously. During the fourth quarter of 2011 we settled a number of the

OsmoPrep and Visicol lawsuits and were notified by our insurer that settlement of these claims exceeded the limits of the policies related to these claims. As a result, we recorded a $3.5 million reserve, which is our estimate of the costs of the remaining claims we are aware of. However, the eventual settlement of these claims could exceed this estimate, and we could receive additional claims we are not currently aware of.

We have exceeded the limits of our liability coverage related to the claims discussed above, so we are responsible for additional damages, fees and expenses, if any. We currently maintain liability coverage for both clinical trials and the commercialization of our products other than the claims discussed above, but it is possible that this coverage and any future coverage will be insufficient to satisfy any liabilities that arise. We would have to assume defense of the lawsuits and be responsible for damages, fees and expenses, if any, that are awarded against us or for amounts in excess of our product liability coverage. 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. 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 government and other third-party payors do not provide coverage or reimburse patients for our products, our ability to derive revenues might 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. We acquired our first medical devices in December 2011, one of which was launched in 2011, and we are navigating the complex medical device reimbursement system. 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 passed in recent years, including the Patient Protection and Affordable Care Act. Many significant changes in this legislation do not take effect until 2014**.** These changes to the healthcare system could increase our costs and reduce the amount we can charge for our products. In addition, an increasing emphasis on managed care in the United States has and will continue to increase pressure on pharmaceutical and medical device 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, which could have a material adverse effect on our business, financial condition and results of operations. 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.

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

We currently intend to in-license or acquire additional pharmaceutical products or medical devices, as we did with crofelemer and budesonide, 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 Relistor, Deflux and Solesta, that have already received regulatory approval. These kinds of pharmaceutical products and medical devices 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.

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, the raw material used in production of the crofelemer drug substance, our anti-secretory agent that is approved for marketing in the United States under the trade name Fulyzaq for the treatment of HIV-associated

diarrhea, grows in select countries in South America. Our ability to successfully obtain raw material is not within our control. Failure to obtain crofelemer drug substance, whether due to international, political or economic conditions or otherwise, could delay development, increase expenses, delay regulatory approval, or eventually prevent us from generating revenue from crofelemer, if approved, any of which could have a material adverse effect on our business. A key raw material for Relistor grows in Tasmania. Our inability to obtain this raw material, whether due to international, political or economic conditions or otherwise, could delay development, increase expenses, delay regulatory approval, or eventually prevent us from generating revenue from additional indications for Relistor, if approved, which could have a material adverse effect on our business. Likewise, interruption of supply of any of our other products, whether for clinical use or commercial use, could have a material adverse effect on our business.

We are dependent on third parties to manufacture our products.

We own no manufacturing facilities, and we have limited capabilities in manufacturing pharmaceutical products. We do not generally expect to engage directly in the manufacturing of products, but instead contract with and rely on third-party vendors, including Glenmark Pharmaceuticals, Ltd. of India, which manufactures the drug substance for Fulyzaq, for these services. A limited number of contract 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. For example, in April 2010 we received a complete response letter from the FDA on our NDA for balsalazide tablets. The sole issue raised in this letter concerned a deficiency of the manufacturing facility for this application, which delayed FDA approval almost two years. Given our ongoing dependence on third party vendors for supply of material for use in clinical trials and for commercial product, 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 our needs or limit our 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 current Good Manufacturing Practices, or cGMP, regulations and similar foreign standards, and we do not have control over compliance with these regulations by the third-party manufacturers;
- if we need to change manufacturers, transfers of technical expertise would be required which would include educating the new manufacturer in the processes necessary for the production of our products, which might not be successful; and
- if we need to change manufacturers, FDA and comparable foreign regulators might require additional testing and compliance inspections prior to the new manufacturer being qualified for the production of our products.

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

We and our third-party manufacturers are also required to comply with the applicable cGMP regulations which include requirements relating to manufacturing, packaging, documentation, quality control, and quality assurance. Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our products. For example, in April 2010 we received a complete response letter from the FDA regarding our NDA for our balsalazide tablet. In the complete response letter there were no requests for new pre–clinical or clinical trials. The sole issue raised in this letter concerned a deficiency of the manufacturing facility for this application. The manufacturer responded to the FDA and was able to eventually resolve these deficiencies, allowing the FDA to proceed with the approval of this NDA in 2012. Our third-party manufacturers are subject to periodic 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 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-related compliance issues could cause subsequent withdrawal of the drug approval, reformulation of the drug product, additional testing or changes in labeling of the finished product.

Because our business and industry are highly regulated and scrutinized, any failure to follow such regulations could result in litigation or government enforcement actions that could have a material adverse effect on our business and results of operations.

Our business and industry are highly regulated and scrutinized, and subject to litigation risks, including product liability risks described above and the risk of government enforcement actions. We are subject to extensive and complex laws and regulations, including but not limited to, health care "fraud and abuse" laws, such as the federal False Claims Act, the federal Anti-Kickback Statute, and other state and federal laws and regulations. While we have developed and implemented a corporate compliance program designed to promote compliance with applicable laws and regulations, we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure or alleged failure to be in compliance with such laws or regulations. In recent years, there has been a heightened risk of governmental investigations into pharmaceutical companies' sales and promotional practices for their products, including off-label uses, as evidenced by recent enforcement activity and/or pronouncements by the Office of Inspector General of the Department of Health and Human Services, the Department of Justice and state attorneys general. Matters underlying governmental investigations may also be the subject of private litigation. See "Item 3. Legal Proceedings" for information about a pending federal government investigation concerning our sales and promotional practices for Xifaxan, Relistor and Apriso. If we are not successful in defending ourselves or asserting our rights in this investigation, or any other investigation or litigation, we could incur significant damages, fines or other penalties, which could have a material adverse effect on our business and results of operations.

We are subject to numerous environmental laws and regulations and any failure to comply with such laws and regulations could have a material adverse effect on our business and results of operations.

Our research, development and manufacturing efforts, and those of third parties that research, develop and manufacture our products and product candidates on our behalf or in collaboration with us, involve the controlled use of hazardous materials, including chemicals, viruses, bacteria and various radioactive compounds, and are therefore subject to numerous U.S. and international environmental and safety laws and regulations and to periodic inspections for possible violations of these laws and regulations. In addition, we, and our collaborators and third-party manufacturers may also become subject to laws and regulations related to climate change, including the impact of global warming. The costs of compliance with environmental and safety laws and regulations are significant, and the costs of complying with climate change laws could also be significant. Any violations, even if inadvertent or accidental, of current or future environmental, safety or climate change laws or regulations could subject us to substantial fines, penalties or environmental remediation costs, or cause us to lose permits or other authorizations to operate affected facilities, any of which could adversely affect our operations.

We are subject to complex laws and regulations governing our employees and contractors and any failure to comply with such laws and regulations could have a material adverse effect on our business and results of operations.

The laws and regulations applicable to our relationships with our employees and contractors are complex, extensive and fluid, and are subject to evolving interpretations by regulatory and judicial authorities. Failure to comply with these laws and regulations could result in significant damages, orders and/or fines and therefore could adversely affect our operations. For example, a 2010 decision by the U.S. Court of Appeals for the Second Circuit, *In re Novartis Wage & Hour Litigation*, in a split from an earlier decision from the U.S. Court of Appeals for the Third Circuit, held that Novartis' pharmaceutical sales representatives were non-exempt employees under the Fair Labor Standards Act. The Second Circuit's decision might trigger additional litigation against pharmaceutical companies, including us. An adverse result in any such litigation could result in significant damages to us and could therefore have a material adverse effect on our business and results of operations.

Failure to integrate acquired businesses into our operations successfully could adversely affect our business.

Our strategy is to identify and acquire rights to products that we believe have potential for near-term regulatory approval or are already approved, through the purchase or license of products and purchase of companies. Our integration of the operations of acquired products and businesses, including Oceana, which we acquired in December 2011 and which includes foreign employees and operations, requires significant efforts, including the coordination of information technologies, research and development, sales and marketing, operations, manufacturing and finance. These efforts result in additional expenses and involve significant amounts of management's time. Factors that will affect the success of our acquisitions include the strength of the acquired companies' or products' underlying technology and ability to execute, results of clinical trials, regulatory approvals and reimbursement levels of the acquired products and related procedures, our ability to adequately fund acquired in-process research and development projects and retain key employees, and our ability to achieve synergies with our acquired companies and products, such as increasing sales of our products, achieving cost savings and effectively combining technologies to develop new products. Our failure to manage successfully and coordinate the growth of these acquisitions could have an adverse impact on our business. In addition, we cannot be certain that the businesses or products we acquire will become profitable or remain so and if our acquisitions are not successful, we may record related asset impairment charges in the future.

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.

As they have in the past, 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.

We expect to be profitable and have positive cash flow during 2013, but we might need additional capital.

We expect to be profitable and have positive cash flow during 2013, and 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 2013 and beyond, but that might not be the case. Our future capital requirements will depend on many factors, including but not limited to:

- our business development activities, including potential acquisition of products or companies, or entry into additional collaborative arrangements;
- the results, costs and timing of our research and development activities, regulatory approvals and product launches;
- the status of competitive products, including current and potential generics;

- the cost and number of products we acquire or in-license;
- any impact on us of current conditions and uncertainties in the economy generally and the financial markets;
- patient and physician demand for our products; and
- 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.

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 required to raise additional capital.

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, 2010 and December 31, 2012, the price of a share of our common stock varied from a low of $23.53 to a high of $55.99. Our stock price increased or decreased by 5% or more on 15 days in 2011 and 4 days in 2012.

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.

Provisions in our charter documents and under Delaware law could discourage a takeover or changes in our current directors or management that stockholders consider favorable.

Provisions in our certificate of incorporation and amended and restated bylaws could have the effect of discouraging, delaying or preventing a takeover or other change of control of us or the removal of our current directors and management, even if these events could be beneficial to stockholders. These provisions, which could also limit the price that investors might be willing to pay for our common stock, include the following:

- Our stockholders may not act by written consent. As a result, a stockholder, or stockholders, controlling a majority of our common stock would not be able to take certain actions without holding a stockholders' meeting.
- Our board of directors may issue, without stockholder approval, up to 5,000,000 shares of undesignated preferred stock. The ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.
- Only our board of directors has the right to elect directors to fill vacancies created by the expansion of the board of directors or the resignation, death, or removal of directors, which prevents stockholders from being able to fill vacancies on our board of directors.
- Stockholders must provide advance notice to nominate individuals for election to our board of directors or to propose matters that can be acted upon at a stockholders' meeting. These provisions might discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

As a Delaware corporation, we are also subject to certain Delaware anti-takeover provisions. Under Delaware law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Our board of directors could rely on Delaware law to prevent or delay an acquisition of us.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 170,000 square feet of office space in Raleigh, North Carolina. We also lease a small amount of additional space in Palo Alto, California and Edison, New Jersey. 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, except as otherwise discussed below.

We are currently and might continue to be subject to product liability claims that arise through the testing, manufacturing, marketing and sale of our products, including a number of claims relating to OsmoPrep, Visicol and Metozolv ODT in connection with their respective "box" label warning. We are vigorously defending these claims and intend to continue to do so. During the fourth quarter of 2011 we recorded a $3.5 million reserve, which is our estimate of the settlements of the remaining claims we are aware of, after being notified by our insurer that settlement of certain OsmoPrep and Visicol lawsuits exceeded the limits of the policies related to these claims. However, the eventual settlement of these claims could exceed this estimate, and we could receive additional claims we are not currently aware of.

On May 5, 2011, Napo Pharmaceuticals, Inc. filed a lawsuit against us in the Supreme Court of the State of New York, County of New York, alleging that we had engaged in fraudulent conduct, breached our Collaboration Agreement with Napo dated December 9, 2008, and breached our duty of good faith and fair dealing. Napo also sought a declaratory judgment that Napo had the right to terminate the Collaboration Agreement and sought unspecified damages in excess of $150 million. On or about December 28, 2011, Napo filed an Amended Complaint seeking an unspecified amount of damages for alleged breaches of the Collaboration Agreement by the Company and replacing Napo's original Complaint. Napo's Amended Complaint no longer seeks a declaratory judgment that Napo has the right to terminate the Collaboration Agreement and removed the need for the Court to rule on the Company's motion to dismiss the original Complaint. We believe that Napo's allegations continue to be without merit and their lawsuit baseless. We filed an Answer to the Amended Complaint and Counterclaims on or about January 17, 2012, and intend to continue to vigorously defend against the lawsuit. Napo filed a Reply to our Counterclaim on or about February 7, 2012. Discovery is ongoing. We are moving forward with our development plan for crofelemer in accordance with the existing Collaboration Agreement.

On June 22, 2011, we, in our capacity as a shareholder of Napo Pharmaceuticals, Inc., filed a complaint against Napo in the Court of Chancery of the State of Delaware. The Complaint sought to compel Napo to allow us to inspect certain corporate books and records in connection with possible breaches of fiduciary duty and mismanagement by certain members of Napo's board. Napo filed its Answer and Affirmative Defenses to the Complaint on July 27, 2011. Napo and the Company exchanged written discovery requests and responses. On or about January 5, 2012, we filed a motion for voluntary dismissal of the Delaware lawsuit. The Delaware Court granted our motion, without penalty or fees being awarded to Napo or us.

On September 7, 2012, we and Dr. Falk Pharma filed a patent infringement complaint against Lupin Ltd. and Lupin Pharmaceuticals, Inc. in the U.S. District Court for the District of Delaware. The Complaint alleges infringement of U. S. Patent No. 6,551,620, or the 620 patent, based on Lupin's filing of an Abbreviated New Drug Application, or ANDA, seeking approval to market and sell a generic version of Apriso before the expiration of the 620 patent. The filing of this suit within the 45 day response period provided by the Hatch Waxman Act imposes an automatic 30 month stay of approval of Lupin's ANDA. We continue to evaluate our intellectual property protecting Apriso in which we have full confidence. We intend to vigorously enforce its intellectual property rights.

On February 1, 2013, our wholly owned subsidiary Salix Pharmaceuticals, Inc. received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents regarding our sales and promotional practices for Xifaxan® (rifaximin), Relistor® (methyinaltrexone bromide) and Apriso® (mesalamine). The Company is in the process of responding to the subpoena and intends to cooperate fully with the subpoena and related government investigation. Currently, we cannot predict or determine the timing or outcome of this inquiry or its impact on financial condition or results of operations.

Item 4. Mine Safety Disclosures

Not applicable.

Executive Officers of the Registrant

The following table sets forth information concerning our executive officers as of February 28, 2013:

Name	Age	Position
Carolyn J. Logan	64	President, Chief Executive Officer, and Director
Adam C. Derbyshire	47	Executive Vice President, Finance and Administration, and Chief Financial Officer
William P. Forbes	51	Executive Vice President, Research and Development and Chief Development Officer
Rick D. Scruggs	53	Executive Vice President, Business Development

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 Executive Vice President, Finance and Administration and Chief Financial Officer since January 2009. Mr. Derbyshire previously served as Senior Vice President, Finance and Administration and Chief Financial Officer from June 2003 to January 2009 and 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 has served as Executive Vice President, Research and Development and Chief Medical Officer since January 2010. Dr. Forbes previously served as Senior Vice President, Research and Development and Chief Medical Officer from January 2009 to January 2010. Dr. Forbes previously served as Vice President, Research and Development, and Chief Medical Officer from January 2005 to January 2009. 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. Dr. Forbes received his Doctor of Pharmacy degree from Creighton University.

Rick D. Scruggs has served as Executive Vice President, Business Development since January 2011. Mr. Scruggs previously served as Senior Vice President, Business Development from January 2009 to January 2011. Mr. Scruggs previously served as Vice President, Business Development from January 2006 to January 2009. From January 2004 to January 2006, Mr. Scruggs served as Vice President, Commercial Development. From 2000 to 2006, Mr. Scruggs was in various sales and commercial trade related positions at Salix. Before joining Salix, he served as Director of Managed Markets at Watson Pharmaceuticals, Inc., from May 1997 to July 2000. Prior to that, Mr. Scruggs served as Director, Managed Markets and Trade at Oclassen Pharmaceuticals, Inc., from January 1995 to February 1997. Before joining Oclassen, Mr. Scruggs held various sales and marketing positions of increasing responsibility with Johnson & Johnson and Ciba-Geigy. Mr. Scruggs received a B.S. degree in Criminal Justice from Appalachian State 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, 2012.

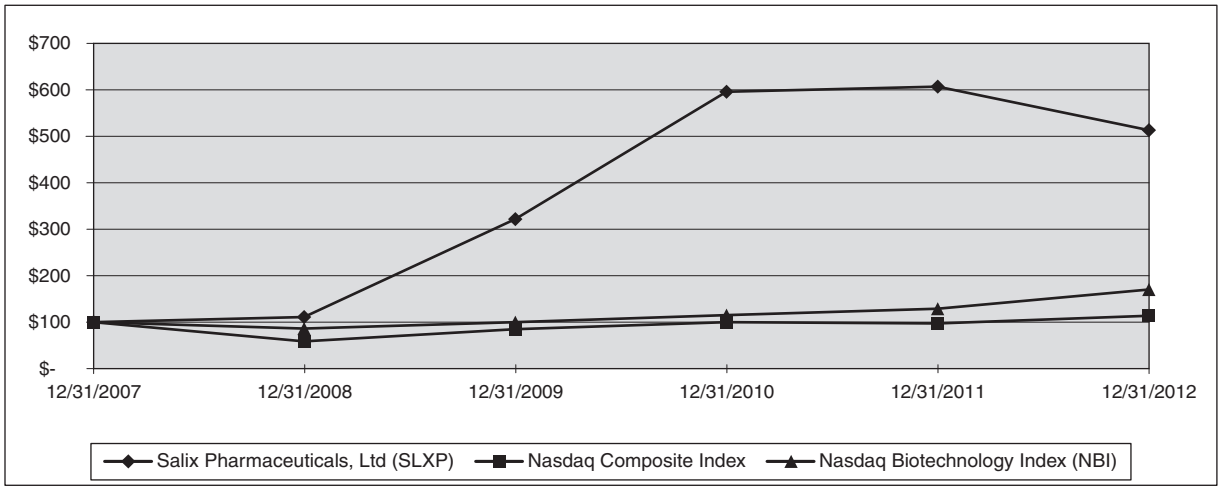
	High	Low
Fiscal year ended December 31, 2011		
First quarter	$48.33	$31.29
Second quarter	41.49	34.46
Third quarter	41.50	25.64
Fourth quarter	48.17	28.21
Fiscal year ended December 31, 2012		
First quarter	$53.99	$44.52
Second quarter	54.57	47.45
Third quarter	55.99	41.51
Fourth quarter	43.24	37.52

On February 24, 2013 the closing price for the common stock as reported on the Nasdaq Global Market was $46.11. As of February 24, 2013 there were 231 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 approximate 51.1% single-day increase on September 14, 2009 when we announced data from our Phase 3 IBS trials, the approximate 20.5% single-day increase on February 24, 2010, the day after the Gastrointestinal Drugs Advisory Committee of the FDA recommended by a vote of 14 to 4 in favor of the approval of Xifaxan 550 mg for the maintenance of remission of hepatic encephalopathy, and the approximate 23.7% single-day decrease on February 24, 2011 when we announced that we expected to receive a CRL for the NDA for Xifaxan for IBS. 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, 2007 with those of the Nasdaq Composite Index and the Nasdaq Biotech Index and assumes that all dividends were reinvested. The graph assumes that U.S. $100 was invested on December 31, 2007 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.



	12/31/07	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12
SLXP	$100	$112	$322	$596	$607	$514
Nasdaq Composite Index	$100	$ 59	$ 86	$100	$ 98	$114
Nasdaq Biotech Index	$100	$ 87	$101	$116	$130	$171

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.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

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,				
	2012	2011	2010	2009	2008
	(U.S. dollars, in thousands, except per share data)				
Revenues:					
Net product revenues	$735,444	$540,488	$336,973	$232,890	$178,766
Costs and expenses:					
Cost of products sold	124,597	95,369	68,677	52,025	36,710
Amortization of product rights and intangible assets	45,351	10,908	10,370	11,485	9,891
Intangible impairment charge	41,600	—	34,656	—	—
Research and development	123,234	104,350	73,346	89,466	83,735
Selling, general and administrative	258,187	186,988	156,101	120,020	95,088
Change in acquisition-related contingent consideration	(29,598)	27,000	—	—	—
Total costs and expenses	563,371	424,615	343,150	272,996	225,424
Income (loss) from operations	172,073	115,873	(6,177)	(40,106)	(46,658)
Loss on extinguishment of debt	(15,580)	—	—	—	—
Interest expense	(55,518)	(32,121)	(20,652)	(6,746)	(3,755)
Interest and other income	10,853	2,349	2,626	1,221	2,690
Income (loss) before income tax expense	111,828	86,101	(24,203)	(45,631)	(47,723)
Income tax (expense) benefit	(47,582)	1,298	(2,858)	2,012	116
Net income (loss)	$ 64,246	$ 87,399	$ (27,061)	$ (43,619)	$ (47,607)
Net income (loss) per share, basic(1)	$ 1.09	$ 1.49	$ (0.47)	$ (0.88)	$ (0.99)
Net income (loss) per share, diluted(1)	$ 1.01	$ 1.44	$ (0.47)	$ (0.88)	$ (0.99)
Shares used in computing net income (loss) per share, basic(1)	58,747	58,718	57,300	49,350	47,898
Shares used in computing net income (loss) per share, diluted(1)	63,699	65,483	57,300	49,350	47,898

Consolidated Balance Sheet Data:

	As of December 31,				
	2012	2011	2010	2009	2008
Cash and cash equivalents	$ 751,006	$ 292,814	$ 518,030	$ 192,512	$ 120,153
Working capital	927,661	356,449	560,110	217,537	113,795
Total assets	1,874,784	1,304,255	851,543	543,040	400,484
Borrowings under credit facility	—	—	—	15,000	15,000
Convertible senior notes	857,209	340,283	323,005	47,299	44,759
Long term portion of capital lease obligations	—	—	90	499	791
Accumulated deficit	(71,380)	(135,626)	(223,025)	(195,964)	(152,345)
Stockholders' equity	560,501	549,637	401,919	370,024	265,401

(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 and medical devices 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
- market our products through our approximately 335-member specialty sales and marketing team primarily focused on high-prescribing U.S. physicians in the following specialties: gastroenterologists, who are doctors who specialize in gastrointestinal disorders; hepatologists, who are doctors who specialize in liver disease; and colorectal surgeons, who are doctors who specialize in disorders of the colon and rectum.

Our current products demonstrate our ability to execute this strategy. As of December 31, 2012, our products were:

- XIFAXAN® (rifaximin) Tablets 200 mg, indicated for travelers' diarrhea;
- XIFAXAN®550mg (rifaximin) Tablets 550 mg, indicated for overt hepatic encephalopathy, or HE;
- MOVIPREP® (PEG 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate and Ascorbic Acid for Oral Solution), indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older;
- APRISO™ (mesalamine) extended-release capsules, indicated for the maintenance of remission of ulcerative colitis;
- RELISTOR® (methylnaltrexone bromide) subcutaneous injection (SI) indicated for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient, which we began promoting in the second quarter of 2011;
- OSMOPREP™ (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets, indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older;
- SOLESTA®, a biocompatible tissue-bulking agent indicated for the treatment of fecal incontinence, acquired in our purchase of Oceana in December 2011;
- DEFLUX®, a biocompatible tissue-bulking agent indicated for the treatment of vesicoureteral reflux (VUR), acquired in in our purchase of Oceana in December 2011;
- FULYZAQ™, (crofelemer) delayed-release tablets, indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy, which the FDA approved on December 31, 2012;
- GIAZO™, (balsalazide disodium) tablets, indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older;
- METOZOLV™ ODT (metoclopramide hydrochloride) 5mg and 10mg orally disintegrating tablets, indicated for short-term (4 to 12 weeks) use in adults for treatment of refractory GERD, which is symptomatic, documented gastroesophageal reflux disease that fails to respond to conventional therapy, and for relief of symptoms of acute and recurrent diabetic gastroparesis;
- AZASAN® Azathioprine Tablets, USP, 75mg and 100 mg, indicated as an adjunct for the prevention of rejection in renal homotransplantations and to reduce signs and symptoms of severe active rheumatoid arthritis;
- ANUSOL-HC® 2.5% (Hydrocortisone Cream, USP), ANUSOL-HC® 25 mg Suppository (Hydrocortisone Acetate), indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses;

- PROCTOCORT® Cream (Hydrocortisone Cream, USP) 1% and PROCTOCORT® Suppository (Hydrocortisone Acetate Rectal Suppositories) 30 mg, indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses;
- PEPCID® (famotidine) for Oral Suspension, indicated for the short-term treatment of gastroesophageal reflux disease (GERD), active duodenal ulcer, active benign gastric ulcer, erosive esophagitis due to GERD, and peptic ulcer disease;
- DIURIL® (Chlorothiazide), indicated for the treatment of hypertension and also as adjunctive therapy in edema associated with congestive heart failure, cirrhosis of the liver, corticosteroid and estrogen therapy, and kidney disease; and
- COLAZAL® (balsalazide disodium) Capsules 750 mg, indicated for the treatment of mildly to moderately active ulcerative colitis (UC) in patients 5 years of age and older.

We generate revenue primarily by selling our products 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 FDA, to U.S. gastroenterologists, hepatologists, colorectal surgeons 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. As of December 31, 2012, this sales force had approximately 235 sales representatives in the field marketing 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 generally 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. As a result of our acquisition of Oceana Therapeutics, Inc. in December 2011, we have approximately ten sales representatives based in Europe who sell Solesta and Deflux there. We also sell Deflux through distributors in approximately 20 countries outside the United States and Europe. As of December 31, 2012, our sales and marketing staff, including our sales representatives, consisted of approximately 335 people.

Because demand for our products originates with doctors, our sales force calls on high-prescribing specialists, primarily gastroenterologists, hepatologists and colorectal surgeons, 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 consumed.

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

Compound	Indication	Status
Rifaximin	Irritable bowel syndrome, or IBS	Supplemental New Drug Application, or sNDA, submitted June 7, 2010; Complete Response Letter, or CRL, received on March 7, 2011; FDA meeting held on June 20, 2011; Advisory Committee held on November 16, 2011; currently in Phase 3 retreatment study
Methylnaltrexone bromide oral	Opioid induced constipation in patients with chronic non-malignant pain; oral	Phase 3
Budesonide foam	Ulcerative proctitis	Phase 3
Rifaximin EIR	Crohn's disease	Phase 2

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 from sales transactions where the buyer has the right to return the product at the time of sale only if (1) our price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid us, or the buyer is obligated to pay us and the obligation is not contingent on resale of the product, (3) the buyer's obligation to us 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 any provided by us, (5) we do not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated. We recognize revenues for product sales at the time title and risk of loss are transferred to the customer, which is generally at the time products are shipped. Our net product revenue represents our total revenues less allowances for customer credits, including estimated discounts, rebates, chargebacks, and product returns.

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

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

In our analyses, we use prescription data purchased from a third-party data provider to develop estimates of historical inventory channel pull-through. We utilize an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, we develop an estimate of the quantity of product in the channel that might be subject to various rebate, chargeback and product return exposures. At least quarterly for each product line, we prepare an internal estimate of ending inventory units in the distribution channel by adding

estimated inventory in the channel at the beginning of the period, plus net product shipments for the period, less estimated prescriptions written for the period. Based on that analysis, we develop an estimate of the quantity of product in the channel that might be subject to various rebate, chargeback and product return exposures. This is done for each product line by applying a rate of historical activity for rebates, chargebacks and product returns, adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product estimated to be in the distribution channel. Internal forecasts that are utilized to calculate the estimated number of months in the channel are regularly adjusted based on input from members of our sales, marketing and operations groups. The adjusted forecasts take into account numerous factors including, but not limited to, new product introductions, direct communication with customers and potential product expiry issues. Adjustments to estimates are recorded in the period when significant events or changes in trends are identified.

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, we record the discounts as a reduction of revenue in the period that we offer the program. 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, chargebacks and promotional programs were $103.8 million and $69.2 million as of December 31, 2012 and 2011, respectively. 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 for the year ended December 31, 2012, we would have recorded an adjustment to revenues of approximately $9.3 million, or 1.3%, for the year.

Allowances for product returns were $36.4 million and $28.7 million as of December 31, 2012 and 2011, 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. 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 as well as review prior period activity to ensure that our methodology is still reasonable.

For the years ended December 31, 2012, 2011 and 2010, our absolute exposure for rebates, chargebacks and product returns grew primarily as a result of increased sales of our existing products, the approval of new products and the acquisition of products. Accordingly, reductions to revenue and corresponding increases to allowance accounts have likewise increased. The estimated exposure to these revenue-reducing items as a percentage of gross product revenue in the years ended December 31, 2012, 2011 and 2010 was 15.7%, 14.6% and 14.9% for rebates, chargebacks and discounts and was 2.3%, 3.9% and 2.9% for product returns, respectively.

During the second quarter of 2010 we recognized product revenue related to initial shipments to wholesalers of Xifaxan 550mg, which the FDA approved on March 24, 2010 for reduction in risk of overt hepatic encephalopathy, or HE, recurrence in patients 18 years of age or older, and we launched to physicians in May 2010. Based on our historical experience with Xifaxan 200mg, which we distribute through the same distribution channels and is prescribed by the same physicians as Xifaxan 550mg, we have the ability to estimate returns for Xifaxan 550mg, and therefore we recognize revenue upon shipment to the wholesalers.

During the second quarter of 2011, we recognized product revenue related to shipments to wholesalers of Relistor, which we acquired from Progenics in February 2011. Based on historical experience with Relistor obtained from Progenics, and historical experience with our products, specifically Xifaxan 200mg, Xifaxan 550mg and Apriso, which we distribute through the same distribution channels and are prescribed by the same physicians as Relistor, management has the ability to estimate returns for Relistor, and therefore we recognize revenue upon shipment to the wholesalers.

In December 2011 we acquired an exclusive worldwide license to Solesta and Deflux with the completion of our acquisition of Oceana. Solesta and Deflux are medical devices that we sell to specialty distributors who then sell the products to end users, primarily hospitals, surgical centers and physicians. The specialty distributors generally do not purchase these products until an end user is identified. Based on historical experience with these products obtained from Oceana, and historical experience with our products, specifically Xifaxan 200mg, Xifaxan 550mg and Apriso, which are prescribed by the same physicians as Solesta, management has the ability to estimate returns for Solesta and Deflux, and therefore we recognize revenue upon shipment to the specialty distributors.

The enactment of the "Patient Protection and Affordable Care Act" and "The Health Care and Education Reconciliation Act of 2010" in March 2010 brings significant changes to U.S. health care. These changes began to take effect in the first quarter of 2010. Changes to the rebates for prescription drugs sold to Medicaid beneficiaries, which increase the minimum statutory rebate for branded drugs from 15.1 percent to 23.1 percent, were generally effective in the first quarter of 2010. This rebate has been expanded to managed Medicaid, a program that provides for the delivery of Medicaid benefits via managed care organizations, under arrangements between those organizations and state Medicaid agencies. Additionally, a prescription drug discount program for outpatient drugs in health care facilities that serve low-income and uninsured patients, known as 340B facilities, has been expanded. The effect of these changes was not material to our 2010, 2011 or 2012 financial results. Based on our current product and payor mix, we believe the effect of these changes should not be material to our future financial results.

Also, there are changes to the tax treatment of subsidies paid by the government to employers who provide their retirees with a drug benefit at least equivalent to the Medicare Part D drug benefit. Beginning in 2013, the federal government will tax the subsidy it provides to such employers. We do not provide retirees with any drug benefits, therefore this change should not affect our financial results.

Beginning in 2011, drug manufacturers will provide a discount of 50 percent of the cost of branded prescription drugs for Medicare Part D participants who are in the "doughnut hole" coverage gap in Medicare prescription drug coverage. The doughnut hole will be phased out by the federal government between 2011 and 2020. Based on our current product and payor mix, the cost of this discount was less than 1% of our gross revenue for the year ended December 31, 2012, however, the cost of this discount might have a material effect on our results of operations in future periods.

Beginning in 2011, pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs had to pay a non-tax deductible annual fee to the federal government. Companies have to pay an amount based on their prior calendar year market share for branded prescription drug sales into these government programs. Based on our current product and payor mix, the effect of this tax was not material to our financial results in 2012 and we do not believe the effect of this tax will be material to future periods.

Additionally, the 2010 healthcare reform legislation imposes a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in 2013. This tax had no effect on our financial statements for 2012, and we do not believe the effect of this tax will be material to future periods.

Inventories

Inventory at December 31, 2012 consisted of $42.9 million of raw materials, $14.8 million of work-in-process and $32.8 million of finished goods. Inventory at December 31, 2011 consisted of $28.2 million of raw materials, $9.2 million of work-in-process and $11.8 million of finished goods.

We state raw materials, work-in-process and finished goods inventories 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. Inventory adjustments are measured as the difference between the cost of the inventory and estimated market value based upon assumptions about future demand and charged to the provision for inventory, which is a component of cost of sales. At the point of the loss recognition, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

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 3 data or filed an New Drug Application, or 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. At December 31, 2012 and 2011, there were no amounts included in inventory related to pre-approval inventory.

On November 3, 2010, we received a paragraph IV notification from Novel stating that Novel had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of U.S. Patent No. 6,413,549 ("the '549 patent"). Upon examination of the relevant sections of the ANDA, we concluded that the '549 patent would not be enforced against Novel. As a result of this event, we evaluated the net realizable value of Metozolv inventory and recorded a $4.0 million reduction to the value of Metozolv inventory during the fourth quarter of 2010.

Valuation of Intangible Assets and Contingent Consideration Liabilities Acquired in Business Combinations

We have acquired and expect to continue to acquire intangible assets in connection with business combinations. These intangible assets consist primarily of technology associated with currently marketed prescription drugs and medical devices, as well as product candidates. We typically use discounted cash flow models to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in a business combination. These models require the use of significant estimates and assumptions, including, but not limited to:

- determining the timing and expected costs to complete in-process projects taking into account the stage of completion at the acquisition date;
- projecting the probability and timing of obtaining marketing approval from the FDA and other regulatory agencies for product candidates;
- estimating the timing of and future net cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates to calculate the present values of those cash flows.

Significant estimates and assumptions are also required to determine the acquisition date fair values of any contingent consideration liabilities incurred in connection with business combinations. In addition, we must revalue

these liabilities each subsequent reporting period until the related contingencies are resolved and record changes in their fair values in earnings. We determined the acquisition date fair values of the various contingent consideration liabilities incurred in our business acquisitions using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included, but were not limited to, the probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. We update these estimates and assumptions each reporting period in order to revalue these contingent consideration liabilities. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these liabilities.

We believe the fair values used to record intangible assets acquired and contingent consideration liabilities incurred in connection with business combinations are based upon reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Intangible Assets and Goodwill

Our 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 we make product acquisitions that include license agreements, product rights and other identifiable intangible assets, we record the purchase price of such intangibles, along with the value of the product-related liabilities that we assume, as intangible assets. We allocate 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 amortize 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. We assess the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value might not be recoverable. We believe 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; approval of generic products; and significant negative industry or economic trends.

In assessing the recoverability of our intangible assets, we 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, we must determine the fair value of the intangible assets. If the fair value of the intangible assets is less than the carrying value, we will recognize an impairment loss equal to the difference. We review 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.

In September 2005, we 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. We 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 we believed was an appropriate amortization period due to the product's patent protection and the estimated economic lives of the product rights and related intangibles. In September 2010 we entered into a Sublicense Agreement which granted Novel Laboratories, Inc. a license under the patents covering OsmoPrep permitting Novel to launch a generic OsmoPrep on November 16, 2019. As a result of this agreement, we adjusted the amortization period prospectively, and we are amortizing the remaining net book value of the intangible asset through November 16, 2019, which is our revised estimate of its remaining economic life. As a result of this agreement, we assessed whether there was an impairment to the carrying value of the related intangible asset due to its reduced economic life and determined that there was no impairment. At December 31, 2012 and 2011, accumulated amortization for the InKine intangibles was $20.4 million and $18.1 million, respectively. There is no future research or development planned for the products purchased from InKine.

In December 2005, we 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, we received FDA marketing approval for NRL 944 under the branded name of MoviPrep. In January 2007 the USPTO issued a patent providing coverage to September 1, 2024. Pursuant to the terms of the Agreement, Salix paid Norgine milestone payments of $15.0 million in August 2006, $5.0 million in December 2008 and $5.0 million in December 2009. We were amortizing these milestone payments over a period of 17.3 years through 2022, which we believed was an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. In August 2010 we entered into a Sublicense Agreement that granted Novel Laboratories, Inc. a license to the patents covering MoviPrep permitting Novel to launch a generic MoviPrep on September 24, 2018. As a result of this agreement, we adjusted the amortization period prospectively, and we are now amortizing the remaining net book value of the intangible asset through September 24, 2018, which is our revised estimate of its remaining economic life. As a result of this agreement, we assessed whether there was an impairment to the carrying value of the related intangible asset due to its reduced economic life and determined that there was no impairment. At December 31, 2012 and 2011, accumulated amortization for the MoviPrep intangible was $11.5 million and $9.2 million, respectively.

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 from Merck. We 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, we believe 15 years was an appropriate amortization period based on established product history and management experience. In May 2010, the FDA approved a generic famotidine oral suspension product, and we launched an authorized generic famotidine product. In June 2010 the FDA approved another generic famotidine oral suspension product. As a result of these events, we assessed whether there was an impairment to the carrying value of the related intangible asset. Based on this analysis, we recorded a $30 million impairment charge to reduce the carrying value of the intangible asset to its estimated fair value during the three-month period ended June 30, 2010. At December 31, 2012 and 2011, accumulated amortization for the Merck products was $15.1 million and $14.0 million, respectively.

In July 2002, we 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, we made a $8.0 million milestone payment to Dr. Falk. In December 2009, we made a $2.0 million milestone payment to Dr. Falk. We are amortizing these milestone payments over a period of 9.5 years, which we believe is an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. At December 31, 2012 and 2011, accumulated amortization for the Apriso intangible was $3.5 million and $2.7 million, respectively.

In September 2007, we acquired the exclusive, worldwide right to sell metoclopramide–Zydis® (trade name Metozolv) from Wilmington Pharmaceuticals, LLC. On September 8, 2009 the FDA granted marketing approval for Metozolv™ ODT (metoclopramide HCl) 5 mg and 10 mg orally disintegrating tablets. Metozolv ODT is indicated for the relief of symptomatic gastroesophageal reflux or short-term (4-12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy and diabetic gastroparesis or the relief of symptoms in adults associated with acute and recurrent diabetic gastroparesis. In October 2009, we made a $7.3 million milestone payment to Wilmington. We are amortizing this milestone payment over a period of eight years, which we believe is an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. On November 3, 2010, we received a paragraph IV notification from Novel stating that Novel had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of U.S. Patent No. 6,413,549 ("the '549 patent"). Upon examination of the relevant sections of the ANDA, we concluded that the '549 patent would not be enforced against Novel Laboratories. As a result of this event, we assessed whether there was an impairment to the carrying value of the related intangible asset. Based on this analysis, we recorded a $4.6 million impairment charge to reduce the carrying value of the intangible asset to its estimated fair value during the three-month period ended December 31, 2010. At December 31, 2012 and 2011 accumulated amortization for the Metozolv intangible was $2.6 million and $1.9 million, respectively.

In February 2011, we acquired an exclusive worldwide license to develop and commercialize the products containing methylnaltrexone bromide, or the MNTX Compound, marketed under the name Relistor®, from Progenics

Pharmaceuticals, Inc. (except in Japan, where Ono Pharmaceutical Co. Ltd. has previously licensed the subcutaneous formulation of the drug from Progenics) and a non-exclusive license to manufacture the MNTX Compound and products containing that compound in the same territory. Relistor Subcutaneous Injection is indicated for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. We paid Progenics an up-front license fee payment of $60.0 million. We also agreed to pay development milestone payments of up to $90.0 million contingent upon achieving specified regulatory approvals and commercialization milestone payments of up to $200.0 million contingent upon achieving specified targets for net sales. We must pay Progenics 60% of any revenue received from sublicensees in respect of any country outside the United States. Additionally, we must pay Progenics royalties based on a percentage ranging from the mid- to high-teens of net sales by the Company and its affiliates of any product containing the MNTX Compound.

We accounted for the Progenics transaction as a business combination under the acquisition method of accounting. Under the acquisition method of accounting, we recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the assets acquired was $113.0 million, including our estimate of the fair value of the contingent consideration related to the transaction discussed above of $53.0 million which is included as a long-term liability on the consolidated balance sheet. We determined this liability amount using a probability-weighted discounted cash flow model based on the current regulatory status of the methylnaltrexone bromide development programs. We assess the fair value of the contingent consideration quarterly, or whenever events or changes in circumstances indicate that the fair value may have changed, primarily as a result of clinical or regulatory results in the related in-process development programs. In December 2011, we announced positive Phase 3 data from the OIC Oral development program. Based on this information, we reassessed the fair value of the contingent consideration and recorded a $27.0 million increase in the contingent consideration and a corresponding charge to earnings in the fourth quarter of 2011. At December 31, 2012 and 2011, accumulated amortization for the intangible related to the currently approved indication for Relistor was $4.6 million and $2.0 million, respectively.

On July 27, 2012 we received a Complete Response Letter, or CRL, from the FDA following its review of a Supplemental New Drug Application (sNDA) for methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in adult patients with chronic, non-cancer pain. The CRL requested additional clinical data. In October 2012 Salix and Progenics held an End-of-Review meeting with the Division of Gastroenterology and Inborn Errors Products to better understand the contents of the CRL. Based on the results of this meeting, we reassessed the value of the indefinite lived intangible asset related to methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in chronic non-cancer pain and recorded a non-cash charge to earnings of $41.6 million in the three-month period ended September 30, 2012. Based on these events, we reassessed the fair value of the contingent consideration related to the Progenics transaction and recorded a $33.0 million decrease in the contingent consideration and a corresponding non-cash charge to earnings in the three-month period ended September 30, 2012. We are currently evaluating the oral OIC development program and currently believe we will continue this program. However, additional information and additional guidance from the FDA could result in the termination of the oral OIC development program, which would result in impairment of the related intangible asset and a decrease in the related contingent consideration.

In December 2011 we acquired Oceana Therapeutics, Inc. Oceana has two products, Deflux and Solesta. Deflux is indicated for children affected by Grades II-IV vesicoureteral reflux, a malformation of the urinary bladder that can result in severe infections of the kidneys and irreversible kidney damage. Deflux has been on the market in the United States since 2001. Solesta is a biocompatible tissue bulking agent, consisting of dextranomer microspheres and stabilized sodium hyaluronate. Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy such as diet, fiber therapy, anti-motility medications. It is the only injectable gel to be administered in an outpatient setting without the need for surgery or anesthesia. Solesta was approved by the FDA through the premarket approval process as a Class III Medical Device in May 2011 and launched in September 2011 by Oceana. Solesta also is CE Mark-approved and marketed in Europe. Oceana has a license agreement with Q-MED AB, which provide us the worldwide right to commercialize Deflux and Solesta. Under the license agreements and a related stock purchase agreement with Q-Med that we have assumed, we are obligated to pay up to $45.0 million contingent upon achieving specified targets for net sales of Solesta over the term of the agreement.

We accounted for the Oceana acquisition as a business combination under the acquisition method of accounting. Under the acquisition method of accounting, we recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in its consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the assets acquired was $342.8 million, including our estimate of the fair value of the contingent consideration related to the transaction discussed above of $39.7 million which is included as a long-term liability on the consolidated balance sheet. We determined this liability amount using a probability-weighted discounted cash flow model. We assess the fair value of the contingent consideration whenever events or changes in circumstances indicate that the fair value may have changed, primarily as a result of significant changes in our forecast of net sales for Solesta. At December 31, 2012, accumulated amortization for the intangible related to Deflux was $4.7 million and $29.0 million for the intangible related to Solesta.

In August 2012 we amended our 1996 License Agreement with Alfa Wassermann to develop rifaximin. The new agreement provides us with an exclusive license to develop and commercialize rifaximin products for travelers' diarrhea (TD), hepatic encephalopathy (HE) or irritable bowel syndrome (IBS) in the United States and Canada. We are obligated to pay Alfa royalties, at the same range of rates as under the previous agreement, on net sales of such products. In addition, the Restated Agreement provides us with an exclusive license to develop and commercialize rifaximin products for Crohn's disease (CD) in the United States and Canada and a non-exclusive license to develop such products worldwide. We paid Alfa a non-refundable upfront fee of $10.0 million in August 2012, and are obligated to make a $25.0 million milestone payment upon receipt of marketing authorization in the United States for an extended intestinal release, or EIR, formulation product for CD, and additional milestones based on net sales of EIR formulation products for CD of up to $200.0 million. In addition, we are required to pay Alfa royalties on sales of rifaximin products for Crohn's at percentage rates ranging in the low double digits.

We accounted for the Alfa Wassermann transaction as a business combination under the acquisition method of accounting. Under the acquisition method of accounting, we recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in its consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the assets acquired was $23.4 million which is included as an indefinite lived intangible asset on the consolidated balance sheet, and includes our estimate of the fair value of the contingent consideration related to the transaction discussed above of $13.4 million which is included as a long-term liability on the consolidated balance sheet. We determined this liability amount using a probability-weighted discounted cash flow model based on the current regulatory status of the EIR development program. We assess the fair value of the contingent consideration quarterly, or whenever events or changes in circumstances indicate that the fair value may have changed, primarily as a result of clinical or regulatory results in the related in-process development programs.

Research and Development

We expense 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, we initially capitalize the advance payment. We then recognize such amounts as an expense as the related goods are delivered or the related services are performed. At December 31, 2012 and 2011, the net liability related to on-going research and development activities was $14.1 million and $8.1 million, respectively.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the cost to complete projects and development timelines for their completion cannot be reasonably estimated. Enrollment in clinical trials might be delayed for reasons beyond our control, requiring additional cost and time. Results from clinical trials might not be favorable, or might require us to perform additional unplanned clinical trials, requiring additional cost and time, or resulting in termination of the project. Further, data from clinical trials is subject to varying interpretation, and might be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals, requiring additional cost and time, or resulting in termination of the project. Process development and manufacturing scale-up for production of clinical and commercial product supplies might take longer and cost more than our forecasts. As such, clinical development and regulatory programs are subject to risks and changes that might significantly impact cost projections and timelines.

The following table summarizes costs incurred for our significant projects, in thousands. We consider a project significant if expected spend for any year exceeds 10% of our development project budget for that year.

Project	Year ended December 31, 2012	2011	2010	Cumulative through December 31, 2012
Rifaximin for hepatic encephalopathy, or HE	$ 3,700	$ 5,112	$ 6,037	$44,310
Rifaximin for irritable bowel syndrome, or IBS	21,209	3,415	93	71,028
Crofelemer for HIV-associated diarrhea	8,052	4,206	10,979	34,841
Balsalazide disodium tablet for ulcerative colitis	—	—	—	40,030
Budesonide foam for ulcerative proctitis	7,560	9,407	9,707	32,770
Methylnaltrexone bromide for opioid-induced constipation in patients with chronic pain	14,405	19,054	—	33,459
Other non-significant rifaximin clinical projects (4 in 2012, 4 in 2011, 6 in 2010)	5,431	5,985	4,362	N/A
All other clinical programs (5 in 2012, 6 in 2011, 8 in 2010)	9,312	4,301	5,924	N/A

Convertible Debt Transactions

We separately account for the liability and equity components of convertible debt instruments by allocating the proceeds from issuance between the liability component and the embedded conversion option, or equity component, in accordance with accounting for convertible debt instruments that may be settled in cash (including partial cash settlement) upon conversion. The value of the equity component is calculated by first measuring the fair value of the liability component, using the interest rate of a similar liability that does not have a conversion feature, as of the issuance date. The difference between the proceeds from the convertible debt issuance and the amount measured as the liability component is recorded as the equity component. We recognize the accretion of the resulting discount as part of interest expense in our consolidated statements of income.

Upon settlement of our convertible senior notes, we revalue the liability component, utilizing an interest rate of comparable nonconvertible debt. We allocate a portion of the consideration transferred to the liability component equal to the fair value of that component immediately prior to repurchase. Any difference between the consideration attributed to the liability component and the net carrying amount of the liability component is recognized as a gain or loss in the statement of income. Any remaining consideration is allocated to the reacquisition of the equity component and is recognized as a reduction of stockholders' equity.

Deferred Tax Asset Valuation Allowance

We calculate the valuation allowance in accordance with the provisions of ASC 740, "Income Taxes," which requires an assessment of both positive and negative evidence regarding the realizability of these deferred tax assets, when measuring the need for a valuation allowance. Significant management judgment is required in determining any valuation allowance recorded against deferred tax assets. Due to a history of operating losses, resulting in a cumulative loss position, management concluded that a full valuation allowance was needed to offset all of the deferred tax assets, net of deferred tax liabilities, as of December 31, 2010. At December 31, 2011, management concluded that it was more likely than not that a majority of our deferred tax assets will be realized through future taxable income. This conclusion was based, in part, on our achieving sustained profitability in 2011 and projections of positive future earnings. Therefore, we released a significant portion of the valuation allowances related to these deferred tax assets in the fourth quarter of 2011. We will reassess the ability to realize the deferred tax benefits on a quarterly basis. If it is more likely than not that we will not realize the deferred tax benefits, then all or a portion of the valuation allowance may need to be re-established, which would result in a charge to tax expense. The release of these valuation allowances resulted in an income tax benefit of $41.4 million, which was recorded as a discrete item during the year ending December 31, 2011. The release of the valuation allowance will not affect the amount of cash paid for income taxes. We continue to provide a valuation allowance for net deferred tax assets related to several state net operating loss carryforwards.

RESULTS OF OPERATIONS

Years Ended December 31, 2012, 2011 and 2010

Revenues

The following table summarizes net product revenues, in thousands, for the years ended December 31, 2012, 2011 and 2010:

	Year ended December 31,		
	2012	2011	2010
Xifaxan	$514,480	$371,653	$250,459
% of net product revenues	70%	69%	74%
Purgatives—MoviPrep/OsmoPrep	64,932	88,746	54,207
% of net product revenues	9%	16%	16%
Inflammatory Bowel Disease—Colazal/Apriso/Giazo	85,504	49,736	24,459
% of net product revenues	12%	9%	7%
Other—Anusol/Azasan/Diuril/Pepcid/Proctocort/Relistor/Deflux/Solesta	70,528	30,353	7,848
% of net product revenues	9%	6%	3%
Net product revenues	$735,444	$540,488	$336,973

Net product revenues for 2012 were $735.4 million, compared to $540.5 million for 2011. The net product revenue increase from 2011 to 2012 was primarily due to:

- increased unit sales of Xifaxan and Apriso;
- increased unit sales of Relistor, which we began promoting in the second quarter of 2011;
- sales of Deflux, which we acquired in connection with our acquisition of Oceana in December 2011; and
- price increases on our products.

These increases were partially offset by reduced unit sales of OsmoPrep and MoviPrep.

Total milligrams of Xifaxan prescribed during 2012 increased 24% compared to 2011. Prescriptions for our purgatives as a group decreased 5% for 2012 when compared to 2011. Prescriptions for MoviPrep decreased 3% for 2012 compared to prescriptions for 2011. Prescriptions for OsmoPrep for 2012 declined 21% compared to prescriptions for 2011. Prescriptions for Apriso increased 29% for 2012 compared to prescriptions for 2011.

Net product revenues for 2011 were $540.5 million, compared to $337.0 million for 2010. The net product revenue increase from 2010 to 2011 was primarily due to:

- increased unit sales of Xifaxan, primarily due to the approval of Xifaxan 550mg for hepatic encephalopathy, which we began selling in the second quarter of 2010;
- increased unit sales of Apriso, MoviPrep and OsmoPrep;
- sales of Relistor, which we in-licensed from Progenics in February 2011; and
- price increases on our products.

Total milligrams of Xifaxan prescribed during 2011 increased 58% compared to 2010. Prescriptions for our purgatives as a group were generally flat for 2011 when compared to 2010. Prescriptions for MoviPrep increased 4% for 2011 compared to prescriptions for 2010. Prescriptions for OsmoPrep for 2011 declined 19% compared to prescriptions for 2010.

Costs and Expenses

Total costs and expenses were $563.4 million, $424.6 million and $343.2 million for 2012, 2012 and 2010, respectively. Higher operating expenses in absolute terms for 2012 compared to 2011 were due primarily to increased

selling, general and administrative costs due to the acquisition of Oceana in December 2011 and an expansion of our sales force in 2012, increased cost of products sold related to the corresponding increase in product revenue and the intangible impairment charge recorded in the three-month period ended September 30, 2012, partially offset by the change in acquisition-related contingent consideration recorded in the three-month period ended September 30, 2012. Higher operating expenses in absolute terms for 2011 compared to 2010 were due primarily to increased cost of products sold related to the corresponding increase in product revenue, the change in acquisition-related contingent consideration, increased research and development expenses, and increased selling, general and administrative expenses.

Cost of Products Sold

Cost of products sold were $124.6 million, $95.4 million and $68.7 million for 2012, 2011 and 2010, respectively. Gross margin on total product revenue, excluding $45.4 million, $10.9 million and $10.4 million in amortization of product rights and intangible assets for 2012, 2011 and 2010, respectively, was 83%, 82% and 80% in 2012, 2011 and 2010, respectively. The increase in cost of products sold in absolute terms was due to the increase in net product revenues discussed above. The period-to-period changes in gross margin are due to the product revenue mix in the respective periods, primarily due to increasing sales of Xifaxan. Included in cost of products sold for 2010 are $6.2 million of costs related to Metozolv that were expensed. Cost of products sold does not include amortization of product rights and intangibles. Refer to "Critical Accounting Policies—Intangible Assets and Goodwill" above.

Amortization of Product Rights and Intangible Assets

Amortization of product rights and intangible assets consists of amortization of the costs of license agreements, product rights and other identifiable intangible assets, which result from product and business acquisitions. The increase for 2012 compared to 2011 was primarily due to amortization of intangibles related to Deflux and Solesta, which we acquired in connection with our acquisition of Oceana in December 2011.

Intangible Impairment Charges

On July 27, 2012 we received a CRL from the FDA following its review of an sNDA for methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in adult patients with chronic, non-cancer pain. The CRL requested additional clinical data. Salix and Progenics held an End-of-Review meeting with the Division of Gastroenterology and Inborn Errors Products to better understand the contents of the CRL in October 2012. Based on the results of this meeting, we reassessed the value of the indefinite lived intangible asset related to methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in chronic non-cancer pain and recorded a non-cash charge to earnings of $41.6 million in the three-month period ended September 30, 2012.

Intangible impairment charges for 2010 consist of a $30.0 million impairment charge recorded during the three-month period ended June 30, 2010 related to Pepcid OS, and a $4.6 million impairment charge recorded during the three-month period ended December 31, 2010 related to Metozolv. The Pepcid charge was a result of FDA approval of two generic famotidine oral suspension products in May 2010 and June 2010. The Metozolv charge was a result of Novel filing an ANDA to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg, and our determination that the applicable patent could not be enforced against Novel. We did not incur any intangible impairment charges in 2011 or 2009.

Research and Development

Research and development expense was $123.2 million, $104.4 million and $73.3 million for 2012, 2011 and 2010, respectively. This represents a reduction in research and development expenses as a percentage of net product revenues to 16.7% for 2012 from 19.3% for 2011 and 21.8% for 2010, as we have significantly increased revenues over this period.

The increase in research and development expenses in absolute terms from 2011 to 2012 was due primarily to:

- increased expenses related to our development programs for crofelemer and rifaximin for irritable bowel syndrome; and
- increased personnel costs.

These increases were partially offset by:

- the $10.0 million upfront payment for our Amended License Agreement with Lupin in March 2011, which did not recur in 2012;
- decreased expenses related to investigator-initiated studies; and
- decreased expenses related to our development programs for methylnaltrexone bromide, rifaximin for HE and budesonide foam.

The increase in research and development expenses from 2010 to 2011 was due primarily to:

- the $10.0 million upfront payment for our March 2011 Amended License Agreement with Lupin;
- increased expenses related to our development program for methylnaltrexone bromide, which we acquired from Progenics in February 2011; and
- increased personnel costs.

These increases were partially offset by decreases in expenses related to our development programs for crofelemer as it progressed to a less expensive stage of development, and for rifaximin for hepatic encephalopathy, which the FDA approved in March 2010.

Since inception through December 31, 2012, we have incurred research and development expenditures of approximately $41.6 million for balsalazide, $166.0 million for rifaximin, $32.2 million for granulated mesalamine, $34.9 million for crofelemer, $33.5 million for methylnaltrexone bromide and $32.8 million for budesonide foam.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, we cannot reasonably estimate the cost to complete projects and development timelines for their completion. Enrollment in clinical trials might be delayed or occur faster than anticipated for reasons beyond our control, requiring additional cost and time or accelerating spending. Results from clinical trials might not be favorable, or might require us to perform additional unplanned clinical trials, accelerating spending, requiring additional cost and time, or resulting in termination of the project. Further, as evidenced by the Complete Response Letter for rifaximin as a treatment for IBS, data from clinical trials is subject to varying interpretation, and might be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals, requiring additional cost and time, or resulting in termination of the project. Regulatory reviews can also be delayed. For example the PDUFA action dates for Relistor and crofelemer were each extended by three months. Process development and manufacturing scale-up for production of clinical and commercial product supplies might take longer and cost more than our forecasts. As a result, clinical development and regulatory programs are subject to risks and changes that might significantly impact cost projections and timelines.

Selling, General and Administrative

Selling, general and administrative expenses were $258.2 million, $187.0 million and $156.1 million for 2012, 2011 and 2010, respectively. Selling, general and administrative expenses as a percentage of net product revenues was 35.1% for 2012 compared to 34.6% for 2011 and 46.3% for 2010.

The increase from 2011 to 2012 was primarily due to:

- increased personnel costs, including costs related to the addition of 25 key account managers in April 2011, our acquisition of Oceana in December 2011 and the addition of 10 sales representatives in the second quarter of 2012 and 22 sales representatives in the third quarter of 2012;
- increased marketing expenses related to Relistor, which we in-licensed in February 2011 and launched in April 2011, Solesta, which we acquired in December 2011, and Xifaxan ;
- pre-marketing expenses related to Giazo and Fulyzaq, which we expect to begin promoting in 2013; and
- increased legal expenses related to our product liability litigation, which was previously covered by our products liability insurance, the limits of which we exceeded in the fourth quarter of 2011.

These increases were partially offset by reduced pre-marketing expenses related to Xifaxan 550mg for irritable bowel syndrome incurred in 2011 prior to our receipt of the CRL from the FDA.

The increase from 2010 to 2011 was primarily due to:

- increased personnel costs, including the addition of 25 key account managers relating to the launch of Relistor in April 2011;
- costs related to our acquisition of Oceana in December 2011;
- increased administrative fees related to our managed care contracts;
- a $3.5 million charge taken in the fourth quarter of 2011 related to products liability litigation; and
- increased marketing costs relating to the launch of Relistor in April 2011.

These increases were partially offset by reduced legal costs as a result of our settlement of the patent litigation related to MoviPrep and OsmoPrep in the third quarter of 2010, and reduced marketing costs related to Xifaxan 550mg due to the launch for the HE indication in 2010.

We expect selling, general and administrative expenses to continue to increase in absolute terms as we expand our sales and marketing efforts for our current products, including Relistor, which we acquired in February 2011, Solesta and Deflux, which we acquired in December 2011, and other indications for rifaximin and methylnaltrexone bromide, if approved.

Change in Acquisition-Related Contingent Consideration

We accounted for the Progenics transaction as a business combination under the acquisition method of accounting. Under the acquisition method of accounting, we recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the contingent consideration related to the transaction was $53.0 million, which we included as a long-term liability on the consolidated balance sheet. We determined this liability amount using a probability-weighted discounted cash flow model based on the current regulatory status of the methylnaltrexone bromide development programs. We assess the fair value of the contingent consideration quarterly, or whenever events or changes in circumstances indicate that the fair value might have changed, primarily as a result of clinical or regulatory results in the related in-process development programs. In December 2011 we announced the successful outcome of the Phase 3 trial to evaluate the efficacy and safety of oral methylnaltrexone for the treatment of opioid–induced constipation in subjects with chronic, non–cancer pain. As a result of this event, we reassessed the fair value of the contingent consideration and recorded an increase of $27.0 million and a corresponding charge in the fourth quarter of 2011.

On July 27, 2012 we received a CRL from the FDA following its review of an sNDA for methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in adult patients with chronic, non-cancer pain. The CRL requested additional clinical data. Salix and Progenics held an End-of-Review meeting with the Division of Gastroenterology and Inborn Errors Products to better understand the contents of the CRL in October 2012. Based on the results of this meeting, we reassessed the value of the indefinite lived intangible asset related to methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in chronic non-cancer pain and recorded a non-cash charge to earnings of $41.6 million in the three-month period ended September 30, 2012. Based on these events, we reassessed the fair value of the contingent consideration related to the Progenics transaction and recorded a $33.0 million decrease in the contingent consideration and a corresponding non-cash charge to earnings in the three-month period ended September 30, 2012. The remaining increase of $3.4 million for the year ended December 31, 2012 relates to the increase in the value of the contingent consideration for Progenics, Oceana and EIR, due to the passage of time.

Loss on Extinguishment of Debt

In March 2012, we entered into a note repurchase agreement with the holder of a majority in principal amount of the 2028 Notes. We used a portion of the proceeds from the offering of the 2019 Notes to purchase from this holder

and another holder approximately 42.1% of the 2028 Notes for an aggregate purchase price of approximately $137.2 million. In addition, for a period of 90 days after March 12, 2012, the majority holder had the option to require us to purchase its remaining 2028 Notes at the same price, which represents approximately 37.1% of the 2028 Notes. This option expired unexercised in June 2012.

In December 2012 one of the holders of the 2028 Notes converted notes with a par value of $22.3 million under the terms of the note indenture, and received cash equal to the par value of the notes and interest on these notes through February 15, 2013, and 1.9 million shares of common stock.

Loss on extinguishment of debt primarily consists of $9.3 million in estimated fair market value of the put option granted to the majority holder, $3.6 million in estimated fair market value of the notes extinguished over their book value at the extinguishment date, and $2.2 million paid to the note holders for interest that the note holders would have been due subsequent to the extinguishment date.

Interest Expense

Interest expense was $55.5 million, $32.1million and $20.6 million in 2012, 2011 and 2010, respectively. Interest expense for 2012 consisted of:

- $26.4 million of interest expense on our 2015 convertible notes issued in June 2010, including $15.2 million of amortization of debt discount;
- $5.1 million of interest expense on our 2028 convertible notes issued in August 2008, including $2.4 million of amortization of debt discount; and
- $24.0 million of interest expense on our 2019 convertible notes issued in March 2012, including $14.0 million of amortization of debt discount.

Interest expense for 2011 consisted of:

- $25.2 million of interest expense on our 2015 convertible notes issued in June 2010, including $14.0 million of amortization of debt discount; and
- $6.9 million of interest expense on our 2028 convertible notes issued in August 2008, including $3.3 million of amortization of debt discount.

Interest expense for 2010 consisted of:

- $13.7 million of interest expense on our 2015 convertible notes issued in June 2010, including $7.2 million of amortization of debt discount;
- $6.6 million of interest expense on our convertible notes issued in August 2008, including $2.9 million of amortization of debt discount; and
- $0.3 million of interest expense on our credit facility, which we paid off in May 2010.

Interest and Other Income

Interest and other income was $10.9 million, $2.3 million and $2.6 million for 2012, 2011 and 2010, respectively. Other income for 2012 includes $9.3 million related to the put option granted to the majority holder of the 2028 notes discussed above, which expired unexercised in June 2012.

Due to the current economic climate, we expect 2013 interest rates paid to us on our cash and cash equivalents will be equal to or lower than we experienced during 2012.

Provision for Income Tax

Income tax (benefit) expense was $47.6 million, ($1.3) million and $2.9 million in 2012, 2011 and 2010, respectively. Our effective tax rate was 42.6%, (1.5)% and (11.6)% in 2012, 2011 and 2010, respectively.

The significant change in the effective tax rate between 2012 and 2011 was primarily related to the release of the valuation allowance at December 31, 2011. The release of these valuation allowance resulted in an income tax benefit of $41.4 million, which was recorded as a discrete item during the year ending December 31, 2011. We continue to provide a valuation allowance for net deferred tax assets related to several state and non-U.S. net operating loss carryforwards.

Our 2012 effective tax rate of 42.6% varies from the federal statutory rate of 35% due primarily to: state income taxes, net of federal income tax benefit, of 3.5%; reserve for uncertain tax positions of 11.4%; debt costs of (8.5%); various non-deductible expenses 2.5%; and the change in valuation allowance related to certain state deferred tax assets (2.0%).

At December 31, 2012, 2011 and 2010, we had U.S. federal net operating loss carryforwards of approximately $3.6 million, $12.8 million and $90.3 million, respectively. These carryforwards will expire on various dates beginning in 2029 through 2031 if not utilized. Utilization of the federal net operating loss and credit carryforwards might 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. At December 31, 2012, and 2011 our non-U.S. tax losses totaled approximately $11.8 million and $8.4 million, respectively. The Company provides a full valuation allowance against these non-U.S. tax losses. At December 31, 2012, 2011 and 2010, we also had state net operating loss carryforwards available to offset future taxable income of approximately $162.2 million, $149.9 million and $204.0 million, respectively. Certain of these state net operating loss carryforwards have full valuation allowances set up against them.

Quarterly Results of Operations

See Note 14 of Notes to Consolidated Financial Statements for a presentation of our quarterly results of operations for the years ended December 31, 2012 and 2011.

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 collaborators. Since launching Colazal in January 2001, net product revenue has been a growing source of cash. In August 2008 we closed an offering of $60.0 million in convertible senior notes due 2028 ("2028 Notes"), with net proceeds of $57.3 million. On June 3, 2010 the Company closed an offering of $345.0 million in convertible senior notes due May 15, 2015 ("2015 Notes"), with net proceeds of approximately $334.2 million. On March 16, 2012 the Company closed an offering of $690.0 million in convertible senior notes due March 15, 2019 ("2019 Notes"), with net proceeds of approximately $668.3 million. As of December 31, 2012, we had $751.0 million in cash and cash equivalents, compared to $292.8 million as of December 31, 2011.

We believe our cash and cash equivalent balances should be sufficient to satisfy our cash requirements for the foreseeable future. At December 31, 2012, our 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, 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. Based on our current projections, we believe that we will continue positive cash flow from operations 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: whether we acquire additional products or companies; risk associated with acquisitions; FDA and foreign regulation and regulatory processes; the status of competitive products, including potential generics in an increasingly global industry; intellectual property and related litigation risks in an increasingly global industry; product liability litigation; our success selling products; the results of research and development activities; establishment of and change in collaborative relationships; general economic conditions; and technological advances by us and other pharmaceutical companies. 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.

Cash Flows

Net cash provided by operating activities was $87.6 million in 2012 and was primarily attributable to our net income for the period, net of non-cash charges, offset by an increase in accounts receivable and inventory. Net cash provided by operating activities was $119.2 million in 2011 and was primarily attributable to our net income for the period, net of non-cash charges, offset by an increase in accounts receivable and inventory. Net cash provided by operating activities was $25.5 million in 2010 and was primarily attributable to our net loss for the period, net of non-cash charges including the intangible impairment charges, offset by an increase in accounts receivable due to increased sales in the fourth quarter of 2010.

Net cash used in investing activities was $15.4 million in 2012 and was primarily due to the purchase of Rifaximin EIR in August 2012 and purchases of property and equipment. Net cash used in investing activities was $388.6 million in 2011 and was primarily due to the purchase of Relistor in February 2011, the purchase of Oceana in December 2011 and purchases of property and equipment. Net cash provided by investing activities was $9.4 million in 2010 and was primarily due to the decrease in restricted cash as a result of our repayment of our credit facility, net of purchases of property and equipment.

Net cash provided by financing activities of $385.6 million in 2012 related primarily to our offering of $690.0 million in convertible senior notes, including net proceeds of $669.0 million and the receipt of $99.0 million from the sale of warrants, offset by $167.0 million for the purchase of call options, $159.6 million for the repurchase of a portion of our 2028 convertible senior notes, and $74.8 million for the repurchase of common stock. Net cash provided by financing activities of $44.4 million in 2011 consisted primarily of proceeds from the exercise of stock options and tax benefits from stock-based compensation. Net cash provided by financing activities of $290.6 million in 2010 consisted primarily of the net proceeds from the closing of our offering of 2015 Notes in June 2010 and proceeds from the exercise of stock options.

Commitments

As of December 31, 2012, we had non-cancelable purchase order commitments for inventory purchases of approximately $217.0 million, which included any minimum purchase commitments under our manufacturing agreements. 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, methylnaltrexone bromide 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, 2012 were as follows (in thousands):

	Total	< 1 year	1-3 years	3-5 years	> 5 years
Operating leases	$ 35,529	$ 2,352	$ 7,735	$ 7,964	$ 17,478
Purchase commitments	216,961	84,961	66,000	66,000	—
2028 convertible senior notes(1)	12,930	12,930	—	—	—
2015 convertible senior notes(2)	367,929	9,488	358,441	—	—
2019 convertible senior notes(3)	754,688	10,350	20,700	20,700	702,938
Capital lease obligations	49	49	—	—	—
Total	$1,388,086	$120,130	$452,876	$94,664	$720,416

(1) Contractual interest and principal obligations related to our 2028 convertible senior notes total $12.9 million at December 31, 2012, including $12.9 million due in one year or less. If these notes had been converted at

December 31, 2012 based on the closing price of our stock of $40.47 per share on that date and we chose to settle them in cash, the settlement amount would have been approximately $54.7 million.

(2) Contractual interest and principal obligations related to our 2015 convertible senior notes total $367.9 million at December 31, 2012, including $9.5 million and $358.4 million due in one year or less and one to three years, respectively.

(3) Contractual interest and principal obligations related to our 2019 convertible senior notes total $754.7million at December 31, 2012, including $10.4 million, $20.7 million, $20.7 million and $702.9 million due in one year or less, one to three years, and three to five years, and greater than five years, respectively.

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

Credit Facility

In February 2007, we entered into a $100.0 million revolving credit facility that was to mature 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 2028 Notes described below. On May 6, 2010, the Company repaid the $15.0 million then drawn under our credit facility and terminated the facility.

2028 Notes

On August 22, 2008 we closed an offering of $60.0 million in 2028 Notes. Net proceeds from the offering were $57.3 million. The 2028 Notes are governed by an indenture, dated as of August 22, 2008, between us and U.S. Bank National Association, as trustee. The 2028 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 2028 Notes will mature on August 15, 2028, unless previously converted or repurchased in accordance with their terms prior to such date. The 2028 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 2028 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 2028 Notes, in whole or in part, at any time after August 15, 2013 for cash equal to the principal amount of the 2028 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 2028 Notes for cash at 100% of the principal amount of the 2028 Notes being purchased, plus any accrued and unpaid interest.

In March 2012, we entered into a note repurchase agreement with the holder of a majority in principal amount of the 2028 Notes. We used a portion of the proceeds from our offering of the 2019 Notes discussed below to purchase from this holder and another holder approximately 42.1% of the 2028 Notes for an aggregate purchase price of approximately $137.2 million. In addition, for a period of 90 days after March 12, 2012, the majority holder had the option to require us to purchase at the same price its remaining 2028 Notes, which represented approximately 37.1% of the 2028 Notes. This put option expired unexercised in June 2012. In December 2012 one of the holders of the 2028 Notes converted notes with a par value of $22.3 million under the terms of the note indenture, and received cash equal to the par value of the notes and interest on these notes through February 15, 2013, and 1.9 million shares of common stock.

The remaining outstanding 2028 Notes are convertible into approximately 1,351,000 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

2028 Notes, which represents a conversion price of approximately $9.25 per share, subject to adjustment under certain conditions. Holders of the 2028 Notes may convert their 2028 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 2028 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 2028 Notes, per $1,000 principal amount of the 2028 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 2028 Notes on such date; (3) if we enter into specified corporate transactions; or (4) upon a redemption notice. The first of these conditions was met as of December 31, 2012. The 2028 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.

Prior to March 2012, the 2028 Notes prohibited us 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. The 2015 Notes described below were "permitted debt" under the Indenture. In March 2012, the Company and holders of a majority in outstanding principal amount of the 2028 Notes amended the indenture to delete this prohibition.

2015 Notes

On June 3, 2010 we closed an offering of $345.0 million in 2015 Notes. Net proceeds from the offering were $334.2 million. The 2015 Notes are governed by an indenture, dated as of June 3, 2010, between us and U.S. Bank National Association, as trustee. The 2015 Notes bear interest at a rate of 2.75% per year, payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2010. The 2015 Notes will mature on May 15, 2015, unless previously converted or repurchased in accordance with their terms prior to such date. The 2015 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 2015 Notes, and (iii) effectively junior to any secured indebtedness to the extent of the value of the assets securing such indebtedness.

The 2015 Notes are convertible into approximately 7,439,000 shares of our common stock under certain circumstances prior to maturity at a conversion rate of 21.5592 shares per $1,000 principal amount of 2015 Notes, which represents a conversion price of approximately $46.38 per share, subject to adjustment under certain conditions. Holders may convert their 2015 Notes at their option on any day prior to the close of business on the business day immediately preceding the maturity date of May 15, 2015 only if one or more of the following conditions is satisfied: (1) during any fiscal quarter commencing after June 30, 2010, 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 2015 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 2015 Notes, per $1,000 principal amount of the 2015 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 2015 Notes on such date; or (3) if we enter into specified corporate transactions. None of these conditions had been met as of December 31, 2012. The 2015 Notes will be convertible, regardless of whether any of the foregoing conditions have been satisfied, on or after January 13, 2015 at any time prior to the close of business on the second scheduled trading day immediately preceding the stated maturity date of May 15, 2015. Upon conversion, we may pay cash, shares of our common stock or a combination of cash and stock, as determined by us at our discretion.

In connection with the issuance of the 2015 Notes, we entered into capped call transactions covering approximately 7,439,000 shares of our common stock. The capped call transactions have a strike price of $46.38 and a cap price of $62.44, and are exercisable when and if the 2015 Notes are converted. If upon conversion of the 2015 Notes, the price of our common stock is above the strike price of the capped calls, the counterparties will deliver shares

of our common stock and/or cash with an aggregate value approximately equal to the difference between the price of our common stock at the conversion date (as defined, with a maximum price for purposes of this calculation equal to the cap price) and the strike price, multiplied by the number of shares of our common stock related to the capped call transactions being exercised. We paid $44.3 million for these capped calls, and charged that amount to additional paid-in capital.

2019 Notes

On March 16, 2012 we closed an offering of $690.0 million in 2019 Notes. Net proceeds from the offering were approximately $668.3 million. The 2015 Notes are governed by an indenture, dated as of March 16, 2012 between the Company and U.S. Bank National Association, as trustee. The 2019 Notes bear interest at a rate of 1.50% per year, payable semiannually in arrears on March 15 and September 15 of each year, beginning on September 15, 2012. The 2019 Notes will mature on March 15, 2019, unless earlier converted or repurchased in accordance with their terms prior to such date. The 2019 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 them, and (iii) effectively junior to any secured indebtedness to the extent of the value of the assets securing such indebtedness.

The 2019 Notes are convertible into approximately 10,484,000 shares of our common stock under certain circumstances prior to maturity at a conversion rate of 15.1947 shares per $1,000 principal amount of 2019 Notes, which represents a conversion price of approximately $65.81 per share, subject to adjustment under certain conditions. Holders may convert their 2019 Notes at their option on any day prior to the close of business on the business day immediately preceding the maturity date of March 15, 2019 only if one or more of the following conditions is satisfied: (1) during any fiscal quarter commencing after June 30, 2012, 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 2019 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 2019 Notes, per $1,000 principal amount of the 2019 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 2019 Notes on such date; or (3) if we enter into specified corporate transactions. None of these conditions had been met as of December 31, 2012. The 2019 Notes will be convertible, regardless of whether any of the foregoing conditions have been satisfied, on or after November 9, 2018 at any time prior to the close of business on the second scheduled trading day immediately preceding the stated maturity date of March 15, 2019. Upon conversion, we may pay cash, shares of our common stock or a combination of cash and stock, as determined by us at our discretion.

In connection with the issuance of the 2019 Notes, we entered into convertible bond hedge transactions with certain counterparties covering approximately 10,484,000 shares of our common stock. The convertible bond hedge transactions have a strike price of $65.81 and are exercisable when and if the 2019 Notes are converted. If upon conversion of the 2019 Notes, the price of our common stock is above the strike price of the convertible bond hedge transactions, the counterparties will deliver shares of our common stock and/or cash with an aggregate value approximately equal to the difference between the price of our common stock at the conversion date and the strike price, multiplied by the number of shares of our common stock related to the convertible bond hedge transaction being exercised. We paid $167.0 million for these convertible bond hedge transactions and charged this to additional paid-in capital.

Simultaneously with entering into the convertible bond hedge transactions, we entered into privately negotiated warrant transactions whereby we sold the counterparties to these transactions warrants to acquire, subject to customary adjustments, approximately 10,484,000 shares of our common stock at a strike price of $85.31 per share, also subject to adjustment. We received $99.0 million for these warrants and credited this amount to additional paid-in capital.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In September 2011, the FASB issued ASU 2011-08, “Intangibles—Goodwill and Other” (“ASU 2011-08”). ASU 2011-08 amends current guidance to allow an entity to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. Under this amendment an entity would not be

required to calculate the fair value of a reporting unit unless the entity determines, based on a qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The provisions of ASU 2011-08 are effective for reporting periods beginning after December 15, 2011 and early adoption is permitted. We adopted ASU 2011-08 in the fourth quarter of 2011. There was no material impact to our consolidated financial position, results of operations or cash flows upon adoption of this guidance.

In July 2012, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2012-02 "Intangibles—Goodwill and Other (Topic 350) Testing Indefinite-Lived Intangible Assets for Impairment" ("ASU 2012-02"). Previous guidance required an entity to test indefinite-lived intangible assets for impairment, on at least an annual basis, by comparing the fair value of the asset with its carrying amount. If the carrying amount of the intangible asset exceeds its fair value, an entity should recognize an impairment loss in the amount of that excess. In accordance with the amendments in ASU 2012-02, an entity will have an option not to calculate annually the fair value of an indefinite-lived intangible asset if the entity determines that it is not more likely than not that the asset is impaired. The amendment permits an entity first to assess qualitative factors to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 and early adoption is permitted. We adopted ASU 2012-02 in the fourth quarter of 2012. There was no material impact to our consolidated financial position, results of operations or cash flows upon adoption of this guidance.

CAUTIONARY STATEMENT

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. The following statement highlights some of these risks. For more detail, see "Part II. Item 1A. Risk Factors" below.

Statements contained in this Form 10-Q that are not historical facts are or might constitute forward-looking statements under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Although we believe the expectations reflected in such forward-looking statements are based on reasonable assumptions, our expectations might not be attained. Forward-looking statements involve known and unknown risks that could cause actual results to differ materially from expected results. Factors that could cause actual results to differ materially from our expectations expressed in the report include, among others: our dependence on our first seven pharmaceutical products, particularly Xifaxan, and the uncertainty of market acceptance of our products; 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; intense competition, including from generics in an increasingly global market; the possible impairment of, or inability to obtain intellectual property rights and the costs of obtaining such rights from third parties in an increasingly global market; general economic conditions; our need to maintain profitability; the uncertainty of obtaining, and our dependence on, third parties to manufacture and sell our products; results of ongoing and any 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 and finished goods are denominated primarily in U.S. dollars and purchases denominated in currencies other than the U.S. dollar are insignificant. Additionally, our net assets denominated in currencies other than the U.S. dollar are insignificant and 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.

We have outstanding $12.5 million of 5.5% convertible senior notes due 2028, $345.0 million of 2.75% convertible senior notes due 2015 and $690.0 million of 1.5% convertible senior notes due 2019. The interest rates on these notes are fixed and therefore they do not expose us to risk related to rising interest rates.

In connection with the June 2010 offering of the 2015 Notes, we paid $44.3 million to purchase capped call options covering approximately 7,439,000 shares of our common stock. If the per share price of our common stock remains below $46.38, these call options will be worthless. If the per share price of our common stock exceeds $62.44, then to the extent of the excess, these call options will not provide us protection against dilution from conversion of the 2015 Notes.

In connection with the March 2012 offering of the 2019 Notes, we paid $167.0 million to purchase convertible bond hedge transactions covering approximately 10,484,000 shares of our common stock. If the per share price of our common stock remains below $65.81, these call options will be worthless. Simultaneously with entering into the convertible bond hedge transactions, we sold warrants to acquire, subject to customary adjustments, approximately 10,484,000 shares of our common stock at a strike price of $85.31 per share, also subject to adjustment. If the per share price of our common stock exceeds $85.31, then to the extent of the excess, these warrants will counter any benefit of the convertible bond hedges we purchased.

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

None.

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 Executive Vice President, 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 Executive Vice President, 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. 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 Chief Executive Officer and our Executive Vice President, 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, 2012.

The effectiveness of our internal control over financial reporting as of December 31, 2012, has been audited by Ernst & Young 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 2013 Annual Meeting of Stockholders scheduled to be held on June 13, 2013, 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 5605(c)(2)(A) of the Nasdaq listing standards, and the members of the Compensation Committee meet the standards set forth in Nasdaq Rule 5605 (d)(2)(A). The Board of Directors has also determined that John F. Chappell, Thomas W. D'Alonzo and William P. Keane are "audit committee financial experts" as defined in Item 407 (d)(5) 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., 8510 Colonnade Center Drive, Raleigh, NC 27615, Attn: General Counsel. In addition, you can find those codes on our website at www.salix.com/assets/pdf/about/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 2012," "—Outstanding Equity Awards at 2012 Fiscal Year End," "—Option Exercises and Stock Vested in 2012," "—Director Compensation For 2012," "—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, 2012 with respect to our equity compensation plans:

Plan Category	(a) Number of Securities to be issued Upon Exercise of Outstanding Options, Warrants and Rights, or Vesting of Restricted Shares	(b) Weighted Average Exercise Price of Outstanding Options, Warrants, Rights and Restricted Shares	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Related in Column (a))
Equity Compensation Plans Approved by Security Holders	2,351,821	$31.98	3,499,458
Equity Compensation Plans Not Approved by Security Holders	—	—	—
Total	2,351,821	$31.98	3,499,458

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" contained in the proxy statement.

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 Accounting 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:

2. Financial Statement Schedules

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

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
2.4*	Stock Purchase Agreement, dated as of April 22, 2009, by and between Oceana Therapeutics LLC and Q-Med AB	10-K	02/28/12	2.4	
2.5*	Stock Purchase Agreement, dated as of November 8, 2011, by and between Salix Pharmaceuticals, Inc. and Oceana Therapeutics, LLC	10-K	02/28/12	2.5	
3.1	Certificate of Incorporation, as amended.	10-Q	05/10/11	3.1	
3.4	Amended and Restated Bylaws.	8-K	09/30/10	3.4	
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	
4.3	Form of Convertible Senior Note due 2015.	S-3	05/27/10	4.1	
4.4	Form of Indenture for Convertible Senior Notes due 2015.	S-3	05/27/10	4.2	
4.5	First Supplemental Indenture dated March 14, 2012 by and between Salix Pharmaceuticals, Ltd. and U.S. Bank National Association for 5.5% Convertible Senior Notes due 2028.	8-K	03/16/12	4.3	
4.6	Indenture dated March 16, 2012 by and between Salix Pharmaceuticals, Ltd. and U.S Bank National Association for 1.5% Convertible Senior Notes due 2019.	8-K	03/16/12	4.4	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
4.7	Form of 1.5% Convertible Senior Note due 2019 (included in Exhibit 4.4).	8-K	03/16/12	4.5	
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	
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	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
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	
10.29.1*	Second Amendment to Lease dated February 11, 2011 between EOS Acquisition I LLC and Salix Pharmaceuticals, Inc.	10-Q	05/10/11	10.29.1	
10.29.2	Third Amendment to Lease dated October 18, 2011 between EOS Acquisition I LLC and Salix Pharmaceuticals, Inc	10-Q	08/09/11	10.29.2	
10.30*	License Agreement between Biorex Laboratories Limited and Glycyx Pharmaceuticals, Ltd. dated August 22, 2001.	10-Q	11/14/01	10.30	
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	
10.39*	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	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
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	
10.49	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	
10.53	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	
10.58*	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	
10.62*	License Agreement dated March 13, 2008 between Dr. Falk Pharma GmbH and Salix Pharmaceuticals, Inc.	10-Q	5/07/08	10.62	
10.64*	Collaboration Agreement between Napo Pharmaceuticals, Inc. and Salix Pharmaceuticals, Inc.	10-K	3/11/09	10.64	
10.65*	Manufacturing and Supply Agreement between Salix Pharmaceuticals, Inc. and Glenmark Pharmaceuticals Ltd.	10-K	3/11/09	10.65	
10.66*	Commercial Manufacturing Agreement between Salix Pharmaceuticals, Inc. and Catalent Pharma Solutions, LLC	10-Q	8/17/09	10.66	
10.67*	Development, Commercialization and License Agreement Between Lupin Ltd. and Salix Pharmaceuticals, Inc.	10-Q	11/09/09	10.67	
10.68*	Rifaximin Manufacturing and Supply Agreement Between Salix Pharmaceuticals, Inc. and Lupin Ltd.	10-Q	11/09/09	10.68	
10.68.1*	First Amendment to Rifaximin Manufacturing and Supply Agreement dated March 31, 2011 between Salix Pharmaceuticals, Inc. and Lupin Ltd.	10-Q	05/10/11	10.68.1	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.69	Confirmation for base capped call transaction dated as of May 27, 2010, between Bank of America, N.A. and the Company.	8-K	6/03/10	10.69	
10.70	Confirmation for additional capped call transaction dated as of June 2, 2010, between Bank of America N.A. and the Company.	8-K	6/03/10	10.70	
10.71*	Settlement Agreement dated August 27, 2010, by and among Salix Pharmaceuticals, Inc., Norgine B.V., Norgine Europe B.V., Novel Laboratories, Inc., and Actavis Inc.	10-Q	11/09/10	10.71	
10.72*	Sublicense Agreement dated August 27, 2010, by and among Salix Pharmaceuticals, Inc., Norgine B.V., Norgine Europe B.V., and Novel Laboratories, Inc.	10-Q	11/09/10	10.72	
10.73*	Supply Agreement dated August 27, 2010, by and among Salix Pharmaceuticals, Inc, Actavis Inc., and Novel Laboratories, Inc.	10-Q	11/09/10	10.73	
10.74*	First Amendment to License and Supply Agreement dated August 27, 2010, by and between Norgine B.V. and Salix Pharmaceuticals, Inc.	10-Q	11/09/10	10.74	
10.75*	Settlement Agreement dated September 29, 2010, by and among Salix Pharmaceuticals, Inc., CDC III, LLC, a general partnership of Craig Aronchick, William H. Lipshutz and Scott H. Wright, Novel Laboratories, Inc., and Actavis Inc.	10-Q	11/09/10	10.75	
10.76*	Sublicense Agreement dated September 29, 2010, by and among Salix Pharmaceuticals, Inc., CDC III, LLC, a general partnership of Craig Aronchick, William H. Lipshutz and Scott H. Wright, and Novel Laboratories, Inc.	10-Q	11/09/10	10.76	
10.77*	Supply Agreement dated September 29, 2010, by and between Salix Pharmaceuticals, Inc. and Novel Laboratories, Inc.	10-Q	11/09/10	10.77	
10.78*	Second Amendment to License Agreement dated September 29, 2010, by and among CDC III, LLC, a general partnership of Craig Aronchick, William H. Lipshutz and Scott H. Wright, and Salix Pharmaceuticals, Inc.	10-Q	11/09/10	10.78	
10.79*	License Agreement dated October 19, 2010 by and between Photocure ASA, a Norwegian corporation and Salix Pharmaceuticals, Inc.	10-Q	03/01/11	10.79	
10.80*	License Agreement dated February 3, 2011, between Salix Pharmaceuticals, Inc. and Progenics Pharmaceuticals, Inc., Progenics Pharmaceuticals Nevada, Inc. and Exelsior Life Sciences Ireland Limited	10-Q	05/10/11	10.80	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.81*	2010 Agreement Related to Progenics's MNTX In-License dated February 3, 2011, by and among Salix Pharmaceuticals, Inc., the University of Chicago, Progenics Pharmaceuticals, Inc. and Progenics Pharmaceuticals Nevada, Inc.	10-Q	05/10/11	10.81	
10.82*	Office Lease dated February 14, 2011 between Cornerstone Colonnade LLC and Salix Pharmaceuticals, Inc.	10-Q	05/10/11	10.82	
10.83*	Amended and Restated Development, Commercialization and License Agreement dated March 31, 2011 between Lupin Ltd. and Salix Pharmaceuticals, Inc.	10-Q	05/10/11	10.83	
10.84*	Finished Product Manufacturing and Supply Agreement dated March 31, 2011 between Salix Pharmaceuticals, Inc. and Lupin Ltd.	10-Q	05/10/11	10.84	
10.85*	Amended and Restated Manufacturing and Supply Agreement dated July 18, 2011, between Salix Pharmaceuticals, Inc. and Glenmark Pharmaceuticals Ltd.	10-Q	08/09/11	10.85	
10.86*	Agreement for Advance Against Commitment Fee dated July 18, 2011 between Salix Pharmaceuticals, Inc. and Glenmark Pharmaceuticals Ltd.	10-Q	08/09/11	10.86	
10.87*	License Agreement, dated as of June 2, 2009, by and between Q-Med AB and Q-Med Scandinavia Inc. (n/k/a Oceana Therapeutics, Inc.)	10-K	02/28/12	10.87	
10.88*	License Agreement, dated as of June 2, 2009, by and between Q-Med AB and Cetacea Limited (n/k/a Oceana Therapeutics Limited)	10-K	02/28/12	10.88	
10.89*	Supply Agreement, dated as of June 2, 2009, by and between Q-Med AB and Q-Med Scandinavia Inc. (n/k/a Oceana Therapeutics, Inc.)	10-K	02/28/12	10.89	
10.90	Supply Agreement, dated as of June 2, 2009, by and between Q-Med AB and Cetacea Limited (n/k/a Oceana Therapeutics Limited)	10-K	02/28/12	10.90	
10.91*	Manufacturing and Supply Agreement, dated as of October 20, 2010, by and between Oceana Therapeutics Limited and Bio Hospital AB	10-K	02/28/12	10.91	
10.92	Form of Letter Agreements relating to the Base Convertible Bond Hedge Transactions and the Additional Convertible Bond Hedge Transactions, each dated March 13, 2012, by and between Salix Pharmaceuticals, Ltd. and each of Bank of America N.A. and Royal Bank of Canada.	8-K	03/13/12	10.92	
10.93	Form of Letter Agreements relating to the Base Issuer Warrant Transactions and the Additional Issuer Warrant Transactions, each dated March 13, 2012 by and between Salix Pharmaceuticals, Ltd. and each of Bank of America N.A. and Royal Bank of Canada.	8-K	03/13/12	10.93	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.94	Note Repurchase Agreement dated March 12, 2012 by and between Salix Pharmaceuticals, Ltd. and 14159, L.P., 667, L.P. and Baker Brothers Life Sciences, L.P.	8-K	03/13/12	10.94	
10.95**	Amended and Restated License Agreement, dated August 6, 2012, with Alfa Wassermann S.p.A.	10-Q	11/08/12	10.95	
10.96**	EIR Supply Agreement, dated August 6, 2012, with Alfa Wassermann S.p.A.	10-Q	11/08/12	10.96	
10.97**	Amendment Number Two to Supply Agreement, dated August 6, 2012, with Alfa Wassermann S.p.A.	10-Q	11/08/12	10.97	
10.98**	Trademark License Agreement (Alfa to Salix), dated August 6, 2012, with Alfa Wassermann Hungary Kft.	10-Q	11/08/12	10.98	
10.99**	Trademark License Agreement (Salix to Alfa), dated August 6, 2012, with Alfa Wassermann S.p.A.	10-Q	11/08/12	10.99	
10.100**	Letter Amendment, dated September 5, 2012, with Alfa Wassermann S.p.A.	10-Q	11/08/12	10.100	
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
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
101	Financials in XBRL format				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

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: February 28, 2013	/s/ CAROLYN J. LOGAN Carolyn J. Logan President, Chief Executive Officer (Principal Executive Officer) and Director
Date: February 28, 2013	/s/ ADAM C. DERBYSHIRE Adam C. Derbyshire Executive Vice President, Finance & Administration and Chief Financial Officer (Principal Financial and Accounting Officer)
Date: February 28, 2013	/s/ THOMAS W. D'ALONZO Thomas W. D'Alonzo Chairman of the Board
Date: February 28, 2013	/s/ JOHN F. CHAPPELL John F. Chappell Director
Date: February 28, 2013	/s/ WILLIAM P. KEANE William P. Keane Director
Date: February 28, 2013	/s/ MARK A. SIRGO Mark A. Sirgo Director

SALIX PHARMACEUTICALS, LTD.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Salix Pharmaceuticals, Ltd internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Salix Pharmaceuticals, Ltd.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting appearing in Item 9A. Our responsibility is to express an opinion on the company's internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

In our opinion, Salix Pharmaceuticals, Ltd. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Salix Pharmaceuticals, Ltd. as of December 31, 2012 and 2011, and the related consolidated statements of comprehensive income (loss), stockholders' equity, and cash flows for the two years in the period ended December 31, 2012 of Salix Pharmaceuticals, Ltd. and our report dated February 28, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Raleigh, North Carolina
February 28, 2013

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Salix Pharmaceuticals, Ltd. as of December 31, 2012 and 2011, and the related consolidated statements of comprehensive income (loss), stockholders' equity, and cash flows for the two years in the period ended December 31, 2012. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(2). 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 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 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 financial position of Salix Pharmaceuticals, Ltd. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2012, 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Salix Pharmaceuticals, Ltd.'s internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Raleigh, North Carolina
February 28, 2013

Report of Independent Registered Public Accounting Firm

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

In our opinion, the consolidated balance sheet as of December 31, 2010 and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for the year ended December 31, 2010 present fairly, in all material respects, the financial position of Salix Pharmaceuticals, Ltd. at December 31, 2010, and the results of its operations and its cash flows for the year ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule for the year ended December 31, 2010 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina
March 1, 2011

SALIX PHARMACEUTICALS, LTD.

Consolidated Balance Sheets

	December 31, 2012	December 31, 2011
	(U.S. dollars, in thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 751,006	$ 292,814
Accounts receivable, net	268,239	151,207
Inventory	90,533	49,205
Deferred tax assets	57,050	50,519
Prepaid expenses and other current assets	21,753	23,350
Total current assets	1,188,581	567,095
Property and equipment, net	27,878	29,540
Goodwill	180,905	180,905
Product rights and intangibles, net	441,506	504,839
Other assets	35,914	21,876
Total assets	$1,874,784	$1,304,255
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 31,110	$ 21,142
Accrued liabilities	81,062	80,398
Income taxes payable	8,507	11,039
Reserve for product returns, rebates and chargebacks	140,191	97,879
Current portion of capital lease obligations	50	187
Total current liabilities	260,920	210,645
Long-term liabilities:		
Convertible senior notes	857,209	340,283
Lease incentive obligation	7,554	6,235
Acquisition-related contingent consideration	103,500	119,698
Deferred tax liabilities	64,255	69,924
Other long-term liabilities	20,845	7,833
Total long-term liabilities	1,053,363	543,973
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, issuable in series, none outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized, 60,918,391 and 59,205,259 shares issued and outstanding at December 31, 2012 and 2011, respectively	61	59
Additional paid-in-capital	631,364	685,315
Accumulated other comprehensive income (loss)	456	(111)
Accumulated deficit	(71,380)	(135,626)
Total stockholders' equity	560,501	549,637
Total liabilities and stockholders' equity	$1,874,784	$1,304,255

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

SALIX PHARMACEUTICALS, LTD.

Consolidated Statements of Comprehensive Income (Loss)

	Year Ended December 31,		
	2012	2011	2010
	(U.S. dollars, in thousands, except per share data)		
Revenues:			
Net product revenues	$735,444	$540,488	$336,973
Costs and expenses:			
Cost of products sold (excluding $45,351, $10,908 and $10,370 in amortization of product rights and intangible assets for the years ended December 31, 2012, 2011 and 2010, respectively)	124,597	95,369	68,677
Amortization of product rights and intangible assets	45,351	10,908	10,370
Intangible impairment charges	41,600	—	34,656
Research and development	123,234	104,350	73,346
Selling, general and administrative	258,187	186,988	156,101
Change in acquisition-related contingent consideration	(29,598)	27,000	—
Total costs and expenses	563,371	424,615	343,150
Income (loss) from operations	172,073	115,873	(6,177)
Loss on extinguishment of debt	(15,580)	—	—
Interest expense	(55,518)	(32,121)	(20,652)
Interest and other income	10,853	2,349	2,626
Income (loss) before provision for income tax	111,828	86,101	(24,203)
Income tax (expense) benefit	(47,582)	1,298	(2,858)
Net income (loss)	$ 64,246	$ 87,399	$ (27,061)
Net income (loss) per share, basic	$ 1.09	$ 1.49	$ (0.47)
Net income (loss) per share, diluted	$ 1.01	$ 1.44	$ (0.47)
Shares used in computing net loss per share, basic	58,747	58,718	57,300
Shares used in computing net loss per share, diluted	63,699	65,483	57,300
Comprehensive income (loss)	$ 64,813	$ 87,288	$ (27,061)

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	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	(U.S. dollars, in thousands, except share amounts)					
Balance at December 31, 2009	56,245,759	56	565,932	—	(195,964)	370,024
Issuance of common stock upon exercise of stock options	1,140,862	1	17,120	—	—	17,121
Payments related to net settlements of stock-based awards	—	—	(2,952)	—	—	(2,952)
Issuance of common stock upon vesting of restricted stock	753,320	1	(1)	—	—	—
Purchase of call options	—	—	(44,333)	—	—	(44,333)
Issuance of convertible debt	—	—	76,923	—	—	76,923
Income tax expense from non-qualified stock option exercises	—	—	2,257	—	—	2,257
Compensation expense related to restricted stock awards	—	—	9,940	—	—	9,940
Net loss	—	—	—	—	(27,061)	(27,061)
Balance at December 31, 2010	58,139,941	58	624,886	—	(223,025)	401,919
Issuance of common stock upon exercise of stock options	370,874	—	5,396	—	—	5,396
Payments related to net settlement of stock-based awards	—	—	(3,030)	—	—	(3,030)
Issuance of common stock upon vesting of restricted stock	694,444	1	(1)	—	—	—
Income tax benefit from non-qualified stock option exercises	—	—	42,272	—	—	42,272
Foreign translation adjustments	—	—	—	(111)	—	(111)
Compensation expense related to restricted stock awards	—	—	15,792	—	—	15,792
Net income		—	—	—	87,399	87,399
Balance at December 31, 2011	59,205,259	59	685,315	(111)	(135,626)	549,637
Issuance of common stock upon exercise of stock options	850,204	1	8,531	—	—	8,532
Payments related to net settlement of stock-based awards	—	—	(2,926)	—	—	(2,926)
Issuance of common stock upon vesting of restricted stock	536,981	—	—	—	—	—
Income tax benefit from non-qualified stock option exercises	—	—	10,971	—	—	10,971
Foreign translation adjustments	—	—	—	567	—	567
Issuance of convertible debt, net of tax	—	—	92,153	—	—	92,153
Sale of warrants	—	—	98,994	—	—	98,994
Purchase of convertible note hedge, net of tax			(98,702)			(98,702)
Repurchase of common stock	(1,534,800)	(1)	(74,821)	—	—	(74,822)
Compensation expense related to restricted stock awards	—	—	21,202	—	—	21,202
Extinguishment of 2028 Notes	—	—	(184,507)	—	—	(184,507)
Issuance of common stock upon conversion of 2028 Notes	1,860,747	2	75,154	—	—	75,156
Net income	—	—	—	—	64,246	64,246
Balance at December 31, 2012	60,918,391	$ 61	$ 631,364	$ 456	$ (71,380)	$ 560,501

Other comprehensive income (loss) is composed entirely of adjustments resulting from the translation of the financial statements of the Company's foreign subsidiary into U.S. dollars.

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

SALIX PHARMACEUTICALS, LTD.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2012	2011	2010
	(U.S. dollars, in thousands)		
Cash Flows from Operating Activities			
Net income (loss)	$ 64,246	$ 87,399	$ (27,061)
Adjustments to reconcile net income to net cash provided by operating activities:			
Loss/(gain) on disposal of property and equipment	233	534	(59)
Depreciation and amortization	52,150	15,247	13,315
Intangible impairment charge	41,600	—	34,656
Amortization of debt discount	31,655	17,278	10,124
Loss on extinguishment of debt	12,842	—	—
Gain on adjustment of put option to fair market value	(9,325)	—	—
Stock-based compensation expense	21,202	15,792	9,940
Deferred income taxes	(7,460)	(76,239)	—
Change in acquisition-related contingent consideration	(29,598)	27,000	—
Changes in operating assets and liabilities:			
Accounts receivable, inventory, prepaid expenses and other assets	(154,696)	(60,427)	(32,119)
Accounts payable, accrued and other liabilities	22,431	55,327	(11,775)
Reserve for product returns, rebates and chargebacks	42,312	37,239	28,497
Net cash provided by operating activities	87,592	119,150	25,518
Cash Flows from Investing Activities			
Purchases of property and equipment	(5,370)	(26,139)	(5,572)
Business acquisitions, net of cash acquired	(10,000)	(362,482)	—
Decrease in restricted cash	—	—	15,000
Net cash provided (used) by investing activities	(15,370)	(388,621)	9,428
Cash Flows from Financing Activities			
Principal payments on credit facility	—	—	(15,000)
Proceeds from convertible senior note offering	690,000	—	345,000
Debt issuance costs	(21,159)	—	(10,839)
Purchase of call options	(166,980)	—	(44,333)
Proceeds from sale of warrants	98,994	—	—
Repurchase of common stock	(74,822)	—	—
Extinguishment of 2028 convertible senior notes	(156,851)	—	—
Principal payments on capital lease obligations	(138)	(272)	(682)
Excess tax benefit from stock-based compensation	10,971	42,272	2,257
Payments related to net settlement of stock-based awards	(2,926)	(3,030)	(2,952)
Proceeds from issuance of common stock upon exercise of stock awards	8,532	5,396	17,121
Net cash provided by financing activities	385,621	44,366	290,572
Effect of exchange rate changes on cash	349	(111)	—
Net increase (decrease) in cash and cash equivalents	458,192	(225,216)	325,518
Cash and cash equivalents at beginning of year	292,814	518,030	192,512
Cash and cash equivalents at end of year	$ 751,006	$ 292,814	$518,030
Supplemental Disclosure of Cash Flow Information			
Cash paid (refunded) for income taxes	$ 33,811	$ 14,855	$ (1,587)
Cash paid for interest	$ 17,239	$ 12,788	$ 7,655
Acquisition-related contingent consideration	$ 103,500	$ 119,698	$ —

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

(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 and medical devices 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 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) ACQUISITION OF OCEANA

Description of the Transaction

On December 20, 2011, the Company acquired all of the outstanding stock of Oceana Therapeutics, Inc. (Oceana) for an estimated consideration of approximately $342.8 million. The Company accounted for the merger as a business combination under the purchase method of accounting. Under this method, the assets and liabilities of Oceana are recorded as of the completion of the merger, at their respective fair values, and consolidated with the Company's assets and liabilities. The results of operations of Oceana were consolidated beginning on the date of the merger.

Fair Value of Consideration Transferred and Purchase Price Allocation

The following table summarizes the fair value of the consideration given and the allocation of the purchase price to the assets acquired and liabilities as of the acquisition date (in thousands):

	December 20, 2011 (as initially reported)	Measurement Period Adjustments	December 20, 2011 (as adjusted
Fair Value of Purchase Consideration			
Cash paid for Oceana's outstanding shares	$ 303,088	$ —	$303,088
Acquisition-related contingent consideration	39,698	—	39,698
Total consideration	$ 342,786	$ —	$342,786
Purchase Price Allocation			
Identifiable intangible assets at fair value	$ 338,170	—	$338,170
Deferred tax liability related to intangible assets acquired	(101,771)	6,127	(95,644)
Goodwill	101,775	(6,127)	95,648
Cash	606	—	606
Accounts receivable, net	6,577	—	6,577
Inventory, net	2,092	—	2,092
Property and equipment, net	407	—	407
Restricted cash	100	—	100
Other assets	660	—	660
Accounts payable	(1,804)	—	(1,804)
Accrued liabilities	(4,026)	—	(4,026)
	$ 342,786	$ —	$342,786

Actual and Pro Forma Impact of Acquisition

The following table presents information for Oceana that is included in Salix's consolidated statements of comprehensive income (loss) from the acquisition date, December 20, 2011, through December 31, 2011 (in thousands):

Net product revenues	$949
Net income	$ 6

The following table presents supplemental pro forma information as if the acquisition of Oceana had occurred on January 1, 2010 for the years ended December 31, 2011 and 2010 (in thousands):

	Unaudited Pro Forma Consolidated Results Year ended December 31,	
	2011	2010
Net product revenues	$574,999	$368,560
Net income (loss)	$ 55,592	$ (61,482)

The unaudited pro forma consolidated results were prepared using the acquisition method of accounting and are based on the historical financial information of Salix and Oceana, reflecting both in 2011 and 2010, Salix and Oceana results of operations for a 12-month period. The historical financial information has been adjusted to give effect to the pro forma events that are: (i) directly attributable to the acquisition: (ii) factually supportable; and (iii) expected to have a continuing impact on the combined results. The unaudited pro forma consolidated results are not necessarily indicative of what the consolidated results of operations actually would have been had the Company completed the acquisition on January 1, 2010. In addition, the unaudited pro forma consolidated results do not purport to project the future results of operations of the combined company nor do they reflect the expected realization of any cost savings associated with the acquisition. The unaudited pro forma consolidated results reflect primarily the following pro forma adjustments:

- Elimination of Oceana's historical intangible asset amortization expense (approximately $10.9 million in the pre-acquisition period in 2011 and $9.5 million in 2010);
- Additional amortization expense (approximately $33.8 million in 2011 and 2010) related to the fair value of identifiable intangible assets acquired; and
- Elimination of the change in contingent consideration (approximately $5.1 million in 2011 and $1.6 million in 2010) related to acquisition-related contingent consideration previously recorded on Oceana's financial statements.

(3) 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 of assets and liabilities reported at the date of the financial statements, the disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses recognized during the reporting periods. On an ongoing basis, the Company evaluates its estimates, including but not limited to those related to product returns, rebates, chargebacks, collectability of receivables, inventory, intangible assets, income taxes and contingencies and litigation. Actual results could differ materially from those estimates.

Revenue Recognition

The Company recognizes revenue when it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (a) persuasive evidence of an arrangement exists; (b) delivery has

occurred or services have been rendered; (c) the Company's price to the buyer is fixed or determinable; and (d) collectability is reasonably assured.

The Company recognizes revenue from sales transactions where the buyer has the right to return the product at the time of sale only if (1) the Company's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the Company, or the buyer is obligated to pay the Company and the obligation is not contingent on resale of the product, (3) the buyer's obligation to the Company 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 any provided by the Company, (5) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated. The Company recognizes revenues for product sales at the time title and risk of loss are transferred to the customer, which is generally at the time products are shipped. The Company's net product revenue represents the Company's total revenues less allowances for customer credits, including estimated discounts, rebates, chargebacks and product returns.

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

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

In its analyses, the Company uses prescription data purchased from a third-party data provider to develop estimates of historical inventory channel pull-through. The Company utilizes an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, management 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. The Company regularly adjusts internal forecasts that are utilized to calculate the estimated number of months in the channel 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. Adjustments to estimates are recorded in the period when significant events or changes in trends are identified.

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, chargebacks and promotional programs were $103.8 million and $69.2 million as of December 31, 2012 and 2011, respectively. These allowances reflect an estimate of the Company's liability for items such as rebates due to various governmental organizations under the Medicare/Medicaid regulations, rebates due to managed care organizations under specific contracts and chargebacks due to various organizations purchasing 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 $36.4 million and $28.7 million as of December 31, 2012 and 2011, respectively. These allowances reflect an estimate of the Company's liability for products that may be returned by the original purchaser in accordance with the Company's stated return policy. The Company estimates its liability for product returns at each reporting period based on historical return rates, 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 and also reviews prior period activity to ensure that the Company's methodology is still reasonable.

The Company's provision for revenue-reducing items such as rebates, chargebacks, and product returns as a percentage of gross product revenue in the years ended December 31, 2012, 2011 and 2010 was 15.7%, 14.6% and 14.9% for rebates, chargebacks and discounts and was 2.3%, 3.9% and 2.9% for product returns, respectively.

During the second quarter of 2010 the Company recognized product revenue related to initial shipments to wholesalers of Xifaxan 550mg, which the FDA approved on March 24, 2010 for reduction in risk of overt hepatic encephalopathy, or HE, recurrence in patients 18 years of age or older, and launched to physicians in May 2010. Based on our historical experience with Xifaxan 200mg, which the Company distributes through the same distribution channels and is prescribed by the same physicians as Xifaxan 550mg, we have the ability to estimate returns for Xifaxan 550mg and therefore recognized revenue upon shipment to the wholesalers.

During the second quarter of 2011, the Company began recognizing product revenue related to shipments to wholesalers of Relistor, which the Company acquired from Progenics Pharmaceuticals, Inc. in February 2011. Based on historical experience with Relistor obtained from Progenics, and historical experience with the Company's products, specifically Xifaxan 200mg, Xifaxan 500mg and Apriso, which the Company distributes through the same distribution channels and are prescribed by the same physicians as Relistor, management has the ability to estimate returns for Relistor and therefore recognized revenue upon shipment to the wholesalers.

In December 2011, the Company acquired an exclusive worldwide license to Solesta and Deflux with the completion of its acquisition of Oceana Therapeutics, Inc. Solesta and Deflux are medical devices that the Company sells to specialty distributors who then sell the products to end users, primarily hospitals, surgical centers and physicians. The specialty distributors generally do not purchase these products until an end user is identified. Based on historical experience with these products obtained from Oceana, and historical experience with the Company's products, specifically Xifaxan 200mg, Xifaxan 550mg and Apriso, which are prescribed by the same physicians as

Solesta, management has the ability to estimate returns for Solesta and Deflux and therefore recognized revenue upon shipment to the specialty distributors.

Research and Development

The Company expenses research and development costs, both internal and externally contracted, as incurred. For nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities, the Company initially capitalizes the advance payment. The Company then recognizes such amounts as an expense as the related goods are delivered or the related services are performed. At December 31, 2012 and 2011, the net liability related to on-going research and development activities was $14.1 million and $8.0 million, respectively.

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, 2012, 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.

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. The allowance for uncollectible accounts at December 31, 2012 and 2011 was $2.5 million and $2.0 million, respectively. As a result of the Company's acquisition of Oceana in December 2011, at December 31, 2012 and 2011, the allowance included $0.5 million and $0.4 million related to $8.9 million and $5.6 million, respectively, of receivables from various institutions within and outside of the United States.

Financial Instruments, Recurring and Nonrecurring Fair Value Measurements

Recurring Fair Value Measurements

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, approximated their fair values as of December 31, 2012 and 2011 due to the short-term nature of these financial instruments and are considered Level 1 investments. Level 1 investments are investments where there are quoted prices in active markets available for identical assets or liabilities. Accounts receivable, accounts payable, accrued liabilities and capital lease obligations approximated their fair values at December 31, 2012 and 2011 due to the short-term nature of these financial instruments.

The Company's convertible senior notes are considered Level 2 instruments, which are defined as those with significant other observable inputs. The fair value of the convertible senior notes was estimated using a Black-Scholes model incorporating the period-ending price of the Company's common stock and other inputs.

The fair value of the contingent consideration liability, consisting of future potential milestone payments related to the Oceana, Progenics and Alfa Wassermann EIR acquisitions was $103.5 million and $119.7 million as December 31, 2012 and 2011, respectively. The Company considers this liability a Level 3 instrument in the fair value hierarchy

which is defined as one with significant unobservable inputs. The Company determined fair values based on the income approach using probability-weighted discounted cash flows that included probability assessments of occurrence of triggering events appropriately discounted considering the uncertainties associated with the obligation, calculated in accordance with the terms of the acquisition agreement based on management's forecasts, and Monte-Carlo simulation models. The most significant unobservable inputs are the probability of receiving FDA approval for the relevant compounds and the subsequent commercial success of these compounds, if approved. The fair value of the related contingent consideration would be minimal if a compound does not receive FDA approval. The Company reviews the fair value of contingent consideration quarterly or whenever events or changes in circumstances occur that indicate there has been a change in the fair value.

The following table summarizes the activity related to the Company's contingent consideration liability for the years ended December 31:

	2012	2011
Balance at January 1	$119,698	$ —
Increase related to Progenics acquisition	—	80,000
Increase related to Oceana acquisition	—	39,698
Increase related to Alfa Wassermann EIR acquisition	13,400	—
Decrease related to Relistor OIC Chronic Pain indication	(33,000)	—
Other changes in contingent consideration value	3,402	—
Balance at December 31	$103,500	$119,698

Nonrecurring Fair Value Measurements

The fair value of the put option granted to the majority holder of the Company's 2028 Notes, a Level 3 instrument in the fair value hierarchy which is defined as one with significant unobservable inputs, was $5.6 million at March 31, 2012. The Company determined the fair value based on a Black-Scholes model incorporating the period-ending price of the Company's common stock and other inputs. The put option expired unexercised in June 2012.

The Company's non-financial assets, such as intangible assets and property and equipment are measured at fair value when there is an indicator of impairment and recorded at fair value only when an impairment charge is recognized. As discussed below under "Intangible Assets and Goodwill", the Company reassessed the value of the indefinite lived intangible asset related to methylnaltrexone bromide injection for subcutaneous use for the treatment of opioid-induced constipation, or OIC, in adult patients with chronic, non-cancer pain and recorded a non-cash charge to earnings of $41.6 million in the three-month period ended September 30, 2012. The Company determined the fair value of the indefinite lived intangible asset using a discounted cash flow approach, which contains significant unobservable inputs and therefore is considered a Level 3 fair value measurement. The unobservable inputs in the analysis included future cash flow projections and a discount rate.

Inventories

The Company states raw materials, work-in-process and finished goods inventories 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 measures inventory adjustments as the difference between the cost of the inventory and estimated market value based upon assumptions about future demand and charged to the provision for inventory, which is a component of cost of sales. At the point of the loss recognition, the Company establishes a new, lower-cost basis for that inventory, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

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 3 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. At December 31, 2012 and 2011, there were no amounts included in inventory related to pre-approval inventory.

Inventory at December 31, 2012 consisted of $42.9 million of raw materials, $14.8 million of work-in-process, and $32.8 million of finished goods. Inventory at December 31, 2011 consisted of $28.2 million of raw materials, $9.2 million of work-in-process, and $11.8 million of finished goods.

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.

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 finite lived intangible assets as an expense in its consolidated statements of comprehensive income (loss) over the estimated economic useful life of the related assets. Finite lived intangible assets consist primarily of product rights for currently marketed products and are amortized over their expected economic life. The Company accounts for acquired in-process research and development as indefinite lived intangible assets until regulatory approval or discontinuation. The Company assesses the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value might not be recoverable. The Company believes that the following factors could trigger an impairment review: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business; approval of generic products; 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 and indefinite lived intangibles for impairment on an annual basis in the fourth quarter, 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. As discussed below, the Company reassessed the value of the indefinite lived intangible asset related to methylnaltrexone bromide injection for subcutaneous use for the treatment of opioid-induced constipation, or OIC, in adult patients with chronic, non-cancer pain and recorded a non-cash charge to earnings of $41.6 million in the three-month period ended September 30, 2012. At December 31, 2012 there was no impairment to goodwill.

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

	2012				2011			
	Gross Amount	Accumulated Amortization	Foreign Exchange Translation	Net Carrying Value	Gross Amount	Accumulated Amortization	Foreign Exchange Translation	Net Carrying Value
Goodwill	$180,905	$ —	$—	$180,905	$180,905	$ —	$—	$180,905
Finite lived intangible assets	490,367	104,679	218	385,906	490,367	59,328	—	431,039
Indefinite lived intangible assets	55,600	—	—	55,600	73,800	—	—	73,800
Total	$726,872	$104,679	$218	$622,411	$745,072	$59,328	$—	$685,744

The weighted-average remaining life of our finite lived intangible assets was nine years and eleven years at December 31, 2012 and 2011, respectively.

The following table summarizes the activity related to the Company's goodwill:

Balance at January 1, 2011	$ 85,257
Increase related to Oceana acquisition	101,775
Balance at December 31, 2011, as initially reported	$187,032
Measurement period adjustment for Oceana acquisition	(6,127)
Balance at December 31, 2011, revised and December 31, 2012	$180,905

The Company recorded goodwill of $101.8 million in connection with the Oceana acquisition in December 2011, which was decreased by $6.1 million in 2012, upon completion of purchase accounting . The measurement period adjustments were primarily related to adjustment related to deferred tax liability balances.

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, 2012, 2011 and 2010 was $45.4 million, $10.9 million and $10.4 million, respectively. Estimated amortization expense related to intangible assets existing as of December 31, 2012 is approximately $45.4 million annually for each of the succeeding five years.

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, 2012 and 2011, accumulated amortization for the Azasan intangible was $1.8 million and $1.6 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, 2012 and 2011, accumulated amortization for the King product intangibles was $11.0 million and $9.7 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 InKine product rights and related intangibles were being amortized over an average period of 14 years, which the Company believed was an appropriate amortization period due to the product's patent protection and the estimated economic lives of the product rights and related intangibles. In September 2010, the Company entered into a Sublicense Agreement which granted Novel Laboratories, Inc. a license under the patents covering OsmoPrep such permitting Novel to launch a generic OsmoPrep on November 16, 2019. As a result of this agreement the amortization period was adjusted prospectively, and the remaining net book value of the intangible asset will be amortized through November 16, 2019, which is the Company's revised estimate of its remaining economic life. The Company assessed whether there was an impairment to the carrying value of the related intangible asset due to its reduced economic life and determined that there was no impairment. At December 31, 2012 and 2011, accumulated amortization for the InKine intangibles was $20.4 million and $18.1 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. Pursuant to the terms of the Agreement, Salix paid Norgine milestone payments of $15.0 million in August 2006, $5.0 million in December 2008 and $5.0 million in December 2009. The Company was amortizing these milestone payments over a period of 17.3 years through 2022, which the Company believed was an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. In August 2010 the Company entered into a Sublicense Agreement that granted Novel Laboratories, Inc. a license to the patents covering MoviPrep permitting Novel to launch a generic MoviPrep on September 24, 2018. As a result of this agreement the amortization period was adjusted prospectively, and the remaining net book value of the intangible asset will be amortized through September 24, 2018, which is the Company's revised estimate of its remaining economic life. The Company assessed whether there was an impairment to the carrying value of the related intangible asset due to its reduced economic life and determined that there was no impairment. At December 31, 2012 and 2011, accumulated amortization for the MoviPrep intangible was $11.5 million and $9.2 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 Company fully allocated the purchase price to product rights and related intangibles, and it is being amortized over a period of 15 years. Although Pepcid and Diuril do not have patent protection, the Company believes 15 years was an appropriate amortization period based on established product history and management experience. In May 2010, the FDA approved a generic famotidine oral suspension product, and the Company launched an authorized generic famotidine product. In June 2010 the FDA approved another generic famotidine oral suspension product. As a result of these events, the Company assessed whether there was an impairment to the carrying value of the related intangible asset. Based on this analysis, the Company recorded a $30 million impairment charge to reduce the carrying value of the intangible asset to

its estimated fair value during the three-month period ended June 30, 2010. At December 31, 2012 and 2011, accumulated amortization for the Merck products was $15.1million and $14.0 million, respectively and the carrying value was $9.9 million and $11.0 million at December 31, 2011 and 2012, 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 $8.0 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, 2012 and 2011, accumulated amortization for the Apriso intangible was $3.5 million and $2.7 million, respectively.

In September 2007, the Company acquired the exclusive, worldwide right to sell metoclopramide-Zydis® (trade name Metozolv) from Wilmington Pharmaceuticals, LLC. On September 8, 2009 the FDA granted marketing approval for Metozolv™ ODT (metoclopramide HCl) 5 mg and 10 mg orally disintegrating tablets. Metozolv ODT is indicated for the relief of symptomatic gastroesophageal reflux or short-term (4-12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy and diabetic gastroparesis or the relief of symptoms in adults associated with acute and recurrent diabetic gastroparesis. In October 2009, the Company made a $7.3 million milestone payment to Wilmington. The Company was amortizing this milestone payment over a period of eight years, which the Company believed was an appropriate amortization period due to the product's patent protection and the estimated economic life of the related intangible. On November 3, 2010, the Company received a paragraph IV notification from Novel stating that Novel had filed an ANDA application to seek approval to market a generic version of Metoclopramide Hydrochloride ODT, 5 mg and 10 mg. The notification letter asserted non-infringement of U.S. Patent No. 6,413,549 (the '549 patent). Upon examination of the relevant sections of the ANDA, the Company concluded that the '549 patent would not be enforced against Novel Laboratories. As a result of this event, the Company assessed whether there was an impairment to the carrying value of the related intangible asset. Based on this analysis, the Company recorded a $4.6 million impairment charge to reduce the carrying value of the intangible asset to its estimated fair value during the three-month period ended December 31, 2010. At December 31, 2012 and 2011 accumulated amortization for the Metozolv intangible was $2.6 million and $1.9 million, respectively and the carrying value was $0.0 million and $0.7 million at December 31, 2012 and 2011, respectively.

In February 2011, the Company acquired an exclusive worldwide license to develop and commercialize the products containing methylnaltrexone bromide, or the MNTX Compound, marketed under the name Relistor®, from Progenics Pharmaceuticals, Inc. (except in Japan, where Ono Pharmaceutical Co. Ltd. has previously licensed the subcutaneous formulation of the drug from Progenics) and a non-exclusive license to manufacture the MNTX Compound and products containing that compound in the same territory. Relistor Subcutaneous Injection is indicated for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. The Company paid Progenics an up-front license fee payment of $60.0 million. The Company also agreed to pay development milestone payments of up to $90.0 million contingent upon achieving specified regulatory approvals and commercialization milestone payments of up to $200.0 million contingent upon achieving specified targets for net sales. The Company must pay Progenics 60% of any revenue received from sublicensees in respect of any country outside the United States. Additionally, the Company must pay Progenics royalties based on a percentage ranging from the mid- to high-teens of net sales by the Company and its affiliates of any product containing the MNTX Compound.

The Company accounted for the Progenics transaction as a business combination under the acquisition method of accounting. Under the acquisition method of accounting, the Company recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in its consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the assets acquired was $113.0 million, including the Company's estimate

of the fair value of the contingent consideration related to the transaction discussed above of $53.0 million which is included as a long-term liability on the consolidated balance sheet. The Company determined this liability amount using a probability-weighted discounted cash flow model based on the current regulatory status of the methylnaltrexone bromide development programs. The Company assesses the fair value of the contingent consideration quarterly, or whenever events or changes in circumstances indicate that the fair value may have changed, primarily as a result of clinical or regulatory results in the related in-process development programs. In December 2011, the Company announced positive Phase 3 data from the OIC Oral development program. Based on this information, the Company reassessed the fair value of the contingent consideration and recorded a $27.0 million increase in the contingent consideration and a corresponding charge to earnings in the fourth quarter of 2011. At December 31, 2012 and 2011, accumulated amortization for the intangible related to the currently approved indication for Relistor was $4.6 million and $2.0 million, respectively.

On July 27, 2012 the Company received a Complete Response Letter, or CRL, from the FDA following its review of a Supplemental New Drug Application (sNDA) for methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in adult patients with chronic, non-cancer pain. The CRL requested additional clinical data. In October 2012 the Company and Progenics held an End-of-Review meeting with the Division of Gastroenterology and Inborn Errors Products to better understand the contents of the CRL. Based on the results of this meeting, the Company reassessed the value of the indefinite lived intangible asset related to methylnaltrexone bromide injection for subcutaneous use for the treatment of OIC in chronic non-cancer pain and recorded a non-cash charge to earnings of $41.6 million in the three-month period ended September 30, 2012. Based on these events, the Company reassessed the fair value of the contingent consideration related to the Progenics transaction and recorded a $33.0 million decrease in the contingent consideration and a corresponding non-cash charge to earnings in the three-month period ended September 30, 2012. The Company is currently evaluating the oral OIC development program and currently believes it will continue this program. However, additional information and additional guidance from the FDA could result in the termination of the oral OIC development program, which would result in impairment of the related intangible asset and a decrease in the related contingent consideration.

In December 2011, the Company completed its acquisition of Oceana Therapeutics, Inc. for a purchase price of approximately $303 million. Under license agreements and a related stock purchase agreement with Q-Med acquired with this acquisition, the Company is obligated to pay development milestone payments of up to $45.0 million contingent upon achieving specified targets for net sales. Additionally, the Company must pay low double-digit royalties under these license agreements based on a percentage of net sales of these products by the Company and its affiliates.

The Company accounted for the Oceana transaction as a business combination under the acquisition method of accounting. Under the acquisition method of accounting, the Company recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in its consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the assets acquired was approximately $342.8 million, including the Company's estimate of the fair value of the contingent consideration related to the transaction discussed above of $39.7 million which is included as a long-term liability on the consolidated balance sheet. The Company determined this liability amount using a probability-weighted discounted cash flow model. The Company assesses the fair value of the contingent consideration quarterly, or whenever events or changes in circumstances indicate that the fair value may have changed, primarily as a result of significant changes in our forecast of net sales for Solesta. At December 31, 2012 accumulated amortization for the Deflux intangible was $4.7 million and $29.0 million for the Solesta intangible.

In August 2012 the Company amended its 1996 License Agreement with Alfa Wassermann to develop rifaximin. The new agreement provides the Company with an exclusive license to develop and commercialize rifaximin products for travelers' diarrhea (TD), hepatic encephalopathy (HE) or irritable bowel syndrome (IBS) in the United States and Canada. The Company is obligated to pay Alfa royalties, at the same range of rates as under the previous agreement, on

net sales of such products. In addition, the Restated Agreement provides the Company with an exclusive license to develop and commercialize rifaximin products for Crohn's disease in the United States and Canada and a non-exclusive license to develop such products worldwide. The Company paid Alfa a non-refundable upfront fee of $10.0 million in August 2012, and is obligated to make a $25.0 million milestone payment upon receipt of marketing authorization in the United States for an extended intestinal release, or EIR, formulation product for CD, and additional milestones based on net sales of EIR formulation products for CD of up to $200.0 million. In addition, the Company is required to pay Alfa royalties on sales of rifaximin products for Crohn's at percentage rates ranging in the low double digits.

The Company accounted for the Alfa Wassermann transaction as a business combination under the acquisition method of accounting. Under the acquisition method of accounting, the Company recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in its consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the assets acquired was $23.4 million which is included as an indefinite lived intangible asset on the consolidated balance sheet, and includes the Company's estimate of the fair value of the contingent consideration related to the transaction discussed above of $13.4 million which is included as a long-term liability on the consolidated balance sheet. The Company determined this liability amount using a probability-weighted discounted cash flow model based on the current regulatory status of the EIR development program. The Company assesses the fair value of the contingent consideration quarterly, or whenever events or changes in circumstances indicate that the fair value may have changed, primarily as a result of clinical or regulatory results in the related in-process development programs.

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 $21.4 million, $11.3 million and $14.3 million for the years ended December 31, 2012, 2011 and 2010, 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):

	Year ended December 31,		
	2012	2011	2010
Xifaxan	$514,480	$371,653	$250,459
Purgatives—OsmoPrep/MoviPrep	64,932	88,746	54,207
Inflammatory Bowel Disease—Colazal/Apriso/Giazo	85,504	49,736	24,459
Other—Anusol/Azasan/Diuril/Pepcid/Proctocort/Relistor/Deflux/ Solesta	70,528	30,353	7,848
Net product revenues	$735,444	$540,488	$336,973

Other Comprehensive Income (Loss)

Other comprehensive income (loss) is composed entirely of adjustments resulting from the translation of the financial statements of the Company's foreign subsidiary, Ocean Therapeutics, Limited, which the Company acquired in December 2011, into U.S. dollars.

Stock-Based Compensation

At December 31, 2012, the Company had one active share-based compensation plan, the 2005 Stock Plan, allowing for the issuance of stock options and restricted stock. The Company estimates the fair value of share-based payment awards on the date of the grant. The cost is to be recognized over the period during which an employee is required to provide service in exchange for the award.

Translation of Foreign Currencies

The functional currency of the Company's foreign subsidiary, Oceana Therapeutics Limited, is the Euro. The Company translates its assets and liabilities using the current exchange rate as of the consolidated balance sheet date. The Company translates its stockholders' equity using historical rates at the consolidated balance sheet date. The Company translates its expenses and items of income using a weighted-average exchange rate over the period ended on the consolidated balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiary into U.S. dollars are excluded from the determination of net income (loss) and are accumulated in a separate component of stockholders' equity. The Company includes foreign exchange transaction gains and losses in its consolidated results of operations.

Pharmaceutical Manufacturers Fee

Effective January 1, 2011 the Company adopted Accounting Standard Update ("ASU") No. 2010-27, Other Expenses (Topic 720): *Fees Paid to the Federal Government by Pharmaceutical Manufacturers*. This ASU provides guidance on how pharmaceutical manufacturers should recognize and classify in their income statements fees mandated by the Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act, both enacted in March 2010, referred to in this Note as the "Acts". The Acts impose an annual fee on the pharmaceutical manufacturing industry for each calendar year beginning on or after January 1, 2011, payable no later than September 30 of the applicable calendar year and not tax deductible. The amount payable by a company is based on its brand prescription drug sales (including authorized generic product sales) for the preceding year as a percentage of the industry's brand prescription drug sales (including authorized generic product sales) for the same period. The ASU specifies that the liability for the fee should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable. The annual fee is an operating expense in the consolidated statement of comprehensive income (loss). The annual impact of this fee on the Company will be highly variable depending on the volume of product sales. There was no material impact of the adoption of this guidance on the consolidated financial statements of the Company.

Income Taxes

The Company provides for income taxes under the liability method. This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of differences between the tax basis of assets or liabilities and their carrying amounts in the consolidated financial statements. The Company provides a valuation allowance for deferred tax assets if it is more likely than not that these items will either expire before the Company is able to realize their benefit or if future deductibility is uncertain. During the year ended December 31, 2011, management concluded that it was more likely than not that a majority of our deferred tax assets will be realized through future taxable income and released a significant portion of the valuation allowances related to these deferred tax assets during 2011.

The Company applies the provisions of ASC 740-10, "Income Taxes" with respect to accounting for uncertainty in income taxes. The Company's net unrecognized tax benefits could change significantly due to tax benefits and liabilities that may be effectively settled within the next twelve months. The Company recognizes any interest accrued related to unrecognized tax benefits and penalties in income tax expense. During the twelve-month periods ended December 31, 2012, 2011 and 2010 there was no such interest or penalties.

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.

Net Income (Loss) Per Share

The Company computes basic net income (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding. The Company computes diluted net income (loss) per share by dividing net income (loss) by the weighted average number of common shares and dilutive common share equivalents then outstanding. Common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and the impact of unvested restricted stock grants. The Company accounts 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 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 2028 Notes, $46.38 for the 2015 Notes, and $65.81 for the 2019 Notes. For the year ended December 31, 2010, the effect of the approximately 6,486,000 shares issuable upon conversion of the 2028 Notes and the approximately 7,439,000 shares issuable upon conversion of the 2015 Notes was excluded from the diluted net income per share calculation, because their inclusion would have an anti-dilutive effect due to the net loss during that period. For the year ended December 31, 2011, net income used to calculate diluted earnings per share includes in weighted average common shares, diluted, the effect of approximately 6,486,000 share issuable upon conversion of the 2028 Notes calculated using the treasury stock method, since the Company's average stock price exceeded $9.25 during that period. For the year ended December 31, 2011, the effect of the approximately 7,439,000 shares issuable upon conversion of the 2015 Notes were excluded from the diluted net income per share calculation, because the Company's average stock price did not exceed $46.38 during those periods. For the year ended December 31, 2012, weighted average common shares, diluted, includes the effect of approximately 6,486,000 shares issuable upon conversion of the 2028 Notes calculated using the treasury stock method, taking into effect the repurchase in March and December 2012 of 2028 Notes convertible into approximately 2,730,000 and 2,405,000 shares, respectively, since the Company's average stock price exceeded $9.25 during the period. For the year ended December 31, 2012, weighted average common shares, diluted, includes the effect of the approximately 7,439,000 shares issuable upon conversion of the 2015 Notes, since the Company's average stock price exceeded $46.38 during the period. For the year ended December 31, 2012, the effect of the approximately 10,484,000 shares issuable upon conversion of the 2019 Notes issued in March 2012, were excluded from the diluted net income per share calculation, because the Company's average stock price did not exceed $65.81during that period.

For the year ended December 31, 2010, weighted average common shares, diluted were equal to weighted average common shares, basic, because inclusion of the 1,438,241 and 1,527,186 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 2012, 2011 and 2010, there were 33,771, 129,671, and 113,957, 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. For the years ended 2012, 2011 and 2010 there were 4,214,888, 4,850,459 and 4,890,188 potential common shares outstanding, respectively, as a result of our convertible debt that were excluded from the diluted net income (loss) per share calculation because their effect would have been anti-dilutive.

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

	Year ended December 31,		
	2012	2011	2010
Numerator:			
Net income (loss)	$64,246	$87,399	$(27,061)
Denominator:			
Weighted average common shares, basic	58,747	58,718	57,300
Dilutive effect of restricted stock	606	782	—
Dilutive effect of convertible debt	3,521	4,856	—
Dilutive effect of stock options	825	1,127	—
Weighted average common shares, diluted	63,699	65,483	57,300

Recently Issued Accounting Pronouncements

In September 2011, the FASB issued ASU 2011-08, "Intangibles—Goodwill and Other" ("ASU 2011-08"). ASU 2011-08 amends current guidance to allow an entity to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. Under this amendment an entity would not be required to calculate the fair value of a reporting unit unless the entity determines, based on a qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The provisions of ASU 2011-08 are effective for reporting periods beginning after December 15, 2011 and early adoption is permitted. The Company adopted ASU 2011-08 in the fourth quarter of 2011. There was no material impact to the Company's consolidated financial position, results of operations or cash flows upon adoption of this guidance.

In July 2012, the FASB issued ASU 2012-02 "Intangibles—Goodwill and Other (Topic 350) Testing Indefinite-Lived Intangible Assets for Impairment" ("ASU 2012-02"). Previous guidance required an entity to test indefinite-lived intangible assets for impairment, on at least an annual basis, by comparing the fair value of the asset with its carrying amount. If the carrying amount of the intangible asset exceeds its fair value, an entity should recognize an impairment loss in the amount of that excess. In accordance with the amendments in ASU 2012-02, an entity will have an option not to calculate annually the fair value of an indefinite-lived intangible asset if the entity determines that it is not more likely than not that the asset is impaired. The amendment permits an entity first to assess qualitative factors to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 and early adoption is permitted. The Company adopted ASU 2012-02 in the fourth quarter of 2012. There was no material impact to the Company's consolidated financial position, results of operations or cash flows upon adoption of this guidance.

(4) PROPERTY AND EQUIPMENT

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

	2012	2011
Cost:		
Furniture and equipment	$ 24,430	$ 24,690
Computer equipment	17,542	14,670
Assets under capital lease	951	1,880
	42,923	41,240
Accumulated depreciation:		
Furniture and equipment	(5,363)	(3,423)
Computer equipment	(8,731)	(6,488)
Assets under capital lease	(951)	(1,789)
	(15,045)	(11,700)
Net property and equipment	$ 27,878	$ 29,540

Depreciation expense was approximately $6.8 million, $4.3 million and $2.9 million in 2012, 2011 and 2010, respectively.

(5) OTHER ASSETS

In July 2011 the Company entered into an Amended and Restated Manufacturing and Supply Agreement with Glenmark Pharmaceuticals for the manufacture of crofelemer. The Amended Agreement replaced the agreement entered into in December 2008. Simultaneously upon entering the Amended Agreement, the Company entered into an Agreement for Advance Against Commitment Fee and provided a $15.0 million advance to Glenmark in order for them to meet the potential commercial demands for Crofelemer. This advance is included in other assets. The Company also agreed to fund an additional $1.3 million advance annually beginning with the first anniversary of the Amended Agreement, as long as the Amended Amendment has not been terminated.

The Company announced positive Phase 3 data for Crofelemer in November 2010 and submitted an NDA for crofelemer the proposed treatment of HIV–associated diarrhea in December 2011. On December 31, 2012, the FDA granted marketing approval for this product, under the trade name Fulyzaq. Therefore the Company believes this advance will have future commercial use. The Company plans to amortize the advance over its estimated economic life as a component of the cost of commercial supply of crofelemer upon approval. Consistent with the Company's policy for capitalizing pre-approval inventory, the Company will monitor, on a quarterly basis, the status of crofelemer within the regulatory approval process. The Company could be required to expense this advance 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 will evaluate this advance to determine if any lower of cost or market adjustment is required. The Company considers several factors in this evaluation, including expected timing of FDA approval, projected sales volume, estimated cost of goods and estimated selling price.

(6) ACCRUED LIABILITIES

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

	2012	2011
Accrued expenses	$46,293	$50,946
Accrued clinical expenses	16,514	11,550
Accrued terms discounts	5,587	2,876
Accrued royalties	12,668	15,026
Total accrued liabilities	$81,062	$80,398

(7) CREDIT FACILITY

In February 2007, the Company entered into a $100.0 million revolving credit facility that was to mature 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 2028 notes described in Note 6 below. As a result of the execution of the amendment to the 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 to interest expense. On May 6, 2010, the Company repaid the $15.0 million then drawn under the credit facility and terminated the facility.

(8) CONVERTIBLE SENIOR NOTES

Convertible Senior Notes Due 2028

On August 22, 2008 the Company closed an offering of $60.0 million in Convertible Senior Notes due 2028 (“2028 Notes”). Net proceeds from the offering were $57.3 million. The 2028 Notes are governed by an indenture, dated as of August 22, 2008, between the Company and U.S. Bank National Association, as trustee.

The 2028 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 2028 Notes will mature on August 15, 2028, unless previously converted or repurchased in accordance with their terms prior to such date.

The 2028 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 2028 Notes, and (iii) effectively junior to any secured indebtedness to the extent of the value of the assets securing such indebtedness.

The Company may redeem the 2028 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 2028 Notes for cash at 100% of the principal amount of the Notes being purchased, plus any accrued and unpaid interest.

In March 2012, the Company entered into a note repurchase agreement with the holder of a majority in principal amount of the 2028 Notes. The Company used a portion of the proceeds from its offering of the 2019 Notes discussed below to purchase from this holder and another holder approximately 42.1% of the 2028 Notes for an aggregate purchase price of approximately $137.2 million. In addition, for a period of 90 days after March 12, 2012, the majority

holder had the option to require the Company to purchase its remaining 2028 Notes at the same price, which represented approximately 37.1% of the 2028 Notes. This option expired unexercised in June 2012. The Company incurred a loss on extinguishment of debt during the three-month period ended March 31, 2012 of $14.4 million, which primarily consists of $9.3 million in estimated fair market value of the put option granted to the majority holder, $2.5 million in estimated fair market value of the notes extinguished over their book value at the extinguishment date, and $2.0 million paid to the note holder for interest that the note holders would have received through August 2013, the first date we could call the debt under the original debt indenture. In December 2012 one of the holders of the 2028 Notes converted notes with a par value of $22.3 million under the terms of the note indenture, and received cash equal to the par value of the notes and interest on these notes through February 15, 2013 , and 1.9 million shares of common stock. The Company incurred a loss on extinguishment of debt during the three-month period ended December 31, 2012 of $1.2 million, which primarily consists of $1.1 million in estimated fair market value of the notes extinguished over their book value at the extinguishment date, and $0.1 million paid to the note holder for interest that the note holders would have received through February 2013.

The remaining 2028 Notes are convertible into approximately 1,351,000 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 2028 Notes, which represents a conversion price of approximately $9.25 per share, subject to adjustment under certain conditions. Holders may convert their 2028 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 2028 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 2028 Notes, per $1,000 principal amount of the 2028 Notes, for each such trading day was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate of the Notes on such date; (3) if the Company enters into specified corporate transactions; or (4) upon a redemption notice. The first of these conditions was met as of December 31, 2012. The 2028 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.

Prior to March 2012, as long as the 2028 Notes were outstanding, the Company and its subsidiaries were prohibited from incurring any debt other than "permitted debt", as defined in the indenture, except that the Company and its subsidiaries may have incurred debt in certain circumstances, including meeting a consolidated leverage ratio test and a consolidated fixed charge coverage ratio test. The 2015 Notes described below were "permitted debt" under the indenture. In March 2012, the Company and the holders of a majority in outstanding principal amount of the 2028 Notes amended the indenture to delete this prohibition.

In connection with the issuance of the 2028 Notes, the Company incurred $2.7 million of issuance costs, which primarily consisted of investment banker, 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 2028 Notes.

The Company has separately accounted for the liability and equity components of the convertible debt instrument by allocating the proceeds from issuance of the 2028 Notes between the liability component and the embedded conversion option, or equity component. This allocation was done by first estimating an interest rate at the time of issuance for similar notes that do not include the embedded conversion option. This interest rate of 12.5% was used to compute the initial fair value of the liability component of $44.1 million.

The excess of the initial proceeds received from the convertible 2028 Notes over the initial amount allocated to the liability component, of $15.9 million, is allocated to the embedded conversion option, or equity component. This excess is reported as a debt discount and subsequently amortized as interest cost, using the interest method, through August 2013, the first scheduled date on which the holders have the option to require the Company to repurchase the 2028 Notes.

The carrying value of the equity component at December 31, 2012 and 2011 was $6.6 million. The effective interest rate on the liability component for the years ended December 31, 2012, 2011 and 2010 was 12.6%. Total interest cost of $5.2 million, $7.0 million and $6.6 million was recognized during the years ended December 31, 2012, 2011 and 2010, respectively, including $2.5 million, $3.3 million, and $2.9 million of amortization of debt discount, respectively. The fair value of the 2028 Notes was approximately $58.1 million at September 30, 2012.

Convertible Senior Notes Due 2015

On June 3, 2010 the Company closed an offering of $345.0 million in Convertible Senior Notes due May 15, 2015 ("2015 Notes"). Net proceeds from the offering were approximately $334.2 million. The 2015 Notes are governed by an indenture, dated as of June 3, 2010 between the Company and U.S. Bank National Association, as trustee.

The 2015 Notes bear interest at a rate of 2.75% per year, payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2010. The 2015 Notes will mature on May 15, 2015, unless earlier converted or repurchased in accordance with their terms prior to such date.

The 2015 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 2015 Notes, and (iii) effectively junior to any secured indebtedness to the extent of the value of the assets securing such indebtedness.

The 2015 Notes are convertible into approximately 7,439,000 shares of the Company's common stock under certain circumstances prior to maturity at a conversion rate of 21.5592 shares per $1,000 principal amount of 2015 Notes, which represents a conversion price of approximately $46.38 per share, subject to adjustment under certain conditions. Holders may convert their 2015 Notes at their option on any day prior to the close of business on the business day immediately preceding the maturity date of May 15, 2015 only if one or more of the following conditions is satisfied: (1) during any fiscal quarter commencing after June 30, 2010, 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 2015 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 2015 Notes, per $1,000 principal amount of the 2015 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 2015 Notes on such date; or (3) if the Company enters into specified corporate transactions. None of these conditions had been met as of December 31, 2012. The 2015 Notes will be convertible, regardless of whether any of the foregoing conditions have been satisfied, on or after January 13, 2015 at any time prior to the close of business on the second scheduled trading day immediately preceding the stated maturity date of May 15, 2015. 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.

The Company is required to separately account for the liability and equity components of the convertible debt instrument by allocating the proceeds from issuance of the 2015 Notes between the liability component and the embedded conversion option, or equity component. This allocation was done by first estimating an interest rate at the time of issuance for similar notes that do not include the embedded conversion option. This interest rate of 8.35% was used to compute the initial fair value of the liability component of $265.6 million. The excess of the initial proceeds received from

the convertible 2015 Notes over the initial amount allocated to the liability component, of $79.4 million, is allocated to the embedded conversion option, or equity component. This excess is reported as a debt discount and subsequently amortized as interest cost, using the interest method, through May 2015, the maturity date of the 2015 Notes.

In connection with the issuance of the 2015 Notes, the Company incurred $10.8 million of issuance costs, which primarily consisted of investment banker, legal and other professional fees. The portion of these costs related to the equity component of $2.5 million was charged to additional paid-in capital. The portion of these costs related to the debt component of $8.3 million is being amortized and are recorded as additional interest expense through May 2015, the maturity date of the 2015 Notes.

In connection with the issuance of the 2015 Notes, the Company entered into capped call transactions with certain counterparties covering approximately 7,439,000 shares of the Company's common stock. The capped call transactions have a strike price of $46.38 and a cap price of $62.44, and are exercisable when and if the 2015 Notes are converted. If upon conversion of the 2015 Notes, the price of the Company's common stock is above the strike price of the capped calls, the counterparties will deliver shares of the Company's common stock and/or cash with an aggregate value approximately equal to the difference between the price of the Company's common stock at the conversion date (as defined, with a maximum price for purposes of this calculation equal to the cap price) and the strike price, multiplied by the number of shares of the Company's common stock related to the capped call transactions being exercised. The Company paid $44.3 million for these capped calls and charged this to additional paid-in capital.

The carrying value of the equity component related to the 2015 Notes at December 31, 2012 was $79.4 million. The effective interest rate on the liability component for the years ended December 31, 2012, 2011 and 2010 was 8.35%. Total interest cost of $26.4 million, $25.2 million and $13.7 million was recognized during the years ended December 31, 2012, 2011 and 2010, respectively, including $15.2 million, $14.0 million and $7.2 million of amortization of debt discount, respectively. The fair value of the 2015 Notes was approximately $380.6 million at December 31, 2012.

Convertible Senior Notes Due 2019

On March 16, 2012 the Company closed an offering of $690.0 million in Convertible Senior Notes due March 15, 2019 ("2019 Notes"). Net proceeds from the offering were approximately $668.3 million. The 2019 Notes are governed by an indenture, dated as of March 16, 2012 between the Company and U.S. Bank National Association, as trustee.

The 2019 Notes bear interest at a rate of 1.50% per year, payable semiannually in arrears on March 15 and September 15 of each year, beginning on September 15, 2012. The 2019 Notes will mature on March 15, 2019, unless earlier converted or repurchased in accordance with their terms prior to such date.

The 2019 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 2019 Notes, and (iii) effectively junior to any secured indebtedness to the extent of the value of the assets securing such indebtedness.

The 2019 Notes are convertible into approximately 10,484,000 shares of the Company's common stock under certain circumstances prior to maturity at a conversion rate of 15.1947 shares per $1,000 principal amount of 2019 Notes, which represents a conversion price of approximately $65.81 per share, subject to adjustment under certain conditions. Holders may convert their 2019 Notes at their option on any day prior to the close of business on the business day immediately preceding the maturity date of March 15, 2019 only if one or more of the following conditions is satisfied: (1) during any fiscal quarter commencing after June 30, 2012, 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 2019 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 2019 Notes, per $1,000 principal amount of the 2019 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 2019 Notes on such date; or (3) if the Company enters into specified corporate transactions. None of these conditions had been met as of December 31, 2012. The 2019 Notes will be convertible, regardless of whether any of the foregoing conditions have been satisfied, on or after November 9, 2018 at any time prior to the close of business on the second scheduled trading day immediately preceding the stated maturity date of March 15, 2019. 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.

The Company is required to separately account for the liability and equity components of the convertible debt instrument by allocating the proceeds from issuance of the 2019 Notes between the liability component and the embedded conversion option, or equity component. This allocation was done by first estimating an interest rate at the time of issuance for similar notes that do not include the embedded conversion option. This interest rate of 5.50% was used to compute the initial fair value of the liability component of $529.3 million. The excess of the initial proceeds received from the convertible 2019 Notes over the initial amount allocated to the liability component, of $160.7 million, is allocated to the embedded conversion option, or equity component. This excess is reported as a debt discount and subsequently amortized as interest cost, using the interest method, through March 2019, the maturity date of the 2019 Notes.

In connection with the issuance of the 2019 Notes, the Company incurred $21.7 million of issuance costs, which primarily consisted of investment banker, legal and other professional fees. The portion of these costs related to the equity component of $5.1 million was charged to additional paid-in capital. The portion of these costs related to the debt component of $16.6 million is being amortized and is recorded as additional interest expense through March 2019, the maturity date of the 2019 Notes.

In connection with the issuance of the 2019 Notes, the Company entered into convertible bond hedge transactions with certain counterparties covering approximately 10,484,000 shares of the Company's common stock. The convertible bond hedge transactions have a strike price of $65.81 and are exercisable when and if the 2019 Notes are converted. If upon conversion of the 2019 Notes, the price of the Company's common stock is above the strike price of the convertible bond hedge transactions, the counterparties will deliver shares of the Company's common stock and/or cash with an aggregate value approximately equal to the difference between the price of the Company's common stock at the conversion date and the strike price, multiplied by the number of shares of the Company's common stock related to the convertible bond hedge transaction being exercised. The Company paid $167.0 million for these convertible bond hedge transactions and charged this to additional paid-in capital.

Simultaneously with entering into the convertible bond hedge transactions, the Company entered into privately negotiated warrant transactions whereby the Company sold the counterparties to these transactions warrants to acquire, subject to customary adjustments, approximately 10,484,000 shares of the Company's common stock at a strike price of $85.31 per share, also subject to adjustment. The Company received $99.0 million for these warrants and credited this amount to additional paid-in capital.

The carrying value of the equity component related to the 2019 Notes at December 31, 2012 was $160.7 million. The effective interest rate on the liability component for the year ended December 31, 2012 was 5.50%. Total interest cost of $24.0 million was recognized during the year ended December 31, 2012, including $14.0 million of amortization of debt discount. The fair value of the 2019 Notes was approximately $633.9 million at December 31, 2012.

The following table summarizes information on the convertible debt at December 31(in thousands):

	2012	2011
Convertible Notes due 2028:		
Principal amount of the liability component	$ 12,500	$ 60,000
Unamortized discount	(609)	(6,565)
Net carrying amount	$ 11,891	$ 53,435
Convertible Notes due 2015:		
Principal amount of the liability component	$ 345,000	$345,000
Unamortized discount	(42,914)	(58,152)
Net carrying amount	$ 302,086	$286,848
Convertible Notes due 2019:		
Principal amount of the liability component	$ 690,000	$ —
Unamortized discount	(146,768)	—
Net carrying amount	$ 543,232	$ —
Total Convertible Senior Notes		
Principal amount of the liability component	$1,047,500	$405,000
Unamortized discount	(190,291)	(64,717)
Net carrying amount	$ 857,209	$340,283

(9) 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, 2012 or 2011.

Common Stock

As of December 31, 2012 the Company was authorized to issue up to 150,000,000 shares of $0.001 par value common stock. As of December 31, 2012 and 2011, there were 60,918,391 and 59,205,259 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 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 was 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 would only have become exercisable based upon certain limited conditions related to acquisitions of stock, tender offers and business combinations involving the Company. This stockholder rights plan expired, in accordance with its terms, on January 9, 2013.

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 exercise prices must be at least 100% of the fair market value on the date of grant. 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 must be at least 110% of the fair market value and the option may 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, 2012, the Company had one active share-based compensation plan, the 2005 Stock Plan, allowing for the issuance of stock options and restricted stock. The Company estimates the fair value of share-based payment awards on the date of the grant. The Company recognizes cost over the period during which an employee is required to provide service in exchange for the award.

Starting in 2006, the Company began issuing restricted shares to employees, executives and directors of the Company. 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 9.6% and is being expensed on a straight-line basis over the period during which the restrictions lapse. For the years ended December 31, 2012, 2011 and 2010, the Company recognized $21.2 million, $15.8 million and $9.9 million in share based compensation expense related to the restricted shares, respectively. As of December 31, 2012, the total amount of unrecognized compensation cost related to nonvested restricted stock awards, to be recognized as expense subsequent to December 31, 2012, was approximately $37.7 million, and the related weighted-average period over which it is expected to be recognized is approximately 2.5 years.

Aggregate stock plan activity is as follows:

		Stock Options		Restricted Shares		Stock Options and Restricted Shares	
	Total Shares Available For Grant	Number	Weighted Average Price	Number Subject to Issuance	Weighted Average Price	Number	Weighted Average Price
Balance at December 31, 2009	1,859,868	3,181,634	$14.68	2,103,417	$10.08	5,285,051	$12.85
Granted	(590,208)	—	—	590,208	$36.78	590,208	$36.78
Exercised	—	(1,140,862)	$14.96	—	—	(1,140,862)	$14.96
Vested	—	—	—	(699,065)	$11.22	(699,065)	$11.22
Canceled/forfeited	281,911	(32,260)	$40.29	(250,861)	$ 9.03	(283,121)	$12.59
Balance at December 31, 2010	1,551,571	2,008,512	$14.11	1,743,699	$18.81	3,752,211	$16.30
Granted	(774,409)	—	—	774,409	$37.38	774,409	$37.38
Exercised	—	(370,874)	$14.55	—	—	(370,874)	$14.55
Vested	—	—	—	(694,444)	$12.36	(694,444)	$12.36
Canceled/forfeited	228,691	(25,187)	$44.08	(203,504)	$29.68	(228,691)	$31.27
Balance at December 31, 2011	1,005,853	1,612,451	$13.54	1,620,160	$29.08	3,232,611	$21.33
Granted	(699,204)	—	—	699,204	$50.18	699,204	$50.18
Additional shares authorized	3,000,000	—	—	—	—	—	—
Exercised	—	(850,204)	$10.03	—	—	(850,204)	$10.03
Vested	—	—	—	(536,981)	$22.75	(536,981)	$22.75
Canceled/forfeited	192,809	—	—	(192,809)	$41.91	(192,809)	$41.91
Balance at December 31, 2012	3,499,458	762,247	$17.46	1,589,574	$38.94	2,351,821	$31.98

Exercise prices for options outstanding as of December 31, 2012 ranged from $7.60 to $24.18 per share.

	Options Outstanding and Exercisable		
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (Yrs)	Weighted Average Exercise Price
$ 7.60 – 8.00	49,706	0.55	$ 7.61
$11.94 – 14.46	47,533	1.85	13.76
$15.02 – 17.77	289,294	2.25	17.36
$18.46 – 19.68	319,859	1.50	18.89
$20.55 – 24.18	55,855	2.24	21.79
	762,247	1.80	$17.47

At December 31, 2012, there were 762,247 exercisable options with a weighted average exercise price of $17.47. At December 31, 2011, there were 1,612,451 exercisable options with a weighted average exercise price of $13.55. At December 31, 2010, there were 2,008,512 exercisable options with a weighted average exercise price of $14.12.

For the year ended December 31, 2012, 0.9 million shares of the Company's outstanding stock with a market value of $41.3 million were issued upon the exercise of stock options. For the year ended December 31, 2011, 0.4 million shares of the Company's outstanding stock with a market value of $13.5 million were issued upon the exercise of stock options. For the year ended December 31, 2010, 1.1 million shares of the Company's outstanding stock with a market value of $41.4 million were issued upon the exercise of stock options. The Company recognized no share-based compensation expense related to stock options for the years ended December 31, 2012, 2011 or 2010, nor any income tax benefit. The total intrinsic value of options exercised for the years ended December 31, 2012, 2011 and

2010 was $32.8 million, $8.1 million, and $24.3 million, respectively. As of December 31, 2012, 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 years ended December 31, 2012, 2011 and 2010, the Company received $8.5 million, $5.4 million and $17.1 million in cash from stock option exercises, respectively.

The following table summarizes stock-based compensation expense incurred for the years ended December 31, in thousands:

	2012	2011	2010
Research and development	$ 5,039	$ 3,591	$2,470
Selling, general and administrative	16,163	12,201	7,470
Total	$21,202	$15,792	$9,940

(10) INCOME TAXES

The provision for (benefit from) income taxes in the accompanying consolidated statements of comprehensive income (loss) for the years ended December 31, 2012, 2011 and 2010 consisted of the following (in thousands):

	2012	2011	2010
Current:			
Federal	$38,414	$ 37,539	$ 10
State	13,751	13,423	2,848
Total current taxes	52,165	50,962	2,858
Deferred:			
Federal	4,237	(47,843)	—
State	(8,820)	(4,417)	—
Total deferred taxes	(4,583)	(52,260)	—
Total tax expense (benefit)	$47,582	$ (1,298)	$2,858

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

	2012	2011	2010
Federal statutory income tax rate	35.0%	35.0%	35.0%
State income taxes, net of federal income tax benefit	3.5%	3.8%	6.8%
Federal research and development credit	—	(2.0)%	6.4%
Change in deferred tax estimate	(1.1)%	(0.6)%	(0.6)%
Debt costs	(8.5)%	—	—
Change in tax status	0.8%	—	—
Increase in reserve for uncertain tax positions	11.4%	4.5%	(1.2)%
Non-deductible section 162(m) limitation	1.2%	2.6%	—
Non-deductible meals and entertainment	1.3%	2.2%	(6.5)%
Non-deductible transaction costs	—	0.9%	—
Provision to return adjustments	0.9 %	—	—
Change in valuation allowance	(2.0)%	(48.1)%	(50.3)%
Other non-deductible expenses	0.1%	0.2%	(1.2)%
	42.6%	(1.5)%	(11.6)%

The tax effects of temporary differences that give rise to significant portions of the net deferred tax asset at December 31, 2012 and 2011 are as follows (in thousands):

	2012	2011
Deferred Tax Assets:		
Research and development credits	$ 2,841	$ 17,256
Net operating loss carryforwards	11,754	14,030
Capitalized research and development expenses	140	275
Other credits	31	31
Intangible assets	26,112	29,575
Charitable contribution carryforward	—	4,805
Timing differences, including reserves, accruals, and writeoffs	85,719	61,465
Total gross deferred tax assets	126,597	127,437
Less: Valuation allowance	(6,913)	(8,066)
Deferred tax assets	119,684	119,371
Deferred Tax Liabilities:		
Property, plant & equipment	(10,156)	(9,208)
Debt discount and issuance costs	(13,919)	(25,122)
481 (a) adjustments	(2,033)	(132)
Intangible assets acquired in Oceana transaction	(98,386)	(104,314)
Timing differences, including reserves, accruals, and writeoffs	(2,395)	—
Deferred tax liabilities	(126,889)	(138,776)
Net deferred tax asset (liability)	$ (7,205)	$ (19,405)

The following table presents the breakdown between current and non-current deferred tax assets (liabilities) (in thousands):

	2012	2011
Current deferred tax asset	$ 57,050	$ 50,519
Non current deferred tax asset	—	—
Non current deferred tax liability	(64,255)	(69,924)
Net deferred tax asset (liability)	$ (7,205)	$(19,405)

The amounts recorded as gross deferred tax assets as of December 31, 2012 and 2011 represent the amount of tax benefits of existing deductible temporary differences and carryforwards that are more likely than not to be realized through the generation of sufficient future taxable income within the carryforward period. Significant management judgment is required in determining any valuation allowance recorded against deferred tax assets. The Company reassesses the ability to realize the deferred tax benefits on a quarterly basis. If it is more likely than not that the Company will not realize the deferred tax benefits, then all or a portion of the valuation allowance might need to be re-established, which would result in a charge to tax expense. During the three months ended September 30, 2012, the Company determined that it was more likely than not that a portion of the net deferred tax assets related to certain state net operating loss carryforwards would be utilized and released a portion of the valuation allowance. The release of this valuation allowance resulted in an income tax benefit of $2.5 million. The Company will continue to provide a valuation allowance for a portion of the net deferred tax assets related to certain state net operating loss carryforwards.

At December 31, 2012, the Company had federal net operating loss carryforwards available to offset future taxable income of approximately $3.6 million. These net operating losses were acquired through the acquisition of Oceana. Due to Internal Revenue Code section 382 limitations, a portion of these net operating losses were not

available for use during 2012, but should be available for use in future years. The Company has non-U.S. tax losses, which at December 31, 2012 totaled approximately $11.8 million. The Company provides a full valuation allowance against the non-U.S. tax losses. At December 31, 2012, the Company also had state net operating loss carryforwards available to offset future taxable income of approximately $162.2 million. The operating loss carryforwards will begin to expire in 2017. As mentioned above, certain of these state net operating loss carryforwards have full valuation allowances set up against them. The Company also has minimum tax credit carryforwards of approximately $.03 million and federal research & development credit carryforwards of $2.8 million.

At December 31, 2012, the Company realized excess tax benefits related to stock based compensation totaling $11.5 million. In accordance with ASC 718, the amount realized as excess stock based compensation was credited in additional paid in capital.

The following table summarizes the activity related to the Company's unrecognized tax benefits for the years ended December 31, 2012, 2011 and 2010 (in thousands):

	2012	2011	2010
Balance at January 1	$ 7,833	$3,641	$3,338
Increases related to prior year tax positions	527	3,516	593
Increases related to current year tax positions	12,440	676	—
Decreases related to prior year tax positions	(180)	—	(290)
Balance at December 31	$20,620	$7,833	$3,641

The Company's unrecognized tax benefits as of December 31, 2012, which, if recognized, would affect the Company's effective tax rate are approximately $19.0 million. The Company recognizes interest and penalties related to unrecognized tax benefits in income tax expense. The Company has recorded $0.2 million of interest expense and no penalties have been recorded by the Company through December 31, 2012. The Company's net unrecognized tax benefits could change significantly due to tax benefits and liabilities that may be effectively settled within the next 12 months. The results and timing of the settlements is highly uncertain and the Company is unable to estimate the range of the possible changes to the balance of unrecognized tax benefits.

The Company files a consolidated U.S. federal income tax return, Irish Corporate Tax return for the Company's Irish subsidiary, 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. Currently Salix is under audit in certain state jurisdictions and at this time we are not aware of any potential audit adjustments that will materially impact the Company's financial statements.

(11) SIGNIFICANT CONCENTRATIONS

The Company operates in a single industry acquiring, developing and commercializing prescription drugs and medical devices used in the treatment of a variety of gastrointestinal diseases, which are those affecting the digestive tract. The Company's 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 bank deposits might 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:

	Year Ended December 31,		
	2012	2011	2010
Customer 1	37%	47%	30%
Customer 2	36%	20%	30%
Customer 3	16%	13%	18%
Customer 4	—	12%	—

Additionally, 94% and 97% of the Company's accounts receivable balances were due from these four customers at December 31, 2012 and 2011, respectively.

Under the Company's supply agreement with Alfa Wassermann, the Company is obligated to purchase from Alfa Wassermann bulk rifaximin drug substance, the active pharmaceutical ingredient in Xifaxan 200mg rifaximin tablets and Xifaxan 550mg rifaximin tablets, until July 2014 or introduction of a generic product, whichever occurs first. The Company's supply of rifaximin drug substance supplied by Alfa Wassermann is manufactured by ZaCh Systems in Lonigo, Italy, and Sanofi-Aventis in Brindisi, Italy. Under a supply agreement with Lupin, the Company is obligated to purchase 50% of its annual requirements of bulk rifaximin drug substance from Lupin, subject to certain minimum purchase requirements. 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 Patheon and packaged into Xifaxan commercial blister packs by Pharma Packaging Solutions 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 Perrigo Company in Minneapolis, Minnesota, Perrigo produces the Company's commercial supply of finished product of Anusol-HC Cream, Anusol-HC Suppositories, Proctocort Suppositories, Pepcid Oral Suspension and Diuril Oral Suspension. 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.

In September 2010 the Company entered into a supply agreement with Novel Laboratories, Inc. in Somerset, New Jersey. In October 2011 Novel began producing commercial supply of bulk OsmoPrep tablets which are then packaged into finished OsmoPrep commercial bottles by Pharma Packaging Solutions in Norris, Tennessee.

In August 2010 the Company entered into a supply agreement with Novel Laboratories, Inc. and Actavis Inc. Under this supply agreement the Company agreed to purchase from Actavis all of its requirements in excess of a certain amount of MoviPrep in 2011 and all of its requirements of MoviPrep beginning in 2012.

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 Pharma Packaging Solutions in Norris, Tennessee.

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 Pharma Packaging Solutions in Norris, Tennessee.

Under long-term supply agreements, the Company uses balsalazide drug substance, the active pharmaceutical ingredient in Colazal capsules, manufactured by Omnichem s.a., a subsidiary of Ajinomoto in Belgium, and by 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; balsalazide drug substance from OmniChem s.a. is also converted into Giazo 100mg tablets by Nexgen Pharma. Bulk Colazal capsules and bulk Giazo tablets are packaged into finished commercial bottles by Nexgen and Pharma Packaging Solutions in Norris, Tennessee.

Relistor subcutaneous injection in a vial presentation is produced in bulk by DSM Pharmaceutical Products in Greenville, North Carolina and then packaged into finished Relistor single vials or vial kits by Packaging Coordinators, Inc. in Philadelphia, Pennsylvania. Relistor subcutaneous injection in a pre-filled syringe presentation is produced and packaged into finished Relistor kits by Vetter Pharma International GmbH in Ravensburg, Germany. The drug substance for these Relistor subcutaneous injection presentations is supplied by Mallinckrodt, a subsidiary of Covidien, in St. Louis, Missouri.

Both Deflux and Solesta are produced and packaged into finished Deflux and Solesta kits, respectively, by Q-MED AB in Uppsala, Sweden.

Under the Company's supply agreement with Glenmark Pharmaceuticals, Ltd. in Mumbai, India, Glenmark supplies the Company with crofelemer drug substance. With respect to the Company's budesonide foam formulation, the Company's methylnaltrexone bromide tablet formulation, and the Company's methylnaltrexone bromide multi-dose pen subcutaneous injection formulation, all of which are currently under development, the Company plans to negotiate commercial supply agreements with the manufacturers who produced the drug substance and drug product for the Phase 3 clinical trial material, or the manufacturers who produced the pivotal registration batches, if these products receive FDA approval. We are currently negotiating a commercial supply agreement for the manufacture of crofelemer tablets.

(12) 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 $2.1 million, $1.7 million and $1.5 million in 2012, 2011 and 2010, respectively. Additional discretionary employer contributions may be made on an annual basis.

(13) COMMITMENTS

At December 31, 2012, the Company had binding purchase order commitments for inventory purchases aggregating approximately $217.0 million over the next five years, which includes any minimum purchase commitments under our manufacturing agreements.

Lease Agreements

In February 2011 the Company notified the landlord for its corporate headquarters in Morrisville, NC that it was terminating this lease as of October 2011. In February 2011 the Company entered into a lease for approximately 127,000 square feet for a corporate headquarters in Raleigh, North Carolina, which began in September 2011 and expires in 2023. In February 2011 the Company extended the lease on its former corporate headquarters located in Raleigh, North Carolina, of approximately 26,000 square feet of office space to 2018, and in October 2011 the Company leased an additional 12,000 square feet in this building. In 2012 the Company leased an additional 5,000

square feet in this building. The Company leases office facilities, primarily its headquarters discussed above, under various non-cancelable operating leases, the last of which expires in 2023. Certain of these leases contain future payment obligations that escalate over time. Rent expense was approximately $3.1 million, $2.3 million and $1.5 million for the years ended December 31, 2012, 2011 and 2010, respectively.

As of December 31, 2012, future minimum payments for leases were as follows (in thousands):

Years ending December 31,	Operating Leases	Capital Leases
2013	$ 2,352	$ 50
2014	3,866	—
2015	3,869	—
2016	3,932	—
2017	4,032	—
Thereafter	17,478	—
Total future minimum payments required	$35,529	50
Less: Amount representing interest		—
Present value of net minimum lease payments		50
Less: Current portion of capital lease obligations		50
Long term portion of capital lease obligations		$—

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.

Amended and Restated License Agreement with Alfa Wassermann S.p.A—In August 2012 the Company amended its 1996 License Agreement with Alfa Wassermann to develop rifaximin. The Restated Agreement provides the Company with an exclusive license to develop and commercialize rifaximin products for Crohn's disease in the United States and Canada and a non-exclusive license to develop such products worldwide. The Company paid Alfa a non-refundable upfront fee of $10.0 million in August 2012, and is obligated to make a $25.0 million milestone payment upon receipt of marketing authorization in the United States for a rifaximin product for Crohn's, and additional milestone payments of up to $200.0 million based on net sales of rifaximin products for Crohn's. No milestone payments had been earned or made as of December 31, 2012.

License Agreement with Dr. Falk Pharma GmbH for budesonide—In March 2008, the Company entered into a license agreement with Dr. Falk Pharma. The agreement provides the Company with an exclusive license to develop and commercialize in the United States Dr. Falk Pharma's budesonide products. The products covered in the license agreement include U.S. patent-protected budesonide rectal foam and budesonide gastro-resistant capsule, patents for which expire in 2015 and 2016, respectively. Pursuant to the license agreement the Company is obligated to make an upfront payment and regulatory milestone payments that could total up to $23.0 million to Dr. Falk Pharma, with the majority contingent upon achievement of U.S. regulatory approval. As of December 31, 2012, the Company had paid $1.0 million of these milestone payments.

Development, Commercialization and License Agreement with Lupin Ltd—In September 2009, the Company entered into a Development, Commercialization and License Agreement with Lupin for Lupin's proprietary drug delivery technology for rifaximin. The Company made an upfront payment of $5.0 million to Lupin upon execution of this agreement.

In March 2011, the Company entered into an amendment and restatement of its Development, Commercialization and License Agreement with Lupin, and further amended it in February 2013 (as so amended, the "Amended License Agreement"). The Amended License Agreement replaces in its entirety the September 2009 agreement. This agreement provides that the Company is obligated to pay Lupin an additional upfront payment of $10.0 million, milestone payments that could total up to $53.0 million over the term of the agreement and royalties in connection with the commercialization of relevant products. During the portion of the term of the Amended License Agreement ending September 30, 2019, the Company must pay Lupin a minimum quarterly payment unless specified payments by the Company to Lupin during that quarter exceed that amount. The Company is permitted to charge against such minimum quarterly payments as it makes in respect of quarters beginning on or after January 1, 2012, the purchase price for certain rifaximin to be supplied to it by Lupin pursuant to a Rifaximin Manufacturing and Supply Agreement into which the Company and Lupin entered in September 2009 and subsequently amended. In the event the Company should exercise its right to terminate the Amended License Agreement for convenience, it must pay Lupin as an early termination fee a specified portion of the minimum quarterly payments payable by it to Lupin through September 30, 2019, that have not been paid or otherwise satisfied as of the date of termination. As of December 31, 2012, the Company had paid the additional $10.0 million upfront payment. The milestone payments are contingent upon achievement of certain clinical and regulatory milestones.

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. None of these sales thresholds had been met at December 31, 2012.

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 specified territory. The Company also has a non-exclusive, worldwide, royalty-bearing license to use Napo-controlled trademarks associated with crofelemer. The Company has made an initial payment of $5.0 million to Napo and will make up to $50.0 million in milestone payments to Napo contingent on regulatory approvals and up to $250.0 million in milestone payments contingent on reaching certain sales thresholds. The Company is responsible for the 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. On December 31, 2012, the FDA granted marketing approval for this product, under the trade name Fulyzaq. At December 31, 2012 development costs exceeded $12.0 million by more than the amount of the milestone due upon FDA marketing approval, therefore there was no payment due to Napo.

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, 2012, the Company had paid $27.0 million of milestone payments. The remaining milestone payments are contingent upon reaching sales thresholds.

License Agreement with Photocure ASA—In October 2010, the Company entered into a license agreement with Photocure for the worldwide exclusive rights, excluding the Nordic region, to develop and commercialize Lumacan™ for diagnosing, staging or monitoring gastrointestinal dysplasia or cancer. The Company made an initial payment of $4.0 million to Photocure, and will be responsible for development costs of Lumacan, but Photocure will reimburse the Company up to $3.0 million for certain out-of-pocket costs. In December 2012 the Company made a $4.5 million milestone payment. In addition, the Company is obligated to make up to $72.0 million in milestone payments to

Photocure contingent on development and regulatory milestones, and up to $50.0 million in milestone payments contingent on reaching certain sales thresholds over the term of the agreement. No milestone payments had been earned or made as of December 31, 2012.

License Agreement with Progenics Pharmaceuticals, Inc.—In February 2011, the Company acquired an exclusive worldwide license to develop and commercialize the products containing methylnaltrexone bromide, or the MNTX Compound, marketed under the name Relistor®, from Progenics. The Company paid Progenics an up-front license fee payment of $60.0 million. In addition, the Company is obligated to pay development milestone payments of up to $90.0 million contingent upon achieving specified regulatory approvals and commercialization milestone payments of up to $200.0 million contingent upon achieving specified targets for net sales over the term of the agreement. No milestone payments had been earned or made as of December 31, 2012.

License Agreement with Q-MED AB—In connection with the Company's acquisition of Oceana Therapeutics, Inc. in December 2011, the Company acquired two license agreements with Q-MED AB, which provide it the worldwide right to commercialize Deflux and Solesta. Under the license agreements and a related stock purchase agreement with Q-Med, the Company is obligated to pay commercialization milestone payments of up to $45.0 million contingent upon achieving specified targets for net sales over the term of the agreement. No milestone payments had been earned or made as of December 31, 2012.

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 September 30, 2012, the Company had paid these milestone payments in full. The Company also loaned Wilmington $2.0 million, which was netted against the payment of the approval milestone as a result of FDA approval on September 8, 2009.

(14) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2012 and 2011:

(in thousands, except per share amounts)	Mar 31	June 30	Sept 30	Dec 31
		(unaudited)		
2012				
Net product revenue	$171,133	$181,006	$185,132	$198,173
Cost of products sold, excluding amortization of product rights and intangible assets	34,190	33,257	26,471	30,679
Net income	9,953	20,134	16,536	17,623
Net income per share, basic(1)	0.17	0.35	0.28	0.30
Net income per share, diluted(1)	0.15	0.32	0.26	0.28
2011				
Net product revenue	$105,897	$133,162	$146,247	$155,182
Cost of products sold, excluding amortization of product rights and intangible assets	18,586	25,242	24,056	27,485
Net income	278	19,247	34,279	33,595
Net income per share, basic(1)	0.00	0.33	0.58	0.57
Net income per share, diluted(1)	0.03	0.32	0.55	0.56

(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.

(15) LEGAL PROCEEDINGS

From time to time, the Company is involved in various litigation matters that are being defended and handled in the ordinary course of business. The assessment of whether a loss is probable or reasonably possible, and whether the loss or a range of loss is estimable, often involves a series of complex judgments about future events. Management maintains accruals for such losses that are probable of being incurred and subject to reasonable estimation. For current matters not specifically reported herein, management does not anticipate that the ultimate liabilities, if any, arising from the resolution of such current matters would have a material effect on the Company's financial condition or results of operations. It is possible, however, that future results of operations for any particular period could be materially affected by changes in the Company's assessment related to any of these matters.

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

During the fourth quarter of 2011 the Company settled a number of the OsmoPrep and Visicol lawsuits and was notified by its insurer that settlement of these claims exceeded the limits of the policies related to these claims. Based on the Company's settlement history with these cases, the Company recorded a $3.5 million charge in the fourth quarter of 2011 as an estimate of the settlements remaining on cases the Company is currently aware of. Actual settlements of these claims could exceed this estimate, and additional claims may be made against the Company that the Company is not currently aware of. In addition, the Company will incur additional litigation costs that will be expensed when incurred.

On May 5, 2011, Napo Pharmaceuticals, Inc. filed a lawsuit against the Company in the Supreme Court of the State of New York, County of New York, alleging that the Company had engaged in fraudulent conduct, breached its Collaboration Agreement with Napo dated December 9, 2008, and breached its duty of good faith and fair dealing. Napo also sought a declaratory judgment that Napo had the right to terminate the Collaboration Agreement and sought unspecified damages in excess of $150 million. On or about December 28, 2011, Napo filed an Amended Complaint seeking an unspecified amount of damages for alleged breaches of the Collaboration Agreement by the Company and replacing Napo's original Complaint. Napo's Amended Complaint no longer seeks a declaratory judgment that Napo has the right to terminate the Collaboration Agreement and removed the need for the Court to rule on the Company's motion to dismiss the original Complaint. The Company believes that Napo's allegations continue to be without merit and their lawsuit baseless. The Company filed an Answer to the Amended Complaint and Counterclaims on or about January 17, 2012, and intends to continue to vigorously defend against the lawsuit. Napo filed a Reply to the Company's Counterclaim on or about February 7, 2012. Discovery is ongoing. The Company is moving forward with its development plan for crofelemer in accordance with the existing Collaboration Agreement. The Company believes the likelihood of loss is remote, and no accrual has been recorded for this matter.

On June 22, 2011, the Company, in its capacity as a shareholder of Napo Pharmaceuticals, Inc., filed a complaint against Napo in the Court of Chancery of the State of Delaware. The complaint sought to compel Napo to allow the Company to inspect certain corporate books and records in connection with possible breaches of fiduciary duty and mismanagement by certain members of Napo's board. Napo filed its answer and affirmative defenses to the complaint on July 27, 2011. Napo and the Company exchanged written discovery requests and responses. On or about January 5, 2012, the Company filed a motion for voluntary dismissal of the Delaware lawsuit. The Delaware Court granted the Company's motion, without penalty or fees being awarded to Napo or us.

On September 7, 2012, the Company and Dr. Falk Pharma filed a patent infringement complaint against Lupin Ltd. and Lupin Pharmaceuticals, Inc. in the U.S. District Court for the District of Delaware. The Complaint alleges

infringement of U. S. Patent No. 6,551,620, or the '620 patent, based on Lupin's filing of an Abbreviated New Drug Application, or ANDA, seeking approval to market and sell a generic version of Apriso before the expiration of the '620 patent. The filing of this suit within the 45 day response period provided by the Hatch Waxman Act imposes an automatic 30 month stay of approval of Lupin's ANDA. The Company continues to evaluate its intellectual property protecting Apriso in which it has full confidence. The Company intends to vigorously enforce its intellectual property rights.

In addition, on February 1, 2013, the Company's wholly owned subsidiary Salix Pharmaceuticals, Inc. received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents regarding the Company's sales and promotional practices for Xifaxan® (rifaximin), Relistor® (methylnaltrexone bromide) and Apriso® (mesalamine). The Company is in the process of responding to the subpoena and intends to cooperate fully with the subpoena and related government investigation. Currently, the Company cannot predict or determine the timing or outcome of this inquiry or its impact on the Company's financial condition or results of operations.

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS

Allowance for Rebates, and Chargebacks

Year ended December 31,	Beginning Balance	Additions: Provision Related to Current Period Sales	Additions: Provision Related to Period Prior Sales	Deductions: Rebates, Chargebacks and Discounts or Credits	Ending Balance
(in thousands)					
2012	$69,167	$155,219	$5,104	$125,671	$103,819
2011	$40,833	$100,433	$5,481	$ 77,580	$ 69,167
2010	$17,158	$ 75,660	$2,217	$ 54,202	$ 40,833

Allowance for Returns

Year ended December 31,	Beginning Balance	Additions: Provision Related to Current Period Sales	Additions: Provision Related to Prior Period Sales	Deductions: Returns or Credits Related to Prior Period Sales	Ending Balance
(in thousands)					
2012	$28,712	$22,192	$ 296	$14,828	$36,372
2011	$19,705	$17,933	$10,638	$19,564	$28,712
2010	$14,883	$10,255	$ 5,357	$10,790	$19,705

Allowance for Uncollectible Accounts

Year ended December 31,	Beginning Balance	Additions: Charged to Costs and Expenses	Deductions: Accounts Written Off During Period	Ending Balance
(in thousands)				
2012	$831	$664		$1,495
2011	$508	$323		$ 831
2010	$508	—	—	$ 508

Valuation Allowance on Deferred Tax Assets

Year ended December 31,	Beginning Balance	Additions: Provisions for Valuation Allowance	Deductions: Release of Valuation Allowance /Other	Ending Balance
(in thousands)				
2012	$ 7,711	$1,694	$ 2,492	$ 6,913
2011	$48,727	—	$41,016	$ 7,711
2010	$74,497	—	$25,770	$48,727

Exhibit 21.1

Salix Pharmaceuticals, Ltd. Subsidiaries

Name	Jurisdiction
Salix Pharmaceuticals, Inc.	California
Oceana Therapeutics, Inc.	Delaware
Oceana Therapeutics, Limited	Ireland
Glycyx Pharmaceuticals, Ltd.	Delaware
InKine Pharmaceutical Company, Inc.	New York
Corbec Pharmaceuticals, Inc.	Delaware
Sangen Pharmaceutical Company	Delaware

EXHIBIT 23.1

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 Nos. 333-110942 and 333-167112) of Salix Pharmaceuticals, Ltd., and

(2) Registration Statement (Form S-8 Nos. 333-126685, 333-126290, 333-116675, 333-96771, 333-63604, 333-61497, 333-135268, 333-47586, 333-151658, 333-41801, 333-160294 and 333-183174) pertaining to various stock-based compensation plans of Salix Pharmaceuticals, Ltd.;

of our reports dated February 28, 2013, with respect to the consolidated financial statements and schedule of Salix Pharmaceuticals, Ltd., and the effectiveness of internal control over financial reporting of Salix Pharmaceuticals, Ltd. included in this Annual Report (Form 10-K) of Salix Pharmaceuticals, Ltd. for the year ended December 31, 2012.

/s/ Ernst & Young LLP

Raleigh, North Carolina
February 28, 2013

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (Nos. 333-110942 and 333-167112) and Form S-8 (Nos. 333-126685, 333-126290, 333-116675, 333-96771, 333-63604, 333-61497, 333-135268, 333-47586, 333-151658, 333-41801, 333-160294 and 333-183174) of Salix Pharmaceuticals, Ltd. of our report dated March 1, 2011 relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina
February 28, 2013

EXHIBIT 31.1

CERTIFICATION

I, Carolyn J. Logan, certify that:

1. I have reviewed this annual report on Form 10-K of Salix Pharmaceuticals, Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2013

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

EXHIBIT 31.2

CERTIFICATION

I, Adam C. Derbyshire, certify that:

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

Date: February 28, 2013

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

EXHIBIT 32.1

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, 2012 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

February 28, 2013

EXHIBIT 32.2

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, 2012 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Adam C. Derbyshire, Executive Vice President, Finance and Administration and Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. 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

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

February 28, 2013