Salix®

Pharmaceuticals, Ltd.

Annual Report 2003

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Advancing Treatment in Gastroenterology™

[redacted] is dedicated to being the leading specialty pharmaceutical company providing products to gastroenterologists and their patients.

Salix®
PHARMACEUTICALS, LTD.

To Our Shareholders:

I would like to begin, not end, my comments regarding 2003 by thanking our employees, board members, stockholders and the vast network of friends and supporters we have within the gastroenterology community for their ongoing confidence and enduring commitment to our success. Our future is predicated on this foundation of mutual trust and collaboration. Together, because of a shared vision and appreciation for the value our products provide, we look forward to a prosperous future.

The resolve of each and every Salix employee was tested during 2003. Looking back on the year, I can unequivocally say that we seized the opportunities presented by the events of 2003 and have emerged a stronger, more successful organization. We succeeded during the year because of our commitment, determination, focus, teamwork and a strong work ethic. Looking forward to 2004 and beyond, Salix is on the cusp of realizing its potential as we continue to execute our business plan.

COLAZAL® continues to be the fastest-growing oral product for the treatment of ulcerative colitis and remains an excellent foundation for our business. More than 300,000 COLAZAL prescriptions were written during 2003, compared to approximately 200,000 prescriptions written during 2002. Sales of COLAZAL totaled $55.8 million for the year, an increase of 67% compared to the $33.5 million in sales for 2002. We firmly believe that COLAZAL, with its targeted delivery of the active ingredient to the colon, represents a significant step forward in the treatment of mildly to moderately active ulcerative colitis. We expect COLAZAL will continue to gain market share as physicians and patients gain experience with the product.

During 2003 we demonstrated ongoing progress in the development of Rifaximin, our non-systemic, gastrointestinal site-specific antibiotic. In May 2003 we completed the Phase III trial requested by the U.S. Food and Drug Administration in its October 25, 2002 approvable letter. On November 25, 2003 we submitted an amendment to our New Drug Application, and, two weeks later, on December 11, the FDA acknowledged that they considered the amendment to be a complete response. At that time the FDA assigned a user fee goal date of May 26, 2004 to review and act upon the application.

In parallel with the travelers' diarrhea program, during 2003 we also advanced the development of Rifaximin as a treatment for other gastrointestinal bacterial infections. We believe Rifaximin is unique because there is no U.S.-approved oral antibiotic with its lack of systemic absorption and highly favorable safety profile. We believe these unique qualities of Rifaximin provide an opportunity for us to establish this product in the treatment and prevention of a number of gastrointestinal bacterial infections. Additionally, we believe Rifaximin may also have potential in the treatment of other diseases where infections of the gastrointestinal tract may play a role. A company-sponsored study of Rifaximin for the treatment of hepatic encephalopathy was analyzed during the year, and plans are in progress to pursue discussions with the FDA with respect to next steps. During the fourth quarter of the year a company-funded, independent research study of Rifaximin for the prophylaxis of travelers' diarrhea was completed. Results of a company-funded, independent research study of Rifaximin for the treatment of Crohn's disease were presented at the 2003 annual meeting of the American College of Gastroenterology. Currently, other studies, both company-sponsored and company-funded, supporting additional uses of Rifaximin are underway or soon to be initiated.

We achieved great strides during 2003 in preparing the marketplace for Rifaximin. Throughout the year we created opportunities to ensure that the potential for Rifaximin is clearly understood and widely recognized as the product approaches commercialization in the United States. Market research and discussions with leading medical thought leaders indicate that our current targeted universe of 8,000 gastroenterologists—plus an additional 1,000 travel clinic and infectious disease physicians—represent the target market for Rifaximin. Consequently, during the third quarter of 2003, in anticipation of a mid-2004 launch, we increased our sales force to 68 representatives—making us one of the largest specialty sales forces in gastroenterology. We now are positioned to leverage our established presence in the marketplace as our 100-member sales and marketing team transitions from carrying one product in their bag to being able to offer physicians three products—

COLAZAL, AZASAN® and Rifaximin. Clearly, Rifaximin should serve as a key driver for significant growth and profitability, as well as stockholder value, as the Company continues to execute its business plan.

On December 11, 2003 the FDA permitted us to initiate clinical trials under our Investigational New Drug for Granulated Mesalamine. Currently, two preliminary dose characterization trials are underway. We intend to initiate two Phase III trials by mid 2004. We believe that Granulated Mesalamine's unique, dual-release mechanism represents a significant improvement over current therapies. Dr. Falk Pharma GmbH markets Granulated Mesalamine in Germany, and we look forward to commercializing the product in the United States. Dr. Falk Pharma has an impressive reputation throughout the gastroenterology community worldwide, and we are extremely pleased to be associated with their organization.

In November 2003 we acquired from aaiPharma LLC the exclusive rights to sell AZASAN, or azathioprine tablets, in 25, 75 and 100 mg strengths in North America. Our launch of the 75 and 100 mg dosage strengths in February 2004 provides the first significant opportunity for us to expand our business with the physicians with whom our sales force has diligently worked to build strong relationships over the past three years. We believe AZASAN should differentiate itself from the competition by offering consistent, more convenient dosing at a lower cost, and we look forward to its contribution to our operating results.

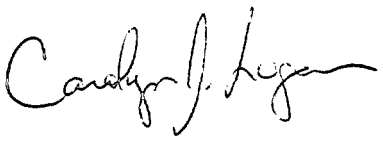
We continued with our efforts during 2003 to expand our access to additional, potential gastrointestinal products. In October we signed an agreement with Chong Kun Dang Pharmaceutical Corporation to market COLAZAL in South Korea. As part of the agreement, we secured a first right of negotiation for all CKD gastrointestinal products available for commercialization in the United States. In a similar manner, as part of our agreement with aaiPharma, we secured a first right of negotiation with respect to certain other future aaiPharma gastrointestinal disease products that it out-licenses. In addition to these arrangements, we have the right of first negotiation with respect to rights to develop and market certain Dr. Falk Pharma products in the United States.

The growth and evolution of our business during 2003 was accompanied by positive change within our Board of Directors and senior management. In June 2003 Institutional Shareholder Services, the leading independent proxy advisory firm in the United States, gave Salix a Corporate Governance Quotient rating of 92.2%. Even with this commendable level of performance, in keeping with our commitment to excellence, the Company instituted changes during 2003 to improve the Company's corporate governance. In September Mr. John Chappell, an independent Board member since 1993, was named Chairman of the Board, and in January 2004 Mr. William Keane was appointed to the Board. Bill's appointment created a Board of Directors comprised of a super-majority of independent, outside Directors. We welcome the guidance and oversight provided by the Board and will continue to seek its input as we work to maximize stockholder value.

We were pleased to have Dr. Arthur Kamm join the Company in July as Senior Vice President, Research and Development and Chief Development Officer. Dr. Kamm has been instrumental in directing the timely submission of the Rifaximin amendment and has done an exemplary job in advancing our other development programs. In June Mr. Adam Derbyshire was promoted to Senior Vice President, Finance and Administration and Chief Financial Officer. I look forward to continuing to work with Art and Adam and the entire senior management team as we continue to build Salix.

During 2003 Salix was added to the NASDAQ Biotechnology Index®. We are honored that Salix has been included in this Index, which includes the largest and most actively traded NASDAQ biotechnology and pharmaceutical stocks. It is my hope that this recognition reflects not only the tremendous progress the Company has achieved over the past several years, but also portends the growth and success we seek to achieve as we leverage our established infrastructure in the years ahead.

Sincerely,



Carolyn J. Logan
President and Chief Executive Officer

Salix®

PHARMACEUTICALS, LTD.

2003 Form 10-K

Advancing Treatment in Gastroenterology™

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, 2003 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.)

8540 Colonnade Center Drive, Suite 501
Raleigh, North Carolina 27615
(Address of principal executive offices, including zip code)

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

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

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

Title of Each Class

Common Stock, $0.001 Par Value
Preferred Share Purchase Rights

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

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

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

The aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant on June 30, 2003 (based on the closing sale price of US $10.39 of the Registrant's common stock, as reported on The Nasdaq National Market on such date) was approximately U.S. $130,839,067. Common stock held by each officer and director and by each person known to the Company who owned 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the Registrant's common stock outstanding at March 9, 2004 was 23,947,240.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement to be filed for its 2004 Annual Meeting of Stockholders currently scheduled to be held June 17, 2004 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 21E of the Securities Exchange Act of 1934. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from historical results or those anticipated in these forward-looking statements as a result of certain factors, including those set forth under "Cautionary Statement" under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report.

PART I

Item 1. Business

Our website address is www.salix.com. We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission.

Overview

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

- identify and acquire rights to products that we believe have potential for near-term regulatory approval or are already approved;
- apply our regulatory, product development, and sales and marketing expertise to commercialize these products; and
- use our approximately 100-member specialty sales and marketing team focused on high-prescribing U.S. gastroenterologists, who are doctors who specialize in gastrointestinal diseases, to sell our products.

Our first four products demonstrate our ability to execute this strategy. These products are:

- balsalazide disodium, which we sell in the United States under the brand name Colazal ® ;
- three dosage strengths of azathioprine, an FDA-approved product licensed by us, two of which strengths, we launched in the United States through our direct sales force in February 2004 under the brand name Azasan ®.
- rifaximin, which, if approved by the U.S. Food and Drug Administration, or FDA, we intend to sell in the United States for the treatment of travelers' diarrhea; and
- a patented, granulated formulation of mesalamine, which, if approved by the FDA, we intend to sell in the United States to expand our range of treatment options for ulcerative colitis.

We currently market Colazal and two dosage strengths of Azasan, and intend, if approved by the FDA, to market future products to U.S. gastroenterologists through our own direct sales force, and enter into distribution relationships outside the United States and in markets where a larger sales organization is appropriate. Currently, our specialty sales and marketing team consists of approximately 100 persons. We believe our sales and marketing team should also position us to sell additional products.

PRODUCTS

Colazal ® (balsalazide disodium)

Our first marketed product, Colazal, was the first new molecular entity approved in 10 years by the FDA for the treatment of mildly to moderately active ulcerative colitis and the first new oral therapy approved by the FDA for this indication in seven years. Ulcerative colitis is a chronic form of inflammatory bowel disease characterized by

inflammation of the lining of the colon. Symptoms of active ulcerative colitis include rectal bleeding, abdominal pain, increased stool frequency, loss of appetite, fever and weight loss. This disease affects roughly 500,000 people in the United States, typically with onset under the age of 40. The cause of ulcerative colitis is unknown and no known cure exists except for the removal of the colon. Oral branded prescription products containing the active therapeutic agent 5-ASA are the first line of treatment and most frequently prescribed class of drugs for ulcerative colitis, with 2003 U.S. retail sales of approximately $474 million. In terms of prescription dollar sales, the market for 5-ASA products has been growing at a 25% annual compound rate for the last 12 years. Colazal contains 5-ASA, as does Asacol®, the market-leading drug with retail sales of approximately $314 million in 2003.

In clinical trials, Colazal demonstrated at least comparable efficacy and had an improved safety profile as compared to some other oral 5-ASA products. Other 5-ASA products often do not deliver optimal doses of the active therapeutic agent to the colon. However, because Colazal's proprietary formulation allows approximately 99% of the drug to reach the colon, it can work more quickly and effectively than comparable doses of other 5-ASA products that deliver less drug to the diseased area. In addition, some other 5-ASA products have historically been associated with side effects that cause up to 15-40% of patients to discontinue treatment.

We launched Colazal in the United States in January 2001 using our own sales force. We sold $14.1 million, $33.5 million and $55.8 million worth of Colazal in the United States in the years ended December 31, 2001, 2002 and 2003, respectively. The number of prescriptions written in 2001, 2002 and 2003 for Colazal was approximately 62,500, 208,000 and 313,000, respectively, making Colazal the fastest-growing oral 5-ASA product of its kind in the marketplace during that time period.

Azasan ® (azathioprine tablets)

In November 2003, we acquired from aaiPharma LLC the exclusive right to sell 25, 75 and 100 milligram dosage strengths of azathioprine tablets in North America under the brand name Azasan. Azasan is an FDA-approved drug that suppresses immune system responses and is indicated for preventing rejection of kidney transplants and treatment of severe arthritis. Azasan is commonly prescribed by gastroenterologists for treatment of Crohn's disease and ulcerative colitis, even though the drug was not approved for these treatments. We agreed to make an upfront payment and ongoing royalties on net sales to aaiPharma in exchange for supplying us with the drug product. In February 2004, we launched the 75 and 100 milligram dosage strengths of Azasan in the United States.

Rifaximin

Rifaximin is a gastrointestinal-specific oral antibiotic that, if approved by the FDA, we intend to establish as the drug of choice for the treatment of infectious diarrhea in travelers and a broad range of other gastrointestinal bacterial infections. According to the National Ambulatory Medical Care and National Hospital Ambulatory Medical Care surveys, between 1992 and 1996 (the most recent period for which we are aware there is publicly available information) patients visited physicians on average over 15 million times annually in the United States due to diarrhea, vomiting or gastrointestinal infections. According to the Centers for Disease Control, each year between 20% and 50% of international travelers, an estimated 10 million people, develop diarrhea, with approximately 80% of the cases caused by bacteria. Based upon recent data, approximately 6.2 million people sought treatment in the United States for infectious diarrhea in 2003 and approximately 4.1 million of those patients were prescribed a drug.

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

We submitted an NDA for the treatment of travelers' diarrhea to the FDA in December 2001. In October 2002, we received an approvable letter from the FDA in response to our application, in which the FDA requested additional

clinical data necessary to gain approval for rifaximin. In November 2003, we submitted to the FDA an amendment to our NDA to report the results of an additional clinical study and to respond to the other items outlined in the FDA's 2002 approvable letter. The FDA considered our amendment to be a complete response and has assigned a user fee goal date of May 26, 2004 to review and act upon the application.

We believe that rifaximin should, once introduced, be even more successful than Colazal in terms of revenue. This belief is based on the uniqueness of rifaximin as a gastrointestinal-specific antibiotic, combined with results of our market research and discussions with leading medical authorities highlighting the large number of diseases in which rifaximin could be used. Specifically, rifaximin will potentially compete in an annual U.S. retail market in excess of $2 billion, comprised of over 12 million patients. By comparison, Colazal competes in an annual U.S. retail market of approximately $450 million, comprised of approximately 500,000 patients. While the potential market for rifaximin is larger than that for Colazal, we expect to capture only a portion of each market and might not achieve the same success in the rifaximin market as with Colazal due to competition, market acceptance and/or other factors. We are exploring potential additional indications, formulations, clinical trials and co-promotion arrangements to capitalize on the potential for rifaximin.

Granulated Mesalamine

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 companies worldwide in gastroenterology. As part of that transaction, we also received a right of first negotiation with respect to additional Falk products in the United States. The Falk granulated mesalamine product has already been approved in most of the principal markets of Europe. If approved in the United States, the Falk granulated mesalamine product's unique prolonged release mechanism might allow us to expand the range of treatment options for ulcerative colitis. In December 2003, the FDA permitted us to initiate clinical trials of the product under our investigational new drug application, or IND. We are in the process of initiating a study designed to determine the appropriate dose. Thereafter, we plan to initiate Phase III studies during mid-2004 to investigate the product as a treatment for ulcerative colitis utilizing a dosing regimen that represents significant improvements over current therapies. The patent for the treatment of the intestinal tract with the granulated mesalamine product will expire in 2018.

Strategic Alliances

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

aaiPharma LLC

In November 2003, we acquired from aaiPharma LLC the exclusive right to sell 25, 75 and 100 milligram dosage strengths of azathioprine tablets in North America under the name Azasan. Under the terms of the agreement, we agreed to pay aaiPharma an upfront payment and ongoing royalties on net sales in exchange for supplying us with the drug product.

Alfa Wassermann S.P.A.

We in-licensed rifaximin from Alfa Wassermann, a privately held pharmaceutical company headquartered in Italy. Alfa Wassermann has developed several glycosaminoglycans, rifaximin and alpha-interferon from human leukocytes. Alfa Wassermann's principal areas of therapeutic focus include anti-thrombotics, antibiotics, gastrointestinal products, NSAIDs, immunomodulators, anti-hypertensives and bronchopulmonary products.

Pursuant to our agreement, Alfa Wassermann granted us the exclusive right in the United States and Canada to develop, make, use and sell or have sold rifaximin for the treatment of gastrointestinal and respiratory tract diseases. Alfa Wassermann has agreed separately to supply the Company with bulk active ingredient rifaximin at a fixed price.

Pursuant to the license agreement, we agreed to pay Alfa Wassermann a net sales-based royalty, as well as certain milestone payments. Our obligation to pay royalties commences upon the commercial launch of the

product and continues until the later of (1) the expiration of the period in which the manufacture, use or sale of the products by an unlicensed third party would constitute an infringement on the patent covering the product or (2) 10 years from commercial launch. Thereafter, the licenses granted to us shall continue as irrevocable royalty-free paid-up licenses. However, we would remain obligated to pay a net sales based royalty for use of the product trademark if we choose to continue using it after the other licenses expired.

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

Biorex Laboratories Limited

Biorex, a private, independent drug company headquartered in England, developed the new chemical entity balsalazide and completed limited Phase III clinical trials. We in-licensed balsalazide and all its salts, including our first product, balsalazide disodium, from Biorex. Under its agreements with us, Biorex will participate in future milestone revenues, royalties and profits from balsalazide.

Pursuant to an agreement entered into between us and Biorex in 1992, Biorex granted us the exclusive worldwide right (other than Japan, Taiwan, Korea and the United States) to develop, manufacture and sell balsalazide for all disease indications for a period of 15 years from the date of commercial launch, subject to early termination in certain circumstances, including upon the material breach by either party and, in the case of Biorex, in the event of our bankruptcy or if a sublicensee of ours terminates or becomes entitled to terminate its sublicense as a result of actions by us. Under a separate agreement, Biorex granted us the exclusive right to develop, manufacture and sell balsalazide for all disease indications in the United States for a period of nine years from the date of commercial launch or the term of the applicable patent, whichever is longer. Under these agreements, we paid Biorex fees upon entering into the agreements and are obligated to make additional milestone and royalty payments for the drug. The royalty payments to be made by us pursuant to the agreement governing the United States market are based on net sales, subject to minimum royalty payments for the first five years following commercial launch. Under the agreement governing territories other than the United States, we are obligated to pay to Biorex a portion of any gross profit on sales of balsalazide outside the United States. Under these agreements, we undertook to complete preclinical testing, perform clinical trials and obtain regulatory approvals for balsalazide. During 2001, we acquired from Biorex the exclusive right and license to develop, manufacture and sell balsalazide in Japan, Korea and Taiwan. There were no fees paid to Biorex upon entering into this agreement, but we are obligated to pay Biorex a portion of any upfront payments, milestone payments and gross profit on sales of balsalazide in Japan, Korea and Taiwan as well.

Dr. Falk Pharma GmbH

In July 2002, we in-licensed rights to a granulated formulation of mesalamine under an agreement with Dr. Falk Pharma of Freiburg, Germany. The agreement gives us the exclusive rights to develop and market the product in the United States. In return we will make upfront, milestone and royalty payments to Falk. The agreement also provides us a right of first negotiation with respect to rights to develop and market certain additional Falk products in the United States.

Menarini Pharmaceutical Industries S.R.L.

Menarini, headquartered in Italy, is the largest manufacturer and distributor of pharmaceuticals in Southern Europe. Menarini also has extensive experience developing and marketing therapies for gastrointestinal disease in its markets. Under our agreements with Menarini, we granted Menarini certain manufacturing rights and exclusive

distribution rights with respect to balsalazide in Italy, Spain, Portugal and Greece. Through December 31, 2001, we had received revenues as partial contribution to research and development costs borne by us of approximately $1.2 million. The agreement calls for additional milestone revenues to be paid to us relating to European marketing approvals in the Menarini territories. During 2001, Menarini paid a $270,000 milestone payment to us related to receipt of marketing approval in Italy. Under the terms of the agreements, we will sell the bulk active ingredient balsalazide to Menarini for marketing and distribution in its territories at cost plus a sales-based royalty. During 2001, Menarini paid us approximately $1.2 million for bulk active ingredient balsalazide. Menarini did not purchase any bulk active ingredient balsalazide from us during 2002 or 2003.

Unless terminated sooner in accordance with its terms, the agreement with Menarini continues until the earlier of the expiration of (1) the patents relating to the product or (2) 15 years from the date of the agreement, provided however that in any case the agreement shall continue for a period of 10 years from the date of first launch. Either party may terminate the agreement upon a material breach by the other party and the failure to remedy such breach within 30 days in the case of a payment breach or 90 days in the case of any other material breach or if a party enters liquidation, bankruptcy or similar proceedings.

Shire Pharmaceuticals Group plc

In May 2000, we signed an agreement with Shire Pharmaceuticals Group under which Shire purchased from us the exclusive rights to balsalazide, for use as a treatment for ulcerative colitis for Austria, Belgium, Denmark, Finland, France, Germany, Iceland, Republic of Ireland, Luxembourg, Norway, The Netherlands, Switzerland, Sweden and the United Kingdom. Under the agreement, Shire agreed to pay us up to a total of approximately $24.0 million, including approximately $12.1 million in up-front fees and up to $12.0 million upon the achievement of certain milestones. In accordance with our license arrangement with Biorex Laboratories Limited, our licensor, we share a portion of these payments with Biorex. In May 2000, Shire paid us $9.6 million of cash and $2.5 million by way of the issue of 160,546 new Shire ordinary shares. In August 2000 Shire paid us $4.4 million in connection with the transfer to Shire of the United Kingdom product license for balsalazide. No such additional payments have been made to us by Shire since August 2000.

Manufacturing

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

Currently, we are using active pharmaceutical ingredient balsalazide manufactured for us by Omnichem s.a., a subsidiary of Ajinomoto in Belgium. Balsalazide is being encapsulated for us by Anabolic in Irvine, California. In addition, we have qualified an additional manufacturer of commercial quantities of the active pharmaceutical ingredient balsalazide and are in negotiations to secure an additional encapsulator.

Under our supply agreement with Alfa Wasserman, Alfa Wassermann is obligated to supply us with bulk active ingredient rifaximin until ten years from commercial launch or introduction of a generic product, whichever occurs first. Currently, Alfa Wassermann manufactures rifaximin for the Italian and other European markets. Alfa Wasserman is in the process of securing additional sources of commercial quantities of the active pharmaceutical ingredient rifaximin.

With respect to the granulated mesalamine product, we are in negotiations to secure a source of bulk active ingredient and a manufacturer of drug product.

Under our supply agreement with aaiPharma, aaiPharma is obligated to supply us with finished product to meet all of our requirements for the 25, 75 and 100 milligram tablets of Azasan for a period of three years from execution of the agreement.

Sales and Marketing

We currently market Colazal and Azasan and intend, if approved by the FDA, to market rifaximin, granulated mesalamine and other future products to U.S. gastroenterologists through our own direct sales force, and enter into distribution relationships outside the United States and in markets where a larger sales organization is appropriate. Currently, our sales and marketing staff consists of approximately 100 people. We believe our sales force should also position us to sell additional products, including rifaximin and the granulated mesalamine product.

PATENTS AND PROPRIETARY RIGHTS

General

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 have been granted an extension of such patent under the Waxman-Hatch Act through July 2006. We have also obtained patent extensions for the composition of balsalazide in Italy and the United Kingdom until July 2006. 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. We have filed applications for patents for additional indications using balsalazide and related chemical substances. The patent for the treatment of the intestinal tract with the granulated mesalamine product will expire in 2018.

Data Exclusivity

In 2000, the FDA granted us five years of new chemical entity data exclusivity for balsalazide. This means that for five years from the date of approval of our NDA for balsalazide, the FDA will not approve an application for a competitive version of balsalazide which relies upon data included in our NDA. Therefore, unless an applicant for a competitive version of balsalazide were to develop its own data supporting approval of its NDA, this data exclusivity will have the effect of preventing generic competition for balsalazide until at least July 2005. This period has now been effectively extended to July 2006 by the grant of the balsalazide patent extension.

Because rifaximin is a new chemical entity, we also expect to obtain similar 5 year exclusivity for it if approved.

Although the granulated mesalamine product is not a new chemical entity, it may be entitled to three years of exclusivity from the date of its approval if new clinical investigations are required for its approval. Such exclusivity would have the effect of preventing FDA from approving an NDA for a granulated mesalamine product which relied upon the new clinical investigation in our NDA for three years from the date of approval. We believe that the patent for the granulated mesalamine will nonetheless prevent any such approval until at least 2018.

Government Regulation

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

The steps ordinarily required before a new pharmaceutical product containing a new chemical entity may be marketed in the United States include: (1) preclinical laboratory tests, preclinical studies in animals and formulation studies; (2) the submission to the FDA of a notice of claimed investigational exemption for a new drug or antibiotic,

which must become effective before clinical testing may commence; (3) adequate and well-controlled clinical human trials to establish the safety and efficacy of the drug for each indication; (4) the submission of an NDA to the FDA; and (5) FDA review and approval of the NDA prior to any commercial sale or shipment of the drug. Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety and efficacy of the product. Preclinical tests must be conducted in compliance with Good Laboratory Practice regulations. The results of preclinical testing are submitted to the FDA as part of an IND. A 30-day waiting period after the filing of each IND is required prior to the commencement of clinical testing in humans. In addition, the FDA may, at any time during this 30-day period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

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

After successful completion of the required clinical testing, generally an NDA is submitted. FDA approval of the NDA is required before marketing may begin in the United States. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. In such an event, the NDA must be resubmitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The FDA has 10 months in which to review the NDA and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. If FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable 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. 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 regulatory approval of any product is granted, such approval will be limited to those disease states and conditions for which the product has been found by the FDA to be safe and effective, as demonstrated through well controlled clinical studies. Furthermore, approval may entail ongoing requirements for post-marketing studies. Even if such regulatory approval is obtained, a marketed product, its manufacturer and its 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 "rare disease or condition," which is 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. We are currently exploring the potential to develop rifaximin as an orphan drug for the treatment of hepatic encephalopathy.

Drug manufacturing establishments are subject to periodic inspection by regulatory authorities and must comply with Good Manufacturing Practice regulations. Either we or our third party manufacturer must pass a preapproval inspection of our respective manufacturing facilities by the FDA before obtaining marketing approval of any products for sale in the United States. These manufacturers are also subject to periodic FDA inspections. In the event that violations of applicable standards are found, we may be required to cease distribution of some or all products and may be required to recall products already distributed.

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.

To market our products in Europe, we or our distributors also must satisfy foreign regulatory requirements, implemented by foreign health authorities, governing human clinical trials and marketing approval. In the United Kingdom, the sale and marketing of new drugs is subject to the approval of the Medicines Control Agency, or MCA. As in the United States, a company seeking regulatory approval must submit an application requesting such approval, which is referred to as a Product License Application, or PLA. The PLA is submitted after completion of pre-clinical and clinical studies. The MCA may request additional clinical information on efficacy or safety before formally reviewing the application. Following a review of the PLA, the MCA makes a determination as to approval of the new drug compound. The review process in the United Kingdom is subject to many of the same uncertainties and risks associated with the approval of new drugs by the FDA in the United States. Furthermore, approval may entail ongoing requirements for post-marketing studies. Even if such regulatory approval is obtained, a marketed product and its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the MCA.

Under a relatively new regulatory system in Europe, marketing authorizations, broadly speaking, may be submitted at a centralized, a decentralized or a national level. The centralized procedure is mandatory for the approval of biotechnology and high technology products and available at the applicant's option for other products. The centralized procedure provides for the first time in the European Union for the grant of a single marketing authorization which is valid in all EU member states. Alternatively, a mutual recognition procedure implemented in January 1995 is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure under the so-called "decentralized procedure". The decentralized procedure, which began in January 1998, created a new system for mutual recognition of national approval decisions, made changes to then existing procedures for national approvals and established procedures for coordinated EU actions on products, suspensions and withdrawals.

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

Competition

Competition in our business is intense and characterized by extensive research efforts and rapid technological progress. Technological developments by competitors, earlier regulatory approval for marketing competitive products, or superior marketing capabilities possessed by competitors could adversely affect the commercial potential of our products and could have a material adverse effect on our revenue and results of operations. We believe that there are numerous pharmaceutical and biotechnology companies, including large well-known pharmaceutical companies, as well as academic research groups throughout the world, engaged in research and development efforts with respect to pharmaceutical products targeted at gastrointestinal diseases and conditions addressed by our current and potential

products. In particular, we are aware of products in research or development by competitors that address the diseases being targeted by our products. Developments by others might render our current and potential products obsolete or non-competitive. Competitors might be able to complete the development and regulatory approval process sooner and, therefore, market their products earlier than us. Many of our competitors have substantially greater financial, marketing and personnel resources and development capabilities than we do. For example, many large, well capitalized companies already offer products in the United States and Europe that target the indications for balsalazide, including mesalamine (GlaxoSmithKline plc, Giuliani S.p.A. and the granulated mesalamine product, Axcan Pharma, Inc., Solvay S.A., The Procter & Gamble Company and Shire Pharmaceuticals Group plc), sulfasalazine (Pharmacia & Upjohn, Inc.), and olsalazine (Pharmacia & Upjohn, Inc.). Asacol, marketed by Proctor & Gamble, is currently the most prescribed product for the treatment of ulcerative colitis in the United States. The most frequently prescribed product for treatment of travelers' diarrhea in the United States currently is ciprofloxacin, commonly known as "Cipro®" and marketed by Bayer AG. The most frequently prescribed products that compete with Azasan are Imuran®, marketed by Prometheus Laboratories, Inc., and its various generics and Purinethol®, marketed by GATE Pharmaceuticals, and its various generics.

Employees

As of December 31, 2003, we had 132 full-time employees. We believe that our future success will depend in part on our continued ability to attract, hire, and retain qualified personnel. 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 2. Properties

Our corporate headquarters are located at 8540 Colonnade Center Drive, Suite 501, Raleigh, North Carolina 27615, where we occupy approximately 26,000 square feet of office space under a lease expiring in August 2011. We have additional space in Palo Alto, California, where we occupy approximately 3,000 square feet under a lease expiring in February 2005.

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.

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

No matter was submitted to a vote of our stockholders during the fourth quarter of the year ended December 31, 2003.

Executive Officers of the Registrant

The following table sets forth certain information concerning our executive officers as of December 31, 2003:

Name	Age	Position
Carolyn J. Logan	55	President, Chief Executive Officer and Director
Adam C. Derbyshire	38	Senior Vice President, Finance and Administration and Chief Financial Officer
Arthur R. Kamm, Ph.D	54	Senior Vice President, Research and Development, and Chief Development Officer

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

Adam C. Derbyshire has served as Senior Vice President, Finance and Administration and Chief Financial Officer since June 2000. Prior to joining us, Mr. Derbyshire was Vice President, Corporate Controller and Secretary of Medco Research, Inc. (acquired by King Pharmaceuticals, Inc. in February 2000) from June 1999 to June 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.

Arthur R. Kamm joined Salix in July 2003 as Senior Vice President, Research and Development and Chief Development Officer. Dr. Kamm has over 20 years experience in the clinical development and regulatory approval of medical products, biotechnology products and medical devices. Prior to joining us, Dr. Kamm was President, CEO and Founder of A.R. Kamm Associates, Inc., a strategic-level consulting and medical product development service organization from June 1991 until June 2002. Prior thereto, Dr. Kamm was employed by Glaxo, Inc. from June 1982 until May 1991, most recently as their Vice President, Clinical Development and Vice President, Zantac Development for Glaxo, Inc. Dr. Kamm received his B.S. degree from the University of South Carolina and his Ph.D. from the Medical College University of Arizona.

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

Our common stock is traded on the Nasdaq National 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 National Market.

	High	Low
Fiscal year ended December 31, 2002		
First quarter	$20.35	$12.90
Second quarter	18.11	13.75
Third quarter	15.21	5.95
Fourth quarter	10.58	4.29
Fiscal year ended December 31, 2003		
First quarter	$ 7.20	$ 5.00
Second quarter	12.30	6.44
Third quarter	20.09	10.14
Fourth quarter	23.00	16.46

On December 31, 2003, the closing price for the common stock as reported on the Nasdaq National Market was $22.68. As of March 5, 2004, there were approximately 3,000 stockholders of record.

The securities markets have from time to time experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. In addition, the market prices of the common stock of 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.

Dividend Policy

We have never declared or paid cash dividends on our common stock. Under the terms of our line of credit agreement with RBC Centura, the Company is prohibited from paying a dividend on its stock without RBC Centura's consent. We currently expect to retain future earnings, if any, for use in the operation and expansion of business and do not anticipate paying any cash dividends in the foreseeable future.

Item 6. Selected Consolidated 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. The following selected financial data are derived from the consolidated financial statements of Salix Pharmaceuticals, Ltd. which have been audited by Ernst & Young LLP, independent auditors. The data should be read in conjunction with the consolidated financial statements, related notes and other financial information included herein.

Consolidated Statements of Operations Data:

	Year Ended December 31,				
	2003	2002	2001	2000	1999
	(U.S. dollars, in thousands, except per share data)				
Revenues:					
Product revenue	$ 55,807	$ 33,456	$ 14,129	$ 6,307	$ 491
Revenues from collaborative agreements and other	—	—	8,221	8,235	2,602
Total revenues	55,807	33,456	22,350	14,542	3,093
Costs and expenses:					
Cost of products sold	13,226	8,192	3,495	2,287	878
License fees and costs related to collaborative agreements	125	125	5,583	4,173	297
Research and development	23,654	17,967	6,629	3,844	4,787
Selling, general and administrative	38,635	33,004	24,688	7,412	1,932
Total expenses	75,640	59,288	40,395	17,716	7,894
Loss from operations	(19,833)	(25,832)	(18,045)	(3,174)	(4,801)
Interest, other income, net	(268)	1,090	547	208	190
Income taxes	—	—	—	(9)	—
Net loss	$(20,101)	$(24,742)	$(17,498)	$ (2,975)	$ (4,611)
Net loss per share, basic and diluted(1)	$ (0.92)	$ (1.21)	$ (1.13)	$ (0.26)	$ (0.45)
Shares used in computing net loss per share(1)	21,862	20,488	15,456	11,356	10,209

Consolidated Balance Sheet Data:

	2003	2002	2001	2000	1999
Cash and cash equivalents	$ 62,795	$ 34,531	$ 27,868	$ 13,244	$ 2,402
Short-term investments	2,012	14,165	—	—	—
Long-term investments	—	7,052	—	—	—
Working capital	69,314	52,053	26,308	12,408	2,013
Total assets	90,852	75,302	38,590	25,761	3,659
Accumulated deficit	(90,727)	(70,626)	(45,884)	(28,386)	(25,411)
Stockholders' equity	73,935	60,389	27,594	12,742	2,215

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

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

Overview

We are a specialty pharmaceutical company dedicated to acquiring, developing and commercializing prescription drugs used in the treatment of a variety of gastrointestinal diseases, which are those affecting the digestive tract. Our strategy is to identify and acquire rights to products that we believe have potential for near-term regulatory approval or are already approved; apply our regulatory, product development, and sales and marketing expertise to commercialize these products; and use our 100-member specialty sales and marketing team focused on high-prescribing U.S. gastroenterologists to sell our products. We rely on distribution relationships with third parties to sell our products outside the United States.

We generate revenue primarily by selling our products, prescription drugs, to pharmaceutical wholesalers. These direct customers of ours resell and distribute our products to and through pharmacies to patients who have had our products prescribed by doctors. Because demand for our products originates with doctors, our sales force calls on high prescribing specialists, primarily gastroenterologists, and we monitor new and total prescriptions for our products as a key performance indicator for our business.

Prescriptions result in our products being used by patients, requiring our direct customers to purchase more products to replenish their inventory. However, our revenue might fluctuate from quarter to quarter due to other factors, such as increased buying by wholesalers in anticipation of a price increase. Revenue could be less than anticipated in subsequent quarters as wholesalers' increased inventory is used up. We believe such increased buying occurred in late 2003, and it could again.

In July 2000, the FDA approved Colazal for marketing in the United States for the treatment of mildly to moderately active ulcerative colitis. In December 2000, we established our own field sales force to market Colazal in the United States. Currently, this sales force has approximately 70 sales representatives in the field. Although the creation of an independent sales organization involved substantial costs, we believe that the financial returns from Colazal, Azasan and rifaximin and other future products, if acquired and approved, will be more favorable to us than those from the indirect sale of product through marketing partners.

In December 2001, we submitted a New Drug Application, or NDA, to the FDA for rifaximin as a treatment for travelers' diarrhea. In October 2002, we received an approvable letter from the FDA in response to our application, in which the FDA requested additional clinical data necessary to gain approval for rifaximin. In November 2003, we submitted to the FDA an amendment to our NDA to report the results of the additional clinical study and to respond to the other items outlined in the FDA's 2002 approvable letter. The FDA considered our amendment to be a complete response and has assigned a user fee goal date of May 26, 2004 to review and act upon the application. If FDA approval is obtained, we intend to market rifaximin to gastroenterologists and infectious disease physicians in the United States through our own direct sales force. We are exploring potential indications, formulations, clinical trials and co-promotion arrangements to capitalize on the potential for rifaximin.

In July 2002, we in-licensed exclusive development and marketing rights in the United States to a granulated formulation of mesalamine from Dr. Falk Pharma. We intend to complete the development work required to secure regulatory approval for the product in the United States.

In November 2003, we acquired from aaiPharma LLC the exclusive right to sell three dosage strengths of Azasan (azathioprine tablets) in North America. In February 2004, we launched two dosage strengths of Azasan in the United States.

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 are believed 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 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

Our product sales are recorded upon shipment of order and transfer of title.

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

Due to the uniqueness of each of our licensing arrangements, we analyze each element of each contract, including milestone payments, to determine the appropriate revenue recognition. In accordance with SAB 101, we recognize revenue upon achievement of contractual milestones only when and to the extent we conclude that a separate earnings process has been culminated or the milestone is representative of the level of effort and progress toward completion of a long-term contract.

Investments

We consider all investments that have a maturity of greater than three months and less than one year to be short-term investments. All securities with maturities beyond one year are considered long-term investments. Our short-term and long-term investments consist of government agency and high-grade corporate bonds. We have the intent and ability to hold these investments until maturity; therefore, the investments are classified as held-to-maturity and are reported at amortized costs.

Inventories

As of December 31, 2003, we had $16.1 million in inventories. Inventories of pharmaceutical products were comprised of $12.2 million of raw materials and $3.9 million of finished goods. As of December 31, 2003, we had approximately $6.4 million in inventories relating to a product that had not received final approval by the FDA. Inventories are stated at the lower of cost (which approximates actual cost on a first-in, first-out cost method) or market. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. As appropriate, provisions are made to reduce inventories to their net realizable value.

Intangible Assets

When we make product acquisitions that include license agreements, product rights and other identifiable intangible assets, we record the aggregate purchase price, along with the value of the product related liabilities that we assume, as intangible assets. We allocate the purchase price to the fair value of the various intangible assets in order to amortize their cost as an expense in our statement 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 may not be recoverable. Some factors that we consider important which could trigger an impairment review include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of our use of the acquired assets or the strategy for our overall business, 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, an impairment loss will be recognized in an amount equal to the difference. We review intangible assets for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Allowance for Uncollectible Accounts

To date, we have not experienced any material accounts receivable collection issues. However, based on a review of specific customer balances, industry experience and the current economic environment, we currently reserve for specific accounts plus 1% of our outstanding trade accounts receivable balance as an allowance for uncollectible accounts, which at December 31, 2003 and December 31, 2002 was approximately $0.3 million and $0.1 million, respectively.

Allowance for Rebates and Coupons

Based on current contracts that allow for rebates and our estimate of revenue associated with those contracts, we currently reserve an allowance for rebate charges, which at December 31, 2003 and December 31, 2002 was $2.1 million and $0.6 million, respectively. Based on the number of available coupons and our estimate of redemption of available coupons from industry experience, we currently have reserved approximately $25,000 as an allowance for coupon redemption.

Results of Operations

Years Ended December 31, 2003, 2002 and 2001

Revenues totaled $55.8 million, $33.5 million and $22.4 million for 2003, 2002 and 2001, respectively. Revenues for the year ended December 31, 2003 consisted solely of product revenues of $55.8 million. Revenues for the year ended December 31, 2002 consisted solely of product revenues of $33.5 million. Revenues for the year ended December 31, 2001 included product revenues of $14.1 million and revenues from collaborative agreements of $8.3 million, of which $5.5 million related to the agreement with Shire. We expect that future revenues will consist solely or primarily of product revenue. Product revenue increases from 2001 to 2002 and from 2002 to 2003 are due to increased sales of Colazal.

Total costs and expenses were $75.6 million, $59.3 million, and $40.4 million for 2003, 2002 and 2001, respectively. The increases in 2003 and 2002 were primarily the result of increased research and development activity associated with rifaximin, as well as expansion of our commercialization infrastructure and marketing campaign for Colazal.

We recognized cost of products sold of $13.2 million, $8.2 million and $3.5 million for 2003, 2002 and 2001, respectively. The increase in cost of products sold in 2003 and 2002 were due primarily to increased sales of Colazal. License fees and costs related to collaborative agreements of $0.1 million, $0.1 million and $5.6 million in 2003, 2002 and 2001, respectively, related primarily to payments made to Biorex and Alfa Wassermann under the terms of the respective license agreements. The decrease in licensee fees and costs related to collaborative agreements in 2002 from 2001 was due to the completion in 2001 of the amortization of upfront payments related to the Shire Agreement.

Research and development expense was $23.7 million, $18.0 million and $6.6 million for 2003, 2002 and 2001, respectively. The increase in research and development expenses in 2003 from 2002 was due primarily to costs

certain legal entities, or VIE's. A legal entity is considered a VIE if it does not have sufficient equity at risk to finance its own activities without relying on financial support from other parties. If the legal entity is a VIE, then the reporting entity that is the primary beneficiary must consolidate it. Even if a reporting entity is not obligated to consolidate a VIE, then disclosure must be made about the VIE if the reporting entity has a significant variable interest. FIN 46 is effective immediately for VIEs created after January 31, 2003 and in the first interim period ending after March 15, 2004 for VIEs created prior to February 1, 2003. We do not expect the adoption of FIN 46 to have a material impact on our results of operations or financial position.

Cautionary Statement

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. The following statement highlights some of these risks.

Statements contained in this Form 10-K that are not historical facts are or might constitute forward-looking statements under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Although we believe the expectations reflected in such forward-looking statements are based on reasonable assumptions, our expectations might not be attained. Forward-looking statements involve known and unknown risks that could cause actual results to differ materially from expected results. Factors that could cause actual results to differ materially from our expectations expressed in the report include, among others: the unpredictability of the duration and results of regulatory review of New Drug Applications and Investigational New Drug Applications; our dependence on our first four pharmaceutical products, Colazal, Azasan, rifaximin and granulated mesalamine, and the uncertainty of market acceptance of those products; the high cost and uncertainty of the research, clinical trials and other development activities involving pharmaceutical products; the uncertainty of obtaining, and our dependence on, third parties to manufacture and sell our products; intense competition; the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties; and results of future litigation and other risk factors detailed from time to time in our other SEC filings.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

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

Item 8. Financial Statements and Supplementary Data

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

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

Not applicable.

Item 9A. Control and Procedures

(a) Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) are designed only to provide reasonable assurance that they will meet their objectives. 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 Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e)) pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective to provide the reasonable assurance discussed above.

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

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
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	
10.14	Lease dated January 1, 1992 by and between Kontrabecki Mason Developers and Salix Pharmaceuticals, Inc., as amended.	S-1	08/15/97	10.14	
10.22	Termination and Settlement Agreement dated as of December 22, 1999, by and between Astra AB and Salix Pharmaceuticals Inc. (a wholly owned subsidiary of Salix Pharmaceuticals, Ltd.).	8-K	12/28/99	10.22	
10.23	Agreement dated December 22, 1999, between Glycyx Pharmaceuticals, Ltd. and Astra AB.	8-K	12/28/99	10.23	
10.25*	Agreement dated May 17, 2000 between Glycyx Pharmaceuticals, Ltd. and Shire Pharmaceuticals Group plc.	10-Q	08/14/00	10.25	
10.26*	Agreement dated May 17, 2000 between Biorex Laboratories Limited and Glycyx Pharmaceuticals, Ltd.	10-Q	08/14/00	10.26	
10.28	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*	License Agreement between Biorex Laboratories Limited and Glycyx Pharmaceuticals, Ltd. dated August 22, 2001.	10-Q	11/14/01	10.30	
10.30	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	
10.33	Loan and Security Agreement dated September 30, 2002 by and between RBC Centura Bank, Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.	10-Q	11/14/02	10.33	
10.34	Commercial Promissory Note Agreement dated September 30, 2002 issued to RBC Centura Bank by Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.	10-Q	11/14/02	10.34	
10.35	Negative Pledge Agreement dated September 30, 2002 between RBC Centura Bank, Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.	10-Q	11/14/02	10.35	
10.36	Rights Agreement, dated as of January 10, 2003, between Salix Pharmaceuticals, Ltd. and Computershare Investor Services LLC, as Rights Agent.	8-K	01/10/03	10.36	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.37	Common Stock Purchase Agreement dated November 6, 2003 among Salix Pharmaceuticals, Ltd. and the investors listed therein.	8-K	11/10/03	10.37	
10.38	Modification to Commercial Promissory Note Agreement dated September 29, 2003 between RBC Centura Bank, Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.	10-Q	11/14/03	10.38	
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.				X
10.41**	License Agreement dated October 31, 2003 between aaiPharma LLC, aaiPharma Inc. and Salix Pharmaceuticals, Ltd.				X
10.42	Modification to Commercial Promissory Note Agreement dated December 31, 2003 between RBC Centura Bank, Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.				X
21.1	Subsidiaries of the Registrant.	S-4	11/20/01	21.1	
23.1	Consent of Independent Auditors.				X
31.1	Certification by the Chief Executive Officer pursuant to Section 240.13a-14 or section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
31.2	Certification by the Chief Financial Officer pursuant to Section 240.13a-14 or section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification by the Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

* The registrant has received confidential treatment with respect to certain portions of this exhibit. Such portions have been omitted from this exhibit and have been filed separately with the United States Securities and Exchange Commission.

** Confidential treatment requested for certain portions of this agreement. (n) Incorporated by referenced to Exhibit file with the Registrant Current Report on Form 8-K dated January 10, 2003.

(B) Reports On Form 8-K.

We furnished or filed the following Current Reports on Form 8-K during the quarter ended December 31, 2003:

Date	Item	Description
October 14, 2003	5	Disclosed results of an open label study regarding Rifaximin.
October 20, 2003	5	Disclosed the signing of an agreement to market Colazal in the Republic of Korea.
October 21, 2003	5	Announced when we would report third quarter 2003 financial results.
October 28, 2003	12	Announced third quarter 2003 financial results.
November 4, 2003	5	Disclosed acquisition of exclusive right to sell Azasan in North America.
November 5, 2003	5	Announced that we would present at the CIBC World Markets Fourteenth Annual Healthcare Conference.
November 10, 2003	5	Disclosed the private placement of 1.7 million shares of common stock to selected institutional investors.
November 14, 2003	5	Announced that the Company would be incorporated into the NASDAQ Biotechnology Index.
November 26, 2003	5	Disclosed submission of an amendment to our NDA for Rifaximin to the FDA in response to the FDA approvable letter of October 25, 2002.
December 10, 2003	5	Disclosed that the FDA has acknowledged receipt of our November 25, 2003 amendment to the Rifaximin NDA.
December 10, 2003	5	Announced we were selected as the featured company on the "Terry Bradshaw's Pick of the Week" television series.
December 11, 2003	5	Disclosed that the FDA permitted clinical trials to initiate under our IND for granulated mesalamine.

(C) Exhibits

See Item 15(a)(3) above.

(D) 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: March 12, 2004

/s/ CAROLYN J. LOGAN

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

Date: March 12, 2004

/s/ ADAM C. DERBYSHIRE

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

Date: March 12, 2004

/s/ JOHN F. CHAPPELL

John F. Chappell
Chairman of the board

Date: March 12, 2004

/s/ THOMAS W. D'ALONZO

Thomas W. D'Alonzo
Director

Date: March 12, 2004

/s/ RICHARD A. FRANCO

Richard A. Franco
Director

Date: March 12, 2004

/s/ WILLIAM P. KEANE

William P. Keane
Director

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SALIX PHARMACEUTICALS, LTD.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT AUDITORS

The Board of Directors
Salix Pharmaceuticals, Ltd.

We have audited the accompanying consolidated balance sheets of Salix Pharmaceuticals, Ltd. and subsidiaries as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule, listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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 audits provide 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. and subsidiaries at December 31, 2003 and 2002, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. 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.

Ernst & Young LLP

Raleigh, North Carolina
February 3, 2004

SALIX PHARMACEUTICALS, LTD. AND SUBSIDIARIES

Consolidated Balance Sheets

	December 31, 2003	December 31, 2002
	(U.S. dollars, in thousands, except share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,795	$ 34,531
Short-term investments	2,012	14,165
Accounts receivable, net	3,598	5,980
Inventory, net	16,094	10,210
Prepaid and other current assets	1,732	2,080
Total current assets	86,231	66,966
Long-term investments	—	7,052
Property and equipment, net	2,621	1,284
Other assets	2,000	—
Total assets	$ 90,852	$ 75,302
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,611	$ 3,029
Accrued liabilities	11,749	8,676
Deferred revenue	3,557	3,208
Total current liabilities	16,917	14,913
Commitments	—	—
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, issuable in series, none outstanding	—	—
Common stock, $0.001 par value; 80,000,000 shares authorized, 23,719,821 and 21,375,846 shares issued and outstanding at December 31, 2003 and 2002, respectively	24	21
Additional paid-in-capital	165,293	131,300
Other comprehensive loss	(655)	(306)
Accumulated deficit	(90,727)	(70,626)
Total stockholders' equity	73,935	60,389
Total liabilities and stockholders' equity	$ 90,852	$ 75,302

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

SALIX PHARMACEUTICALS, LTD. AND SUBSIDIARIES

Consolidated Statements of Operations

	Year Ended December 31,		
	2003	2002	2001
	(U.S. dollars, in thousands, except per share data)		
Revenues:			
Product revenue	$ 55,807	$ 33,456	$ 14,129
Revenue from collaborative agreements	—	—	8,221
Total revenues	55,807	33,456	22,350
Costs and expenses:			
Cost of products sold	13,226	8,192	3,495
License fees and costs related to collaborative agreements	125	125	5,583
Research and development	23,654	17,967	6,629
Selling, general and administrative	38,635	33,004	24,688
Total costs and expenses	75,640	59,288	40,395
Loss from operations	(19,833)	(25,832)	(18,045)
Interest, and other income (expense), net	(268)	1,090	547
Income taxes	—	—	—
Net loss	$(20,101)	$(24,742)	$(17,498)
Net loss per share, basic and diluted	$ (0.92)	$ (1.21)	$ (1.13)
Shares used in computing net loss per share, basic and diluted	21,862	20,488	15,456

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

SALIX PHARMACEUTICALS, LTD. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional	Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in-capital	Loss	Deficit	Equity
	(U.S. dollars, in thousands, except share amounts)					
Balance at December 31, 2000	13,562,771	$ 14	$ 41,114	$ —	$(28,386)	$ 12,742
Issuance of common stock upon exercise of stock options and warrants	1,185,910	1	4,229	—	—	4,230
Issuance of common stock in connection with the company's private placement, net of issuance costs of $1,281	1,960,000	2	28,118	—	—	28,120
Net loss	—	—	—	—	(17,498)	(17,498)
Balance at December 31, 2001	16,708,681	17	73,461	—	(45,884)	27,594
Issuance of common stock upon exercise of stock options	67,165	—	430	—	—	430
Issuance of common stock in connection with the company's public offering, net of issuance costs of $4,089	4,600,000	4	57,409	—	—	57,413
Other comprehensive loss	—	—	—	(306)	—	(306)
Net loss	—	—	—	—	(24,742)	(24,742)
Balance at December 31, 2002	21,375,846	21	131,300	(306)	(70,626)	60,389
Issuance of common stock upon exercise of stock options	643,975	1	4,949	—	—	4,950
Issuance of common stock in connection with the company's private placement, net of issuance costs of $1,552	1,700,000	2	29,046	—	—	29,048
Dividends issued in conjunction with redemption of shareholder rights plan	—	—	(2)	—	—	(2)
Other comprehensive loss	—	—	—	(349)	—	(349)
Net loss	—	—	—	—	(20,101)	(20,101)
Balance at December 31, 2003	23,719,821	$ 24	$165,293	$(655)	$(90,727)	$ 73,935

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

SALIX PHARMACEUTICALS, LTD. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2003	2002	2001
	(U.S. dollars, in thousands)		
Cash Flows from Operating Activities			
Net loss	$(20,101)	$(24,742)	$(17,498)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	475	408	223
Loss on disposal of fixed asset	—	—	21
Changes in assets and liabilities:			
Accounts receivable	2,382	(3,602)	3,778
Inventory and other assets	(5,536)	(5,013)	(905)
Accounts payable and accrued liabilities	1,655	3,611	3,562
Deferred revenue	349	306	(5,585)
Net cash used in operating activities	(20,776)	(29,032)	(16,404)
Cash Flows from Investing Activities			
Purchases of property and equipment	(1,812)	(625)	(1,107)
Proceeds from the disposal of property and equipment	—	—	4
Purchases of investments	—	(26,376)	—
Proceeds from maturity of investments	19,205	5,159	—
Purchase of other assets	(2,000)	—	(219)
Net cash provided by (used in) investing activities	15,393	(21,842)	(1,322)
Cash Flows from Financing Activities			
Proceeds from issuance of common stock	33,996	57,843	32,350
Net cash provided by financing activities	33,996	57,843	32,350
Effect of exchange rate changes on cash	(349)	(306)	—
Net increase in cash and cash equivalents	28,264	6,663	14,624
Cash and cash equivalents at beginning of year	34,531	27,868	13,244
Cash and cash equivalents at end of year	$ 62,795	$ 34,531	$ 27,868

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 used in the treatment of a variety of gastrointestinal diseases, which are those affecting the digestive tract.

These 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 subsidiaries. All significant intercompany balances and transactions have been eliminated.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Revenue Recognition

Product sales are recorded upon shipment of order and transfer of title.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin, or SAB, No. 101, "Revenue Recognition in Financial Statements," which among other guidance clarifies certain conditions to be met in order to recognize revenue. SAB 101 requires companies to recognize certain up-front non-refundable fees over the term of the related agreement unless the fee is in exchange for products delivered or services performed that represent the culmination of a separate earnings process.

Research and Development

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

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 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.

Investments

The Company considers all investments that have a maturity of greater than three months and less than one year to be short-term investments. All securities with maturities beyond one year are considered long-term investments. The Company's short-term and long-term investments consist of government agency and high-grade corporate bonds. The Company has the intent and ability to hold these investments until maturity; therefore, the investments are classified as held-to-maturity and are reported at amortized cost.

Property and Equipment

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

Inventories

Raw materials, work-in-process and finished goods inventories are stated at the lower of cost (which approximates actual cost on a first-in, first-out cost method) or market value. At December 31, 2003, inventories were comprised of $12.2 million of raw material and $3.9 million of finished goods. At December 31, 2002, inventories were comprised of $7.3 million of raw material and $2.9 million of finished goods. As of December 31, 2003 the Company had approximately $6.4 million in inventories relating to products that had not been approved by the U.S. Food and Drug Administration.

Intangible Assets

When the Company makes product acquisitions that include license agreements, product rights and other identifiable intangible assets, it records the aggregate purchase price, along with the value of the product related liabilities that it assumes, as intangible assets. The Company allocates the purchase price to the fair value of the various intangible assets in order to amortize their cost as an expense in its statement of operations over the estimated economic useful life of the related assets. The Company assesses the impairment of identifiable intangible assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Some factors that the Company considers important which could trigger an impairment review include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business, and significant negative industry or economic trends.

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

Asset Impairment

The Company periodically reviews the value of its long-lived assets to determine if an impairment has occurred. In accordance with Financial Accounting Standards Board Statement of Financial Accounting Standards, or SFAS, No. 121, "Accounting for Long-Lived Assets and Long-Lived Assets to be Disposed Of", if this review indicates that the assets will not be recoverable, based on an analysis of undiscounted cash flows over the remaining amortization period, the Company will reduce the carrying value of its long-lived assets accordingly.

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

Advertising costs are charged to expense as incurred. Advertising expenses were approximately $1.3 million, $0.6 million and $0.2 million for 2003, 2002 and 2001, respectively.

Foreign Currency Translation

The functional currency for the Company is the U.S. dollar. All balance sheet accounts have been translated using the exchange rates in effect at the balance sheet date. The gains and losses resulting from the changes in exchange rates

from year to year were immaterial in 2001. In 2002 and 2003, the loss was reported in other comprehensive loss. The effect on the consolidated statements of operations of transaction gains and losses is insignificant for all years presented.

Comprehensive Loss

The Company adopted SFAS No. 130, "Reporting Comprehensive Income" effective January 1, 1998. SFAS 130 requires that the Company display an amount representing comprehensive income (loss) for the year in a financial statement, which is displayed with the same prominence as other financial statements. The Company elected to present this information in the Statement of Stockholders' Equity.

Stock-Based Compensation

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

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock Based Compensation-Transition and Disclosure an amendment of FASB Statement No. 123". This statement amends SFAS Statement No. 123 "Accounting for Stock Based Compensation", to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock based employee compensation. In addition, this statement amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock based employee compensation and the effects of the method used on reported results (see below). The standard is effective beginning with these financial statements and the provisions have been adopted herein.

Had compensation cost for the Company's stock-based compensation plan been determined based on the fair value at the grant dates for awards under those plans consistent with the method of SFAS No. 123, the Company's net loss and loss per share would have been increased to the pro forma amounts indicated below for the years ended December 31, 2003, 2002 and 2001, respectively.

	2003	2002	2001
Net loss:			
As reported	$(20,101)	$(24,742)	$(17,498)
Stock-based compensation expense under fair value method	(5,017)	(4,285)	(2,200)
Pro forma	$(25,118)	$(29,027)	$(19,698)
Net loss per share basic and diluted:			
As reported	$ (0.92)	$ (1.21)	$ (1.13)
Stock-based compensation expense under fair value method	(0.23)	(0.21)	(0.14)
Pro forma	$ (1.15)	$ (1.42)	$ (1.27)

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

Net Loss Per Common Share

In accordance with SFAS No. 128, "Earnings Per Share," basic and diluted net loss per common share have been computed using the weighted-average number of common shares outstanding during each year. Common equivalent shares related to outstanding options and warrants are excluded from the computation because their effect is anti-dilutive in all periods.

Recently Issued Accounting Pronouncements

In April 2003, the FASB issued SFAS 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities". SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS 133, "Accounting for Derivative Instruments and Hedging Activities". The standard became effective for the Company for contracts entered into or modified after June 30, 2003. The Company does not expect the adoption of SFAS 149 to have a material impact on its results of operations or financial position.

In May 2003, the FASB issued SFAS 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity". SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability, or an asset in some circumstances. The standard became effective for the Company for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 had no impact on the Company's results of operations or financial position for the three and twelve months ended, nor as of December 31, 2003.

In January 2003, the FASB issued FIN 46, "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51", which requires a new approach in determining if a reporting entity should consolidate certain legal entities, or VIE's. A legal entity is considered a VIE if it does not have sufficient equity at risk to finance its own activities without relying on financial support from other parties. If the legal entity is a VIE, then the reporting entity that is the primary beneficiary must consolidate it. Even if a reporting entity is not obligated to consolidate a VIE, then disclosure must be made about the VIE if the reporting entity has a significant variable interest. FIN 46 is effective immediately for VIEs created after January 31, 2003 and in the first interim period ending after March 15, 2004 for VIEs created prior to February 1, 2003. The Company does not expect the adoption of FIN 46 to have a material impact on its results of operations or financial position.

(3) INVESTMENTS

The following is a summary as of December 31, 2003 of held-to-maturity securities (amounts in thousands):

	Cost	Unrealized gains	Gross unrealized losses	Gross Market value
U.S. corporate securities	$2,000	$25	$ —	$2,025
Total securities	$2,000	$25	$ —	$2,025

(4) PROPERTY AND EQUIPMENT

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

	2003	2002
Cost:		
Furniture and equipment	$2,680	$1,283
Computer equipment	1,217	869
	3,897	2,152
Accumulated depreciation:		
Furniture and equipment	588	433
Computer equipment	688	435
	1,276	868
Net property and equipment	$2,621	$1,284

(5) ACCRUED LIABILITIES

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

	2003	2002
Accrued payables	$ 4,626	$4,383
Accrued compensation	3,236	2,730
Allowance for rebates and coupons	2,132	643
Accrued royalties	1,687	803
Other	68	117
Total accrued liabilities	$11,749	$8,676

(6) LICENSE REVENUE AND REVENUE FROM COLLABORATIVE AGREEMENTS

In May 2000, the Company signed an agreement with Shire Pharmaceuticals Group under which Shire purchased from Salix the exclusive rights to balsalazide as a treatment for ulcerative colitis for Austria, Belgium, Denmark, Finland, France, Germany, Iceland, Republic of Ireland, Luxembourg, Norway, The Netherlands, Switzerland, Sweden and the United Kingdom. Under the agreement, Shire agreed to pay Salix up to a total of approximately $24.0 million, including approximately $12.1 million in up-front fees and up to $12.0 million upon the achievement of milestones. In accordance with the Company's license arrangement with Biorex Laboratories Limited, its licensor, Salix will share a portion of these payments, including all of the new Shire ordinary shares, with Biorex. In May 2000, Shire paid the Company $9.6 million of cash and $2.5 million by way of the issue of 160,546 new Shire ordinary shares. In August 2000 Shire paid the Company $4.4 million in connection with the transfer to Shire of the United Kingdom product license for balsalazide.

During the year ended December 31, 2001, the Company recognized $8.2 million of license fee income primarily related to the agreement with Shire.

(7) STOCKHOLDERS' EQUITY

On December 12, 2001, the Board of Directors of the Company approved the Reorganization of the Company as a Delaware corporation. As a result of the Reorganization, each share of no par value common stock was converted into one share of $0.001 par value common stock. All common stock amounts for all periods presented in the accompanying consolidated financial statements have been restated to reflect the establishment of the $0.001 par value.

Preferred Stock

A total of 5,000,000 shares of preferred stock are authorized and issuable in series. No shares of preferred stock were issued or outstanding as of December 31, 2003.

Common Stock

As of December 31, 2003 the Company was authorized to issue up to 80,000,000 shares of $0.001 par value common stock. As of December 31, 2003 and 2002, there were 23,719,821 and 21,375,846 shares of common stock issued and outstanding, respectively.

In May 2001, the Company completed a private placement of its common stock to a limited number of accredited and sophisticated investors. The Company raised approximately $28.1 million, net of offering costs, through the issuance of 1,960,000 shares of common stock.

In March 2002, the Company completed a public offering of its common stock. The Company raised approximately $57.4 million, net of offering costs, through the issuance of 4,600,000 shares of common stock.

In November 2003, the Company completed a private placement of its common stock to a limited number of accredited and sophisticated investors. The Company raised approximately $29.0 million, net of offering costs, through the issuance of 1,700,000 shares of common stock.

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 is designed to enhance the Board's ability to prevent an acquirer from depriving stockholders of the long-term value of their investment and to protect stockholders against attempts to acquire the Company by means of unfair or abusive takeover tactics. The rights become exercisable based upon certain limited conditions related to acquisitions of stock, tender offers and certain business combinations involving the Company.

Stock Option 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 Option Plan (the "1996 Plan") was adopted by the Board of Directors and approved by the Company's stockholders in February 1996. The options granted under the 1994 Plan and the 1996 Plan may be either incentive stock options or non-statutory stock options. Options granted expire no later than ten years from the date of grant.

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

Aggregate option activity is as follows:

	Outstanding Options		
	Shares Available For Grant	Number of Shares	Weighted-Average Exercise Price
Balance at December 31, 2000	158,822	1,682,497	$ 4.04
Additional shares authorized	1,822,793	—	—
Options granted	(1,083,500)	1,083,500	$12.15
Options exercised	—	(510,823)	$ 2.71
Options canceled	89,708	(89,708)	$ 4.03
Balance at December 31, 2001	987,823	2,165,466	$ 8.41
Additional shares authorized	1,000,000	—	—
Options granted	(1,331,200)	1,331,200	$ 7.29
Options exercised	—	(67,165)	$ 6.41
Options canceled	201,890	(201,890)	$11.19
Balance at December 31, 2002	858,513	3,227,611	$ 7.82
Options granted	(1,205,000)	1,205,000	$12.80
Options exercised	—	(643,975)	$ 7.69
Options canceled	674,845	(674,845)	$10.74
Balance at December 31, 2003	328,358	3,113,791	$ 9.14

Exercise prices for options outstanding as of December 31, 2003 ranged from $0.47 to $19.99 per share.

	Options Outstanding			Options Currently Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (Yrs)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 0.47 – 2.24	327,625	6.45	$ 1.81	275,123	$ 1.79
$ 4.45 – 6.70	1,082,244	8.19	5.91	421,417	6.02
$ 7.38 – 10.62	479,898	7.41	9.32	291,177	8.95
$ 11.32 – 13.63	851,524	9.02	11.98	175,637	12.54
$ 17.35 – 19.99	372,500	9.52	18.20	26,766	17.40
	3,113,791	8.27	$ 9.14	1,190,120	$ 6.98

At December 31, 2002, there were 1,081,423 exercisable options with a weighted average exercise price of $7.36. At December 31, 2001 there were 480,331 exercisable options with a weighted average exercise price of $4.90.

The weighted-average fair value of options granted in 2003, 2002 and 2001 was $10.16, $6.01 and $12.15, respectively.

Stock-Based Compensation

The fair value of the Company stock-based awards to employees was estimated using a Black-Scholes option pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, the Black-Scholes model requires the input of highly subjective assumptions including the expected stock price volatility. Because the Company's stock-based awards to employees have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the

existing models do not necessarily provide a reliable single measure of the fair value of its stock-based awards to employees. The fair value of the Company's stock-based awards to employees was estimated assuming no expected dividends and the following weighted-average assumptions:

	2003	2002	2001
Expected life (years)	5	5	5
Expected volatility	1.08	1.17	1.26
Risk-free interest rate	2.53%	3.79%	4.19%

(8) INCOME TAXES

As of December 31, 2003, the Company had a U.S. federal net operating loss carryforward of approximately $82.8 million. This loss will expire on various dates from 2004 through 2022, if not utilized.

Significant components of the Company's deferred tax assets for federal and state income taxes were as follows at December 31 (in thousands):

	2003	2002
Net operating loss carry-forwards	$ 30,411	$ 23,826
Capitalized research and development expenses	524	580
Research and development credits and other	2,112	1,150
Total deferred tax assets	33,047	25,556
Valuation allowance	(33,047)	(25,556)
Net deferred taxes	$ —	$ —

Because of the Company's history of net operating losses, the deferred tax asset has been fully reserved by a valuation allowance. The valuation allowance increased by approximately $7.5 million and $10.0 million during the years ended December 31, 2003 and 2002, respectively. Of the deferred tax asset of $33.0 million, approximately $1.3 million was generated from deductions related to the exercise stock options. As a result, approximately $1.3 million of the realization of the deferred tax asset will be recognized as an increase to equity.

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 of 1986. If this limitation applies, the ultimate ability for the Company to use existing net operating loss carryovers and tax credit carryovers to offset future income may be limited.

A reconciliation of the statutory rate to the effective rate as recognized in the statements of operations is as follows:

	2003	2002	2001
Federal statutory rate	35.0%	35.0%	35.0%
State tax rate, net of federal benefit	4.5%	4.5%	4.5%
Tax credits and non-deductible expenses	(2.3)%	2.8%	6.7%
Change in valuation allowance	(37.2)%	(42.3)%	(46.2)%
	—	—	—

(9) SIGNIFICANT CONCENTRATIONS

The Company operates in a single industry acquiring, developing and commercializing prescription drugs used in the treatment of a variety of gastrointestinal diseases, which are those affecting the digestive tract. The Company's principal financial instruments subject to potential concentration of credit risk are accounts receivable, which are unsecured.

During 2000, the Company made its first sales of Colazal to U.S. wholesalers. This significantly diversified the Company's customer base and reduced the risks associated with serving a limited number of significant customers. A significant majority of all revenue in the three-year period ended December 31, 2003 was associated with the Company's single product, Colazal.

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

	Year Ended December 31,		
	2003	2002	2001
Customer 1	30%	21%	27%
Customer 2	25%	39%	37%
Customer 3	16%	11%	18%

Additionally, 28% and 74% of the Company's accounts receivable balances were due from these three customers at December 31, 2003 and 2002, respectively.

Currently, the Company is using active pharmaceutical ingredient balsalazide manufactured for us by Omnichem s.a., a subsidiary of Ajinomoto in Belgium. Balsalazide is being encapsulated for the Company by Anabolic in Irvine, California. In addition, the Company has qualified an additional manufacturer of commercial quantities of the active pharmaceutical ingredient balsalazide and is in negotiations to secure an additional encapsulator.

Under its supply agreement with the Company, Alfa Wassermann is obligated to supply the Company with active pharmaceutical ingredient rifaximin. Currently, Alfa Wassermann manufactures rifaximin for the Italian and other European markets. Alfa Wasserman is in the process of securing additional sources of commercial quantities of the active pharmaceutical ingredient rifaximin.

Under the Company's supply agreement with aaiPharma, aaiPharma is obligated to supply the Company with finished product to meet all of its requirements for the 25, 75 and 100 milligram tablets of Azasan.

(10) 401(K) PLAN

In 1996, the Company adopted the Salix Pharmaceuticals, Inc. 401(k) Retirement Plan. Eligible participants may elect to defer a percentage of their compensation. The Company matches up to 50% of participant deferrals, up to 6% of the participant's compensation. The Company's total matching contributions for all participants were approximately $302,000, $275,000, and $150,000 in 2003, 2000 and 2001, respectively. Additional discretionary employer contributions may be made on an annual basis.

(11) COMMITMENTS

The Company leases office facilities under various non-cancelable operating leases, the last of which expires on August 31, 2011. Certain of these leases contain future payment obligations that escalate over time. Rent expense was approximately $813,000, $776,000 and $800,000, for the years ended December 31, 2003, 2002 and 2001, respectively. In addition to the office space, the Company leases automobiles, for use by its direct sales force, under a three-year operating lease.

As of December 31, 2002, future payments for operating leases were as follows (in thousands):

Years ending December 31,	Operating Leases
2004	$1,413
2005	1,195
2006	939
2007	647
2008	662
Thereafter	1,782
Total minimum payments required	$6,638

At December 31, 2003, the Company had binding purchase order commitments for inventory purchases aggregating approximately $16.6 million throughout 2004.

During the third quarter of 2002, the Company entered into a $7.0 million revolving working capital line of credit, with borrowing capacity of up to 75% of its eligible accounts receivable under 90 days old from the date of invoice. As amended, the facility expires in January 2005. The Company had no outstanding balance under this line as of December 31, 2003.

(12) QUARTERLY RESULTS OF OPERATIONS

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2003 and 2002:

(in thousands, except per share amounts)	Mar 31	June 30	Sept 30	Dec 31
		(unaudited)		
2003				
Product revenue	$11,522	$12,933	$14,124	$17,228
Cost of products sold	2,764	3,070	3,287	4,105
Net loss	(5,472)	(7,003)	(3,973)	(3,653)
Net loss per common share (basic and diluted)(1)	(0.26)	(0.33)	(0.18)	(0.16)
2002				
Product revenue	$ 6,211	$ 7,337	$ 8,673	$11,235
Cost of products sold	1,566	1,797	2,185	2,644
Net loss	(4,724)	(5,214)	(8,653)	(6,151)
Net loss per common share (basic and diluted)(1)	(0.26)	(0.24)	(0.41)	(0.29)

(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.

SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS

Allowance for Rebates and Coupons

Year ended December 31,	Beginning Balance	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Deductions: Rebates and Coupons Honored During Period	Ending Balance
(in thousands)					
2003	$ 668	$7,034	$ —	$5,545	$2,157
2002	$1,187	$3,273	$ —	$3,792	$ 668
2001	$ 310	$1,219	$ —	$ 342	$1,187

Allowance for Uncollectable Accounts

Year ended December 31,	Beginning Balance	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Deductions: Accounts Written Off During Period	Ending Balance
(in thousands)					
2003	$ 61	$ 488	$ —	$ 235	$ 314
2002	$ 14	$ 142	$ —	$ 95	$ 61
2001	$ —	$ 14	$ —	$ —	$ 14

Inventory Allowance

Year ended December 31,	Beginning Balance	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Deductions: Amounts Recovered During Period	Ending Balance
(in thousands)					
2003	$ 63	$ —	$ 40	$ 33	$ 70
2002	$ 213	$ —	$ —	$ 150	$ 63
2001	$ —	$ —	$ 213	$ —	$ 213

EXHIBIT INDEX

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
2.1	Certificate of Domestication.	S-3	02/12/02	2.1	
3.1	Certificate of Incorporation, as amended.	S-3	02/12/02	3.1	
3.2	Amended and Restated Bylaws.	S-4	11/20/01	3.2	
10.2	Form of 1994 Stock Plan for Salix Holdings, Ltd. and form of Stock Option and Restricted Stock Purchase Agreements thereunder.	S-1	08/15/97	10.2	
10.3	Form of 1996 Stock Plan for Salix Holdings, Ltd., as amended September 2000 and form of Notice of Stock Option Grant and Stock Option Agreement thereunder, as amended March 12, 2001.	S-8	06/22/01	10.1	
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	
10.14	Lease dated January 1, 1992 by and between Kontrabecki Mason Developers and Salix Pharmaceuticals, Inc., as amended.	S-1	08/15/97	10.14	
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	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.23	Agreement dated December 22, 1999, between Glycyx Pharmaceuticals, Ltd. and Astra AB.	8-K	12/28/99	10.23	
10.25*	Agreement dated May 17, 2000 between Glycyx Pharmaceuticals, Ltd. and Shire Pharmaceuticals Group plc.	10-Q	08/14/00	10.25	
10.26*	Agreement dated May 17, 2000 between Biorex Laboratories Limited and Glycyx Pharmaceuticals, Ltd.	10-Q	08/14/00	10.26	
10.28	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*	License Agreement between Biorex Laboratories Limited and Glycyx Pharmaceuticals, Ltd. dated August 22, 2001.	10-Q	11/14/01	10.30	
10.30	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	
10.33	Loan and Security Agreement dated September 30, 2002 by and between RBC Centura Bank, Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.	10-Q	11/14/02	10.33	
10.34	Commercial Promissory Note Agreement dated September 30, 2002 issued to RBC Centura Bank by Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.	10-Q	11/14/02	10.34	
10.35	Negative Pledge Agreement dated September 30, 2002 between RBC Centura Bank, Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.	10-Q	11/14/02	10.35	
10.36	Rights Agreement, dated as of January 10, 2003, between Salix Pharmaceuticals, Ltd. and Computershare Investor Services LLC, as Rights Agent.	8-K	01/10/03	10.36	
10.37	Common Stock Purchase Agreement dated November 6, 2003 among Salix Pharmaceuticals, Ltd. and the investors listed therein.	8-K	11/10/03	10.37	
10.38	Modification to Commercial Promissory Note Agreement dated September 29, 2003 between RBC Centura Bank, Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.	10-Q	11/14/03	10.38	
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.				X
10.41**	License Agreement dated October 31, 2003 between aaiPharma LLC, aaiPharma Inc. and Salix Pharmaceuticals, Ltd.				X
10.42	Modification to Commercial Promissory Note Agreement dated December 31, 2003 between RBC Centura Bank, Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.				X

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
21.1	Subsidiaries of the Registrant.	S-4	11/20/01	21.1	
23.1	Consent of Independent Auditors.				X
31.1	Certification by the Chief Executive Officer pursuant to Section 240.13a-14 or section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
31.2	Certification by the Chief Financial Officer pursuant to Section 240.13a-14 or section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification by the Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

* The registrant has received confidential treatment with respect to certain portions of this exhibit. Such portions have been omitted from this exhibit and have been filed separately with the United States Securities and Exchange Commission.

** Confidential treatment requested for certain portions of this agreement. (n) Incorporated by referenced to Exhibit file with the Registrant Current Report on Form 8-K dated January 10, 2003.

EXHIBIT 23.1

Consent of Independent Auditors

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-110942) and on Form S-8 (Nos. 333-96771, 333-41801, 333-63604, 333-61497 and 333-47586) of Salix Pharmaceuticals, Ltd., of our report dated February 3, 2004, with respect to the consolidated financial statements and schedule of Salix Pharmaceuticals, Ltd. included in the Annual Report (Form 10-K) for the year ended December 31, 2003.

Ernst & Young LLP

Raleigh, North Carolina
March 12, 2004

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 annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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-14 and 15d-14) 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 annual report is being prepared;

   b. 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 (the "Evaluation Date"); and

   c. 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 this 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, 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: March 12, 2004

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 annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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-14 and 15d-14) 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 annual report is being prepared;

   b. 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 (the "Evaluation Date"); and

   c. 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 this 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, 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: March 12, 2004

By: /s/ Adam C. Derbyshire

Adam C. Derbyshire
Senior 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, 2003 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Carolyn J. Logan, President and Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ Carolyn J. Logan

Carolyn J. Logan
President and Chief Executive Officer

March 12, 2004

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, 2003 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Adam C. Derbyshire, Senior Vice President, Finance and Administration and Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ Adam C. Derbyshire

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

March 12, 2004

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Shareholder Information

FORWARD LOOKING STATEMENTS

This annual report contains forward-looking statements regarding future events. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include risks of regulatory review and clinical trials, intellectual property risks, the need to acquire additional products and management of rapid growth. The reader is referred to the documents that the Company files from time to time with the Securities and Exchange Commission.

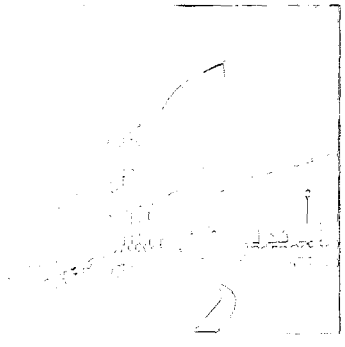

Photo by Jim Sink — 919.845.7872

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