MGI PHARMA, INC.

2003 Annual Report

LIFE
just got BETTER

for cancer PATIENTS

In September 2003, chemotherapy-induced nausea and vomiting (CINV), one of patients' most feared side effects of chemotherapy, became easier to prevent when we introduced Aloxi™ (palonosetron hydrochloride) injection. Aloxi injection is the first and only 5-HT_3 receptor antagonist that provides powerful, prolonged CINV prevention with a single intravenous dose.

for HEALTHCARE PROVIDERS

Prolonged clinical benefit with Aloxi injection is reported by oncologists and nurses who prescribe and administer it for their cancer patients.

for MGI PHARMA

We are pleased to be able to address a major cancer supportive care need with Aloxi injection. The growing market in the United States for 5-HT_3 receptor antagonists is approximately $1.5 billion and includes the nearly $900 million market for CINV prevention and treatment.

It's been an EXCITING YEAR at MGI PHARMA

- **Presentations of positive Aloxi injection data at major medical meetings:**
  - **The American Society of Clinical Oncology (ASCO),**
  - **The Multinational Association of Supportive Care in Cancer (MASCC),**
  - **San Antonio Breast Cancer Symposium (SABCS),**
  - **American Society of Health-System Pharmacists (ASHP), and**
  - **American Society of Hematology (ASH)**

- **Expanded our oncology sales and marketing operations in the United States to full-scale and breadth**

- **Aloxi injection was approved by the U.S. Food and Drug Administration (FDA) at a fixed intravenous dose of 0.25 mg for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy, and acute nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy**

- **Completed a successful follow-on stock offering that generated total net proceeds of approximately $169 million**

- **Launched Aloxi injection for commercial availability in the United States**

- **Opened the NASDAQ National Market in celebration of being listed on the NASDAQ for 20 years and in recognition of the FDA approval of Aloxi injection**

- **Published two pivotal trial manuscripts in medical journals**

- **Expanded and strengthened the Aloxi franchise to include rights for the post operative nausea and vomiting (PONV) application and an oral formulation**

- **Received news from the Centers for Medicare and Medicaid Services (CMS) that Aloxi injection qualified for pass-through status and was assigned to a Healthcare Common Procedure Coding System (HCPCS), whereby hospitals may obtain reimbursement under the hospital outpatient prospective payment system (OPPS).**

- **Advanced irofulven, our broadly active cytotoxic agent, in a series of phase 1 and 2 clinical trials. This paved the way for identification of second-line, hormone refractory prostate cancer as a type of cancer we intend to further evaluate for potential registration trials**

On September 15, 2003 MGI PHARMA opened the NASDAQ National Market at Times Square in New York City.

and this is just the BEGINNING

Lonnie Moulder, President and Chief Executive Officer

Dear shareholders: **It is with great enthusiasm and pride that we report MGI PHARMA's accomplishments and progress for 2003. With the successful FDA approval and commercial launch of Aloxi injection, we are confident that we are truly poised for success in oncology.**

We set a dramatic pace of progress in 2003 by achieving our business objectives including FDA approval and commercial launch of Aloxi injection, expansion to a full-scale oncology commercial organization, advancement of our clinical programs, successful completion of a follow-on stock offering and expansion of Aloxi product rights. These achievements position us well to effectively execute on our business model as we enter 2004. As exciting and productive as this past year has been, I am confident that the future will be a time of even greater opportunity for MGI PHARMA as we strive to deliver meaningful products to cancer patients and healthcare providers.

Transforming our vision into reality

Aloxi injection Our most significant accomplishment in 2003 was the commercial launch of Aloxi injection last September. Aloxi injection is a potent, highly selective 5-HT_3 receptor antagonist developed for the prevention of chemotherapy-induced nausea and vomiting (CINV). Aloxi injection was approved during the third quarter of 2003 by the U.S. Food and Drug Administration (FDA) for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy and acute nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy. It should be noted that Aloxi injection is the first and only 5-HT_3 receptor antagonist to be indicated for the prevention of delayed CINV. The 10 month review and approval of the New Drug Application (NDA), submitted by our partner, Helsinn, was based upon well designed and executed phase 3 trials comparing Aloxi injection to the market leaders. Aloxi injection is differentiated from other drugs in this class by a very strong receptor binding affinity, a nearly 40-hour plasma half-life, and an extended duration of activity. The results from these clinical trials clearly show that Aloxi injection can prevent

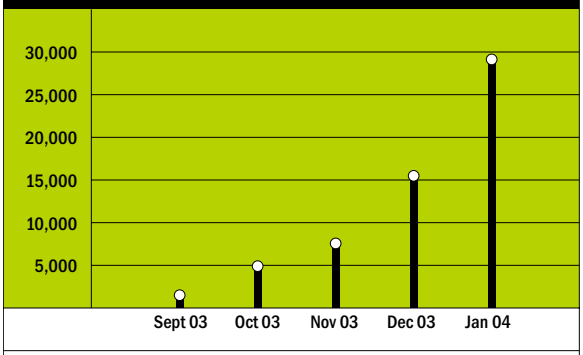
CINV over several days following a single intravenous dose. The quality of this data has allowed the clinical trials results to be published in *Cancer* and *Annals of Oncology*, and resulted in presentation at the American Society for Clinical Oncology (ASCO) and the Multinational Association of Supportive Care in Cancer (MASCC) annual meetings. This data forms the foundation of our marketing message: "Aloxi injection starts strong and lasts long."

Following FDA approval, the MGI PHARMA sales force launched Aloxi injection on September 15, 2003. Since that time, we have made significant progress in the promotion of Aloxi injection to healthcare professionals across the country. Additionally, to supplement our sales efforts, MGI PHARMA entered into agreements with the leading oncology drug distributors and group purchasing organizations. We are confident that these collaborations will help to ensure that Aloxi injection is available to large networks of physicians dedicated to treating patients with cancer.

We were also very pleased to announce that the Centers for Medicare and Medicaid Services (CMS) qualified Aloxi injection for pass-through status and assigned it to a Healthcare Common Procedure Coding System (HCPCS) whereby hospitals may obtain reimbursement for Aloxi injection under the hospital outpatient prospective payment system beginning January 1, 2004. We believe this will make Aloxi injection readily available to more patients in the hospital outpatient setting.

If not prevented, CINV occurs in 80% to 85% of cancer patients undergoing chemotherapy. The growing U.S. market for 5-HT_3 antagonists was approximately $1.5 billion in 2003 and includes the CINV prevention and treatment market of over $900 million.

Aloxi™ launch success
Monthly end-user demand/unit sales



IMS DDD and distributor unit sales represent 95%+ of all units purchased by offices and hospitals

Following the initial success of the Aloxi injection launch, we expanded our license and distribution agreement with Helsinn Healthcare to include rights for the post-operative nausea and vomiting (PONV) application as well as an oral formulation. PONV is a common consequence of anesthetic and surgical procedures. In the United States, more than 40 million surgical procedures are performed annually, and the incidence of PONV is estimated at 25% to 30%. If not prevented, PONV can cause hospital re-admissions and increase healthcare costs for patients who undergo surgery. Pivotal trials of Aloxi injection for PONV and Aloxi oral are planned to begin in 2004. When approved, we believe these Aloxi products could add more than $100 million of annual sales potential to our Aloxi franchise.

We look forward to leveraging the unique features of Aloxi products in order to maximize the overall market opportunity and provide differentiated therapeutic options for patients who suffer from nausea and vomiting as a side effect of various origins.

Other marketed products

We are pleased to report that Salagen® Tablets (pilocarpine hydrochloride) maintained the leadership position in 2003 with more than a 60 percent dollar share of its market. Salagen Tablets are marketed by MGI PHARMA for the treatment of radiation-induced chronic dry mouth symptoms in head and neck cancer patients, and for the treatment of dry mouth symptoms in patients with Sjögren's syndrome, an autoimmune disease that damages the salivary glands.

Advancing our pipeline

Irofulven is MGI PHARMA's novel chemotherapeutic agent and a member of our proprietary class of anti-cancer compounds called acylfulvenes. Irofulven's unique mechanism of action allows it to retain activity against a variety of solid tumors, including drug-resistant cancers, and to be synergistic with several classes of approved cancer drugs. Irofulven is currently being studied in a broad clinical development program designed to evaluate its activity in several types of cancer.

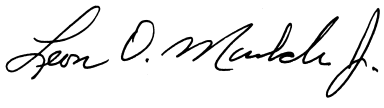
Last November, we presented data from the irofulven clinical programs at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. These presentations detailed phase 1 and pharmacokinetic data for irofulven, in combination with cisplatin and capecitabine in patients with solid tumors. The results from these studies demonstrated antitumor activity of irofulven in a variety of solid tumor types including prostate cancer. Furthermore, the data presented, indicates that irofulven in combination with other anti-tumor drugs is tolerated and may have clinical utility. After analyzing data from both single-agent and combination studies of irofulven, in February 2004 we announced that we would pursue treatment of hormone refractory prostate cancer in phase 2 combination therapy clinical trials.

Business activities

We remain committed to managing our business on a sound financial basis. To this end, we have completed two financings, a follow-on common stock offering and a convertible notes offering that together generated more than $420 million of net proceeds. The capital obtained from these offerings positions us well for executing on our business model of acquiring rights to additional products.

Our commitment to the future

Performance was no doubt the overriding theme at MGI PHARMA for the year 2003. We take great pride in our accomplishments as we have effectively established our position as a growing oncology franchise in the United States. Indeed, the year 2003 stands as one of the most productive years in the history of the company. Our commitment to you, our shareholders, is to continue to build a company capable of delivering long-term sustainable growth and value while advancing the management of cancer treatment for those who suffer from this devastating disease. All of us here at MGI PHARMA thank you for your continued support and look forward to an exciting 2004.



Leon O. Moulder, Jr.
President and Chief Executive Officer

LIFE just got

"Being able to offer Aloxi injection to patients in our clinic has made a real difference in administering chemotherapy. Patients are here to get their treatment, and I don't need to worry about how they'll feel after they go home."

Kim Smith, RN
Tennessee Oncology, PLLC

"When I found out I would be getting chemotherapy to treat my cancer, I was worried about the side effects of the treatment, especially what I'd heard about nausea and vomiting. Fortunately, I was given Aloxi injection and have been able to maintain my normal day-to-day routine without worrying about or suffering from these difficult side effects. Aloxi injection has made it easier for me to concentrate on beating cancer."

Glenn Focht
Cancer Patient

Aloxi injection: Improving the lives of cancer patients. Since their introduction in the 1950s, chemotherapy regimens have contributed greatly to advancing the fight against cancer by effectively treating many people with cancer. While new chemotherapy drugs have made it possible to provide treatment for cancer patients, many therapies are associated with challenging side effects. Despite these side effects, chemotherapy is expected to remain the cornerstone of cancer treatment for many years to come.

One of the most feared of these side effects is chemotherapy-induced nausea and vomiting (CINV). Despite the availability of preventative treatments, including first generation 5-HT_3 receptor antagonists, nearly 50%

BETTER

"The efficacy data for Aloxi injection in preventing delayed nausea and vomiting is truly impressive and our results with patients have confirmed its advantages. Our initial use of Aloxi injection was in patients who have failed a previous antiemetic, and the results in this setting have been outstanding."

Jeff Patton, MD
Tennessee Oncology, PLLC

"In my 22 years of pharmaceutical sales, I have never had the opportunity to sell a product that so dramatically impacts the lives of patients from the first dose, and offers the total package of what nurses and doctors want: efficacy, tolerability and ease of use. I thoroughly enjoy what I am doing!"

Rhonda Madge
MGI PHARMA

of patients receiving emetogenic chemotherapy experience nausea and vomiting. Aloxi injection is a potent, highly selective 5-HT_3 receptor antagonist developed for the prevention of CINV. In clinical trials, Aloxi injection has demonstrated that it is effective in preventing both acute and delayed CINV following the most common chemotherapy treatments with just one intravenous dose. Furthermore, Aloxi was shown to provide greater protection for a longer period of time as compared to competing 5-HT_3 receptor antagonists.

Aloxi injection was approved by the U.S. Food and Drug Administration and commercially launched by MGI PHARMA during the third quarter of 2003. MGI PHARMA procured exclusive U.S. and Canadian license and distribution rights to Aloxi injection for CINV in April 2001 from Helsinn Healthcare SA of Lugano, Switzerland.

EXPANDING
our product portfolio

Numerous types of cancer and their catastrophic effects have provided the basis for one of the longest research endeavors in medical history. Despite steady advances, the treatment of cancer remains an area of substantial unmet medical need. At MGI PHARMA, we are committed to acquiring, developing and commercializing proprietary pharmaceutical products that meet the needs of cancer patients. Our oncology products and product candidates are intended to treat cancer patients and assist in providing their supportive care. We currently have three marketed products and several product candidates under development. In addition, our business development and licensing teams are actively pursuing potential new product opportunities.

Commercialized products

Aloxi injection is a potent, highly selective 5-HT_3 receptor antagonist developed for the prevention of chemotherapy-induced nausea and vomiting (CINV). Aloxi injection is the first and only 5-HT_3 receptor antagonist to be indicated for the prevention of both acute and delayed CINV caused by moderately-emetogenic chemotherapy.

Conceived, developed and marketed by MGI PHARMA for the treatment of radiation-induced chronic dry mouth symptoms in head and neck cancer patients and for the treatment of dry mouth symptoms in patients with Sjögren's syndrome, an autoimmune disease that damages the salivary glands. Salagen Tablets were the first prescription drug approved in the U.S. for these indications.

An oral, second-line chemotherapy approved in the United States for the treatment of refractory ovarian cancer. Hexalen capsules are a medically important product that has induced complete responses in patients refractory to first-line therapy and provides the convenience of oral dosing administration.

Products under development

Aloxi injection for PONV and Aloxi oral
A potent, highly selective 5-HT_3 receptor antagonist differentiated by its strong receptor binding affinity and extended half life, Aloxi injection has already been approved for the prevention of chemotherapy-induced nausea. We are working with Helsinn Healthcare to design Phase 3 programs with a goal to seek FDA approval of Aloxi injection for the prevention of post operative nausea and vomiting (PONV) and to develop an oral Aloxi formulation. Phase 3 trials are expected to begin during 2004 for each program.

Irofulven
(hydroxymethylacylfulvene)
The first chemotherapeutic drug candidate in MGI PHARMA's family of proprietary anti-cancer compounds called the acylfulvenes. This novel anti-cancer agent exhibits a unique mechanism of action compared to current anti-cancer drugs that allows it to retain activity against a variety of solid tumors, including drug-resistant cancers, and to be synergistic with several classes of approved cancer drugs. We are developing irofulven through a series of clinical trials as both monotherapy and drug combination therapy.

MG98
A second-generation antisense compound that targets the messenger RNA required to produce the enzyme DNA methyltransferase, which is associated with silencing tumor suppressor genes. MG98 is being developed for the purpose of blocking production of DNA methyltransferase. Preventing DNA methyltransferase production may allow tumor suppressor genes that have been silenced by hypermethylation to be re-activated. Causing re-expression of silenced tumor suppressor genes is considered an exciting new approach for molecular-targeted cancer therapy.

MGI PHARMA product portfolio

Launching Aloxi™ injection

Last September, we successfully launched Aloxi injection in the United States, and we are pleased to report that it is already making a difference in the lives of patients undergoing chemotherapy treatment. We believe that the proven ability of Aloxi injection to provide prolonged protection from CINV for several days without the need for multiple doses will clearly differentiate it from competing 5-HT_3 receptor antagonists.

MGI PHARMA drug does well in trials; Analysts project big boost in sales

StarTribune (Minneapolis, MN), June 3, 2003

Revenue grows at MGI PHARMA

TheStreet.com, July 16, 2003

MGI PHARMA wins F.D.A. approval for antinausea drug

The New York Times, July 26, 2003

MGI PHARMA share offering draws strong response

TheStreet.com, August 8, 2003

MGI PHARMA in-licenses further rights to approved cancer drug Aloxi

BIOWORLD Today, November 18, 2003

Officers

Leon (Lonnie) O. Moulder, Jr.
President and Chief Executive Officer

William C. Brown
Executive Vice President and Chief Financial Officer

John R. MacDonald, Ph.D.
Senior Vice President, Research and Development

Edward B. Rubenstein, M.D.
Senior Vice President, Medical and Commercial Development

Reginald W. Bowerman
Vice President, Marketing

Michael T. Cullen, Jr., M.D.
Vice President, Clinical Affairs and Chief Medical Officer

Nancy S. Evertz
Vice President, Finance and Administration

Kristin Gustafson
Vice President, Human Resources

Robert M. Johnson
Vice President, Manufacturing and International Operations

Stephen J. Waters, Ph.D.
Vice President, Drug Development

Board of directors

Andrew J. Ferrara
President and Chief Executive Officer, Boston Healthcare Associates, Inc.

Gilla Kaplan, Ph.D.
Full Member, The Public Health Research Institute, New Jersey

Edward W. Mehrer
Retired Chief Financial Officer, CyDex, Inc.

Hugh E. Miller
Retired Vice Chairman and Director, ICI Americas, Inc.

Leon (Lonnie) O. Moulder, Jr.
President and Chief Executive Officer, MGI PHARMA, INC.

Lee J. Schroeder
President and Director, Lee Schroeder & Associates, Inc.

David B. Sharrock
Business Consultant

Waneta C. Tuttle, Ph.D.
Chief Executive Officer, Exagen Diagnostics, Inc.
Director, National Center for Genome Resources

Arthur L. Weaver, M.D.
Clinical Professor of Medicine, Division of Rheumatology, University of Nebraska Medical Center

About the company

MGI PHARMA, INC. is an oncology-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of cancer patients. MGI PHARMA markets Aloxi™ (palonosetron hydrochloride) injection, Salagen® Tablets (pilocarpine hydrochloride) and Hexalen® (altretamine) capsules in the United States. One of the Company's major corporate assets is its commercial organization, which is comprised of its highly experienced oncology sales organization and talented marketing team. MGI PHARMA directly markets its products in the United States and collaborates with multinational biopharmaceutical companies in international markets.

MGI PHARMA develops its oncology product candidates with a team experienced in product development, clinical research, medical and regulatory affairs. MGI PHARMA's development team has been involved with FDA approvals for Aloxi injection and Salagen Tablets.

The Company's management team is highly accomplished in the pharmaceutical industry, and plans to continue MGI PHARMA's growth through a focused business development strategy. Its board of directors includes seasoned pharmaceutical industry executives. MGI PHARMA associates share the vision of building a profitable, oncology-focused biopharmaceutical business.

MGI PHARMA is based in Minneapolis, Minnesota, and its common stock is traded on The Nasdaq Stock Market® under the symbol MOGN. For more information, visit www.mgipharma.com.

Financial highlights

(In thousands, except per share data)

Year Ended December 31,	1999	2000	2001	2002	2003
Statement of Operations Data:					
Revenues:					
Sales	$ 18,643	$ 21,333	$ 30,022	$ 25,402	$ 39,858
Licensing	4,955	3,109	2,932	2,801	9,527
Promotion [a]	1,088	770	–	–	–
	24,686	25,212	32,954	28,203	49,385
Costs and expenses:					
Cost of sales	1,209	1,627	3,633	3,240	6,959
Selling, general and administrative	12,713	18,295	28,463	28,827	50,410
Research and development	6,677	17,241	36,101	32,214	50,121
Amortization	–	98	1,182	1,182	1,205
	20,599	37,261	69,379	65,463	108,695
Income (loss) from operations	4,087	(12,049)	(36,425)	(37,260)	(59,310)
Interest income	966	2,146	1,600	1,279	1,553
Interest expense	–	–	–	(83)	(997)
Impairment of investment	–	–	–	–	(3,154)
Income (loss) before taxes and cumulative effect of change in accounting principle	5,053	(9,903)	(34,825)	(36,064)	(61,908)
Provision for income taxes	321	148	–	–	–
Net income (loss) before cumulative effect of change in accounting principle	4,732	(10,051)	(34,825)	(36,064)	(61,908)
Cumulative effect of change in accounting principle	–	(9,403)	–	–	–
Net income (loss)	$ 4,732	$(19,454)	$ (34,825)	$ (36,064)	$ (61,908)
Net income (loss) per common share:					
Basic:					
Income (loss) before effect of accounting change	$ 0.32	$ (0.63)	$ (1.74)	$ (1.44)	$ (2.23)
Cumulative effect of accounting change	–	(0.59)	–	–	–
Net income (loss)	$ 0.32	$ (1.22)	$ (1.74)	$ (1.44)	$ (2.23)
Diluted:					
Income (loss) before effect of accounting change	$ 0.30	$ (0.63)	$ (1.74)	$ (1.44)	$ (2.23)
Cumulative effect of accounting change	–	(0.59)	–	–	–
Net income (loss)	$ 0.30	$ (1.22)	$ (1.74)	$ (1.44)	$ (2.23)
Weighted average number of common shares outstanding:					
Basic	14,742	15,990	19,985	25,110	27,778
Diluted	15,633	15,990	19,985	25,110	27,778

[a] The company concluded its last promotion agreement in 2000.

December 31,	1999	2000	2001	2002	2003
Balance Sheet Data:					
Cash, cash equivalents and marketable investments	$ 24,151	$ 29,899	$ 77,712	$ 60,473	$ 177,753
Working capital	23,240	26,042	63,182	49,999	128,572
Total assets	28,974	52,744	97,668	80,480	204,519
Long-term obligations	–	12,732	13,633	28,427	21,964
Total liabilities	4,329	26,698	28,733	43,877	47,909
Accumulated deficit	(69,097)	(88,551)	(123,376)	(159,440)	(221,347)
Total stockholders' equity	24,644	26,046	68,935	36,604	156,610

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 | Commission File No. 0-10736

MGI PHARMA, INC.
(Exact name of registrant as specified in its charter)

Minnesota	41-1364647
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
5775 West Old Shakopee Road, Suite 100 Bloomington, Minnesota	55437
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code:	952/346-4700
Securities registered pursuant to Section 12(b) of the Act:	None
Securities registered pursuant to Section 12(g) of the Act:	Common Stock, $.01 par value

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 Exchange Act Rule 12b-2). Yes ☒ No ☐

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2003, the last business day of the registrant's most recent second quarter, was approximately $669,000,000 (based on the closing price of the registrant's common stock as reported by the Nasdaq National Market on such date).

The number of shares outstanding of each of the registrant's classes of common stock, as of February 20, 2004, was: Common Stock, $.01 par value; 35,040,426 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Pursuant to General Instruction G the responses to Items 10, 11, 12 and 14 of Part III of this report are incorporated herein by reference to certain information contained in the registrant's definitive Proxy Statement for its 2004 Annual Meeting of Shareholders to be held on May 11, 2004.

PART I

This Form 10-K contains forward-looking statements within the meaning of federal securities laws that may include statements regarding intent, belief or current expectations of the Company and its management. These forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that may cause the Company's actual results to differ materially from the results discussed in these statements. Risks and uncertainties that might affect our results are detailed from time to time in the Company's filings with the Securities and Exchange Commission, and are included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Cautionary Statement of this Form 10-K. The Company does not intend to update any of the forward-looking statements after the date of this Form 10-K to conform them to actual results.

Item 1. Business

Overview

MGI PHARMA, INC. ("MGI" or "Company") is an oncology-focused biopharmaceutical company that acquires, develops and commercializes proprietary pharmaceutical products that meet cancer patient needs. It is our goal to become a leader in oncology through application of our three core competencies of oncology product acquisition, development and commercialization, which we apply toward our portfolio of oncology products and product candidates. We acquire intellectual property or product rights from others after they have completed the basic research to discover the compounds that will become our product candidates or marketed products. This allows us to focus our skills on product development and commercialization rather than directly performing drug discovery.

We currently market several cancer-related products in the United States using our 104 person oncology-focused sales organization. (See Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations—Revenues for a breakdown of sales by product over the last three years.) We focus our sales efforts solely within the United States, where we have retained product rights to our currently marketed products and product candidates under development. We create alliances with other pharmaceutical or biotechnology companies for the sales and marketing of our products in other countries. (See Note 13 to the financial statements for further information on revenues attributable to U.S. and foreign customers.)

We began promotion of Aloxi™ (palonosetron hydrochloride) injection in September 2003 in the United States for the prevention of chemotherapy-induced nausea and vomiting ("CINV"). We market Salagen® Tablets (pilocarpine hydrochloride) in the United States to oncologists as a treatment for the symptoms of radiation-induced dry mouth in head and neck cancer patients and to rheumatologists as a treatment for dry mouth associated with the autoimmune disease Sjögren's syndrome. Historically, the cash flow generated from the U.S. sales of Salagen Tablets has been the primary source of funding for our selling, general and administrative activities. Sales of Salagen Tablets accounted for approximately 67 percent of our $39.9 million of product sales in 2003. In March 2001 we began direct promotion, or face-to-face sales calls, of Hexalen® capsules after acquiring the Hexalen capsules business in November 2000.

Hexalen capsules are a second-line chemotherapy for ovarian cancer patients who are refractory to first-line therapies.

We believe we have a complementary portfolio of oncology product candidates. Our current product candidates are at various stages with an emphasis on advanced stages of development and are intended to have diverse roles in treating cancer patients. Our portfolio includes therapeutic and supportive care product candidates.

On November 17, 2003, we and Helsinn Healthcare SA announced an expansion of our exclusive United States and Canada license and distribution agreement to include rights for the post operative nausea and vomiting ("PONV") application of Aloxi injection and an oral Aloxi formulation. Phase 2 studies of Aloxi injection for

prevention of PONV indicated that Aloxi injection was safe and well tolerated. We expect phase 3 trials to begin in 2004 for use of Aloxi injection in the prevention of PONV and the oral Aloxi formulation.

Irofulven, the lead cancer therapy product candidate from our proprietary family of compounds, called acylfulvenes, is in a series of clinical trials. Based on our analysis of results from our trials of irofulven, we believe that irofulven is adequately tolerated for a chemotherapeutic, with evidence of monotherapy activity against a wide range of cancers including liver, pancreatic, ovarian, and prostate tumors. These results have been seen in patients with refractory tumors, meaning tumors that are unresponsive to first-line chemotherapy. Trials in refractory cancer patients are the usual way to begin development of new chemotherapy agents, followed by trials comparing the activity of currently approved therapies to the investigational chemotherapy agent. If the investigational chemotherapy agent establishes improved safety and/or efficacy compared to the established therapy, regulatory approval may be sought.

We also are conducting a series of phase 1 dose escalation trials of irofulven in combination therapy with currently approved cancer agents. We believe that an advantage of combination therapy is the potential to achieve better anti-cancer benefit with an acceptable side effect profile compared to either agent used as single agents. In preclinical studies, irofulven has demonstrated synergistic activity with a number of marketed chemotherapies, meaning the extent of tumor cell death was greater than would be predicted by simply adding the activity of each agent individually.

The most promising combination therapy clinical activity has been observed in colorectal, hormone-refractory prostate, and thyroid cancers. We plan to initiate phase 2 combination studies of irofulven in patients with hormone refractory prostate cancer during 2004 as a potential path toward U.S food and Drug Administration ("FDA") registration. Throughout phase 1 and 2 monotherapy and combination therapy trials, consistent evidence of clinical activity in hormone refractory prostate cancer ("HRPC") has been reported, including activity in patients previously exposed to chemotherapy. Phase 2 data presented at the 39th Annual Meeting of the American Society of Clinical Oncology ("ASCO") in 2003 indicated that irofulven in combination with prednisone, a steroid, induced decreases of more than 50 percent in prostate specific antigen ("PSA") levels, in 25 percent of evaluable patients and disease stabilization in 86 percent of patients evaluable for objective tumor response. PSA is a blood marker used by clinicians for treatment decisions. Activity has also been shown in prostate cancer patients treated with irofulven plus the marketed chemotherapies, capecitabine or cisplatin, in phase 1 trials. Following comprehensive analysis of our available data, we are preparing to initiate a phase 2 combination program for irofulven in HRPC patients previously treated with docetaxel.

Most HRPC patients in the United States who are receiving chemotherapy are treated with docetaxel, and we believe significant unmet need exists among prostate cancer patients who have failed hormone therapy and who have progressed on docetaxel.

The following table summarizes the principal indications and commercial rights for our currently marketed products and development programs.

Products	Principal Indications	Status	Commercial Rights
Aloxi injection	• Chemotherapy-induced nausea and vomiting	• Currently marketed	U.S. & Canada: MGI
Salagen Tablets	• Symptoms of radiation-induced dry mouth in head and neck cancer patients • Dry mouth, plus dry eyes outside the U.S., in Sjögren's syndrome patients	• Currently marketed • Currently marketed	U.S.: MGI Europe: Novartis Canada: Pfizer Rest of World: Various other collaborators
Hexalen capsules	• Ovarian Cancer	• Currently marketed	U.S.: MGI Outside U.S.: Various collaborators
Didronel IV infusion	• Cancer-related hypercalcemia	• Currently marketed	U.S.: MGI
Aloxi injection	• Post operative nausea and vomiting	• To begin Phase 3	U.S. & Canada: MGI
Oral Aloxi formulation	• Chemotherapy-induced nausea and vomiting	• To begin Phase 3	U.S. & Canada: MGI
Irofulven	• Monotherapy • Combination therapy	• Phase 2 • Phases 1 & 2	Worldwide: MGI
Other Acylfulvene Analogs	• Various cancers	• Preclinicals	Worldwide : MGI
MG98	• Various cancers	• Phase 1	U.S. & Canada: MGI
DNA Methyltransferase Inhibitors	• Various cancers	• Preclinicals	U.S. & Canada: MGI

We were incorporated under the name Molecular Genetics, Inc. in Minnesota in November 1979.

Business Strategy

Our goal is to become a leading oncology-focused biopharmaceutical company serving well-defined markets. The key elements of our strategy are to:

- Capitalize on early launch progress to continue to successfully commercialize Aloxi injection for prevention of chemotherapy-induced nausea and vomiting ("CINV"). We intend to aggressively market Aloxi injection as an enhanced alternative to currently-marketed 5-HT_3 receptor antagonists indicated for prevention of CINV.
- Expand the Aloxi franchise by developing Aloxi injection for prevention of Post-Operative Nausea and Vomiting ("PONV") and by developing an oral Aloxi formulation for nausea and vomiting. Phase 3 trials of Aloxi injection for prevention of PONV and of an oral Aloxi formulation are expected to initiate in 2004.
- Selectively add to our product portfolio through various means, including product acquisition, in-licensing, co-promotion or business combinations. We intend to focus our product acquisition efforts on currently marketed pharmaceutical products or product candidates for which we believe we can effectively add value through our commercial and development capabilities.
- Advance the irofulven clinical program, including initiation of a phase 2 HRPC program during the second quarter of 2004.

- Collaborate with international biopharmaceutical companies outside the United States to develop and commercialize our current products and product candidates when we have international product rights.

Cancer Overview

According to the American Cancer Society, or ACS, there are approximately 1.3 million new cases of cancer diagnosed in the United States each year. Cancer is the second leading cause of death in the United States and is projected to result in approximately 556,500 deaths in the United States in 2003.

Cancer is characterized by the uncontrolled growth and spread of abnormal cells. These abnormal or malignant cells accumulate and form tumors that can compress, invade and destroy normal tissue. If malignant cells break away from the primary tumor, they can travel through the bloodstream or lymphatic system to other areas of the body. There they may settle and form new tumors. The spread of a tumor to a new site is called metastasis.

Different types of cancer vary in their rates of growth and patterns of spread, and, consequently, typically respond in varying degrees to different types of treatment. The three most common forms of treatment for cancer in order of their typical use are:

- surgery—the physical removal of a patient's tumor mass;
- radiation therapy—the use of high energy particles or waves, such as x-rays or gamma rays, to destroy or damage cancer cells; and
- chemotherapy—the use of drugs to inhibit the growth of or kill cancer cells. Systemic chemotherapy uses cancer therapy drugs that are administered intravenously or orally. These drugs enter the bloodstream and can potentially reach all areas of the body, which make this treatment especially useful for cancer that has metastasized.

A cancer patient often receives a combination of treatments depending upon the type and progression of the disease. While surgery attempts to remove the cancer from the patient and radiation attempts to kill the cancer cells, there are significant limitations and complications associated with these treatments that result in high rates of treatment failure. This failure is due primarily to metastasis and dose-limiting severe side effects. Chemotherapeutic agents attempt to address the limitations of surgery and radiation, which are local treatments, by interfering with the replication of cancer cells that may have spread to distant sites in the patient. In addition to treatment of their cancer, cancer patients often need supportive care to prevent or treat the side effects of radiation or chemotherapy. Examples include treatment of chemotherapy-induced nausea and vomiting, pain control or stimulation of blood cell growth.

Cancer is a disease characterized by uncontrolled cell replication, which requires cells to first replicate their DNA. Therefore, many chemotherapeutic agents target the cancer cells' ability to replicate DNA, or following the replication of their DNA, the ability of the cancer cells to divide. Different classes of chemotherapeutic agents are distinguished by their mechanism of action or how they specifically interfere with the cancer cells' ability to replicate DNA or divide.

When a cancer cell's DNA is damaged by a chemotherapeutic agent, DNA synthesis is inhibited or cell division is inhibited, and a cellular process known as apoptosis, or programmed cell death, may be activated. Apoptosis of tumor cells can lead to reduction in tumor size or to the arrest of tumor growth. Certain chemotherapeutic agents may act to directly promote apoptosis in tumor cells.

Because different chemotherapeutic agents may target different cellular processes required for DNA replication and cell division or of apoptosis, chemotherapeutic agents are often used in combination to maximize tumor cell death or inhibition of growth, while more effectively managing the side effect profile of the individual agents. Agents that specifically induce apoptosis or interfere with DNA replication or cell division in novel ways are therefore excellent candidates to be used in combination with existing chemotherapy agents.

One of the principal causes of chemotherapy treatment failure is the development of drug resistance by cancer cells, where cancer cells become resistant or refractory to the intended cytotoxic action of a variety of conventional chemotherapeutic agents. In many cases, resistance developed to a specific chemotherapeutic agent results in multi-drug resistance where the cancer cell becomes cross-resistant to a wide variety of chemotherapeutic agents. Given the current limitations of chemotherapy, there is a clear need for new therapies that are effective against a broad range of resistant and refractory cancers, as well as chemotherapeutics that act by novel mechanisms that can offer benefits as a combination therapy with existing chemotherapeutic agents.

Standard response criteria are used to report the results of oncology clinical trials. In solid tumor clinical trials, a complete response means that all measurable tumor tissue has disappeared and the patient appears to be disease free. A partial response means that measurable tumor tissue has shrunk by at least 50 percent. Stable disease means that the size of the measurable tumor tissue has not shrunk sufficiently to be considered a partial response, but it has not grown more than 25 percent from its smallest size during treatment. Progressive disease means that the tumor has grown by more than 25 percent from its smallest size during treatment.

Developed Products

Chemotherapy-Induced Nausea and Vomiting Overview

Depending on the type of cancer and treatment goals determined by physicians, patients may receive chemotherapy as part of their treatment regimen. One of the most feared side-effects of most chemotherapy treatments is chemotherapy-induced nausea and vomiting, or CINV. In recent years supportive care products to treat the side-effects of chemotherapy, such as CINV, have emerged to improve patient comfort and compliance with treatment regimens. While there are many types of supportive care products for cancer patients, this discussion is focused on the prevention of CINV.

Efforts to treat tumors such as those found in breast and lung cancer have led physicians to administer more aggressive chemotherapy regimens. These cytotoxic agents often cause CINV by triggering release of serotonin from certain cells in the gastrointestinal tract. The released serotonin stimulates nerve receptors that activate the vomiting center via the chemoreceptor trigger zone. When, and if, serotonin stimulates the vagal afferents through the 5-HT_3 receptors, vomiting (emesis) ensues. Although CINV has been managed to a greater degree in recent years, it is estimated that up to 85 percent of cancer patients receiving chemotherapy will experience some degree of emesis if not prevented with an antiemetic. The severity of emesis is dependent upon the type of chemotherapy administered, the dosing schedule of the chemotherapy, how quickly it was administered, and the patient's age and gender, among other predisposing factors. If emesis is not properly managed, it can cause dehydration and poor quality of life, eventually leading to interruption or discontinuation of chemotherapy. Most chemotherapy regimens are classified as low or moderately-emetogenic and, although the majority of patients receiving moderately-emetogenic chemotherapy are administered a currently available 5-HT_3 antagonist, there remains a need to improve upon the prevention of acute, within 24 hours of chemotherapy, CINV and, especially, delayed, more than 24 hours after chemotherapy, CINV.

Aloxi Injection for the Prevention of Chemotherapy-Induced Nausea and Vomiting

Aloxi (palonosetron hydrochloride) injection is a potent, highly selective serotonin subtype 3, or 5-HT_3, receptor antagonist differentiated by its strong receptor binding affinity and extended half life for the prevention of CINV. We obtained exclusive U.S. and Canadian Aloxi injection license and distribution rights from Helsinn Healthcare SA in April 2001. On July 25, 2003, approval was received from the FDA to market Aloxi injection for the prevention of acute and delayed CINV. We launched Aloxi injection in September 2003 through our 104-person oncology-focused sales organization. Aloxi injection competes in the growing U.S. 5-HT_3 receptor antagonist market estimated to be $1.5 billion in 2003. Of this amount, the market for prevention of CINV is estimated to be approximately $900 million.

A primary cause of CINV is the release of serotonin in the body in response to chemotherapy. 5-HT_3 receptor antagonists, like Aloxi injection, act by binding to serotonin receptors in the peripheral and possibly central

nervous system involved with nausea and vomiting, thereby blocking serotonin stimulation of these nerves and reducing or eliminating CINV. CINV can be characterized as acute nausea and vomiting occurring zero to 24 hours post-chemotherapy, or delayed nausea and vomiting occurring 24 to 120 hours post chemotherapy. Despite the availability of preventative treatments, including first generation 5-HT_3 receptor antagonists, nearly fifty percent of all patients receiving chemotherapy experience nausea and vomiting.

The results of phase 3 clinical trials demonstrate that Aloxi injection is more effective than ondansetron (Zofran®), the current 5-HT_3 receptor antagonist market leader by sales, and dolasetron (Anzemet®), the number two product by sales, for treating CINV due to moderately emetogenic chemotherapy. The most frequently prescribed chemotherapies, including those used to treat the most common cancers such as breast, lung and colon, are considered moderately emetogenic or having a moderate to moderately-high potential to cause nausea and vomiting. Based on the phase 3 trials conducted, Aloxi injection is shown statistically to have greater efficacy or to be as effective as ondansetron and dolasetron for prevention of acute and delayed CINV. Overall, the incidence, pattern, duration, and intensity of adverse reactions were similar among patients treated with Aloxi injection and other 5-HT_3 receptor antagonists. In 633 patients treated with Aloxi injection during phase 3 trials, the most common adverse reactions related to the study drug were headache (9%), and constipation (5%). The table below provides a summary of the efficacy results from these pivotal phase 3 clinical trials, where complete response rate is defined as the proportion of treated patients which had no vomiting and no rescue medication.

	Moderately Emetogenic Chemotherapy				**Highly Emetogenic Chemotherapy**	
	Study 99-03		**Study 99-04**		**Study 99-05**	
	Aloxi	**Ondansetron**	**Aloxi**	**Dolasetron**	**Aloxi**	**Ondansetron**
Acute CINV (0 – 24 hours)	81% *	69%	63%	53%	59%	57%
Delayed CINV (24 – 120 hours)	74% *	55%	54% *	39%	45%	39%
Overall (0 – 120 hours)	69% *	50%	46% *	34%	41%	33%

* Indicates results that demonstrate statistically greater efficacy than the alternative 5-HT_3 product compared in trial.

We believe that Aloxi injection will be competitive in the U.S. CINV market for 5-HT_3 receptor antagonists given that Aloxi injection:

- is highly selective for the 5-HT_3 receptor and has a thirty to seven hundred times stronger binding affinity for this receptor than currently marketed 5-HT_3 receptor antagonists;
- is more potent than currently marketed 5-HT_3 receptor antagonists;
- has demonstrated a plasma elimination half-life of almost 40 hours, which is four to ten times longer than any currently marketed 5-HT_3 receptor antagonists;
- has demonstrated in phase 3 trials to have statistically greater efficacy or to be as effective as ondansetron or dolasetron in preventing both acute and delayed CINV; and
- is the only 5-HT_3 receptor antagonist approved to prevent both acute and delayed CINV.

The potency and extended half-life of Aloxi injection may enable patients and their healthcare providers to control both acute and delayed CINV for several days following chemotherapy with a single fixed intravenous dose. We believe this single fixed dose treatment will be more convenient compared to currently marketed 5-HT_3 receptor antagonists, which usually demand patients to adhere to an oral follow-up therapy regimen for several days.

Salagen Tablets for the Symptoms of Xerostomia and Sjögren's Syndrome

MGI conceived, developed and markets Salagen Tablets (pilocarpine hydrochloride) in the United States. Salagen Tablets' clinically-proven efficacy and safety allow it to maintain leadership in the market for treatment

of chronic dry mouth symptoms associated with head and neck cancer patients treated with radiation and with Sjögren's syndrome patients.

Salagen Tablets were the first prescription drug approved to treat the symptoms of chronic dry mouth in these patient populations. Chronic dry mouth can be a painful and debilitating condition. Salagen Tablets stimulate the exocrine glands, including the salivary glands, to increase their moisture-producing activity. Saliva is important to oral health and quality of life in general. People with chronic dry mouth can experience difficulty eating and sleeping, rapid tooth decay, periodontal disease and oral infections. Sales of Salagen Tablets in the United States were $26.5 million in 2003. Underlying demand for Salagen Tablets in the United States, as measured by prescription growth, grew at an annual rate of approximately one percent in 2003 over 2002.

Head and neck cancer

Although often effective in treating primary tumors of the head and neck, radiation therapy can permanently damage a patient's salivary glands, resulting in xerostomia, a significant, chronic reduction of saliva production. Patients using Salagen Tablets for radiation-induced dry mouth typically take one tablet three times per day during the course of radiation therapy, which will last approximately six to eight weeks and may then take it indefinitely to treat the residual dry mouth symptoms that follow radiation therapy.

Salagen Tablets have been shown to stimulate the residual functioning tissue in the damaged salivary glands to increase saliva production and provide patients with a longer-lasting solution for the symptoms of radiation-induced chronic dry mouth. In two 12-week trials that were the primary basis for the approval of Salagen Tablets in 1994, 369 patients who had been treated with radiation therapy for head and neck cancer were assessed for the ability of Salagen Tablets, versus placebo, to relieve the symptoms of dry mouth and to stimulate saliva production. In both studies, patients who received Salagen Tablets experienced significant improvement in their overall condition of dry mouth. Those patients also demonstrated statistically significant improvements in salivary flow compared to the patients receiving placebo tablets. Less than one percent of the patients who received Salagen Tablets withdrew from these studies due to lack of efficacy. Sweating was the most commonly reported side effect; however, less than one percent of patients taking the approved dosing regimen withdrew from the study due to sweating.

Sjögren's syndrome

Sjögren's syndrome is a chronic autoimmune disorder in which the body's own immune system attacks the moisture-producing glands, including the salivary glands, causing them to lose their ability to produce adequate moisture. Symptoms of Sjögren's syndrome vary in degree and type, but the common component is chronic dryness. Patients can exhibit dry mouth, swollen glands, dry eyes, vaginal dryness and fatigue. The syndrome can be manifested alone (primary Sjögren's) or in combination with other autoimmune disorders (secondary Sjögren's). We believe that approximately 50,000 of the 200,000 Sjögren's syndrome patients could benefit from Salagen Tablets.

In patients with Sjögren's syndrome-related dry mouth, Salagen Tablets can help to relieve the symptoms of oral dryness. Salagen Tablets can stimulate the salivary glands to increase production of saliva, which is essential to maintaining good oral health. For Sjögren's syndrome patients, previously available therapies included tear and saliva substitutes. These types of products provide transient relief at best and often fail to prevent complications.

In two 12-week trials that were the primary basis for the supplemental approval of Salagen Tablets for Sjögren's syndrome in 1998, a total of 629 primary or secondary Sjögren's syndrome patients were assessed for the ability of Salagen Tablets, versus placebo, to relieve the symptoms of dry mouth and to stimulate saliva production. Patients receiving Salagen Tablets four times a day reported a significant improvement in their symptoms associated with oral dryness, and they also demonstrated a significant increase in saliva for the full 12 weeks. Similar to the Salagen Tablet trials in head and neck cancer patients, less than one percent of the patients

receiving Salagen Tablets withdrew from the trial due to lack of efficacy. The most common side effect was mild to moderate sweating. Less than four percent of patients taking the approved dosing regimen withdrew from the study due to sweating.

The FDA granted us orphan drug status for Salagen Tablets in 1994 as a treatment for the symptoms of xerostomia induced by radiation therapy in head and neck cancer patients and in 1998 for the symptoms of dry mouth associated with Sjögren's syndrome. Our orphan drug protection for Salagen Tablets for the treatment of symptoms of radiation-induced xerostomia in head and neck cancer patients expired in March 2001 and our orphan drug protection for Sjögren's syndrome will expire in 2005. Expiration of our orphan drug protection for Salagen Tablets may result in competition from manufacturers of generic versions of Salagen Tablets.

Hexalen Capsules for Ovarian Cancer

In November 2000, we purchased worldwide rights to Hexalen (altretamine) capsules from MedImmune Oncology, Inc. Hexalen capsules are an orally administered chemotherapy that is approved as a second-line treatment of ovarian cancer. Hexalen capsules are approved for the treatment of ovarian cancer in 21 countries including the United States. Sales of Hexalen capsules in the United States were $2.8 million in 2003.

In the two trials that were the primary basis for its approval in the United States, Hexalen capsules were administered as a single agent for 14 or 21 days of a 28-day cycle. In the 51 patients with measurable or evaluable disease, there were seven complete responses and two partial responses for an overall response rate of 18 percent. The duration of these responses ranged from two months in a patient with a palpable pelvic mass to 36 months in a patient who achieved a complete response. In some patients, tumor regression was associated with improvement in symptoms and performance status. Side effects of Hexalen capsules are comparable to those seen with other approved chemotherapies and include mild to moderate bone marrow suppression, nausea and vomiting, and peripheral sensations of touch.

A more recent trial in 97 ovarian cancer patients, which was published in Gynecologic Oncology (Vol. 82 pages 317-322, 2001), investigated the ability of six months of treatment with Hexalen capsules to extend survival following achievement of a complete response with front-line therapy. At two years, following completion of front-line therapy, patients in this trial demonstrated a higher survival rate compared to that seen in earlier trials.

Products Under Development

The following table summarizes the status of ongoing development of Aloxi products, irofulven, other acylfulvene analogs, MG98 and DNA methyltransferase inhibitors:

Product	Indication	Status	Sponsor
Aloxi injection	PONV	To begin Phase 3	Helsinn Healthcare
Aloxi oral formulation	CINV	To begin Phase 3	Helsinn Healthcare
Irofulven	Hormone Refractory Prostate Cancer	To begin Phase 2	MGI PHARMA
	Liver Cancer—Inoperable	Phase 2	MGI PHARMA
	Gastric Cancer	Phase 2	National Cancer Institute
	Ovarian Cancer	Phase 2	National Cancer Institute
	Combination study with irinotecan – GI Cancers	Phase 2	MGI PHARMA
	Combination study with gemcitabine	Phase 1	MGI PHARMA
	Combination study with docetaxel	Phase 1	MGI PHARMA
	Combination study with capecitabine	Phase 1	MGI PHARMA
	Combination study with oxaliplatin	Phase 1	MGI PHARMA
MG98	Myelodysplasia and Acute Myelogenous Leukemia	Phase 1	MGI PHARMA
	Solid Tumors	Phase 1	Vernalis
Other Acylfulvene Analogs	Various Cancers	Preclinical	MGI PHARMA
DNA Methyltransferase Inhibitors	Various Cancers	Preclinical	MGI PHARMA/ MethylGene

Post Operative Nausea and Vomiting (PONV) Overview

Post operative nausea and vomiting is a common consequence of anesthetic and surgical procedures. Patients undergoing abdominal, gynecological, ear, nose and throat, cardiovascular, and eye surgery are at the highest risk for PONV. If not prevented, PONV can cause hospital re-admissions and increase healthcare costs for patients who undergo surgery. In the United States, more than 40 million surgical procedures are performed annually, and the incidence of PONV is estimated at 25% to 30%. If approved for the prevention of PONV, Aloxi injection would compete in an approximately $400 million PONV market in the United States.

Aloxi (palonosetron hydrochloride) injection is a potent, highly selective serotonin subtype 3, or 5-HT_3, receptor antagonist differentiated by its strong receptor binding affinity and extended half-life and has already been approved for the prevention of chemotherapy-induced nausea and vomiting. We are working with Helsinn Healthcare, the licensor of palonosetron hydrochloride, to design phase 3 programs with a goal to seek FDA approval of Aloxi injection for the prevention of PONV and to develop an oral Aloxi formulation. Phase 3 trials are expected to begin during 2004 for each program.

Irofulven for Chemotherapy Treatment

Irofulven is our lead cancer therapy product candidate under development and is part of our family of proprietary cancer therapy compounds called acylfulvenes. Acylfulvenes, including irofulven, are semi-synthetic derivatives of the natural product illudin S obtained from the *Omphalotus olearius* mushroom. We licensed rights to the entire class of acylfulvene agents, including irofulven, from the Regents of the University of California in 1993.

Irofulven:

- is potentially active as an anti-cancer agent in treating a broad range of cancers;
- has a unique mechanism of action that may make it effective in treating refractory cancers, or cancers that are unresponsive to existing cancer therapies and useful in combination with existing cancer therapies;
- has demonstrated activity against tumors that are known to be resistant to other cancer therapies; and
- has a side effect profile that is adequately tolerated.

Mechanism of action studies have indicated that irofulven is rapidly taken up by sensitive tumor cell types where it reacts with tumor cell DNA and protein targets in a novel manner, producing rapid inhibition of DNA synthesis and DNA lesions that are difficult for the tumor cell to repair. The initiation of DNA damage by irofulven begins tumor selective apoptosis that ultimately causes cell death. Clinical trials will determine whether the differential effect of irofulven on tumor cells compared to healthy cells translates into important clinical benefit. We further believe that irofulven could be the first of a series of acylfulvene analogs that merit development as cancer therapies.

We believe irofulven has a unique mechanism of action that makes it well-suited for study in refractory patient populations and in combination with other cancer therapies. Preclinical data and early clinical data demonstrate irofulven's activity against tumors that are known to be resistant to other therapies. Preclinical studies have also demonstrated the additive or synergistic effect of irofulven with a number of marketed cancer therapies. To date, irofulven has demonstrated a side effect profile relative to certain marketed cancer therapies, which we believe enhances the prospect of irofulven combining well with these cancer therapies. Therefore, we believe that pursuing multiple development paths in different refractory cancers and in combination with other cancer therapies is warranted. Preclinical toxicology studies in rats and dogs and initial clinical data from the dosing of over 1,000 cancer patients with irofulven have demonstrated that irofulven is adequately tolerated as a chemotherapeutic compound and its side effects are reversible. The primary dose-limiting side effect has been bone marrow suppression, usually observed as decreased blood platelet or white cell counts. Other drug-related side effects have been nausea, vomiting, visual disturbances and fatigue. Bone marrow suppression has been controlled through dose adjustments or treatment delays to allow recovery of platelet or white cell counts. Nausea and vomiting are prophylactically controlled with standard, currently available treatments. Visual disturbances and fatigue are managed by dose adjustments and are reversible after discontinuation of treatment.

One method of identifying cancer therapy targets for further human trials is to conduct preclinical tests on mice that have been implanted with human, solid tumors. Testing of irofulven in these disease models has demonstrated dose-related anti-cancer activity, including an increase in survival or tumor regressions in the following types of cancers:

- Prostate
- Ovarian
- Pancreatic
- Non-small Cell Lung
- Colon
- Rhabdomyosarcoma
- Glioma
- Gastric
- Breast
- Melanoma
- Small Cell Lung
- Head and Neck
- Neuroblastoma

Irofulven Single Agent Trials

An investigational new drug application for irofulven was submitted to the FDA in September 1995 and phase 1 human safety testing was initiated in December 1995. Phase 1 clinical trials are conducted in small patient populations and are generally not designed to measure efficacy. In October 1997, we initiated a second phase 1 trial to evaluate the effect of longer infusion times. Both initial phase 1 trials completed enrollment in 1998 after establishing a maximum tolerated dose level and a recommended dosing regimen for the initial phase 2 trials.

The investigators participating in our initial phase 1 trials observed anti-cancer activity. Seven out of a total of 32 patients who received daily treatments at a dose between 8 and 18 mg/m^2 in these trials demonstrated stabilization of disease or tumor shrinkage as a response to irofulven.

In late 1999, we initiated a phase 1 dose optimization trial using intermittent or weekly dosing in patients with malignant solid tumors that were refractory to anti-cancer treatment or for which no standard treatment exists. In this challenging patient population, greatly improved tolerance to acute effects of treatment were observed compared to the five consecutive day dosing schedule used to initiate our phase 2 trials program. In addition, comparable dose intensity was achieved and evidence of anti-cancer activity was observed in this trial. Based on these results and consultation with our panel of outside oncology experts, weekly or bi-weekly dosing schedules will generally be used in ongoing and future trials.

We have tested irofulven in a variety of phase 2 solid tumor trials. We chose to investigate pancreas, ovary, prostate and liver because:

- these cancer types have significant mortality and morbidity associated with them;
- current therapies are inadequate;
- there was noticeable anti-cancer response in our preclinical studies or clinical trials;
- clinical trials for pancreas and liver cancers tend to be of a relatively short duration; and
- product candidates for these indications may qualify for expedited regulatory review.

Anti-cancer activity of irofulven has been observed in each of these trials, including objective tumor shrinkage.

To obtain marketing approval for irofulven in the United States, pivotal registration trials will need to be successfully completed and submitted to the FDA. Phase 3 trials typically use survival as the primary endpoint, compared to a randomly determined control group and have a higher number of enrolled patients than in earlier phases.

Irofulven for Pancreatic Cancer

Our initial pivotal registration trial of irofulven was for the treatment of refractory pancreatic cancer. Pancreatic cancer is the fifth most common cause of cancer-related death in the United States, and is an aggressive disease that has few effective treatment options. In February 2001, we began a pivotal phase 3 trial of irofulven for treating refractory pancreatic cancer patients. Initiation of this trial was based on phase 2 results in pancreatic cancer patients, improved acute tolerance with every-other-week dosing of irofulven seen in the dose optimization trial, and discussions with the FDA and our panel of outside oncology experts.

The phase 3 trial was a randomized, multi-center, international trial in advanced-stage pancreatic cancer patients whose disease progressed after treatment with gemcitabine, the current standard-of-care treatment. The primary endpoint was overall survival times following treatment with irofulven compared to continuous infusion 5-fluorouracil (5-FU). Two patients were randomized into the irofulven treatment arm for every patient enrolled in the 5-FU control arm. In April 2002, we stopped enrollment in this phase 3 clinical trial of irofulven for gemcitabine-refractory pancreatic cancer patients. Despite evidence of irofulven activity, preliminary analysis of

the phase 3 data by an independent Data and Safety Monitoring Board, or DSMB, indicated that the comparator agent 5-FU demonstrated a greater than expected survival benefit, making it statistically improbable that the final study results could achieve our planned objectives for the trial. For this reason, we will no longer pursue this specific indication for irofulven monotherapy in gemcitabine-refractory pancreatic cancer. Following closure of the trial to enrollment, we continued to make irofulven available to the remaining enrolled pancreatic cancer patients in this trial who had experienced clinical benefit.

Irofulven Combination Trials

We believe that an advantage of combination therapy is the potential to achieve enhanced anti-cancer benefit with an acceptable side effect profile compared to either agent used alone. Because irofulven has a unique mechanism of action, retains activity against tumors that are known to be resistant to other cancer therapies and in preclinical trials demonstrated additive or synergistic effects in combination with a number of marketed chemotherapies, we are conducting drug combination trials with irofulven. The first clinical step in exploring combination therapy is to conduct phase 1, dose-ranging trials to determine the maximum tolerated dose of both drugs together. The anti-tumor activity in a completed phase 1 trial of irofulven in combination with irinotecan led to the initiation of a phase 2 trial of irofulven with irinotecan in patients with advanced gastrointestinal tumors. We are currently conducting four dose-ranging trials of irofulven in combination with gemcitabine, capecitabine, docetaxel, and oxaliplatin. Data from these trials and possible follow-up phase 2 trials in specific tumor types will be evaluated to determine whether further drug combination development with these marketed therapies is warranted.

Irofulven for Hormone Refractory Prostate Cancer

Throughout phase 1 and 2 monotherapy and combination therapy trials, consistent evidence of clinical activity in hormone refractory prostate cancer, or HRPC, has been reported, including activity in patients previously exposed to chemotherapy. Phase 2 data presented at the 39th Annual Meeting of the American Society of Clinical Oncology (ASCO) in 2003 indicated that irofulven in combination with prednisone, a steroid, induced decreases of more than 50 percent in prostate specific antigen (PSA) levels in 25 percent of evaluable patients and disease stabilization in 86 percent of patients evaluable for objective tumor response. PSA is a blood marker used by clinicians for treatment decisions. Activity has also been shown in prostate cancer patients treated with irofulven plus the marketed chemotherapies, capecitabine or cisplatin, in phase 1 trials. Following comprehensive analysis of our available data, we are preparing to initiate a phase 2 combination program for irofulven in HRPC patients previously treated with docetaxel. Most HRPC patients in the United States who are receiving chemotherapy are treated with docetaxel, and we believe significant unmet need exists among prostate cancer patients who have failed hormone therapy and who have progressed on docetaxel.

NCI Clinical Trials

Under a 1996 Clinical Trials Agreement, the National Cancer Institute, or NCI, is sponsoring and overseeing, at its own expense, a clinical trials program using irofulven in its network of designated cancer centers and other institutions. We have agreed to provide drug product for these trials and will have access to any resulting data. We intend to utilize the results from NCI-sponsored trials to further characterize the safety of irofulven as well as evaluate the potential of irofulven in additional refractory solid tumor types. The NCI has sponsored 14 trials of irofulven in a range of solid tumor cancers and leukemias and two trials are ongoing.

Other Acylfulvene Analogs

In addition to irofulven, we have obtained license rights to acylfulvene analogs. The synthesis and the initial biological testing of over 100 of these analogs has been performed at the University of California, San Diego, or UCSD. At UCSD, both *in vitro* and *in vivo* anti-tumor activity has been demonstrated for a significant number of the acylfulvene analogs. Further testing by the NCI of some of these analogs has confirmed broad spectrum anti-

tumor activity. The broad-spectrum anti-tumor activity of the acylfulvene analogs suggests that this class of compounds has the potential to produce additional clinical development candidates. We are currently evaluating these analogs for further preclinical development.

MG98 and Small Molecule DNA Methyltransferase Inhibitor Programs

In August 2000, as part of our strategy to expand our portfolio of marketed and development stage anti-cancer products, we entered into an exclusive license, research and development agreement with MethylGene Inc. for North America rights to its proprietary anti-cancer product candidate MG98 and its DNA methyltransferase small molecule inhibitor program. Included within our license rights is a United States patent on a method for reversing the tumor-causing state of a cell by administering an agent that corrects an aberrant methylation pattern in the DNA of the cell. MethylGene is a chemistry-driven, rational drug design and development company focused on the inhibition of enzyme targets that are associated with disease. It pursues two approaches to enzyme inhibition: rationally designed mRNA inhibitors that block the production of enzymes and rationally designed small molecule inhibitors that block the activity of enzymes.

In a December 2003 amendment to the License Agreement, MethylGene acknowledged full satisfaction of our payment obligations and suspended further payment obligations by us pending a planned June 2004 data review of the small molecule inhibitor program and following completion by MethylGene of a planned clinical trial with MG98. If we resume development, our financial responsibilities under the License Agreement would also resume.

Sales and Marketing

We currently promote our products in the United States directly to medical oncologists, hematologic oncologists, radiation oncologists, rheumatologists, internal medicine physicians, and other physician specialists using our 104-person oncology-focused sales organization. In 2003, we expanded the sales organization in preparation for the commercial launch of Aloxi injection. Our sales organization will continue to be used to promote our current and future oncology products in the United States.

In addition, we have an in-house marketing, manufacturing and commercial management staff of 38 persons who support our commercial activities. We use a variety of marketing programs to reach our targeted audiences, including distribution of product-specific brochures in face-to-face meetings and direct mailings, exhibits at select medical meetings and journal advertising. Our sales and marketing organizations are highly trained and experienced.

We use international collaborations to commercialize our products outside the United States. We currently have agreements with Novartis Pharma AG (formerly CIBA Vision AG), Kissei Pharmaceutical Co., Ltd. and Pfizer Inc. to develop and commercialize Salagen Tablets for the European, Japanese and Canadian markets, respectively. Under these agreements, we receive payments based on development milestones and/or product sales in the pertinent territory. We also have distribution agreements for Salagen Tablets in Israel, Korea, Singapore, Taiwan, Hong Kong, Colombia, Thailand, and Malaysia. We receive payments based upon product sales to these distributors.

Research and Development

We maintain active drug development programs for our new drug candidates and commercialized products. Current drug development efforts are primarily focused on Aloxi products and irofulven. Licensing development milestone payments for Aloxi products are recognized as research and development expense. We also participate in post-marketing studies to support the continued commercialization of Aloxi injection, Salagen Tablets and Hexalen capsules. We seek product candidate acquisitions in order to expand our development pipeline.

We have incurred significant research and development costs in the past and believe that substantial capital resources will be required to support current and future development programs. We spent approximately $36.1 million in 2001, $32.2 million in 2002, and $50.1 million in 2003 on research and development. In recent years, 74 to 80 percent of our research and development expense was attributable to contracts with third parties. Approximately 80 percent of our research and development expense in 2003 was attributable to third party services, license fees or FDA user fees. Funding for research and development is expected to come from internally generated funds, joint ventures, strategic alliances or other sources of capital, including equity or debt offerings.

Successful drug development requires a broad spectrum of scientific, clinical and product development expertise. As part of our strategy, we do not directly conduct basic research or traditional drug discovery activities because we primarily intend to acquire rights to product candidates that are in the human clinical stage of development. This approach substantially reduces our research risk due to product failure and eliminates the need for direct investment in discovery research laboratories and personnel.

We manage our human clinical development of product candidates by selectively outsourcing certain activities. We have in-house medical communications capabilities and regulatory affairs expertise which allow us to maintain support systems, monitor adverse drug experience reporting, and file new drug applications with the FDA. We outsource other development activities, such as the conduct of preclinical studies and clinical trials, product formulation and production of clinical supplies.

We expect to continue to contract with third parties until it is necessary and economical to add these capabilities internally. As of December 31, 2003, we employed 55 persons in research and development, regulatory affairs and product formulation.

International Alliances

Dainippon Pharmaceutical Co., Ltd.

During 1995, we entered into a cooperative development and commercialization agreement with Dainippon, whereby we granted Dainippon an exclusive license to develop and commercialize acylfulvenes, including irofulven, in Japan. Dainippon granted us an irrevocable, exclusive, royalty-free license allowing us to use any technology or data developed by Dainippon relating to the acylfulvenes. Dainippon and MGI agreed in the first quarter of 2003 to terminate this agreement effective August 2003. Under the agreement, Dainippon paid initial and continuing quarterly milestone payments totaling $11.1 million through April 2000. From April 2000 through January 2002, $4.3 million in deposit payments were received from Dainippon, which we repaid to Dainippon in August 2003.

Kissei Pharmaceutical Co., Ltd.

In December 1994, we entered into a license agreement with Kissei under which we granted to Kissei an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Japan. Kissei granted back to us an irrevocable, non-exclusive, royalty-free license allowing us to use any technology or data developed by Kissei relating to Salagen Tablets. Kissei paid us an initial license fee upon execution of the agreement and agreed to pay us additional milestone payments and we have received all $2.5 million of the required license fees and milestone payments. In addition, Kissei agreed to pay us royalties equal to a certain percentage of net sales revenues, subject to annual minimum requirements. In May 2003 Kissei filed a submission to the Japanese regulatory authorities for the use of Salagen Tablets in treating the symptoms of radiation-induced xerostomia in head and neck cancer patients. The product is currently undergoing regulatory review for marketing approval in Japan. Unless earlier terminated by the parties for cause or by mutual agreement, the term of the agreement is for ten years from the date Salagen Tablets are first launched in Japan. Thereafter, the agreement automatically renews for additional one-year periods.

Novartis Pharma AG (formerly CIBA Vision AG)

In April 2000, we entered into a license agreement with Novartis under which we granted Novartis an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Europe, Russia and certain other countries. Novartis granted to us an irrevocable, non-exclusive, royalty-free license allowing us to use any technology or data developed by Novartis relating to Salagen Tablets. Simultaneous with this agreement, the previous agreements with Chiron B.V. for Salagen Tablet rights in Europe were terminated. Novartis paid us $1.5 million of net license fees upon completion of transfer activities. Additional milestone payments may be received if specified sales targets are achieved. Further, Novartis agreed to pay us royalties equal to a percentage of net sales revenues. Unless earlier terminated by the parties, the term of the agreement is for 12 years and may be extended for additional two-year periods.

In addition, we simultaneously entered into a supply agreement with Novartis under which we agree to supply Novartis' requirement of Salagen Tablets until the termination of the license agreement with Novartis.

Pfizer Inc. (formerly Pharmacia Corporation)

In November 1994, we entered into a license agreement with Pfizer Inc, or Pfizer, under which we granted to Pfizer an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Canada. Pfizer granted to us an irrevocable, non-exclusive, royalty-free license allowing us to use any technology or data developed by Pfizer relating to Salagen Tablets. Pfizer paid us an initial license fee of $75,000 upon execution of the agreement and agreed to pay us royalties equal to a percentage of net sales revenues, subject to annual minimum requirements. In addition, we agreed to pay Pfizer royalties if we promote Salagen Tablets in Canada in the first or second year following termination of the agreement. Either party may terminate the agreement upon one-year prior written notice. Thereafter, for an additional two-year period we would pay a portion of Salagen Tablet net sales in Canada to Pfizer. In addition, we simultaneously entered into a supply agreement with Pfizer under which we agree to supply Pfizer's requirement of the product until the termination of the License Agreement with Pfizer.

Technology In-licensing Agreements

Acylfulvenes, Including Irofulven

In August 1993, we entered into an exclusive license agreement with the Regents of the University of California. Under the agreement, the university granted to us an exclusive, worldwide, royalty-bearing license for the commercial development, manufacture, use and sale of acylfulvene analogs, methods of synthesizing acylfulvene analogs and methods of treating tumors using acylfulvene analogs. We have been developing irofulven under this license. We paid the university an initial license fee upon execution of the agreement and agreed to pay license maintenance fees on each anniversary of the execution of the agreement until we submit the first NDA relating to the analogs to the FDA. In addition, we make development milestone payments prior to commercialization of the product. We have also agreed to pay royalties on net sales revenues, subject to annual minimum requirements. Through December 31, 2003, we have made approximately $850,000 in cash payments to the university under this agreement. Unless earlier terminated by the parties, the term of the agreement extends until the later of: (a) the expiration of the last-to-expire patent we have licensed; or (b) ten years from the date of the first commercial sale of products developed from the acylfulvene analogs.

MG98 and Other DNA Methyltransferase Inhibitors

In August 2000, we entered into a license, research and development agreement with MethylGene for two anti-cancer product programs. Under the agreement, MethylGene granted to us an exclusive, royalty-bearing license to develop and commercialize MG98 in North America for all therapeutic indications.

The agreement also included similar rights to small molecule DNA methyltransferase inhibitors for oncology and rheumatology indications. In exchange for the licenses, we agreed to:

- make initial cash payments to MethylGene;

- make certain development milestone payments for both MG98 and the first DNA methyltransferase inhibitor that achieves such development milestones;
- purchase research services from MethylGene; and
- pay MethylGene royalties on annual future net sales revenue.

Through the time of the initial regulatory approvals in the United States and Canada, the initial and milestone cash payments would aggregate to approximately $16 million for each of the two development programs. Unless earlier terminated by the parties, the term of the agreement extends until the later of: (a) the expiration of the last-to-expire patent we have licensed; or (b) ten years from the date of the first commercial sale of any licensed product. Simultaneous with the execution of the license agreement, we entered into a stock purchase agreement and have purchased the $6.8 million of MethylGene common stock required by this agreement.

In a December 2003 amendment to the License Agreement, MethylGene acknowledged full satisfaction of our payment obligations and suspended further payment obligations by us pending a planned June 2004 data review of the small molecule inhibitor program and following completion by MethylGene of a planned clinical trial with MG98.

Aloxi Products

In April 2001, we obtained from Helsinn Healthcare SA ("Helsinn") the exclusive oncology license and distribution rights for Aloxi injection in the United States and Canada. Aloxi injection is a differentiated 5-HT_3 antagonist for the prevention of chemotherapy-induced nausea and vomiting. Under the terms of the agreement, we have made an aggregate of $38 million in license payments as of December 31, 2003. We have also agreed to pay royalties and supply fees based on net sales revenues.

We expanded our agreement with Helsinn in November 2003 to include rights for the post operative nausea and vomiting (PONV) application of Aloxi injection and an oral Aloxi formulation and extended the term through December 31, 2015. Under the terms of the expanded agreement, we made initial payments to Helsinn aggregating to $22.5 million in the fourth quarter of 2003 and the first quarter of 2004. We expect to make additional payments totaling $25 million over the course of the next several years upon achievement of certain development milestones leading up to the approvals of Aloxi injection for prevention of PONV and an oral Aloxi formulation in the United States. We will also pay royalties and product supply fees based upon net sales. Helsinn will continue to fund and conduct all development of Aloxi products for the new applications and will supply finished product for commercialization.

Mylocel Tablets

In January 2001, MGI entered into an agreement with Barr Laboratories, Inc. for the exclusive marketing and distribution rights for Mylocel™ (hydroxyurea) tablets in the United States. Mylocel tablets were approved for the treatment of melanoma, resistant chronic myelocytic leukemia, and recurrent, metastatic, or inoperable carcinoma of the ovary. MGI began marketing and distributing Mylocel tablets in March 2001. Under the terms of the agreement, Barr Laboratories received royalty payments based upon the product contribution derived from MGI's sale of product. This agreement was terminated in April 2002.

Hexalen Product Purchase Agreement

In November 2000, we purchased certain assets and assumed certain liabilities related to the Hexalen capsules business from MedImmune Oncology, Inc. Hexalen (altretamine) capsules are an orally administered cytotoxic drug that was approved for treatment of ovarian cancer in patients with persistent or recurrent disease following first-line therapy with Platinol and/or alkylating agent-based combination chemotherapy. Hexalen capsules are approved for the treatment of ovarian cancer in the United States and a number of other countries. We purchased

worldwide rights subject to existing distribution agreements for territories outside the United States. The purchase price of $7.2 million has been fully paid and royalties are due on net sales or distribution margins.

Distribution Agreements

We entered into distribution agreements granting a license to the following exclusive, independent distributors to promote and distribute Salagen Tablets in the designated territories:

- Megapharm Ltd. (Israel)—expires April 7, 2005;
- Hyundai Pharmaceutical Co., Ltd. (South Korea)—expires February 26, 2006;
- Pharmaforte Singapore Pte. Ltd. (Singapore)—expires September 28, 2004, with one three year extension;
- Jacobson Medical (HK) Ltd. (Hong Kong and Macao SAR) – expires December 2, 2008, with one renewal for an additional two year period;
- Universal Integrated Corp. (Taiwan)—expires September 12, 2007 with an additional three year extension;
- EuroEtika Ltda. (Colombia)—expires July 17, 2006 subject to renewal for an additional two year period;
- American Taiwan Biopharm Co. Ltd. (Thailand)—expires five years after receipt of all regulatory approvals in Thailand with an additional two year extension; and
- Primal Healthcare & Beauty Pte. Ltd. (Malaysia)—expires five years after receipt of all regulatory approvals in Malaysia with an additional two year extension.

We have distribution agreements granting a license to promote and distribute Hexalen capsules in designated territories.

- Teva Pharmaceutical Industries, Ltd. – Teva International Pharmaceutical Division – various countries in Eastern Europe, South America and Africa – expires on a country-by-country basis on the earlier of the 10-year anniversary of the effective date of registration or the six-year anniversary of the date of first sale. Automatically extends for 1-year terms unless terminated;
- Teva Pharmaceutical Industries Ltd. – Israel – license to manufacture for use in Israel or for packaging and sale of imported drug product in Israel or for distribution by Teva International Pharmaceutical Division, expires the earlier of 10th anniversary of launch date or December 26, 2006. Automatically extends for 1-year terms unless terminated prior to termination of current term;
- Taiwan Tung Yang Chemical Ind. Co., Ltd. (“TTY”) (Taiwan, Malaysia, Thailand, The Philippines) – expires January 6, 2009 with additional one year terms. Distribution in Thailand is by TTY’s nominee, American Taiwan Biopharm Co., Ltd., whose distribution agreement expires five years after receipt of all (pending) approvals with an additional two-year renewal period;
- Myung Ji Pharmaceutical Trading Co., Ltd. (South Korea)—expires July 26, 2009 with additional one year renewal periods;
- Swedish Orphan AB (Sweden, Norway, Denmark; Finland, Iceland)—indefinite term subject to written notice;
- Mayne Pharma Pty. Ltd. (Australia and New Zealand)—indefinite term subject to written notice; and
- Ramco Pharm (Egypt)—expires November 22, 2004.

The distributors are required to obtain local authorizations in connection with the import/export and distribution of product in their designated territory. We receive product supply payments and may receive distribution initiation fees.

Manufacturing

We do not own or operate any facilities for the manufacture of our products or product candidates. Our marketed and development-stage pharmaceuticals are manufactured under agreements with third party manufacturers. Our manufacturing and quality assurance personnel authorize, audit and approve virtually all aspects of the manufacturing process. In-process and finished product inventories are analyzed through contract testing laboratories and the results are reviewed and approved by us prior to release for further processing or distribution. We intend to carry at least a six-month inventory of each of our marketable products.

Aloxi Injection

Palonosetron hydrochloride, the active pharmaceutical ingredient for Aloxi products, is manufactured by Helsinn. Helsinn is responsible for the worldwide requirements of both the active pharmaceutical ingredient and finished drug product, a sterile formulation in a single-use vial. Helsinn contracts with Cardinal Healthcare, Inc. for filling vials with a solution of the active pharmaceutical ingredient. Helsinn Birex Pharmaceuticals Ltd., a unit of Helsinn, located in Ireland, finishes (labels and packages) the vials for distribution.

Salagen Tablets

We obtain pilocarpine hydrochloride, the active pharmaceutical ingredient for the manufacture of Salagen Tablets, under an exclusive supply and license agreement with Merck KgaA. The exclusive term of this agreement ends on December 31, 2007, and may be extended for additional five-year terms unless earlier terminated by the parties. Upon termination of the exclusive term, the agreement may continue for an indefinite period on a non-exclusive basis. The refined raw material is a semi-synthetic salt of an extract from plants grown and processed exclusively on carefully managed plantations in South America. We believe that the supply of pilocarpine hydrochloride is adequate for the foreseeable future. Salagen Tablets are currently manufactured for us by Patheon Inc. The initial term of the Patheon agreement was four years, with automatic renewal periods of three years. This agreement may be terminated by either party upon three years written notice. The current agreement's renewal expires November 19, 2005.

Hexalen Capsules

Pharmaceutical grade altretamine for the manufacture of Hexalen capsules is obtained from Heumann Pharma GmbH, a wholly owned subsidiary of Pfizer. Heumann Pharma supplies the bulk active drug substance pursuant to an agreement that we assumed. Hexalen capsules are currently manufactured pursuant to an agreement with aaiPharma Inc. that expires March 8, 2005 (three year initial term). Absent written notice of termination by either party at least 90 days in advance of a renewal date, the term of the agreement is automatically renewed for annual periods on January 1 of each year.

Didronel IV Infusion

Pharmaceutical grade etidronate disodium for the manufacture of Didronel IV infusion is obtained under a supply agreement with Procter & Gamble Pharmaceuticals, Inc. from OSG Norwich, Inc. We may extend these rights two years to December 31, 2006. Didronel IV infusion is currently manufactured at Akorn Inc. (formerly known as Taylor Pharmaceuticals, a unit of Akorn Inc.). Ben Venue Laboratories, Inc., a unit of Boehringer Ingelheim Pharmaceuticals, Inc., is an approved alternate contract manufacturer of Didronel IV infusion.

Development-Stage Pharmaceuticals

As a regular part of our business, we establish contract manufacturing arrangements for our development-stage pharmaceuticals. These arrangements include purchase orders, supply agreements and development-scale manufacturing contracts.

Irofulven

In April 2000, we entered into a development agreement with Abbott Laboratories, Inc. for scale-up of the current fermentation process used to produce raw material for the production of irofulven. The agreement also gives Abbott the opportunity to demonstrate its ability to produce the raw material on a commercial scale. Irofulven is synthesized at Regis Technologies, Inc. from the purified raw material produced by Abbott. Regis has successfully demonstrated synthesis of irofulven's active pharmaceutical ingredient at commercial scale. Regis has the capacity to produce irofulven to meet our long-term worldwide requirements. Irofulven injection, the sterile finished pharmaceutical dosage form, is manufactured by Cardinal Healthcare, Inc., or Cardinal. Cardinal is capable of producing the finished packaged drug product, a liquid formulation in a single-use vial, at commercial scale in the quantities consistent with our long term production requirements for worldwide distribution. Clinical test articles are currently stored, labeled and distributed by McKesson BioServices, Inc.

MG98

The manufacture of the MG98 oligonucleotide is performed under a contract between MethylGene Inc., and Boston Bioservices, Inc., a unit of Avecia. The sterile clinical test article is manufactured by Cardinal.

Patents and Proprietary Rights

We rely on patent rights, orphan drug designation, trade secrets, trademarks, and nondisclosure agreements to establish and protect our proprietary rights in our products in both the United States and selected foreign jurisdictions. Current patent and orphan drug status with respect to certain of our products is as follows:

Subject	Status	Issue Date	Country
Salagen Tablets for symptoms of Sjögren's syndrome	Orphan drug	February 11, 1998	United States
Palonosetron and process for preparation	Four U.S. patents issued; various patent applications pending	April 13, 1993; April 23, 1996; November 19, 1996; and October 22, 1996	United States and various other countries
Irofulven and use of irofulven, as cancer therapy agent	Three U.S. patents issued, various patent applications pending	August 8, 1995; June 4, 1996; and October 8, 1996	United States and various other countries
Synthetic methods for preparing acylfulvenes and compounds useful as intermediates for preparing acylfulvenes	Five U.S. patents issued; various patent applications pending	March 3, 1998; January 5, 1999; December 12, 2000; October 5, 2001; and, October 22, 2002	United States and various other countries
Substituted acylfulvene compounds and use as cancer therapy agents (not including irofulven)	Eight U.S. patents issued; various patent applications pending	August 8, 1995; August 3, 1999; February 15, 2000; May 30, 2000; November 27, 2001; April 30, 2002; April 15, 2003 and April 23, 2003	United States and various other countries

Subject	Status	Issue Date	Country
Irofulven for treatment of pancreatic cancer	Orphan drug	April 6, 1999	United States
Irofulven for treatment of ovarian cancer	Orphan drug	July 12, 1999	United States
Irofulven for treatment of renal cell carcinoma	Orphan drug	July 27, 1999	United States
MG98 antisense compound for treatment of cancer	Seven U.S. patents issued; various patent applications pending	November 26, 1996; July 29, 1997; July 6, 1999; February 1, 2000; April 25, 2000; May 23, 2000; and February 6, 2001	United States and various other countries
Small molecule inhibitors of DNA methyltransferase for treatment of cancer	Three patents issued	February 6, 2001; April 24, 2001; and July 31, 2001	United States and various other countries

The term of a U.S. patent issued from an application filed before June 8, 1995 is the longer of 17 years from its issue date or 20 years from its effective filing date. The term of a U.S. patent issuing from an application filed on or after June 8, 1995 is 20 years from its effective filing date. All of the U.S. patents covering irofulven or its use were issued from applications filed before June 8, 1995. The Drug Price and Competition and Patent Term Restoration Act of 1984, the Generic Animal Drug Act, and the Patent Term Restoration Act generally provide that a patent relating to, among other items, a human drug product, may be extended for a period of up to five years by the U.S. Commissioner of Patents and Trademarks if the patented item was subject to regulatory review by the FDA before the item was marketed. Under these acts, a product's regulatory review period (which consists generally of the period from the time when the exemption to permit clinical investigations becomes effective until the FDA grants marketing approval for the product) forms the basis for determining the length of the extension an applicant may receive. There can be no assurance that any issued patents will be extended in term.

We have licensed or obtained patent protection for palonosetron hydrochloride, irofulven and the other acylfulvene analogs. Patent positions of pharmaceutical companies are generally uncertain and involve complex legal and factual issues. Therefore, although we believe our patents are valid, we cannot predict with any precision the scope or enforceability of the claims. In addition, there can be no assurance that our patent applications will result in issued patents, that issued patents will provide an adequate measure of protection against competitive technology which could circumvent such patents, or that issued patents would withstand review and be held valid by a court of competent jurisdiction. Furthermore, there can be no assurance that infringement of any issued patents cannot be circumvented by others.

Orphan drugs are currently provided seven years of marketing exclusivity for an approved indication following approval to market by the FDA Orphan drug designation for our products does not, however, insulate us from other manufacturers attempting to develop an alternate drug for the designated indication, or the designated drug for another, separate indication.

We also rely on trade secrets and continuing innovation that we seek to protect with reasonable business procedures for maintaining trade secrets, including confidentiality agreements with our collaborators, employees and consultants. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach or that our trade secrets and proprietary know-how will not otherwise be known or be independently discovered by competitors.

In addition to the patents which form the basis of the pharmaceutical focus of this company, we also own four U.S. patents which claim maize plants that are resistant to certain herbicides and that also claim methods for producing such resistant plants. These patents were issued between 1988 and 1998. While these patents have been licensed to BASF (originally licensed to American Cyanamid), we may still incur expenses associated with any litigation, interference or other administrative proceedings related to these patents.

Trademarks

We have obtained registration of the Salagen trademark in the United States and certain foreign jurisdictions. In addition, we have been assigned the Hexalen trademark in the United States and certain foreign jurisdictions, we use the federally registered Didronel trademark under a license with Procter & Gamble and we use the Aloxi trademark under a license with Helsinn Healthcare SA.

Competition

The pharmaceutical industry is intensely competitive, based mostly on product performance and pricing. Many members of the industry have resources far greater than we do, providing them with potentially greater flexibility in developing and marketing their products. While we will seek to protect our products from direct competition through filing patents, seeking marketing exclusivity under the Orphan Drug Act, and maintaining technical information as trade secrets, there is no way to protect us from competition from products with different chemical composition or products made using different technology.

Cevimeline hydrochloride, owned by Snow Brand Pharmaceuticals, Inc. and marketed by Daiichi Pharmaceuticals in the United States, was approved in January 2000 by the FDA as a treatment for dry mouth symptoms associated with Sjögren's syndrome. We cannot estimate what ultimate effect this competing compound will have on the overall size of the Sjögren's syndrome market and future demand for Salagen Tablets, but modest growth in prescription of Salagen Tablets continued in 2003. A product marketed by MedImmune, Inc., amifostine, was approved in June 1999 by the FDA for reducing the incidence of radiation-induced dry mouth in post-operative head and neck cancer patients. Salagen Tablets are approved in part for the treatment of dry mouth symptoms resulting from radiation used to treat head and neck cancer patients. Due to the more restricted patient population for amifostine, as well as other factors such as price and invasive administration, we currently believe that amifostine will not have a significant impact on sales of Salagen Tablets. We are aware of other products currently under development that may compete with Salagen Tablets.

The exclusivity period afforded by orphan drug status for Salagen Tablets as a treatment for symptoms of radiation-induced xerostomia in head and neck cancer patients ended in March 2001. Competitors could develop and introduce generic drugs comparable to Salagen Tablets, or drugs or other therapies that address the underlying causes of the symptoms that Salagen Tablets treat. There can be no assurance that we will be successful in our plan to gain product specific protection for each of our pharmaceuticals or that developments by others will not render our products noncompetitive or obsolete.

Hexalen capsules are approved in the United States for the treatment of ovarian cancer in patients with persistent or recurrent disease following first-line therapy with certain other chemotherapies. Other chemotherapies are also used for second-line treatment of ovarian cancer and are marketed by pharmaceutical companies with greater resources than we have. Further, competitors could develop and introduce generic drugs that are comparable to Hexalen capsules.

Aloxi injection was the fourth 5-HT_3 antagonist approved for marketing in the United States. The companies that market the other 5-HT_3 antagonists have far greater resources than we have. Further, there is no certainty that the patent protection afforded palonosetron will be effective in keeping generic equivalents from entering the market.

Many companies of all sizes, including large pharmaceutical companies as well as specialized biotechnology companies, are developing cancer therapy drugs that will compete with irofulven, if it is approved for sale. There

are also a number of products already on the market that will compete directly with irofulven if it is approved. In addition, colleges, universities, governmental agencies and other public and private research institutions will continue to conduct research and may develop new cancer therapies which would render our cancer therapy drug candidates obsolete or non-competitive. Many of our competitors in the cancer therapy market also have substantially greater financial, research and development, human and other resources than we do.

Government Regulation

Our research and marketing activities are subject to significant regulation by numerous governmental authorities in the United States and other countries. Pharmaceutical products intended for therapeutic use in humans are governed by FDA regulations in the United States and by comparable regulations in foreign countries. The process of completing clinical testing and obtaining FDA approval for a new drug product requires a number of years and the expenditure of substantial resources without any assurance that approval for marketing will be granted.

The FDA has established mandatory procedures to regulate the manufacturing and testing process regarding the identity, strength, quality and purity of a product. Following initial formulation, the steps required before any new prescription pharmaceutical product may be marketed in the United States include (1) preclinical laboratory and animal tests; (2) submission to the FDA of an investigational new drug application, or IND; (3) adequate and well-controlled clinical trials to establish the safety and efficacy of the drug; (4) submission of a new drug application, or NDA and (5) FDA review and approval of the NDA prior to any commercial sale.

Preclinical studies are conducted in the laboratory and in animal model systems to gain information on the drug's efficacy, mode of action, and to identify any significant safety problems. The results of these studies are submitted to the FDA as part of the IND. Testing in humans may commence 30 days after the IND has been filed unless the FDA issues a clinical hold. Additional animal studies may be performed throughout the development process.

A three-phase clinical program is usually required for FDA approval of a pharmaceutical product, unless accelerated approval is granted. Phase 1 clinical trials are conducted to determine the safety profile, including the safe dosage range, metabolism and pharmacologic action of the product, and, if possible, to gain early evidence on efficacy. Although most phase 1 trials are conducted with healthy volunteers, phase 1 cancer trials are conducted with cancer patients. Following establishment of a safe dose from phase 1 studies, a phase 2 clinical program is conducted for dose-ranging and to assess the safety and efficacy of the product in patients with the disease being studied. Phase 3 confirmatory clinical trials are conducted on patients more representative of the intended patient population in terms of medical treatment, age groups, gender and ethnicity. Data from the larger phase 3 program is to provide adequate statistical evidence of safety and efficacy necessary to evaluate the overall benefit and risk relationship in the target patient population. Phase 2 and phase 3 trials are usually multi-center trials in order to achieve greater statistical validity and to have data from a broader patient population that is more representative of the intended patient group. Phase 4, or post-approval trials, may be required under accelerated approval or to provide additional data on safety or efficacy of the product.

Upon completion of clinical testing, and with data successfully demonstrating that the product is safe and effective for a specific indication, an NDA may be filed with the FDA. The NDA contains all the scientific evidence including product formulation, manufacturing, control information, preclinical and clinical data. FDA approval of the NDA is required before the applicant may market the new product.

Even after initial FDA approval has been obtained, further studies may be required to provide additional data on safety or efficacy for current indications, or to obtain approval for uses other than those for which the product was initially approved. Moreover, such approval may entail limitations on the indicated uses for which a drug may be marketed. Even if FDA approval is obtained, there can be no assurance of commercial success for any product. Post-marketing testing may be required, and surveillance programs such as reporting adverse events are

required. The FDA may require withdrawal of an approved product from the market if any significant safety issues arise while a product is being marketed. In addition, before, during and after the process of approval, our prescription drug products must all be manufactured in accordance with current good manufacturing practices as set forth by the FDA. Marketing of products is also regulated by the FDA.

The orphan drug provisions of the Federal Food, Drug, and Cosmetic Act provide incentives to drug and biologics manufacturers to develop and manufacture drugs for the treatment of rare diseases or conditions, currently defined as a disease or condition that affects fewer than 200,000 individuals in the U.S. or, for a disease or condition that affects more than 200,000 individuals in the U.S., where the sponsor does not realistically anticipate that revenue generated from sales of the product will exceed the cost of its development. Under these provisions, a manufacturer of a designated orphan product can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for that product for the orphan indication. While the marketing exclusivity of an orphan drug would deter other sponsors from obtaining approval of the same compound for the same indication, it would not prevent other types of drugs from being approved for the same indication.

The health care industry is changing rapidly as the public, government, medical professionals and the pharmaceutical industry examine ways to broaden medical coverage while controlling health care costs. Potential approaches that may affect us include managed care initiatives, pharmaceutical buying groups, formulary requirements, various proposals to offer an expanded. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 together with rulemaking by the Centers for Medicare and Medicaid Services (CMS) require a number of changes in Medicare practices, including reimbursement. The changes made to date, are not expected to have an adverse affect on our operations or sales, but we cannot predict the impact, if any of future reimbursement changes.

Federal, state and local environmental laws and regulations do not materially affect our operations and we believe that we are currently in material compliance with such applicable laws and regulations.

Employees

As of February 5, 2004, we had 225 employees. Of our employees, 142 are engaged in our marketing, selling and manufacturing effort, 55 are involved in pharmaceutical development, including regulatory affairs and product formulation, and 28 are in other management or administrative positions. None of our employees is represented by a labor union or is subject to a collective bargaining agreement. We believe that our relations with our employees are satisfactory.

Available Information

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through MGI's website (www.mgipharma.com) as soon as reasonably practicable after we electronically file the material with, or furnish it to, the Securities and Exchange Commission.

Item 2. Properties

We currently lease approximately 75,000 square feet of office space for our current headquarters in Bloomington, Minnesota for approximately $118,000 per month. The initial term of this lease expires in May 2008, with two options for renewal, each for an additional three-year period. We also lease approximately 27,000 square feet of office space (our former headquarters) in Bloomington, Minnesota, for $27,000 per month. The initial term of this lease expires in July 2005, with an option for renewal. We have subleased this former headquarter space and we do not expect to recognize future expense related to this lease.

Item 3. Legal Proceedings

None.

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

None.

PART II

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

Our common stock trades on the NASDAQ National Market under the symbol "MOGN." As of February 20, 2004, we had 719 shareholders of record and 35,040,426 shares of common stock outstanding. We have never paid cash dividends on our common stock and have no present intention of paying cash dividends on our common stock.

The following table lists the high and low trading prices for our common stock as reported by the NASDAQ National Market during the quarters listed. Prices represent transactions between dealers and do not reflect retail markups, markdowns, or commissions, and may not necessarily represent actual transactions.

	High	Low
2002		
First Quarter	$17.05	$12.88
Second Quarter	14.75	6.01
Third Quarter	8.74	4.68
Fourth Quarter	9.40	5.84
2003		
First Quarter	$12.99	$ 6.85
Second Quarter	29.50	11.50
Third Quarter	43.12	24.95
Fourth Quarter	42.50	33.09

In August 2003, we completed a sale of 5,060,000 newly issued shares of common stock in a follow-on public offering at $35.50 per share. Our net proceeds, after fees and expenses, were $168,581,477.

On January 5, and February 6, 2004, an aggregate of 2,571,428 shares of our common stock were issued to Deerfield International Limited and Deerfield Partners, L.P. pursuant to their election to, first partially and then fully, convert our 3% convertible subordinated notes issued in December 2002 for gross proceeds of $21 million. Also on February 6, 2004, the common stock purchase warrants that were issued in connection with that December 2002 financing were exercised. We received $3,850,000 upon the exercise of the warrants and issued 400,000 common shares.

Item 6. Selected Financial Data

	Year Ended December 31,				
	1999	2000	2001	2002	2003
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Sales	$18,643	$ 21,333	$ 30,022	$ 25,402	$ 39,858
Licensing	4,955	3,109	2,932	2,801	9,527
Promotion (a)	1,088	770	—	—	—
	24,686	25,212	32,954	28,203	49,385
Costs and expenses:					
Cost of sales	1,209	1,627	3,633	3,240	6,959
Selling, general and administrative	12,713	18,295	28,463	28,827	50,410
Research and development	6,677	17,241	36,101	32,214	50,121
Amortization	—	98	1,182	1,182	1,205
	20,599	37,261	69,379	65,463	108,695
Income (loss) from operations	4,087	(12,049)	(36,425)	(37,260)	(59,310)
Interest income	966	2,146	1,600	1,279	1,553
Interest expense	—	—	—	(83)	(997)
Impairment of investment	—	—	—	—	(3,154)
Income (loss) before taxes and cumulative effect of change in accounting principle	5,053	(9,903)	(34,825)	(36,064)	(61,908)
Provision for income taxes	321	148	—	—	—
Net income (loss) before cumulative effect of change in accounting principle	4,732	(10,051)	(34,825)	(36,064)	(61,908)
Cumulative effect of change in accounting principle	—	(9,403)	—	—	—
Net income (loss)	$ 4,732	$(19,454)	$(34,825)	$(36,064)	$ (61,908)
Net income (loss) per common share:					
Basic:					
Income (loss) before effect of accounting change	$ 0.32	$ (0.63)	$ (1.74)	$ (1.44)	$ (2.23)
Cumulative effect of accounting change	—	(0.59)	—	—	—
Net income (loss)	$ 0.32	$ (1.22)	$ (1.74)	$ (1.44)	$ (2.23)
Diluted:					
Income (loss) before effect of accounting change	$ 0.30	$ (0.63)	$ (1.74)	$ (1.44)	$ (2.23)
Cumulative effect of accounting change	—	(0.59)	—	—	—
Net income (loss)	$ 0.30	$ (1.22)	$ (1.74)	$ (1.44)	$ (2.23)
Weighted average number of common shares outstanding:					
Basic	14,742	15,990	19,985	25,110	27,778
Diluted	15,633	15,990	19,985	25,110	27,778

(a) The company concluded its last promotion agreement in 2000.

	December 31,				
	1999	2000	2001	2002	2003
Balance Sheet Data:					
Cash, cash equivalents and marketable investments	$ 24,151	$ 29,899	$ 77,712	$ 60,473	$ 177,753
Working capital	23,240	26,042	63,182	49,999	128,572
Total assets	28,974	52,744	97,668	80,480	204,519
Long-term obligations	0	12,732	13,633	28,427	21,964
Total liabilities	4,329	26,698	28,733	43,877	47,909
Accumulated deficit	(69,097)	(88,551)	(123,376)	(159,440)	(221,347)
Total stockholders' equity	24,644	26,046	68,935	36,604	156,610

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

Overview

MGI PHARMA is an oncology-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that meet cancer patient needs. We focus our direct sales efforts solely within the United States and create alliances with other pharmaceutical or biotechnology companies for the commercialization of our products in other countries.

We promote products directly to physician specialists in the United States using our own sales force. Our marketed products include Aloxi™ (palonosetron hydrochloride) injection, Salagen® Tablets (pilocarpine hydrochloride), and Hexalen® (altretamine) capsules. Given the large market in which Aloxi injection competes and its favorable clinical profile, sales of Aloxi injection are expected to substantially exceed 2004 sales of our other current products. In the third quarter of 2003, Aloxi injection was approved by the U.S. Food and Drug Administration ("FDA") for the prevention of acute and delayed chemotherapy-induced nausea and vomiting ("CINV") and we began promoting Aloxi injection in September 2003. We obtained exclusive U.S. and Canadian license and distribution rights to Aloxi injection from Helsinn Healthcare SA ("Helsinn") in May 2001. In November 2003, we and Helsinn expanded the agreement to include rights for the prevention of postoperative nausea and vomiting ("PONV") application of Aloxi injection and an oral Aloxi formulation.

Salagen Tablets are approved in the United States for two indications: the symptoms of dry mouth associated with radiation treatment in head and neck cancer patients and the symptoms of dry mouth associated with Sjögren's syndrome, an autoimmune disease that damages the salivary glands. Sales of Salagen Tablets in the United States accounted for 67 percent of our product sales during 2003. Hexalen capsules is an orally administered chemotherapeutic agent approved in the United States for treatment of refractory ovarian cancer patients.

Our current product development efforts include preclinical and clinical programs for the acylfulvenes, including irofulven, our novel anti-cancer agent with demonstrated activity in a variety of cancers and a unique mechanism of action. We have also funded development of MG98 and inhibitors of DNA methyltransferase for North American markets. DNA methyltransferase is an enzyme that has been associated with uncontrolled tumor growth. We provide ongoing clinical support of Aloxi injection and Salagen Tablets. Our research and development expense also includes license fees related to Helsinn's now concluded development of Aloxi injection for CINV and its ongoing development of Aloxi injection for PONV and for an oral Aloxi formulation.

In August 2003, we completed a sale of 5,060,000 newly issued shares of common stock in a follow-on public offering at $35.50 per share. Our net proceeds, after fees and expenses, were $168,581,477. Since our current operations are expected to begin producing positive cash flow near the end of 2004, these proceeds are primarily intended to fund expansion of our product portfolio.

2003 revenues were $49 million and we anticipate 2004 revenues will range between $109 million to $119 million. The anticipated increase would result from increasing Aloxi injection product sales. Net loss for 2003 was $62 million and we expect a net loss in 2004 of approximately $4 million, given our current product portfolio. This expectation is exclusive of any increase in net loss that would result from expanding our product portfolio.

Results of Operations

Critical Accounting Policies

In preparing our financial statements in conformity with accounting principles generally accepted in the United States of America, our management must make decisions which impact reported amounts and related disclosures. Such decisions include the selection of the appropriate accounting principles to be applied and the assumptions on which to base accounting estimates. In reaching such decisions, our management applies judgment based on our understanding and analysis of relevant circumstances. Note 1 to the financial statements provides a summary of the significant accounting policies followed in the preparation of the financial statements. Our critical accounting policies include the following:

Our accounting policy on revenue recognition is fully described in Notes 1 and 6 to the financial statements. The majority of our revenue relates to product sales. We recognize product sales revenue upon shipment to wholesalers, upon fulfillment of acceptance terms, if any, and when no significant contractual obligations remain. As is common in the pharmaceutical industry, our domestic sales are made to pharmaceutical wholesalers for further distribution through pharmacies to the ultimate consumers of our products. As such, our product sales revenue may be less than or greater than the underlying demand for our products. We report sales revenue net of wholesaler chargebacks, allowances for product returns, cash discounts, and other rebates. To determine our estimates for wholesaler chargebacks, product returns and other allowances, we use a combination of historical data and an estimate of future activity. Our estimates are reviewed periodically and are subject to change.

We also recognize revenue related to licensing agreements. Licensing revenue recognition requires management to estimate effective terms of agreements and identify points at which performance is met under the contracts such that the revenue earnings process is complete. Under this policy for out-licensing arrangements, revenue related to up-front, time-based and performance-based licensing payments is recognized over the entire contract performance period. For our major licensing contracts, this results in the deferral of revenue amounts (approximately $2.4 million at December 31, 2003) where non-refundable cash payments have been received, but the revenue is not immediately recognized due to the long-term nature of the respective agreements. Following our initial estimate of the effective terms of these arrangements, subsequent developments such as contract modifications or terminations could increase or decrease the period over which the deferred revenue is recognized.

Research and development expense includes work performed for us by outside vendors and research organizations. At each reporting period, we estimate expenses incurred but not reported or billed to us by these outside vendors. These expense estimates typically cover a period of 1 to 4 weeks of expense. Actual results are recorded on a timely basis and, historically, have not been materially different from our estimates. In addition, costs related to in-licensing arrangements for product candidates are expensed as research and development until their first commercial sale.

Revenues

Sales: Sales revenue decreased 15 percent from $30,021,813 in 2001 to $25,402,300 in 2002, but increased 57 percent to $39,857,620 in 2003. As is common in the pharmaceutical industry, our domestic sales are made to pharmaceutical wholesalers for further distribution through pharmacies to the ultimate consumers of our products. The decrease in sales revenue from 2001 to 2002 reflects decreased revenue from Salagen Tablets, resulting from a drawdown of wholesaler inventory amounts, partially offset by an increase in selling price and a continued increase in patient demand. Beginning in the second quarter of 2001, and continuing throughout the rest of 2001, a substantial increase in wholesaler inventory amounts occurred. A reduction of wholesaler inventories occurred throughout the first half of 2002. In the second half of 2002, sales realigned with underlying demand, which grew approximately 5 percent from 2001 to 2002, as measured by prescription growth.

The increase in sales revenue from 2002 to 2003 reflects increased revenue from Aloxi injection, Salagen Tablets and Hexalen capsules. We began the promotion of Aloxi injection in September 2003, following its approval by the U.S. Food and Drug Administration. We recognized $9.7 million in Aloxi injection net sales in 2003, which provided 24 percent of our sales revenue in 2003. Sales of Salagen Tablets in the United States provided 87 percent of our sales revenue in 2001, 88 percent in 2002 and 67 percent in 2003. Underlying demand for Salagen Tablets in the United States, as measured by prescription growth, grew at an annual rate of approximately one percent from 2002 to 2003. Sales of Aloxi injection for the first quarter of 2004 are expected to be $12 million. Annual 2004 sales for Aloxi injection are expected to range from $80 million to $90 million and for all other product sales are expected to be approximately $27 million.

Licensing: Licensing revenue decreased four percent from $2,932,007 in 2001 to $2,801,189 in 2002, and increased 240 percent to $9,527,433 in 2003. We and Dainippon Pharmaceutical Co. Ltd. terminated our collaborative acylfulvene license agreement in August 2003. Since we had no future obligations to Dainippon after termination, all remaining unamortized licensing revenue related to this relationship was amortized into

license revenue in 2003. For 2003, we amortized $7,141,972 of deferred revenue into licensing revenue related to previously received non-refundable license fees from Dainippon, which included $6,867,280 being amortized in the third quarter of 2003.

Licensing revenue is a combination of deferred revenue amortization from licensing arrangements and from royalties that are recognized when the related sales occur. In 2001, we received a milestone payment of $750,000 from Novartis Ophthalmics AG related to the licensing of Salagen Tablets in Europe. We recognized $841,258, $794,384 and $7,386,972 of amortized deferred revenue in 2001, 2002 and 2003, respectively, related to all payments received under these license agreements. We will recognize the December 31, 2003 unamortized balance of $2,441,250 from our license agreements into licensing revenue over the expected periods of benefit for the related collaborative arrangements, which is expected to continue into 2015. Future licensing revenue will fluctuate from quarter to quarter depending on the level of recurring royalty generating activities, and changes in amortization of deferred revenue, including the initiation or termination of licensing arrangements. We expect licensing revenue for 2004 to be approximately $2 million.

Costs and Expenses

Cost of sales: Cost of sales as a percent of sales was 12 percent for 2001, 13 percent for 2002 and 17 percent for 2003. The increase from 2002 to 2003 in cost of sales as a percentage of sales is a result of sales of Aloxi injection, which launched in September 2003. Cost of sales may vary from quarter to quarter, depending on the product mix and production costs. We believe that cost of sales as a percent of product sales for our currently marketed products for 2004 will be approximately 30 percent.

Selling, general and administrative: Selling, general and administrative expenses increased 1 percent from $28,463,387 in 2001 to $28,827,337 in 2002, and increased 75 percent to $50,409,508 in 2003. Although total costs remained essentially unchanged from 2001 to 2002, our costs increased for field selling expense and decreased for direct product promotion and facility expenses. Promotion costs decreased from 2001 to 2002 due to our initiating promotion of Hexalen capsules and Mylocel tablets in 2001. Facility costs decreased from 2001 to 2002 due to an accrual in 2001 for lease obligations for the former office space in excess of estimated sublease income, and physical move costs related to our move to a new office location in the second quarter of 2001. Costs in 2002 also include $515,766 in expense related to a reduction in our workforce in the second quarter of 2002.

The increase from 2002 to 2003 is primarily a result of increased expenditures for the commercial launch of Aloxi injection in September 2003 and its continued commercialization. We expect selling, general and administrative expenses for 2004 to be approximately $59 million.

Research and development: Research and development expense decreased 11 percent from $36,101,373 in 2001 to $32,213,635 in 2002, and increased 56 percent to $50,120,596 in 2003. All three periods include expense related to milestone payments under our license agreement for Aloxi injection: $13.0 million in 2001, $14.0 million in 2002 and $31.3 million in 2003. Exclusive of these license payments, research and development expense decreased 21 percent from $23,035,123 in 2001 to $18,163,635 in 2002, and increased 4 percent to $18,799,596 in 2003.

Excluding the license payments for the milestones, the decrease from 2001 to 2002 represents decreased spending for irofulven. In April 2002, we stopped our phase 3 trial of irofulven in advanced-stage, gemcitabine-refractory pancreatic cancer patients. We are currently conducting a series of clinical trials designed to evaluate the efficacy and safety of irofulven administered as a single chemotherapy agent or in combination with marketed chemotherapy agents for the treatment of patients with solid tumor cancers who are generally refractory to current therapies. The decrease in irofulven spending was partially offset by $775,278 in expense related to a reduction in our workforce in the second quarter of 2002. The increase from 2002 to 2003 primarily represents clinical trial expenditures for Aloxi injection as we assumed responsibility from Helsinn for further development of Aloxi injection for prevention of CINV following its approval by the FDA. We expect research

and development expense for 2004 to be approximately $24 million, including expected license fees that will become due upon Helsinn's achievement of milestones in the Aloxi development programs.

Interest Income

Interest income decreased 20 percent from $1,600,363 in 2001 to $1,278,645 in 2002, and increased 21 percent to $1,553,483 in 2003. The decrease from 2001 to 2002 is a result of decreases in the investment yields, partially reduced by increases in the average amount of funds available for investment. The increase from 2002 to 2003 is a result of increases in the average amount of funds available for investment partially reduced by declining yields. Funds available in 2001 increased as a result of the sales of stock in the second and fourth quarters of 2001. Funds available in 2002 additionally increased as a result of the issuance of convertible notes and warrants in the fourth quarter of 2002. Funds available in 2003 increased as a result of the sale of stock in the third quarter. Interest income for 2004 will fluctuate depending on the timing of cash flows and changes in interest rates for marketable securities.

Interest Expense

We had no debt in 2001. Interest expense increased from $83,130 in 2002 to $997,563 in 2003. The increase resulted from a full year of interest expense in 2003 related to our issuance of convertible debt in the fourth quarter of 2002. Given the full conversion of the debt on the first quarter of 2004, we expect interest expense related to this convertible debt for 2004 to be approximately $141,000, of which $81,000 will be paid using cash. The non-cash portion of interest expense primarily related to the issuance of warrants in conjunction with the issuance of our convertible debt. (See Note 7 to the financial statements) Our interest expense would increase if we issue new debt securities.

Impairment of Investment

In 2003 we recorded a $3,153,948 impairment to our investment in MethylGene Inc. We own an approximate 13 percent, minority interest in MethylGene Inc., a privately owned Canadian biopharmaceutical company. This minority interest is reported in the financial statements as "Long term equity investment" at the lower of cost or if its value is other than temporarily impaired, then at estimated fair value. Because MethylGene is a privately held company the value in this investment is inherently more difficult to estimate than an investment in a public company. We estimated that the value of the investment declined to $3,646,052 in the year ended December 31, 2003 and an impairment of this asset had occurred that was other than temporary.

Tax Expense

There is no provision for tax expense in 2001, 2002 or 2003, due to net losses of $35 million, $36 million, and $62 million, respectively. Our ability to achieve profitable operations is dependent upon our successful commercialization of Aloxi injection, among other things, and therefore, we continue to maintain a valuation allowance against our deferred tax assets. If and when it is judged to be more-likely-than-not that we will be able to utilize some or all of our deferred tax assets, the related valuation allowance will be reduced and a tax benefit will be recorded, and the portion of the allowance pertaining to the exercise of stock options will increase additional paid-in capital. For subsequent tax periods, our tax provision would likely reflect normal statutory tax rates and utilization of our deferred tax attributes would reduce our deferred tax asset balance. The timing of when this valuation allowance adjustment would occur is primarily dependent upon significant growth in sales of Aloxi injection. It is unlikely that an adjustment to reduce the valuation allowance would occur in 2004, given current operating expectations.

Net Loss

We had net losses of $34,825,322, $36,063,792 and $61,907,504 in 2001, 2002 and 2003, respectively. The increased net loss from 2001 to 2002 reflects a 14 percent decrease in revenues from 2001 to 2002, and a six percent decrease in costs and expenses. The increased net loss from 2002 to 2003 reflects a 75 percent increase in revenues from 2002 to 2003, and a 66 percent increase in costs and expenses. During the next several years, we

expect to direct our efforts towards activities intended to grow long-term revenues, including the continued development and commercialization of Aloxi products and continued development of irofulven and other product candidates. We expect our net loss for 2004 to be approximately $4 million exclusive of increases in net loss that would result from expanding our product portfolio.

Liquidity and Capital Resources

At December 31, 2003, we had cash and marketable investments of $177,753,253 and working capital of $128,571,606, compared with $60,472,901 and $49,999,430, respectively, at December 31, 2002. For the year ended December 31, 2003, we received $168,581,477 in cash from the issuance of 5,060,000 shares of common stock in a follow-on public offering, and $12,255,220 in cash from issuance of shares under stock award plans. We used $56,718,784 of cash to fund our operating activities, repaid a $4,300,000 deposit to Dainippon as a result of the termination of our license agreement, and purchased $744,684 in equipment and furniture. Our investment in inventories increased in 2003 by $5,658,137 due to the launch of Aloxi. Increased sales of Aloxi had accounts receivables increasing by $3,475,143. This was offset by an increase in accounts payable and accrued expenses of $14,977,016 that includes the $10,000,000 Helsinn payment due in the first quarter of 2004.

Our cash use in 2004 will be very dependent upon the pattern of Aloxi injection sales. We expect the rate of Aloxi injection sales to increase during 2004, which will result in increased working capital deployed for Aloxi injection finished product inventory and receivables. However, as sales increase we expect our operations to generate positive cash flow and by the quarter ending December 31, 2004, cash flow from operations could be positive. We expect annual cash use in 2004 to be approximately $15 million, which includes cash needed for operations and is reduced by the receipt in the first quarter of 2004 of $3,850,000 upon the exercise of our outstanding stock purchase warrants. We have sufficient liquidity in our cash and marketable investments to fund these operations.

Substantial amounts of capital will be needed to continue executing on our goal of growing our pharmaceutical business. These capital needs will include funding of continued development and commercialization of our product candidates and marketed products. We intend to expand our product portfolio through various means such as additional product acquisitions or business combinations. These transactions will require the use of capital and their timing is difficult to predict. Our capital needs may exceed the capital available from our future operations, collaborative arrangements and existing liquid assets. For these needs or in anticipation of these needs, we may seek capital from additional equity or debt issuances.

As identified in our risk factors, adverse changes that affect our future demand for our marketed products, continued access to the capital markets, and continued development and expansion of our product candidates would affect our longer-term liquidity.

On January 5, and February 6, 2004, an aggregate of 2,571,428 shares of our common stock were issued to Deerfield International Limited and Deerfield Partners, L.P. pursuant to their election to, first partially and then fully, convert our 3% convertible subordinated notes issued in December 2002 for gross proceeds of $21 million. Also on February 6, 2004, the common stock purchase warrants that were issued in connection with that December 2002 financing were exercised. We received $3,850,000 upon the exercise of the warrants and issued 400,000 common shares.

Payment Obligations

Our future, noncancellable, contractual commitments, are summarized in the following table:

	2004	2005	2006	2007	2008	Thereafter
Lease Payments	$ 1,859,000	$1,733,000	$1,461,000	$1,483,000	$622,000	$ —
Aloxi™ License	10,000,000	—	—	—	—	—
Total	$11,859,000	$1,733,000	$1,461,000	$1,483,000	$622,000	$ —

We expect to make additional payments to Helsinn related to Aloxi product candidates totaling $25 million over the course of the next several years upon achievement of certain development milestones.

Off Balance Sheet Arrangements

We do not have any "off-balance sheet arrangements" (as such term is defined in Item 303 of Regulation S-K) that are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Item 6. Selected Quarterly Operating Results

The following table shows our unaudited financial information for each of the quarters in the two year period ended December 31, 2003. In our opinion, this unaudited quarterly information has been prepared on the same basis as the audited financial statements and includes all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information for the quarters presented, when read in conjunction with the financial statements and notes included elsewhere in this annual report. We believe that quarter-to-quarter comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of future performance.

	Three Months Ended							
	March 31, 2002	June 30, 2002	Sept. 30, 2002	Dec. 31, 2002	March 31, 2003	June 30, 2003	Sept. 30, 2003	Dec. 31, 2003
	(in thousands except per share data)							
Revenues:								
Sales	$ 5,303	$ 4,649	$ 8,223	$ 7,227	$ 6,143	$ 8,529	$ 14,092	$ 11,094
Licensing	499	1,038	824	440	616	1,341	7,109	461
	5,802	5,687	9,047	7,667	6,759	9,870	21,201	11,555
Cost and expenses:								
Cost of sales	686	757	950	847	771	953	2,737	2,499
Selling, general & administrative	7,170	7,340	6,640	7,677	8,819	11,384	14,545	15,662
Research and development (a)	4,263	9,792	4,508	13,651	3,460	4,172	15,224	27,265
Amortization	296	295	295	296	295	295	296	318
	12,415	18,184	12,393	22,471	13,345	16,804	32,802	45,744
Loss from operations	(6,613)	(12,497)	(3,346)	(14,804)	(6,586)	(6,934)	(11,601)	(34,189)
Interest income	320	243	401	315	207	212	429	705
Interest expense	—	—	—	(83)	(249)	(250)	(249)	(249)
Impairment of investment	—	—	—	—	—	—	—	(3,154)
Net loss	$ (6,293)	$(12,254)	$ (2,945)	$(14,572)	$ (6,628)	$ (6,972)	$(11,421)	$(36,887)
Net loss per common share:								
Basic and diluted:								
Basic	$ (0.25)	$ (0.49)	$ (0.12)	$ (0.58)	$ (0.26)	$ (0.27)	$ (0.40)	$ (1.17)
Diluted	$ (0.25)	$ (0.49)	$ (0.12)	$ (0.58)	$ (0.26)	$ (0.27)	$ (0.40)	$ (1.17)
Weighted average number of common shares:								
Basic	25,034	25,063	25,164	25,177	25,320	25,420	28,687	31,605
Diluted (b)	25,034	25,063	25,164	25,177	25,320	25,420	28,687	31,605

(a) Includes $4 million, $10 million, $11 million, $20.3 million in license expense for Aloxi injection products in the three months ended June 30, 2002, December 31, 2002, September 30, 2003 and December 31, 2003, respectively.

(b) During net loss periods, potentially dilutive securities are not included in the calculation of net loss per share since their inclusion would be anti-dilutive.

Cautionary Statement

This document contains forward-looking statements within the meaning of federal securities laws that may include statements regarding intent, belief or current expectations of our Company and our management. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information without fear of litigation so long as those statements are identified as forward-looking and are accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those projected in the statement. We desire to take advantage of these "safe harbor" provisions. Accordingly, we hereby identify the following important factors which could cause our actual results to differ materially from any such results which may be projected, forecast, estimated or budgeted by us in forward-looking statements made by us from time to time in reports, proxy statements, registration statements and other written communications, or in oral forward-looking statements made from time to time by the company's officers and agents. We do not intend to update any of these forward-looking statements after the date of this Form 10-K to conform them to actual results.

RISKS RELATED TO OUR BUSINESS

Our business is dependent on the commercial success of Aloxi injection. If we are unable to successfully commercialize Aloxi injection we may be unable to continue our operations as planned.

The success of our business is dependent on the successful commercialization of Aloxi injection. Aloxi injection is new to the market and may be unfamiliar to members of the medical community. Market acceptance will depend largely on our ability to demonstrate, to the oncology community in particular, the efficacy and safety of Aloxi injection as an alternative to currently marketed therapies. We cannot be certain that Aloxi injection will provide benefits considered adequate by providers of oncology services or that enough providers will use the product to ensure its commercial success.

The FDA subjects an approved product and its manufacturer to continual regulatory review. After approval and use in an increasing number of patients, the discovery of previously unknown problems, such as unacceptable toxicities or side effects, with a product may result in restrictions or sanctions on the product or manufacturer that could affect the commercial viability of the product or could require withdrawal of the product from the market.

We must continually submit any labeling, advertising and promotional material to the FDA for review. There is risk that the FDA will prohibit use of the marketing material in the form we desire. Unfavorable outcomes resulting from factors such as those identified above could limit sales of Aloxi injection or cause sales of Aloxi injection to decline. In those circumstances, our stock price would decline and we may have to find additional sources of funding or scale back or cease operations.

We have a history of net losses. If we do not have net income in the future, we may be unable to continue our operations.

We are not currently profitable and have a very limited history of profitability. We expect to incur significant expenses over the next several years as we devote substantial resources to 1) support of the development efforts of Aloxi products through milestone payments to Helsinn, 2) the continued development of product candidates, including irofulven, and other product candidates and 3) continued commercialization of Aloxi injection and our other marketed products. Therefore, we will not generate net income unless we are able to significantly increase revenues from sales of Aloxi injection or other products. Furthermore, if we continue to sustain losses, we may be unable to fund development of our product candidates or to continue our business operations as planned.

If we fail to obtain additional capital to grow our business, we will be unable to complete our product portfolio development and expansion plans.

We may need to raise additional funds for various reasons including the following:

- to expand our portfolio of marketed products and product candidates;
- to develop products we have acquired or may license;
- to develop irofulven and other acylfulvene analogs;
- to obtain necessary working capital; and
- to fund operating losses.

Adequate funds for these purposes may not be available when needed or on terms acceptable to us. Insufficient funds may cause us to delay, scale back, or abandon some or all of our product acquisition and licensing programs and product development programs. We may seek additional funding through public and private financing, including equity and debt financing or enter into collaborative arrangements. Any sale of additional convertible debt securities or equity securities may result in additional dilution to our shareholders and any debt financing may require us to pledge our assets and enter into restrictive covenants. Entry into collaborative arrangements may require us to give up rights to some of our products or to some potential markets or to enter into licensing arrangements on unfavorable terms.

Clinical trials are complex and unpredictable and may be difficult to complete or produce unexpected results that could delay or prevent our ability to commercialize our product candidates.

Before obtaining regulatory approvals for the commercial sale of any product under development, including irofulven, we, or Helsinn Healthcare SA in the case of the Aloxi products, must demonstrate through preclinical studies and clinical trials that the product is safe and effective for use in each target indication. We depend on collaboration from Helsinn Healthcare SA, medical institutions and laboratories to conduct our clinical and preclinical testing in compliance with good clinical and laboratory practices as required by the FDA. We, or Helsinn Healthcare SA, may depend on contract research organizations to manage a substantial portion of the medical institutions utilized to conduct clinical testing. The results from preclinical animal studies and human clinical trials may not be predictive of the results that will be obtained in large-scale testing. Some of the results reported from phase 2 clinical trials are interim results and may not be predictive of future results, including final results from such phase 2 trials, because, among other factors, patient enrollment and the time period for evaluating patient results are not complete. If we, or Helsinn Healthcare SA, fail to adequately demonstrate the safety and efficacy of a product candidate, the FDA would not provide regulatory approval of the product. The appearance of unacceptable toxicities or side effects during clinical trials could interrupt, limit, delay or abort the development of a product. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in previous animal and human studies.

The time required to complete clinical trials is dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including:

- the size of the patient population;
- the nature of clinical protocol requirements;
- the diversion of patients to other trials or marketed therapies;
- our ability to recruit and manage clinical centers and associated trials;
- the proximity of patients to clinical sites; and
- the patient criteria for the study.

Other factors, such as lack of efficacy and unacceptable toxicities, may result in increased costs and delays or termination of clinical trials prior to completion. In addition, delays in manufacturing of product for our clinical trials could impact our ability to complete our clinical trials as planned. Any failure to meet expectations related to our product candidates could adversely affect our stock price.

Since our product candidates such as irofulven may have many potential applications and we have limited resources, our focus on a particular area may result in our failure to capitalize on more profitable areas and may not result in viable products.

We have limited financial and product development resources. This requires us to focus on product candidates in specific areas and forego opportunities with regard to other product candidates or applications. For example, our most significant product candidate, irofulven, is in clinical and preclinical trials for a number of applications. We expect that a substantial portion of our product development efforts over the next several years may be devoted to the further development of irofulven, including its application to the treatment of cancers or sub-populations of certain types of cancers with limited therapeutic options such as refractory cancers, for which we believe irofulven could most quickly be developed and approved for marketing. We are also investigating the efficacy of irofulven in combination with other cancer therapies. While some of these studies have indicated some effectiveness in relation to the target medical conditions, additional clinical trials must be conducted before product registration may be requested.

If we fail to identify, develop and successfully commercialize applications for irofulven, we may not achieve expectations of our future performance and our stock price may decline. For example, in April 2002 we stopped

enrollment in our phase 3 trial of irofulven in advanced-stage, gemcitabine-refractory pancreatic cancer patients and our stock price declined significantly. In addition, we may focus our development of irofulven on a particular application that may result in our failure to capitalize on another application or another product candidate. Our decisions impacting resource allocation may not lead to the development of viable commercial products and may divert resources away from more profitable market opportunities.

Our operating results may fluctuate significantly, which may adversely affect our stock price.

If our operating results do not meet the expectations of investors or securities analysts, our stock price may decline. Our operating results may fluctuate significantly from period to period due to a variety of factors including:

- the acceptance of, and demand for, Aloxi injection;
- changing demand for our current products, particularly Salagen;
- third parties introducing competing products;
- the pace and breadth of our development programs;
- expenditures we incur to acquire, license, develop or promote additional products;
- availability of product supply from third-party manufacturers;
- changes in sales and marketing expenditures; and
- the timing of licensing and royalty revenues.

For the year ended December 31, 2003, we had a net loss of $61.9 million, compared to a net loss of $36.1 million for the year ended December 31, 2002. The continuing pattern of losses is primarily a result of spending for research and development and spending for launch activities for Aloxi injection exceeding product revenue available from our currently marketed products.

Variations in the timing of our future revenue and expense could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earnings shortfalls or losses.

Sales of Salagen Tablets have accounted for the majority of our product revenues. If any factor adversely impacts sales of Salagen Tablets, our product revenues will decrease.

Historically we derived the majority of our product revenues from the sale of Salagen Tablets. U.S. sales of Salagen Tablets represented 67 percent of our total product sales and 54 percent of our total revenue for the year ended December 31, 2003. Any factor adversely affecting sales of Salagen Tablets could cause our product revenues to decrease and our stock price to decline significantly. In March 2001, our orphan drug status for Salagen Tablets as a treatment for the symptoms of radiation-induced xerostomia, or severe dry mouth, in head and neck cancer patients expired. Our orphan status for Salagen as a treatment of symptoms associated with Sjögren's syndrome expires in April 2005. Because Salagen Tablets does not have patent protection, competing generic products may enter these markets. In addition, we are aware of two currently marketed products that compete in the same or similar markets as Salagen Tablets. If sales of Salagen Tablets decline as a result of this competition, or for any other reason, our product revenues will decrease and our stock price could decline.

We depend on a single supplier to provide us with the finished drug product for Aloxi injection and a single supplier to provide us with the active ingredient for the production of Salagen Tablets. If either supplier terminates its relationship with us, or is unable to fill our demand for the ingredients or products, we may be unable to sell those products.

We rely on Helsinn Birex Pharmaceuticals Ltd. as our sole and exclusive supplier of the Aloxi injection finished drug product. In addition, we rely on the Fine Chemicals Division of Merck KgaA as our sole and exclusive

supplier of oral-grade pilocarpine hydrochloride, the active ingredient in Salagen Tablets. The refined raw material for Salagen Tablets is a semi-synthetic salt of an extract from plants grown and processed exclusively on plantations in South America. To our knowledge, there is currently no other producer of oral-grade pilocarpine hydrochloride that is capable of meeting our commercial needs. If our relationship with Helsinn Birex Pharmaceuticals Ltd. or Merck KgaA terminates, or Helsinn Birex Pharmaceuticals Ltd. or Merck KgaA is unable to meet our needs for any reason, we will need to find an alternative source of the active ingredients and products supplied by those companies. If we are unable to identify an alternative source, we may be unable to continue offering Aloxi injection or producing Salagen Tablets for commercial sale. Even if we were able to procure adequate supplies of Aloxi injection finished drug product or pilocarpine hydrochloride from an alternative source, any disruption in supply could have a material adverse effect on our ability to meet customer demand for Aloxi injection or Salagen Tablets for commercial sale, which could cause our product revenues to decrease and our stock price to decline.

If our third-party manufacturer of Aloxi injection or Salagen Tablets or any of our other products ceases operations or fails to comply with applicable manufacturing regulations, we may not be able to meet customer demand in a timely manner, if at all.

We do not have manufacturing facilities and we rely on Helsinn Birex Pharmaceuticals Ltd. for the production of Aloxi injection, Patheon Inc. for the production of Salagen Tablets, and other third-party manufacturers for our other products. We intend to continue to rely on others to manufacture any future products, including any products that we may acquire or license, and we have no plans to establish manufacturing facilities. Our dependence on third parties for the manufacture of our products may adversely affect our ability to develop and deliver such products.

The manufacture of our products is, and will be, subject to current "good manufacturing practices" regulations prescribed by the FDA or other standards prescribed by the appropriate regulatory agency in the country of use. There is a risk that our manufacturers, including the current manufacturers of Aloxi injection and Salagen Tablets, will not comply with all applicable regulatory standards, and may not be able to manufacture Aloxi injection, Salagen Tablets, or any other product for commercial sale. If this occurs, we might not be able to identify another third-party manufacturer on terms acceptable to us, or any other terms.

Material changes to an approved product, such as manufacturing changes or additional labeling claims, require further FDA review and approval. Even after approval is obtained, the FDA may withdraw approval if previously unknown problems are discovered. Further, if we, our corporate collaborators or our contract manufacturers fail to comply with applicable FDA and other regulatory requirements at any stage during the regulatory or manufacturing process, the FDA may impose sanctions, including:

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

Our business strategy depends on our ability to identify, acquire, license and develop product candidates and identify, acquire or license approved products.

As part of our business strategy we plan to identify, acquire, license and develop product candidates and identify, acquire and license approved products for markets that we can reach through our marketing and distribution channels. If we fail to obtain, develop and successfully commercialize additional products, we may not achieve expectations of our future performance and our stock price could decline. Because we do not directly engage in basic research or drug discovery, we must rely upon third parties to sell or license product opportunities to us. Other companies, including some with substantially greater financial, marketing and sales resources, are competing with us to acquire or license such products or product candidates. We may not be able to acquire or license rights to additional products or product candidates on acceptable terms, if at all. Furthermore, we may not be able to successfully develop any product candidates we acquire or license. In addition, we may acquire or license new products with different marketing strategies, distribution channels and bases of competition than those of our current products. Therefore, we may not be able to compete favorably in those product categories.

If we are unable to maintain relationships with third-party collaborators or enter into new relationships, we may not be able to develop any of our product candidates or commercialize our products in a timely manner, if at all.

Our continued success will depend in large part upon the efforts of third-parties. For the research, development, manufacture and commercialization of our products, we currently have, and will likely continue to enter into, various arrangements with other corporations, licensors, licensees, outside researchers, consultants and others. However, we cannot be certain of the actions these parties will take, and there is a risk that:

- we will be unable to negotiate acceptable collaborative arrangements to develop or commercialize our products;
- any arrangements with third-parties will not be successful;
- third-party collaborators will not fulfill their obligations to us under any arrangements entered into with them;
- strategic collaborators, including Helsinn Healthcare SA, will terminate their relationship with us; or
- current or potential collaborators will pursue treatments for other diseases or seek alternative means of developing treatments for the diseases targeted by our programs or products.

Our third-party collaborators include public research institutions, research organizations, teaching and research hospitals, community-based clinics, testing laboratories, contract product formulation organizations, contract packaging and distribution companies, manufacturers, suppliers and license collaborators. We consider our arrangements with Helsinn Healthcare SA, Patheon Inc., and Merck KgaA to be significant. If any of our collaborators breaches or terminates its agreement with us, or otherwise fails to conduct its collaborative activities in a timely manner, we may experience significant delays in the development or commercialization of the products or product candidates or the research program covered by the agreement and we may need to devote additional funds or other resources to these activities. If we are unable to enter into new or alternative arrangements to continue research and development activities, or are unable to continue these activities on our own, we may have to terminate the development program. As a consequence, we may experience a loss of future commercial product potential and a decline in our stock price.

We have licensed the right to promote, sell and distribute Aloxi products in the United States and Canada from a third party. We are particularly dependent on that third party for our ability to commercialize Aloxi products.

We have entered a license agreement with Helsinn Healthcare SA under which we have acquired a license to sell and distribute Aloxi products in the United States and Canada through December 31, 2015. Furthermore, under

the terms of our license, we are required to purchase all of our Aloxi products from Helsinn Healthcare SA. The license agreement may be terminated for specified reasons, including if the other party is in substantial or persistent breach of the agreement, if we have experienced a change of control and the acquiring entity has competing products or our marketing and sales related commitments to the licensor are not maintained by the acquiring entity, or if either party has declared bankruptcy. Although we are not currently in breach of the license, and we believe that Helsinn Healthcare SA is not currently in breach of the license, there is a risk that either party could breach the license in the future. In addition, if we were to breach the supply agreement with Helsinn Birex Pharmaceutical Ltd. contemplated by the license, Helsinn Healthcare SA would be permitted to terminate the license.

If the license agreement were terminated, we would lose all of our rights to sell and distribute Aloxi products, as well as all of the related intellectual property and all regulatory approvals. In addition, Helsinn Healthcare SA holds the rights to palonosetron (the active ingredient in Aloxi products) through an agreement with Syntex (U.S.A.) Inc. and F. Hoffmann-La Roche AG. We cannot be certain of the actions that these parties will take, and there is a risk that these third parties will end their relationship, which would leave us without rights to the pharmaceutical preparations, products and know-how required to produce Aloxi products. As a consequence of such a termination, we would lose all of our rights to sell and distribute Aloxi products, which would harm our business and could cause our stock price to decline significantly.

We rely on multinational and foreign pharmaceutical companies to develop and commercialize our products and product candidates in markets outside the United States.

With respect to products in which we own rights outside the United States, our strategy for commercialization of such products in markets outside the United States is to enter into development and marketing alliances with multinational and foreign pharmaceutical companies. We have entered into alliances with various companies related to the development and commercialization of our products and product candidates in markets outside the United States. Our continued relationships with strategic collaborators are dependent in part on the successful achievement of development milestones. If we or our collaborators do not achieve these milestones, or we are unable to enter into agreements with our collaborators to modify their terms, these agreements could terminate, which could cause a loss of licensing revenue, a loss of future commercial product potential and a decline in our stock price.

We recognize licensing revenue from our marketing collaborators as a portion of our total revenue. Future licensing revenues from these collaborators will likely fluctuate from quarter-to-quarter and year-to-year depending on:

- the achievement of milestones by us or our collaborators;
- the amount of product sales and royalty-generating activities;
- the timing of initiating additional licensing relationships; and
- our continuing obligation related to license payments.

If we fail to compete successfully with our competitors, our product revenues could decrease and our stock price could decline.

Competition in the pharmaceutical industry is intense. Most of our competitors are large, multinational pharmaceutical companies that have considerably greater financial, sales, marketing and technical resources than we do. Most of our present and potential competitors also have dedicated research and development capabilities that may allow them to develop new or improved products that compete with our products. Currently, Aloxi injection competes with three other products from the 5-HT_3 receptor antagonist class of compounds, as well as products from other chemical classes that are also used for the prevention of chemotherapy-induced nausea and vomiting. Most of these products are marketed by large, multinational competitors, including GlaxoSmithKline,

Roche and Aventis. If Aloxi injection does not compete successfully with existing products on the market, our stock price could decline significantly. Additionally, MedImmune, Inc. and Daichi Pharmaceutical have drugs that are approved for sale and compete in the same markets as Salagen Tablets.

Other pharmaceutical companies are developing products, which, if approved by the FDA, will compete directly with Aloxi injection or Salagen Tablets. Our competitors could also develop and introduce generic drugs comparable to Aloxi injection or Salagen Tablets, or drugs or other therapies that address the underlying causes of the symptoms that Aloxi injection or Salagen Tablets treat. If a product developed by a competitor is more effective than our product, or priced lower than our product, then our product revenue could decrease and our stock price could decline.

We are dependent on our key personnel. If we are not able to attract and retain key employees and consultants, our product development, marketing and commercialization plans could be harmed.

We are highly dependent on the members of our scientific and management staff. If we are not able to retain any of these persons, our product development, marketing and commercialization plans may suffer and our stock price could decline. None of our executive officers has an employment agreement with us. If we are unable to retain our scientific and management staff, we will need to hire additional qualified personnel for us to pursue our product acquisition, development, marketing and commercialization plans.

We may not be able to attract and retain personnel on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. If we are not able to attract and retain qualified personnel, our product acquisition, development, marketing and commercialization plans will suffer and our stock price could decline.

If we are unable to keep up with rapid technological changes in the pharmaceutical or biotechnology industries, we may be unable to continue our operations.

The pharmaceutical and biotechnology industries have experienced rapid and significant technological change. We expect that pharmaceutical technology and biotechnology will continue to develop rapidly. Our future success will depend, in large part, on our ability to develop and maintain technology that is competitive. If other companies achieve technological advances with their products or obtain FDA approval before we are able to obtain such approval, our products may become obsolete before they are marketed or before we recover any of our development and commercialization expenses incurred with respect to such products. In addition, alternative therapies or new medical treatments could alter existing treatment regimens, and thereby reduce the need for one or more of our products, which could result in the termination of the development in one or more of our product candidates, or in the decline in sales of one of our approved products, which could cause our stock price to decline.

RISKS RELATED TO OUR INDUSTRY

If we do not receive regulatory approvals for our product candidates, or if regulatory approval is delayed for any reason, we will be unable to commercialize and sell our products as we expect.

Prior to marketing, each of our product candidates must undergo an extensive regulatory approval process conducted by the FDA in the United States and by comparable agencies in other countries. The product development and approval process can take many years and require the expenditure of substantial resources. There is risk that the FDA or a foreign regulatory authority will not approve in a timely manner, if at all, any product we develop. Generally, the FDA approves for sale only a very small percentage of newly discovered pharmaceutical compounds that enter preclinical development. We may encounter delays or denials in regulatory approvals due to changes in FDA policy during the period of development, or changes in the requirements for regulatory review of each submitted new drug application, or NDA.

There is also risk that regulatory authorities in the United States and elsewhere may not allow us to conduct planned additional clinical testing of any of our product candidates, including irofulven or Aloxi products, or that, if permitted, this additional clinical testing will not prove that these product candidates are safe and effective to the extent necessary to permit us to obtain marketing approvals from regulatory authorities.

Except for those products already approved, none of our product candidates are currently being tested in phase 3 or registration clinical trials. We cannot apply for a regulatory approval to market a product candidate until we successfully complete phase 3 or registration clinical trials for that product.

If we are unable to obtain intellectual property protection, or protect our proprietary technology, we may be unable to compete effectively.

The FDA awarded us orphan drug status for Salagen Tablets in 1994 as a treatment for the symptoms of xerostomia, or severe dry mouth, induced by radiation therapy in head and neck cancer patients and in 1998 for the symptoms of dry mouth associated with Sjögren's syndrome. An orphan drug designation entitles us to marketing exclusivity of the protected drug for the stated condition for a period of seven years. Our orphan drug protection for Salagen Tablets expired in March 2001 for the treatment of symptoms of radiation-induced xerostomia in head and neck cancer patients and will expire in 2005 for the Sjögren's syndrome indication. Upon expiration of any of our orphan drug protection for Salagen Tablets, we may face competition from manufacturers of generic versions of Salagen Tablets.

We hold an exclusive United States and Canada license on patents covering Aloxi injection proprietary rights. In addition, we hold an exclusive, worldwide license on patents and patent applications covering acylfulvene proprietary rights, including irofulven. The license applicable to these technologies is subject to certain statutory rights held by the U.S. government. Even though we have licensed these patents, we may not have exclusive rights to all possible acylfulvene analogs, all possible methods of using acylfulvene analogs to treat tumors or all possible synthetic methods for preparing acylfulvenes. In addition, we licensed rights to patents and patent applications covering MG98 and inhibitors of DNA methyltransferase. Protection of these rights and creation of additional rights involve joint responsibilities between us and the respective license party.

Our pending patent applications, those we may file in the future, or those we license from third parties, may not result in patents being issued. Patents, if issued, may be challenged, invalidated or circumvented. In addition, other entities may develop similar technologies that fall outside the scope of our patents. Thus, any patent rights that we own or license from third parties may not provide sufficient protection against potential competitors.

In the event that our technologies or methods used in the course of developing or selling our products infringe the patents or violate other proprietary rights of third parties, we and our corporate collaborators may be prevented from pursuing product development or commercialization.

In addition to patents, we rely on trade secrets and proprietary know-how. We protect our proprietary technology and processes in part by confidentiality agreements with our collaborators, employees and consultants. There is a risk that:

- these confidentiality agreements will be breached;
- we will not have adequate remedies for any breach of these agreements;
- our trade secrets will otherwise become known; or
- our trade secrets will be independently discovered and used by competitors.

The biotechnology and pharmaceutical industries have been characterized by litigation regarding patents and other intellectual property rights. If we become involved in any litigation, interference or other administrative proceedings, we will incur substantial expense and the efforts of our technical and management personnel will be

diverted. An adverse determination may subject us to significant liabilities or require us to cease using the technology or to seek licenses that may not be available from third parties on commercially favorable terms, if at all, or to cease manufacturing and selling our products. This could cause us to terminate the development of one or more of our product candidates, to discontinue marketing an existing product, or to pay royalties to a third party. Any of these events could result in a decline in the price of our stock.

If the use of one of our products harms people, we may be subject to costly and damaging product liability claims.

We face exposure to product liability claims in the event that the use of our product is alleged to have harmed someone. Although we have taken, and continue to take, what we believe are appropriate precautions, there is a risk that we will not be able to avoid significant product liability exposure. We currently have product liability insurance in the amount of $30 million per occurrence and in the aggregate for the year. There is a risk that our insurance will not be sufficient to cover claims. There is also a risk that adequate insurance coverage will not be available in the future on commercially reasonable terms, if at all. The successful assertion of an uninsured product liability or other claim against us could cause us to incur a significant expense to pay such a claim, could adversely affect our product development and could cause a decline in our product revenue and the price of our stock.

In addition to product liability risks associated with sales of our products, we may be liable to the claims of individuals who participate in clinical trials of our products. A number of patients who participate in trials are already critically ill when they enter a trial. The waivers we obtain may not be enforceable and may not protect us from liability or the costs of product liability litigation. Our product liability insurance may not provide adequate protection against potential liabilities. Moreover, we may not be able to maintain our insurance on acceptable terms. As a result of these factors, a product liability claim, even if successfully defended, could cause us to incur a significant expense to defend such a claim, could adversely affect our product development and could cause a decline in our product revenue and the price of our stock.

We could become the subject of legal proceedings or investigations that could result in substantial fines, penalties, injunctive or administrative penalties and criminal charges, which would increase our expenses and redirect management's attention away from business operations.

Our business operations are subject to a wide range of laws and regulations. Other pharmaceutical companies have been the subjects of legal proceedings or investigations related to pricing, marketing, promotional and clinical trial practices. If we become the subject of legal proceedings or investigations, our expenses would increase and commercialization of our products could be adversely affected. Further, management's attention would be diverted from our business operations.

If we issue a product recall, we may not sell as much of our products in the future and we may incur significant expenses.

The FDA or other government agencies having regulatory authority for product sales may request product recalls or we may issue product recalls. These product recalls may occur due to manufacturing issues, safety concerns or other reasons. We do not carry any insurance to cover the risk of a product recall. Any product recall could have a material adverse effect on our product revenue and could cause the price of our stock to decline.

If we or patients using our products are unable to obtain adequate reimbursement from government health administration authorities, private health insurers and other organizations, our product sales and price of our stock could decline.

There is much uncertainty about the reimbursement status of healthcare products. Our profitability will depend in part on: (1) the price we are able to charge for our products, and (2) the availability of adequate reimbursement

for our products from third-party payors, such as government entities, private health insurers and managed care organizations. Federal and state regulations govern or influence the reimbursement status of healthcare products in many situations and third-party payors are increasingly challenging the pricing of medical products and services.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 together with rulemaking by the Centers for Medicare and Medicaid Services (CMS) require a number of changes in Medicare practices, including reimbursement. The changes made to date, are not expected to have an adverse affect on our operations, sales or the price of our stock, but we cannot predict the impact, if any of future reimbursement changes.

Salagen Tablets generally have been eligible for reimbursement from third-party payors and we have applied for, or in certain cases already received confirmation of, reimbursement eligibility for Aloxi injection. Although third-party reimbursement previously has not been an issue for us, it becomes important to the commercialization of Aloxi products. Reimbursement of newly approved health products is uncertain. There is a risk that reimbursement will not be available for Aloxi products or for our future products. If government entities and other third-party payors do not provide adequate reimbursement levels for our products, our product and license revenues would be materially and adversely affected and our stock price could decline.

In recent years, various parties have proposed a number of legislative and regulatory proposals aimed at changing national healthcare systems. In the United States, we expect that there will continue to be a number of federal and state proposals to implement government control of pricing and profitability of prescription pharmaceuticals. Cost controls, if mandated by a government agency, could decrease the price that we receive for our current or future products. These proposals, if enacted, could have a material adverse effect on our product and license revenues and could cause our stock price to decline. In certain countries, regulatory authorities must also approve the sales price of a product after they grant marketing approval. There is a risk that we will not be able to obtain satisfactory prices in foreign markets even if we obtain marketing approval from foreign regulatory authorities.

Our operations, and the operations of our third-party contractors, involve hazardous materials that could expose us to liability if environmental damage occurs.

Our operations, and the operations of our third-party contractors involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, third parties may hold us liable for any resulting damages, which may exceed our financial resources and may have a material adverse effect on our ability to fund our operations.

RISKS RELATED TO OUR COMMON STOCK

Our stock price is volatile, which may result in significant losses to shareholders.

There has been significant volatility in the market prices of pharmaceutical and biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock, and some of these factors are beyond our control. These factors include:

- fluctuations in our operating results;
- announcements of technological innovations or acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- published reports by securities analysts;
- positive or negative progress with our clinical trials;
- governmental regulation, including healthcare reimbursement policies;
- developments in patent or other proprietary rights;

- developments in our relationship with collaborators and suppliers, and announcements of new strategic collaborations;
- public concern as to the safety and efficacy of our products; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these factors, including the sale or attempted sale of a large amount of our common stock into the market. Our stock price ranged from $4.68 to $43.12 per share during the two-year period ended December 31, 2003. Broad market fluctuations may also adversely affect the market price of our common stock.

In the past, following large falls in the price of a company's shares, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could harm our business. Any adverse determination in litigation could subject us to significant liabilities.

We have outstanding options that have the potential to dilute shareholder value and cause our stock value to decline.

We frequently grant stock options to our employees and other individuals. At December 31, 2003, we had options outstanding for 4,351,237 shares of our common stock at option prices ranging from $3.38 to $51.50. If some or all of such shares are sold into the public market over a short time period, the value of our stock is likely to decline, as the market may not be able to absorb those shares at the prevailing market prices. Such sales may also make it more difficult for us to sell equity securities in the future on terms that we deem acceptable.

Our charter documents, our shareholder rights plan and Minnesota law contain provisions that could delay or prevent an acquisition of our company.

Our charter documents contain provisions that may discourage third parties from seeking to acquire our company. These provisions include:

- advance notice requirements for shareholder proposals and nominations; and
- the authority of the board of directors to issue, without shareholder approval, preferred stock with such terms as the board of directors may determine.

In addition, our board of directors has adopted a shareholder rights plan, or poison pill, which enables our board of directors to issue preferred stock purchase rights that would be triggered by an acquisition of 15 percent or more of the outstanding shares of our common stock. These provisions and specific provisions of Minnesota law relating to business combinations with interested shareholders may have the effect of delaying, deterring or preventing a merger or change in control. Some of these provisions may discourage a future acquisition of our company even if shareholders would receive an attractive value for their shares or if a significant number of our shareholders believed such a proposed transaction to be in their best interests. As a result, shareholders who desire to participate in such a transaction may not have the opportunity to do so.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our operations are not subject to risks of material foreign currency fluctuations, nor do we use derivative financial instruments in our investment practices. We place our marketable investments in instruments that meet high credit quality standards, as specified in our investment policy guidelines. We do not expect material losses with respect to our investment portfolio or exposure to market risks associated with interest rates. The impact on our net loss as a result of a one percentage point change in short-term interest rates would be approximately $1,399,000 based on our cash, cash equivalents and short-term marketable investment balances at December 31, 2003.

Item 8. Financial Statements and Supplementary Data

MGI PHARMA, INC.

BALANCE SHEETS

	December 31, 2002	December 31, 2003
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 52,933,393	$ 116,570,518
Short-term marketable investments	7,539,508	23,362,898
Receivables, less contractual and bad debt allowances of $403,153 and $3,315,399	2,748,821	6,223,964
Inventories	1,779,413	7,437,550
Prepaid expenses	448,559	922,070
Total current assets	65,449,694	154,517,000
Equipment, furniture and leasehold improvements, at cost less accumulated depreciation of $2,121,915 and $3,041,360	3,110,938	2,828,602
Long-term marketable investments	—	37,819,837
Long-term equity investment	6,800,000	3,646,052
Intangible assets, at cost less accumulated amortization of $2,462,455 and $3,667,412	4,629,415	5,653,457
Other assets	490,329	54,206
Total assets	$ 80,480,376	$ 204,519,154
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 1,904,297	$ 4,039,139
Accrued expenses	8,431,446	21,632,345
Deposit payable	4,300,000	—
Deferred revenue	794,383	245,000
Other current liabilities	20,138	28,910
Total current liabilities	15,450,264	25,945,394
Noncurrent liabilities:		
Convertible debt, face value of $21,000,000 net of warrant cost and issuance costs of $1,708,851 and $1,361,288	19,291,149	19,638,712
Deferred revenue	9,033,839	2,196,250
Other noncurrent liabilities	101,589	128,636
Total noncurrent liabilities	28,426,577	21,963,598
Total liabilities	43,876,841	47,908,992
Stockholders' equity:		
Preferred stock, 10,000,000 authorized and unissued shares	—	—
Common stock, $0.01 par value, 70,000,000 authorized shares, 25,236,906 and 31,696,982 issued and outstanding shares	252,369	316,970
Additional paid-in capital	195,919,707	377,664,610
Unearned compensation – restricted shares	(128,756)	(24,129)
Accumulated deficit	(159,439,785)	(221,347,289)
Total stockholders' equity	36,603,535	156,610,162
Total liabilities and stockholders' equity	$ 80,480,376	$ 204,519,154

See accompanying notes to financial statements.

MGI PHARMA, INC.

STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2001	**2002**	**2003**
Revenues:			
Sales	$ 30,021,813	$ 25,402,300	$ 39,857,620
Licensing	2,932,007	2,801,189	9,527,433
	32,953,820	28,203,489	49,385,053
Costs and expenses:			
Cost of sales	3,632,767	3,239,845	6,959,467
Selling, general and administrative	28,463,387	28,827,337	50,409,508
Research and development	36,101,373	32,213,635	50,120,596
Amortization	1,181,978	1,181,979	1,204,958
	69,379,505	65,462,796	108,694,529
Loss from operations	(36,425,685)	(37,259,307)	(59,309,476)
Interest income	1,600,363	1,278,645	1,553,483
Interest expense	—	(83,130)	(997,563)
Impairment of investment	—	—	(3,153,948)
Loss before income taxes	(34,825,322)	(36,063,792)	(61,907,504)
Provision for income taxes	—	—	—
Net loss	$(34,825,322)	$(36,063,792)	$ (61,907,504)
Net loss per common share:			
Basic	$ (1.74)	$ (1.44)	$ (2.23)
Diluted	$ (1.74)	$ (1.44)	$ (2.23)
Weighted average number of common shares outstanding:			
Basic	19,985,192	25,110,023	27,777,860
Diluted	19,985,192	25,110,023	27,777,860

See accompanying notes to financial statements.

MGI PHARMA, INC.

STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2001	2002	2003
Operating activities:			
Net loss	$(34,825,322)	$(36,063,792)	$ (61,907,504)
Adjustments for non-cash items:			
Stock issuance for Aloxi injection license	2,999,992	—	—
Impairment of long-term equity investment	—	—	3,153,948
Depreciation and intangible amortization	1,876,327	2,048,260	2,230,026
Benefit plan contribution	836,507	949,381	1,291,954
Financing transaction costs	516,604	—	—
Noncash consulting payments	189,747	66,962	27,996
Stock option term modification	—	216,064	—
Amortization of restricted stock expense	—	110,688	104,627
Amortization of non-cash financing charges	—	28,963	367,563
Other	155,451	60,433	20,580
Changes in operating assets and liabilities:			
Receivables	976,808	(1,213,044)	(3,475,143)
Inventories	(23,779)	(279,359)	(5,658,137)
Prepaid expenses	5,579,521	(201,820)	(473,511)
Accounts payable and accrued expenses	4,388,684	(2,483,105)	14,977,016
Deferred revenue	(91,259)	(794,384)	(7,386,972)
Other current liabilities	446	(1,719)	8,773
Net cash used in operating activities	(17,420,273)	(37,556,472)	(56,718,784)
Investing activities:			
Purchase of investments	(49,472,664)	(9,360,720)	(62,939,380)
Maturity of investments	35,326,665	34,834,284	9,296,153
Acquisition of Hexalen capsules	(4,800,000)	(1,200,000)	—
Purchase of minority investment in MethylGene	(3,000,000)	—	—
Extension of rights for Aloxi injection	—	—	(2,229,000)
Purchase of equipment, furniture and leasehold improvements	(2,588,234)	(653,029)	(744,684)
Other	(32,255)	(60,260)	436,123
Net cash provided by (used in) investing activities	(24,566,488)	23,560,275	(56,180,788)
Financing activities:			
Proceeds from issuance of shares, net	72,117,460	—	168,581,477
Proceeds from issuance of convertible debt, net	—	20,950,157	—
Restricted cash	(4,000,000)	4,000,000	—
Receipt (payment) of deposit payable	2,200,000	550,000	(4,300,000)
Issuance of shares under stock plans	1,336,995	700,517	12,255,220
Other	—	29,508	—
Net cash provided by financing activities	71,654,455	26,230,182	176,536,697
Increase in cash and cash equivalents	29,667,694	12,233,985	63,637,125
Cash and cash equivalents at beginning of year	11,031,714	40,699,408	52,933,393
Cash and cash equivalents at end of year	$ 40,699,408	$ 52,933,393	$116,570,518
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 0	$ 0	$ 630,000

See accompanying notes to financial statements.

MGI PHARMA, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

	Shares	Common stock	Additional paid-in capital	Unearned compensation – restricted shares	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2000	16,509,008	$165,090	$114,431,198	$ —	$ (88,550,671)	$ 26,045,617
Issuance public offering	4,000,000	40,000	29,128,655	—	—	29,168,655
Issuance private placement	3,025,000	30,250	31,086,712	—	—	31,116,962
Issuance public offering	900,000	9,000	11,822,843	—	—	11,831,843
Issuance for technology license	297,338	2,973	2,997,019	—	—	2,999,992
Exercise of stock options	175,885	1,759	861,138	—	—	862,897
Employee retirement plan contribution	38,226	383	553,235	—	—	553,618
Employee stock purchase plan	45,457	455	473,643	—	—	474,098
Financing transaction costs	—	—	516,604	—	—	516,604
Other issuances	14,136	141	189,606	—	—	189,747
Net loss	—	—	—	—	(34,825,322)	(34,825,322)
Balance at December 31, 2001	25,005,050	250,051	192,060,653	—	(123,375,993)	68,934,711
Exercise of stock options	16,475	165	93,393	—	—	93,558
Employee retirement plan contribution	72,536	725	920,181	—	—	920,906
Employee stock purchase plan	106,561	1,065	605,893	—	—	606,958
Stock option term modification	—	—	214,744	—	—	214,744
Restricted stock issuance	34,702	347	239,097	(239,444)	—	—
Amortization of restricted stock to compensation expense	—	—	—	110,688	—	110,688
Issuance of warrants under convertible debt	—	—	1,687,971	—	—	1,687,971
Other issuances	1,582	16	97,775	—	—	97,791
Net loss	—	—	—	—	(36,063,792)	(36,063,792)
Balance at December 31, 2002	25,236,906	252,369	195,919,707	(128,756)	(159,439,785)	36,603,535
Issuance public offering	5,060,000	50,600	168,530,877	—	—	168,581,477
Exercise of stock options	1,227,322	12,273	11,471,513	—	—	11,483,786
Employee retirement plan contribution	103,794	1,038	1,023,586	—	—	1,024,624
Employee stock purchase plan	72,712	727	762,907	—	—	763,634
Restricted stock cancellation	(4,854)	(48)	(99,765)	—	—	(99,813)
Amortization of restricted stock to compensation expense	—	—	—	104,627	—	104,627
Amortization of warrants value under convertible debt	—	—	20,000	—	—	20,000
Other issuances	1,102	11	35,785	—	—	35,796
Net loss	—	—	—	—	(61,907,504)	(61,907,504)
Balance at December 31, 2003	31,696,982	$316,970	$377,664,610	$ (24,129)	$(221,347,289)	$156,610,162

See accompanying notes to financial statements.

MGI PHARMA, INC.

NOTES TO FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

MGI PHARMA is an oncology-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that meet cancer patient needs. We focus our direct sales efforts solely within the United States and create alliances with other pharmaceutical or biotechnology companies for the commercialization of our products in other countries.

We promote our products directly to physician specialists in the United States using our own sales force. These products include Aloxi™ (palonosetron hydrochloride) injection, Salagen® Tablets (pilocarpine hydrochloride), and Hexalen® (altretamine) capsules. In the third quarter of 2003, Aloxi injection was approved by the U.S. Food and Drug Administration ("FDA") for the prevention of acute and delayed chemotherapy-induced nausea and vomiting ("CINV") and we began promoting Aloxi injection in September 2003. We obtained exclusive U.S. and Canada license and distribution rights to Aloxi injection from Helsinn Healthcare SA in May 2001. In November 2003, we and Helsinn expanded the agreement to include rights for the prevention of postoperative nausea and vomiting ("PONV") application of Aloxi injection and an oral Aloxi formulation. Salagen Tablets are approved in the United States for two indications: the symptoms of dry mouth associated with radiation treatment in head and neck cancer patients and the symptoms of dry mouth associated with Sjögren's syndrome, an autoimmune disease that damages the salivary glands. Sales of Salagen Tablets in the United States accounted for 67 percent of our product sales during 2003. Hexalen capsules is an orally administered chemotherapeutic agent approved in the United States for treatment of refractory ovarian cancer patients.

Our current product development efforts include preclinical and clinical programs for the acylfulvenes, including irofulven, our novel anti-cancer agent with demonstrated activity in a variety of cancers and a unique mechanism of action. We have also funded development of MG98 and inhibitors of DNA methyltransferase for North American markets. DNA methyltransferase is an enzyme that has been associated with uncontrolled tumor growth. We provide ongoing clinical support of Aloxi injection and Salagen Tablets. Our research and development expense also includes license fees related to Helsinn's now concluded development of Aloxi injection for CINV and its ongoing development of Aloxi injection for prevention of PONV and for an oral Aloxi formulation.

In August 2003, we completed a sale of 5,060,000 newly issued shares of common stock in a follow-on public offering at $35.50 per share. Our net proceeds, after fees and expenses, were $168,581,477.

Cash, Cash Equivalents and Investments: We consider highly liquid marketable securities with remaining maturities of ninety days or less at the time of purchase to be cash equivalents. Other highly liquid marketable securities with remaining maturities of one year or less at the balance sheet date are classified as short-term marketable investments. Long-term marketable investments are highly liquid marketable securities with remaining maturities of more than one year at the balance sheet date.

Short-term and long-term marketable investments are classified as held-to-maturity investments because we have the intent and the ability to hold our investments to maturity. As such, they are stated at amortized cost, which approximates estimated fair value. Amortized cost is adjusted for amortization of premiums and discounts to maturity, and this amortization is included in interest income in the accompanying statements of operations.

Concentration of Credit Risk: Financial instruments that may subject us to significant concentrations of credit risk consist primarily of short-term and long-term marketable investments and trade receivables.

Cash in excess of current operating needs is invested in accordance with our investment policy. This policy emphasizes principal preservation, so it requires strong issuer credit ratings and limits the amount of credit exposure from any one issuer or industry.

We grant credit primarily to pharmaceutical wholesale distributors throughout the United States in the normal course of business. Four wholesalers accounted for approximately 80 percent of Company sales in 2003. Customer credit-worthiness is routinely monitored and collateral is not normally required.

Concentration of Supply Risk: We depend on a single supplier to provide the active ingredient for Salagen Tablets, which accounted for 67 percent of our sales during 2003. If this supplier ends its relationship with us, or is unable to meet our demand for the ingredient, we may be unable to produce Salagen Tablets for commercial sale.

We depend on a single supplier to provide Aloxi injection, which accounted for 24 percent of our sales revenue in 2003. If this supplier is unable to meet our demand we may be unable to provide Aloxi injection for commercial sale.

Inventories: Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out basis.

Long-term Equity Investment: We own an approximate 13 percent, minority investment in MethylGene Inc., a privately owned Canadian biopharmaceutical company. This minority investment is reported in the financial statements as "Long-term equity investment" at the lower of cost or if its value is other than temporarily impaired, then at estimated fair value and we review the fair value on a periodic basis.

Because MethylGene is a private company and its securities are not publicly traded, the value of this investment is inherently more difficult to estimate than an investment in a public company. We estimated that the value of its investment declined from its original cost of $6.8 million to $3.6 million as of December 31, 2003 and an impairment of this investment had occurred which is considered to be other than temporary. Accordingly, the Company recorded an impairment charge of $3.2 million in the year ended December 31, 2003. The amount of the charge was based on the difference between the estimated fair value as determined by us and the original cost basis.

Sales Revenue Recognition: We recognize sales revenue upon shipment of products to customers, upon fulfillment of acceptance terms, if any, and when no significant contractual obligations remain. Net sales reflect reduction of gross sales for estimated wholesaler chargebacks (as more fully described below), estimated contractual allowances and estimated early payment discounts. At December 31, 2003, we had a chargeback allowance of $3,057,737 and a bad debt and cash discounts allowance of $257,662, which compared with $293,877 and $109,276, respectively at December 31, 2002. We provide for estimated returns at the time of sale based on historic product return experience and an estimate of future activity.

Chargebacks: The majority of our products are distributed through independent pharmaceutical wholesalers. In accordance with industry practice, sales to wholesalers are initially transacted at wholesale list price. The wholesalers then generally sell to an end user (normally a clinic, hospital, alternative healthcare facility, or an independent pharmacy) at a lower contracted price previously established between the end user and us. We negotiate the end user price through group purchasing organizations.

When we initially record a sale to a wholesaler, the sale and resulting receivable are recorded at our list price. However, experience indicates that most of these selling prices will eventually be reduced to a lower, end-user contract price. Therefore, at the time of the sale, a contra asset is recorded for, and revenue is reduced by, the difference between the list price and the estimated average end-user contract price. This contra asset is calculated by product, taking the expected number of outstanding wholesale units sold that will ultimately be sold under end-user contracts multiplied by the anticipated, weighted-average contract price. Thus, a contra asset is established, reducing the initial wholesaler receivable by the difference between the initial list price and the estimated, ultimate end-user selling price. When the wholesaler ultimately sells the product to the end user at the end-user contract price, the wholesaler charges us ("chargeback") for the difference between the list price and the end-user contract price and such chargeback is offset against our initial estimated contra asset. Wholesalers and group purchasing organizations receive administrative fees from us based on sales units sold. In addition, we

provide an incentive to the end user based on units purchased. We record these administrative fees and incentives as an accrued expenses at the time of our product sale.

Licensing Revenue Recognition: Under Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements", we recognize revenue from licensing arrangements using a contingency-adjusted performance model. Under this method, revenue related to up-front, time-based, and performance-based licensing payments is recognized over the entire contract performance period. We recognize the aggregate of nonrefundable up-front and time-based fees ratably over the effective term of the underlying license and related supply arrangements. Performance-based, contingent license payment amounts are recognized on a pro rata basis in the period the licensee achieves the performance criteria to the extent of the timing of the achievement of the milestone in relation to the term of the underlying arrangements – approximating the extent of contingent performance through the date of the milestone achievement in relation to the full term of the underlying arrangements. We recognize the remaining portion of any milestone payments over the remaining term of the underlying arrangements. Payments received by us in excess of amounts earned are classified as deferred revenue. We recognized $794,384 and $7,386,972 of amortized deferred revenue in 2002 and 2003, respectively. At December 31, 2003, the Company has an unamortized deferred revenue balance of $2,441,250. (See Note 6) Further, we recognize royalties on product sales and support services provided to strategic collaborators in licensing revenue when the related sales or provision of services occur.

Stock-Based Compensation: We apply the intrinsic value method described in Accounting Principles Board (APB) Opinion No. 25 in accounting for the issuance of stock options to employees and directors. Accordingly, as all grants are made at or above the market price, no compensation expense has been recognized in the financial statements. Had we determined compensation cost based on the fair value at the grant date for our stock options and the fair value of the discount related to the employee stock purchase plan under SFAS 123, our net loss would have been reported as shown below:

	2001	2002	2003
Net loss, as reported	($34,825,322)	($36,063,792)	($61,907,504)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(9,083,811)	(7,278,836)	(9,454,843)
Pro forma net loss	($43,909,133)	($43,342,628)	($71,362,347)
Net loss per common share:			
As reported basic and diluted	($1.74)	($1.44)	($2.23)
Pro forma basic and diluted	($2.20)	($1.73)	($2.57)

The per share weighted-average fair value of stock options granted during 2001, 2002 and 2003 was $9.00, $5.17 and $12.93, respectively, on the date of grant, using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	2001	2002	2003
Expected dividend yield	0%	0%	0%
Risk-free interest rate	4.30%	2.70%	2.70%
Annualized volatility	0.80	0.80	0.80
Expected life, in years	5	5	5

Advertising and Promotion Expense: Costs of advertising and promotion are expensed as incurred and were $4,933,137, $2,773,810 and $13,854,557 in 2001, 2002 and 2003, respectively. We do not defer any costs related to direct-response advertising.

Depreciation: Depreciation of equipment and furniture is provided over the estimated useful lives of the respective assets on a straight-line basis. Estimated useful lives of equipment and furniture range from three to ten years. Leasehold improvements are amortized over the shorter of the lease term or the useful life of the improvements.

Convertible Debt: Convertible debt is stated at face value, less issuance costs and the value of warrants issued in conjunction with the convertible debt. Both the issuance costs and the value of the warrants are amortized to interest expense over the 5-year term of the convertible debt.

Research and Development: Research and development costs are expensed as incurred. Costs of in-licensing payments for product candidates that have not yet been sold commercially are expensed as research and development.

Amortization: Amortization of intangible assets relating to the purchase of the Hexalen capsules business is recognized as the greater of the amount computed on a straight-line basis over the six-year estimated commercial life of Hexalen capsules or in proportion to the actual product contribution compared to estimated product contribution over the estimated commercial life of Hexalen capsules.

As a result of amending the Helsinn Healthcare SA license agreement in 2003, the term was extended for our preexisting rights to Aloxi injection for prevention of CINV. We recorded an intangible asset of $2,229,000 related to these rights that is being amortized on a straight-line basis over approximately twelve years. (See Note 6)

Amortized Intangible Assets:

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Hexalen acquisition	$7,091,869	$(3,644,433)	$3,447,436
Helsinn CINV license agreement	2,229,000	(22,979)	2,206,021
Total	$9,320,869	$(3,667,412)	$5,653,457

Amortization for the year ended:	December 31, 2001	December 31, 2002	December 31, 2003
Amortization Expense	$1,181,978	$1,181,979	$1,204,958

Estimated amortization expense for the year ending:

December 31, 2004	$1,365,813
December 31, 2005	1,365,813
December 31, 2006	1,267,315
December 31, 2007	183,835
December 31, 2008	183,835

Income Taxes: Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is carried against deferred tax assets until it is deemed more-likely-than-not that some portion or all of the deferred tax assets will be realized.

Income (Loss) Per Common Share: Basic earnings per share (EPS) is calculated by dividing net income (loss) by the weighted-average common shares outstanding during the period. Diluted EPS reflects the potential dilution to basic EPS that could occur upon conversion or exercise of securities, options, or other such items to common shares using the treasury stock method and if converted method based upon the weighted-average fair value of our common shares during the period. During net loss periods, potentially dilutive securities are not included in the calculation of net loss per share since their inclusion would be anti-dilutive.

Use of Estimates: Preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions affecting

reported asset and liability amounts and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Basis of Presentation: Certain prior year amounts have been reclassified to conform to current year presentation

New Accounting Pronouncements:

EITF 00-21, "Revenue Arrangements with Multiple Deliverables." EITF 00-21 provides revenue recognition guidance for arrangements with multiple deliverables, and the criteria to determine if items in a multiple deliverable agreement should be accounted for separately. The adoption of EITF 00-21 on July 1, 2003 did not have any impact on the financial position or the results of operations of the Company.

SFAS 146, "Accounting for Costs Associated with Exit or Disposal Activities", addresses the costs associated with an exit activity (including restructuring). The Company will account for any future exit or disposal activities after December 31, 2002 under SFAS 146.

SFAS 148, "Accounting for Stock-based Compensation – Transition and Disclosure", amends SFAS 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. Since the Company plans to continue to use APB 25 to account for stock options issued to employees and directors, this portion of SFAS 148 will not have any impact on the financial position or the results of operations of the Company. SFAS 148 also amends the disclosure requirements of SFAS 123 to require additional disclosure in both annual and interim financial statements on the method of accounting for stock-based employee compensation. The Company adopted the disclosure provisions of SFAS 148 as of December 31, 2002.

FIN 46, "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51," requires companies to consolidate certain types of variable interest entities. A variable interest entity is an entity that has inadequate invested equity at risk to meet expected future losses, or whose holders of the equity investments lack any of the following three characteristics: (i) the ability to make decisions about the entity's activities; (ii) the obligation to absorb the entity's losses if they occur; (iii) the right to receive the entity's future returns if they occur. The provisions of the interpretation are effective for financial statements issued for the first period ending after December 15, 2003, or March 15, 2004, depending on the nature of the variable interest entity. The Company does not expect the adoption of FIN46 to have any impact on the financial position or results of operations of the Company.

2. Marketable Investments

Marketable investments consist of held-to-maturity investments and are stated at amortized cost, which approximates estimated fair value. Short-term marketable investments at December 31, 2002 and 2003 are summarized as follows:

	2002	2003
Corporate notes	$4,458,921	$23,362,898
Certificates of deposit	3,080,587	—
	$7,539,508	$23,362,898

Long-term marketable investments of $37,819,837 as of December 31, 2003 consisted of government agencies and corporate notes that mature between June and September of 2005.

	2002	2003
Corporate notes	—	$ 8,040,660
Government agencies	—	29,779,177
	$ 0	$37,819,837

3. Inventories

Inventories at December 31, 2002 and 2003 are summarized as follows:

	2002	2003
Raw materials and supplies	$ 89,757	$ 348,087
Work in process	520,092	593,028
Finished products	1,169,564	6,496,435
	$1,779,413	$7,437,550

4. Accrued Expenses

Accrued expenses at December 31, 2002 and 2003 are summarized as follows:

	2002	2003
Product development commitments	$1,717,380	$11,056,023
Bonuses	1,540,439	2,140,595
Product return accrual	1,109,913	1,484,638
Lease accrual	415,309	251,011
Retirement plan accruals	1,185,039	1,572,626
Product administrative fee accrual	—	1,080,215
Other accrued expenses	2,463,366	4,047,237
	$8,431,446	$21,632,345

5. Leases

We lease office space under noncancellable lease agreements that contain renewal options and require us to pay operating costs, including property taxes, insurance and maintenance. In 2001, we executed a lease agreement for new office space. At December 31, 2003, we have an accrual of $251,011 for lease obligations through July 2005 for the former office space in excess of estimated sublease rental income. Rent expense was $2,233,988, $1,205,027 and $1,436,167 in 2001, 2002 and 2003, respectively.

Gross future minimum lease payments under non-cancellable leases, including both the current and former office spaces, are as follows:

2004	$1,859,000
2005	1,733,000
2006	1,461,000
2007	1,483,000
2008	622,000
Thereafter	—
Subtotal	$7,158,000
Less: Expected receipts on sublease	(482,000)
Net lease obligations	$6,676,000

6. Licensing Arrangements

Technology Out-License Arrangements

During 1995, we entered into a cooperative development and commercialization agreement with Dainippon Pharmaceutical Co., Ltd., whereby we granted Dainippon an exclusive license to develop and commercialize

acylfulvenes, including irofulven, in Japan. Dainippon granted us an irrevocable, exclusive, royalty-free license allowing us to use any technology or data developed by Dainippon relating to the acylfulvenes. In 2003, we agreed with Dainippon Pharmaceutical Co. Ltd. to terminate their license to develop and commercialize the acylfulvenes in Japan effective August 2003. We repaid $4.3 million of deposit payments in cash in August 2003. Since we have no obligations to Dainippon after termination, we amortized $7,141,972 of deferred revenue into licensing revenue during 2003 related to the previously received non-refundable payments, of which $6,867,280 was recognized in the third quarter of 2003.

Under a November 1994 license agreement with Pharmacia Corporation, we granted an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Canada. Pharmacia granted us an irrevocable, non-exclusive, royalty-free license allowing us to use any technology or data developed by Pharmacia. Pharmacia paid us a $75,000 initial fee and agreed to pay us royalties equal to a percentage of Pharmacia's net Salagen Tablet sales revenues, subject to annual minimum requirements. We also agreed to supply Pharmacia's requirement of Salagen Tablets until the termination of the license agreement with Pharmacia. In addition, we agreed to pay Pharmacia royalties if we promote Salagen Tablets in Canada in the first or second year following termination of the agreement. After the initial commercial period concludes in January 2004, either party may terminate the agreement upon one year prior written notice. The agreement automatically expires in January 2006 unless extended by the parties.

In December 1994, we entered into a license agreement with Kissei Pharmaceutical Co., Ltd., a pharmaceutical company in Japan. Under the terms of the agreement, we granted an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Japan. Kissei granted back to us an irrevocable, non-exclusive, royalty-free license allowing us to use any technology or data developed by Kissei related to Salagen Tablets. Kissei paid us an initial license fee and subsequent milestone payments that aggregated to $2.5 million through December 31, 2002. There are no additional milestone payments due under the agreement. In addition, Kissei agreed to pay us royalties equal to a percentage of Kissei's Salagen Tablets net sales revenue. An application for marketing approval by the regulatory authorities in Japan for the initial indication of Salagen tablets was submitted by Kissei in 2003. A decision is pending. Unless earlier terminated by the parties for cause or by mutual agreement, the term of the agreement is for ten years from the date sales of Salagen Tablets begin in Japan. Thereafter, the agreement automatically renews for additional one-year periods.

In April 2000, we entered into a license agreement with Novartis Ophthalmics AG under which we granted Novartis an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Europe, Russia and certain other countries. Novartis granted us an irrevocable, non-exclusive, royalty-free license allowing us to use any technology developed by Novartis related to Salagen Tablets. In addition, we simultaneously entered into a supply agreement with Novartis pursuant to which we agreed to supply Novartis' requirements of Salagen Tablets until termination of the license agreement with Novartis. The term of the license agreement is 12 years and is thereafter automatically extended for additional two-year terms unless otherwise terminated in writing by either party. Either party may terminate the license agreement for cause. In addition, Novartis may terminate the license agreement if the supply agreement is terminated and Novartis has not been supplied with Salagen Tablets for a period of more than 180 days. A $750,000 license fee was received in June 2000 upon receipt of regulatory qualification for Novartis to sell the product in the UK, and an additional $750,000 license fee was received in April 2001 upon satisfaction of certain regulatory approvals or transfers. These amounts are being amortized to licensing revenue over the 12-year term of the agreement. The agreement includes milestone payments which are due if certain annualized and cumulative net sales thresholds are achieved. Royalty payments, based on a percentage of net sales revenue, continue for the term of the agreement.

Technology In-License Arrangements

To build our product pipeline, we acquire rights to develop and market pharmaceutical products from others. Under this approach, we may be required to pay up-front, development services and milestone fees. In addition, we may be required to pay royalties on net sales upon marketing the products. Within a period of time after

providing notice, we generally may terminate the licenses. All material, non-cancellable commitments were recognized as of December 31, 2003.

In August 2000, we entered into a License, Research and Development Agreement (the "License Agreement") and a Stock Purchase Agreement (the "Purchase Agreement") with MethylGene Inc. Under the Purchase Agreement, we purchased a minority investment in MethylGene for $3.8 million and made an additional purchase of MethylGene shares for $3.0 million in April 2001. Under the License Agreement, MethylGene granted us an exclusive, royalty-bearing license to develop and commercialize MG98 in North America for all therapeutic indications. The License Agreement also included a license for similar rights to small molecule inhibitors of DNA methyltransferase. In exchange, we agreed to make initial payments to MethylGene aggregating $5.7 million and agreed to purchase up to $6 million of research services from MethylGene. In a December 2003 amendment to the License Agreement, MethylGene acknowledged full satisfaction of these payment obligations and suspended further payment obligations by us pending a planned June 2004 data review of the small molecule inhibitor program and following completion by MethylGene of a planned clinical trial with MG98. If we resume development, milestone payments are payable to MethylGene based on achievement of development milestones for MG98 and small molecule inhibitor programs. We also agreed to pay royalties on annual net sales revenue related to MG98 and small molecule inhibitors of methyltransferase. The term of the License Agreement extends until the later of the expiration of the last-to-expire patent that we have licensed or ten years after the first commercial sale of any licensed product. Either party may terminate the License Agreement in the event of a breach or bankruptcy by the other party. We may terminate the agreement on a licensed-product-by-licensed-product basis for any reason on 90 days notice to MethylGene.

In January 2001, we entered into an agreement with Barr Laboratories, Inc. for the exclusive marketing and distribution rights for Mylocel™ Tablets (hydroxyurea) in the United States. Mylocel Tablets are approved for the treatment of melanoma, resistant chronic myelocytic leukemia, and recurrent, metastatic, or inoperable carcinoma of the ovary. We began marketing and distributing Mylocel Tablets in March 2001. Under the terms of the agreement, Barr Laboratories receive royalty payments based upon the product contribution derived from our sales of Mylocel Tablets. We terminated this agreement effective April 2002.

In April 2001, we obtained the exclusive U.S. and Canadian oncology license and distribution rights for Aloxi injection from Helsinn Healthcare SA. Aloxi injection is a unique 5-HT_3 antagonist and at that time was being developed for the prevention of CINV. Aloxi was approved for marketing by the FDA on July 25, 2003. Our $11 million upfront obligation was satisfied through a $5 million deposit made upon the execution of the letter of intent in October 2000, $3 million in cash paid in April 2001, and $3 million of our common shares delivered in April 2001. All time-based or performance milestone payments related to Helsinn's development of Aloxi injection for the prevention of CINV were cash payments as follows: $2 million in October 2001, $4 million in April 2002, $10 million in December 2002 and $11 million in August 2003.

In November 2003, we expanded our exclusive United States and Canada license agreement for Aloxi injection to include the prevention of PONV application, an oral Aloxi formulation and extend the term through December 31, 2015 for all of our rights under the expanded agreement. Under the terms of this amendment, we made initial payments to Helsinn totaling $22.5 million and we expect to make additional payments totaling $25 million over the course of the next several years upon achievement of certain development milestones that culminate with the approvals in the United States of Aloxi injection for the prevention of PONV and an oral Aloxi formulation. We will also pay royalties and product supply fees based upon net sales. Helsinn will continue to fund and conduct all development of Aloxi injection for the prevention of PONV and oral Aloxi formulation, and will supply finished product for commercialization.

7. Convertible Debt

In December 2002, we issued $21 million of 3.0 percent convertible subordinated notes due December 1, 2007. These notes and the associated warrants were fully converted and exercised in the first quarter of 2004 (see Note 17 to the financial statements). Interest was payable semi-annually on June 1 and December 1 of each year, commencing on June 1, 2003. The notes were convertible into 2,571,428 shares of our common stock, at the option of the holder, in three tranches with conversion prices of $7.00 per share (1,428,570 shares), $8.75 per share (571,428 shares) and $10.50 per share (571,430 shares), for a weighted average conversion price of $8.17 per share.

In addition, we issued warrants (See Note 9 to the financial statements), for purchase during the five-year period of the agreement of up to 400,000 shares of our common stock at exercise prices of $8.75 per share (200,000 shares) and $10.50 per share (200,000 shares). The total value of the warrants, along with the debt issuance costs, was being amortized to interest expense over the 5-year term of the convertible debt.

Convertible debt, which is stated at face value less issuance costs and value of warrants, at December 31, 2002 and 2003, is summarized as follows:

	2002	2003
Convertible notes	$21,000,000	$21,000,000
Warrants value	(1,659,838)	(1,322,244)
Issuance costs	(49,013)	(39,044)
	$19,291,149	$19,638,712

8. Stockholder Rights Plan

Each outstanding share of our common stock has one preferred share purchase right (Right). Each Right entitles the registered holder to purchase one one-hundredth of a share of Series A Junior Participating Preferred Stock, at a price of $200 per one-hundredth of a preferred share (subject to adjustment). The Rights become exercisable only if certain change in ownership control events occur and we do not redeem the Rights. The Rights expire on July 14, 2008, if not previously redeemed or exercised.

9. Stockholders' Equity

Stock Offerings

In May 2001, we completed a sale of 4,000,000 newly issued shares of common stock to U.S. Bancorp Piper Jaffray Inc., which were offered at a price of $8 per share. Our net proceeds, after fees and expenses, were $29,168,655.

In October 2001, we completed a private placement of 3,025,000 newly issued shares of common stock to accredited investors at $11 per share. Our net proceeds, after fees and expenses, were $31,116,962.

In November 2001, we completed a sale of 900,000 newly issued shares of common stock to U.S. Bancorp Piper Jaffray Inc., which were offered at a price of $13.25 per share. Our net proceeds, after fees and expenses, were $11,831,843.

In August 2003, we completed a sale of 5,060,000 newly issued shares of common stock in a follow-on public offering at $35.50 per share. Our net proceeds, after fees and expenses, were $168,581,477.

Stock Incentive Plans

Under stock incentive plans, designated persons (including officers, employees, directors and consultants) have been or may be granted rights to acquire our common stock. These rights include stock options and other equity rights. At December 31, 2003, shares issued and shares available under stock incentive plans are as follows:

	Shareholder Approved Plans	Other Plans	Total For All Plans
Shares issuable under outstanding options	4,325,174	26,063	4,351,237
Shares available for future issuance	395,466	—	395,466
Total	4,720,640	26,063	4,746,703
Average exercise price for outstanding options	$ 16.03	$ 9.58	$ 16.00

Stock options become exercisable over varying periods and expire up to ten years from the date of grant. Options may be granted in the form of incentive stock options or nonqualified stock options. The option price for incentive stock options cannot be less than fair market value on the date of the grant. The option price for nonqualified stock options may be set by the board of directors.

Stock option activity in the three years ended December 31, 2003 is summarized as follows:

	Number of Shares	Average Price Per Share
Outstanding at December 31, 2000	2,263,766	$11.48
Granted	1,373,919	13.47
Exercised	(175,885)	4.91
Canceled	(77,472)	17.27
Outstanding at December 31, 2001	3,384,328	12.49
Granted	866,721	7.98
Exercised	(16,475)	5.68
Canceled	(105,337)	14.54
Outstanding at December 31, 2002	4,129,237	11.52
Granted	1,586,099	22.33
Exercised	(1,227,322)	9.36
Canceled	(136,777)	14.01
Outstanding at December 31, 2003	4,351,237	$16.00

The following table summarizes information concerning options outstanding and exercisable at December 31, 2003:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$3.38-$7.10	397,023	4.99	$ 5.31	281,526	$ 4.70
$7.30	525,225	8.43	$ 7.30	102,975	$ 7.30
$7.34-$10.25	720,536	7.71	$ 9.22	220,268	$ 9.88
$10.33-$16.16	562,415	7.04	$13.57	285,504	$12.30
$16.29-$16.44	331,655	6.04	$16.44	224,129	$16.44
$16.69-$16.75	495,932	7.00	$16.75	211,904	$16.75
$17.13-$25.58	193,800	8.15	$19.56	46,563	$21.80
$25.84-$26.61	809,508	9.55	$26.60	2,625	$26.04
$26.90-$51.50	315,143	8.24	$32.68	93,401	$32.85
Total	4,351,237		$16.00	1,468,895	$10.57

Employee Stock Purchase Plan Under our employee stock purchase plan, substantially all employees may purchase shares of common stock at the end of semi-annual purchase periods at a price equal to the lower of 85 percent of the stock's fair market value on the first or last day of that period. Plan funding occurs throughout the purchase period by pre-elected payroll deductions of up to 15 percent of regular pay. No compensation expense results from the plan under APB 25. Shares issued under the plan were 45,457, 106,561 and 72,712 at average prices of $10.43, $5.70 and $10.50 per share in 2001, 2002 and 2003, respectively. At December 31, 2003, 77,171 shares remain reserved for future issuance under the plan.

Retirement Plan Participation in our retirement plan is available to substantially all employees. Participants may elect to contribute a percentage of their eligible compensation consistent with Section 401(k) of the Internal Revenue Code and we make contributions that are a portion of participant contributions and a percentage of their eligible compensation. In addition, we may make discretionary contributions ratably to all eligible employees. Our contributions are made in cash or our common stock and become fully vested when a participant attains five years of service. Participants may direct investment of contributions into any of the plan's investment alternatives, but contributions made in the form of our common stock must be fully vested before redirection can occur. Total retirement plan contribution expense was $1,204,388, $1,506,874 and $1,969,704 in 2001, 2002 and 2003, respectively, of which $836,507, $949,381 and $1,291,954 was made in our common stock in 2001, 2002 and 2003, respectively. We had 502,238 shares reserved for future issuance under the retirement plan at December 31, 2003.

Preferred Stock At December 31, 2003, 10,000,000 shares of preferred stock remained issuable. Issuance is subject to action by our board of directors.

Warrants In conjunction with the issuance of convertible debt (See Note 7 to the financial statements), the Company issued warrants to purchase 400,000 shares of common stock. Warrants to purchase 200,000 shares of common stock are exercisable at $8.75 per share and warrants to purchase an additional 200,000 shares are exercisable at $10.50 per share. At December 31, 2003, warrants to purchase 400,000 shares of common stock were outstanding and in February 2004 the warrants were fully exercised (see Note 17 to the financial statements).

Restricted Stock On June 24, 2002, we issued 35,487 shares of restricted common stock to certain non-executive officer employees. One-half of these shares vested one year after the date of grant, and the remainder of these

shares vest in two years after the date of grant, given continued employment through the vesting dates. We recognize compensation expense for the market value ($6.90 per share) of the shares at the date of grant over the vesting periods. As of December 31, 2003, 2,005 shares have been cancelled, 18,899 shares vested (of which, 3,634 were subsequently cancelled for employee tax withholding) and 14,583 shares vest on June 24, 2004.

10. Income Taxes

The provision for income taxes differs from statutory federal income tax rate of 35 percent in the years ended December 31, 2001, 2002 and 2003 as follows:

	2001	2002	2003
Statutory federal income tax rate	($12,188,863)	($12,622,327)	($21,667,626)
Valuation allowance change	14,248,690	17,731,938	21,941,710
Research activities credit	(791,797)	(477,636)	(906,187)
Orphan drug credit	(1,868,469)	(5,436,649)	(573,675)
State income taxes, net of federal benefit	(870,633)	(649,148)	(1,114,335)
Nondeductible items	—	196,725	370,487
Net operating loss expiration	1,193,570	334,127	1,752,739
Other	277,502	922,970	196,887
	$ 0	$ 0	$ 0

Deferred taxes as of December 31, 2002 and 2003 consist of the following:

	2002	2003
Deferred tax assets:		
Receivable allowances	$ 40,213	$ 94,820
Inventory allowances	6,163	6,163
Product return allowance	408,448	546,347
Miscellaneous accrued expenses	399,486	237,924
Deferred revenue	3,616,786	898,380
Amortization of intangibles	543,710	804,691
Net operating loss carryforward	55,203,486	86,676,863
Research credit carryforward	3,870,014	4,776,201
Orphan drug credit	9,420,383	9,994,058
Long term equity impairment	—	1,160,653
Alternative minimum tax credit carryforward	100,270	100,270
	73,608,959	105,296,370
Less valuation allowance	(73,337,567)	(105,147,086)
	$ 271,392	$ 149,284
Deferred tax liabilities:		
Tax depreciation greater than book	$ 271,392	$ 149,284

We maintain a valuation allowance to almost fully reserve against our deferred tax assets due to uncertainty over the ability to realize these assets. As of December 31, 2002 and December 31, 2003, the valuation allowances were $73,337,567 and $105,147,086, respectively. Of these amounts, $4,852,125 as of the year ended December 31, 2002, and $14,719,932 as of the year ended December 31, 2003, were attributable to increases in the net operating loss carryover resulting from the exercise of stock options. These amounts will be recorded as an increase to additional paid-in capital if it is determined in the future that this portion of the valuation allowance is no longer required.

At December 31, 2003, the expiration dates and amounts of our carryforward losses and credits for federal income tax purposes are as follows:

Years Expiring	Net Operating Losses	Research Credits	Orphan Drug Credits
2004-2006	$ 15,336,657	$ 729,858	$ —
2007-2011	40,556,469	1,115,937	512,875
2012-2016	52,733,546	183,577	222,155
2017-2023	126,908,282	2,746,829	9,259,028
	$235,534,954	$4,776,201	$9,994,058

We also had a credit for alternative minimum tax of $100,270, which has no expiration date.

The utilization of the Company's net operating losses and credits is potentially subject to annual limitations under the ownership change rules of Internal Revenue Code Sections 382 and 383. Subsequent equity changes could further limit the utilization of these net operating losses and credits.

11. Loss Per Common Share

Loss per common share for the years ended December 31, 2001, 2002 and 2003 is based on weighted average shares outstanding as summarized in the following table:

	Year Ended December 31,		
	2001	2002	2003
Weighted-average shares—basic	19,985,192	25,110,023	27,777,860
Effect of dilutive stock options	—	—	—
Effect of convertible debt	—	—	—
Weighted-average shares—assuming dilution	19,985,192	25,110,023	27,777,860

Potentially dilutive securities, excluded from the calculation because their inclusion in a calculation of net loss per common share would have been anti-dilutive, include options of 3,384,328, 4,129,237 and 4,351,237 for 2001, 2002 and 2003, respectively, and convertible debt and warrants of 2,971,428 and 2,971,428 in 2002 and 2003, respectively. (See Note 7 to the financial statements).

12. Related Party Transactions

One of our directors, who became a director in May 1998, is the managing partner of Boston Healthcare Associates, a biotechnology consulting firm. We made payments to Boston Healthcare of $101,000 in 2001. Transactions with Boston Healthcare were in the ordinary course of business at prices comparable to transactions with other companies.

13. Segment and Geographical Information

We operate in a single operating segment of specialty pharmaceuticals. Essentially all of our assets are located in the United States. Revenues attributable to the U.S. and foreign customers in the years ended December 31, 2001, 2002 and 2003 are as follows:

	2001	2002	2003
United States	$30,573,044	$25,690,947	$39,907,124
Europe	681,446	797,804	829,266
Japan	701,033	680,029	7,354,804
Other foreign	998,297	1,034,709	1,293,859
	$32,953,820	$28,203,489	$49,385,053

Other foreign areas include Australia, Canada, Colombia, Egypt, Hong Kong (Peoples' Republic of China), Israel, Korea, Singapore, Malaysia and Taiwan.

14. Product Acquisition

On November 21, 2000, we acquired certain assets and assumed certain liabilities related to the business associated with the product Hexalen capsules from MedImmune Oncology, Inc. The $7,091,869 excess of the $7.2 million purchase price over the $108,130 fair value of the net assets acquired was allocated to intangible assets. Under the terms of the agreement, royalties are due to MedImmune on quarterly net sales of Hexalen capsules for a period of ten years. Royalties of $392,914, $342,589 and $418,205 were included in Hexalen cost of sales in 2001, 2002 and 2003, respectively.

15. Research and Development Expense

Research and development expense for the years ended December 31, 2001, 2002 and 2003 consists of the following:

	2001	2002	2003
License payments	$13,066,250	$14,050,000	$31,321,000
Other research and development	23,035,123	18,163,635	18,799,596
	$36,101,373	$32,213,635	$50,120,596

16. Reduction in Workforce

To reduce costs, we reduced our workforce by approximately 10 percent, or 19 positions, in the second quarter of 2002. We recognized total expense of $1,291,044 for this reduction, consisting of $1,076,300 for severance payments, and $214,744 for extending the terms of selected stock option awards. The total expense was allocated as follows: $775,278 to research and development expense and $515,766 to selling, general and administrative expense based on the positions held by the terminated employees. These severance obligations were completely paid during 2003.

17. Subsequent Events

On January 5, and February 6, 2004, an aggregate of 2,571,428 shares of our common stock were issued to Deerfield International Limited and Deerfield Partners, L.P. pursuant to their election to, first partially and then fully, convert our 3% convertible subordinated notes issued in December 2002 for gross proceeds of $21 million. Also on February 6, 2004, the common stock purchase warrants that were issued in connection with that December 2002 financing were exercised. We received $3,850,000 upon the exercise of the warrants and issued 400,000 common shares.

INDEPENDENT AUDITORS' REPORT

The Board of Directors and Shareholders
MGI PHARMA, INC.:

We have audited the accompanying balance sheets of MGI PHARMA, Inc. as of December 31, 2002 and 2003, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2003. These financial statements 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 of America. 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 financial position of MGI PHARMA, Inc. as of December 31, 2002 and 2003, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

/s/KPMG LLP

Minneapolis, Minnesota
February 6, 2004

The remainder of the Form 10-K has been omitted.

The entire 10K is available without charge at www.mgipharma.com or upon written request to:

MGI PHARMA, INC.
Investor Relations
5775 West Old Shakopee Road
Suite 100
Bloomington, MN 55437-3174

Shareholder information

MOGN NASDAQ LISTED

Market price and related matters

MGI PHARMA, INC.'s common stock trades on The Nasdaq National Market System under the symbol "MOGN." MGI PHARMA has not paid cash dividends on its common stock and has no present intention of paying cash dividends on its common stock.

The following table lists the high and low trading prices for MGI PHARMA common stock as reported by The Nasdaq Stock Market® during the quarters listed. Prices represent transactions between dealers and do not reflect retail markups, markdowns, or commissions, and may not necessarily represent actual transactions.

Stock price range

2002	High	Low
First Quarter	$17.05	$12.88
Second Quarter	14.75	6.01
Third Quarter	8.74	4.68
Fourth Quarter	9.40	5.84

2003	High	Low
First Quarter	$12.99	$ 6.85
Second Quarter	29.50	11.50
Third Quarter	43.12	24.95
Fourth Quarter	42.50	33.09

Independent auditors

KPMG LLP
Minneapolis, Minnesota

Legal counsel

Dorsey & Whitney LLP
Minneapolis, Minnesota

Annual meeting

The Annual Meeting of Shareholders will be held on Tuesday, May 11, 2004 at 1:00 p.m. at the Radisson Minneapolis, 35 South 7th Street, Minneapolis, Minnesota.

For MGI PHARMA information

Shareholders and prospective investors seeking information about MGI PHARMA should contact MGI PHARMA's Investor Relations Department at 952-346-4734, or visit the Company's Web Site at www.mgipharma.com.

Transfer agent and registrar

Shareholder inquiries relating to shareholder records, stock transfer, ownership changes, address changes, and lost certificates should be directed to:
Mail: Wells Fargo Bank, N.A.
Shareowner Services
P.O. Box 64854
St. Paul, Minnesota 55164-0854
Web site: www.wellsfargo.com/com/shareowner_services
Phone: 800-468-9716
Fax: 651-450-4033

Form 10K

A copy of MGI PHARMA's Annual Report to the Securities and Exchange Commission on Form 10-K is available without charge at www.mgipharma.com or upon written request to:
MGI PHARMA, INC.
Investor Relations
5775 West Old Shakopee Road, Suite 100
Bloomington, Minnesota 55437-3174

Patient and physician information

Patients and health care providers seeking information on MGI PHARMA clinical trials may call MGI PHARMA toll free at 1-800-562-5580 and press 1 to access our Medical Communications Help Line. In addition, for information about irofulven trials sponsored by the National Cancer Institute call their Cancer Information Service at 1-800-4-CANCER (TTY 1-800-332-8615).

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