

2000 Annual Report



Product Portfolio

Therapeutic Area:



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.



Second-line therapy for patients with ovarian cancer.

MYLOCEL hydroxyurea

For the treatment of melanoma, resistant chronic myelocytic leukemia (CML), and recurrent, metastatic, or inoperable carcinoma of the ovary. Also used in combination with radiation therapy for certain head and neck cancers.

For the treatment of hypercalcemia (elevated blood calcium) in latestage cancer patients.

Commercialized Products:

SALAGEN® TABLETS
Head and neck cancer

Sjögren's syndrome

HEXALEN® CAPSULES

MYLOCEL™ TABLETS

DIDRONEL® IV INFUSION

PALONOSETRON

Palonosetron, a selective 5-HT $_3$ antagonist with an extended half-life, is a late-stage supportive care product candidate, currently under development for the prevention of chemotherapy-induced nausea and vomiting.

Irofulven (hydroxymethylacylfulvene) currently is being tested in a series of clinical trials for the treatment of a variety of cancers. Irofulven has demonstrated anti-tumor activity as a single agent in clinical testing against pancreatic, ovarian and prostate cancers. In 2001, irofulven will be advanced further in a series of single agent and combination therapy trials for other tumor targets.

In addition to irofulven, other acylfulvene analogs are being evaluated to determine their potential as anti-cancer drugs. A group of analogs has progressed through activity screens and is entering further preclinical testing.

MG98, a second-generation anti-sense compound, and its complementary small molecule DNA methyltransferase (Metase) inhibitors are under development for anti-cancer activity. Both programs represent different approaches to targeting the same nuclear enzyme and have the potential to treat a wide variety of tumor types.

IROFULVEN

Pancreatic-advanced
Pancreatic-alternate dosing

Ovarian-advanced

Ovarian-recurrent*

Prostate-hormone refractory

Breast-metastatic*

Endometrial*

Liver - inoperable

Childhood solid tumors*

Leukemias*

Advanced solid tumors –

weekly dosing

Combination with Camptosar®

ACYLFULVENE ANALOGS

MG98

Solid tumors

Head and neck cancer

DNA METASE INHIBITORS

^{*} Sponsored by the National Cancer Institute under a Clinical Trials Agreement

| PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | MARKET |
|-------------|---------|---------|---------|--------|
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Shareholder Information

About the Company

MGI PHARMA, INC. is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that meet patient needs and build shareholder value.

The Company recently initiated a pivotal Phase 3 clinical trial to evaluate its promising anti-cancer drug candidate, irofulven, in pancreatic cancer patients. MGI is developing irofulven through a series of human clinical trials, where it has demonstrated notable anti-cancer activity against a variety of cancers. MGI anticipates that this Phase 3 trial could serve as the basis for regulatory approval of irofulven for commercial sale in the United States. Irofulven is the first product selected for development from the acylfulvenes, MGI's proprietary family of naturally derived oncology compounds.

Irofulven's potential for treating cancer is serving as MGI's springboard for building a balanced portfolio of oncology products. In addition to expanding the development of irofulven, during the past year the Company also acquired a portfolio of additional anti-cancer compounds – two marketed oncology drugs: Hexalen® Capsules and Mylocel™ Tablets;

a Phase 2 trial product: MG98; a complementary preclinical program: small molecule DNA methyltransferase inhibitors; and a second Phase 3 trial product: palonosetron. MGI will continue to expand and balance its oncology product portfolio, with a preference toward later-stage and on-the-market products that satisfy unmet cancer patient needs. Revenues are currently generated from MGI's commercial products, particularly Salagen® Tablets. Raising additional capital will also fund future acquisitions and development of the portfolio.

MGI develops its anti-cancer drug candidates with a proven research and development team and promotes its marketed products with a highly experienced, dedicated sales organization that specializes in oncology. MGI focuses its sales efforts in the United States and collaborates with partners to market its products internationally.

MGI PHARMA is based in Minneapolis, Minnesota, and its common stock is traded on The Nasdaq Stock Market® under the symbol "MOGN."



minute. Despite recent advances made in the treatment of this devastating disease, cancer remains one of the largest underserved medical markets.

To help address the vast unmet needs of cancer patients, MGI PHARMA is building a balanced product portfolio of proprietary pharmaceuticals, and intends to become a leader in oncology. We are striving to make a positive difference in the lives of cancer patients.

Irofulven

A promising new compound with a unique mechanism of action to potentially treat a variety of cancers.



Irofulven is MGI's most promising anti-cancer drug, the first to be developed from the acylfulvenes, our proprietary family of naturally derived oncology compounds. Irofulven exhibits a unique mechanism of action compared to current anti-cancer drugs, leading to an apoptotic or programmed cell death of the tumor. MGI is evaluating irofulven through a series of human clinical trials, where it has demonstrated promising anti-tumor activity against a variety of cancers. This development program includes Phase 1 trials designed to evaluate the safety and maximum tolerated dose using different dosing schedules, as well as Phase 2 trials designed to evaluate the efficacy of irofulven in specific types of cancer. Based on results to date from a series of Phase 2 trials, we believe that irofulven is well tolerated as a chemotherapeutic, and worthy of further clinical exploration in a number of cancers, including pancreatic, ovarian and prostate.

In 2000, MGI selected pancreatic cancer as the first tumor target in its registration strategy for irofulven. In February 2001, we initiated a pivotal Phase 3 trial, designed as a randomized, 300-patient, multi-center, international trial, in which irofulven is tested in advanced-stage, pancreatic cancer patients who have failed gemcitabine, the current standard-of-care therapy. This Phase 3 trial could serve as the basis for regulatory approval

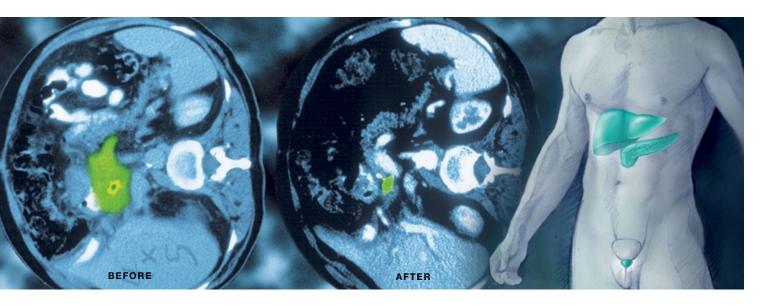
of irofulven in the United States and Europe. With full enrollment targeted to occur in the third quarter of 2002, MGI could file a New Drug Application with the FDA in 2003.

Our optimism for continued development of irofulven is fueled by the greatly improved patient tolerance achieved with a new weekly dosing schedule. This increases the likelihood of delivering clinically meaningful amounts of irofulven in future trials and improves the already promising prospects for clinical benefit with irofulven across a number of cancers.

Another benefit of the once-a-week dosing schedule is the convenience of administering irofulven in combination with existing chemotherapeutics. MGI is currently studying the treatment of solid tumors with irofulven in combination with Camptosar® In 2001, irofulven will be advanced in additional drug combination therapy trials, in addition to its expanded development as a single agent.

As the exclusive worldwide licensee, MGI intends to retain U.S. commercial rights to irofulven, while seeking commercialization partners for the major international markets. In Japan, we have already secured Dainippon Pharmaceutical Company Ltd. as our partner. We anticipate the addition of a European partner sometime in 2001.

| IROFULVEN | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | MARKET |
|---|-------------|---------|---------|---------|--------|
| Pancreatic-advanced Pancreatic-alternate dosing | | | | | |
| Ovarian-advanced Ovarian-recurrent* | | | | | |
| Prostate-hormone refractory Breast-metastatic* Endometrial* | | | | | |
| Liver – inoperable Childhood solid tumors* | | | | | |
| Leukemias* Advanced solid tumors – | | | | | |
| weekly dosing Combination with Camptosar® | | | | | |
| ACYLFULVENE ANALOGS | | | | | |



Before and After: Irofulven-induced tumor reduction over six months in a patient with gemcitabine-refractory pancreatic cancer.

ACYLFULVENE ANALOGS

Beyond irofulven, MGI is developing other acylfulvene analogs, which are different molecules within the acylfulvene class of anti-cancer compounds. A group of analogs has already progressed through activity screens and is entering further preclinical testing. MGI has broad, worldwide patent protection for the acylfulvene class of compounds, including irofulven.

^{*}Sponsored by the National Cancer Institute under a Clinical Trials Agreement

Palonosetron

A supportive care product in Phase 3 development for the prevention of chemotherapy-induced nausea and vomiting.

PALONOSETRON

PRECLINICAL P

PHASE 1 PHAS

PHASE 3

MARKET



Palonosetron is a selective 5-HT₃ antagonist with an extended half-life that is well advanced in a multi-national Phase 3 program for the prevention of chemotherapy-induced nausea and vomiting (CINV). In early 2001, MGI procured exclusive North American license and distribution rights to palonosetron from Helsinn Healthcare SA, of Lugano, Switzerland. The results from the current Phase 3 trials are expected to become the basis for regulatory approval in North America and elsewhere. Enrollment goals for the Phase 3 trials could allow for a New Drug Application submission to the FDA in the first half of 2002.

Chemotherapy-induced nausea and vomiting is estimated to occur in 85 percent of cancer patients treated with chemotherapies and can result in delay or even discontinuation of treatment. The advent of 5-HT₃ antagonists has revolutionized the management of nausea and vomiting experienced by cancer

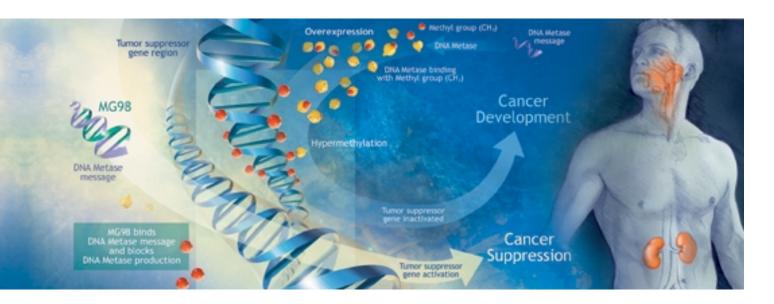
patients undergoing chemotherapy. When launched, palonosetron will compete in the \$1 billion North American CINV market.

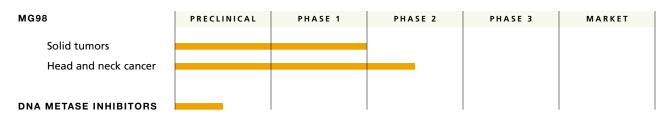
In Phase 2 trials, palonosetron exhibited an extended period of activity with a single dose. This provides the opportunity to evaluate the potential of palonosetron to prevent CINV beyond the usual acute, 24-hour period following the start of chemotherapy. The current Phase 3 program with palonosetron began in April 2000 and is expected to enroll 1,900 patients in several well-controlled, double-blind active comparator trials at approximately 80 centers in North America and Europe. Based on the extended half-life of palonosetron and the results of the Phase 2 trial, its efficacy will be assessed over the second through fifth days following treatment, in addition to the primary efficacy measure of complete response during the 24-hour period after the start of chemotherapy.

In August 2000, MGI licensed North American rights to MG98 and a complementary small molecule, DNA methyltransferase (Metase) inhibitor program from MethylGene Inc., based in Montreal, Canada. We are developing MG98, a second-generation anti-sense compound, for the purpose of blocking expression and production of the nuclear enzyme, DNA methyltransferase. DNA methyltransferase inhibits the expression of genes that would otherwise slow or stop tumor growth. MG98 inhibits DNA methyltransferase overexpression, thus re-activating tumor suppressor genes. It has already demonstrated anti-cancer activity in an ongoing Phase 1 dose escalation trial.

MGI initiated a Phase 2 trial of MG98 in head and neck cancer patients in the fourth quarter of 2000, and intends to further evaluate MG98 in other cancers where silencing of tumor suppressor genes by DNA methyltransferase has been documented, such as tumors of the colon, kidney, breast and prostate. In preclinical models, MG98 used alone and in combination with other anti-cancer agents has caused shrinkage or inhibited growth of human tumors.

The small molecule, DNA methyltransferase inhibitor program, licensed along with MG98, shares the same goal of preventing methylation and silencing tumor suppressor genes. However, the small molecules are being screened for their potential to bind to DNA methyltransferase and block its activity, rather than prevent its production. Targeting the reexpression of silenced tumor suppressor genes at the molecular level is considered one of the most exciting new approaches for cancer therapeutics.





A second-generation anti-sense compound that targets an important nuclear enzyme and inhibits tumors.

MG98

Salagen® Tablets

The first prescription drug approved in the U.S. to treat the symptoms of dry mouth in head and neck cancer and Sjögren's syndrome patients.

| SALAGEN | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | MARKET |
|----------------------|-------------|---------|---------|---------|--------|
| Head and neck cancer | | | | | |
| | | | | | |
| Siögren's syndrome | | | | | |



MGI conceived, developed and continues to market Salagen® Tablets (pilocarpine hydrochloride) in the United States. Clinically-proven efficacy and time-proven safety allow Salagen Tablets to maintain a dominant presence in the treatment of chronic dry mouth symptoms associated with head and neck cancer patients treated with radiation, and with Sjögren's syndrome patients.

Salagen Tablets are 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.

When head and neck cancer patients receive radiation treatment, this therapy often damages the salivary glands and

diminishes their ability to produce moisture. When treatment is started at the beginning of radiation therapy, Salagen Tablets can stimulate the glands to generate more moisture. Salagen Tablets have become the standard of care for these patients.

Sjögren's syndrome is a chronic, inflammatory, autoimmune disease that, left untreated, can ultimately cause neurological, muscular and gastrointestinal disorders. It gradually damages the body's moisture-producing glands, including the salivary glands, causing patients to suffer significantly from the resulting dryness. Symptoms of the disease can include severe dry mouth, dry eyes, dry skin, and vaginal dryness, depending upon which moisture-producing glands are affected.

Outside the United States, MGI markets Salagen Tablets through its partners, Pharmacia Corporation in Canada and Novartis throughout Europe, where it has been approved to also treat dry eye symptoms associated with Sjögren's syndrome, in addition to the U.S.-approved indications.

Hexalen® Capsules (altretamine) are an orally administered chemotherapeutic agent approved in the United States for the treatment of ovarian cancer in patients with persistent or recurrent disease following first-line therapy with cisplatin and/or alkylating agent-based combination chemotherapy.

MGI purchased the worldwide rights to Hexalen Capsules from MedImmune, Inc. in November 2000.

Hexalen Capsules are an important product that has induced complete responses in patients refractory to first-line therapy and provides the convenience of oral dosing administration. In addition to near-term revenue potential, Hexalen provides an opportunity to enhance our sales and marketing organization's

experience within an area of oncology that overlaps with irofulven's development for ovarian cancer. MGI's sales organization began direct promotion of Hexalen Capsules to prescribing physicians in March 2001. We are providing the required attention to re-establish Hexalen as a prescribed second-line therapy against advanced, refractory ovarian cancer.

Ovarian cancer is the leading cause of gynecological cancerrelated deaths among American women. Recent early data, presented at the 2000 Annual American Society of Clinical Oncology Meeting, suggests that survival time is enhanced when patients who have achieved a clinical complete response with first-line therapy are treated with Hexalen Capsules.



HEXALEN PRECLINICAL PHASE 1 PHASE 2 PHASE 3 MARKET

Offers women with ovarian cancer another chance for response and prolonged survival.

Hexalen® Capsules

Mylocel[™] Tablets

A hydroxyurea tablet that offers simplified dosing for treating certain malignancies.

MYLOCEL

| PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | MARKET |
|-------------|---------|---------|---------|--------|
| | | | | |



Mylocel™ Tablets (hydroxyurea) are an anti-cancer agent indicated for the treatment of melanoma, resistant chronic myelocytic leukemia (CML), and recurrent, metastatic, or inoperable carcinoma of the ovary. It is also indicated for use in combination with radiation therapy for certain head and neck cancers. The U.S. market for all forms of hydroxyurea totals approximately \$20 million annually.

MGI gained the exclusive U.S. marketing and distribution rights for Mylocel Tablets from Barr Laboratories, Inc., in January 2001. MGI began marketing and distributing Mylocel Tablets, recently approved by the FDA, in the United States in March 2001.

Mylocel Tablets are the only triple-scored, 1000-mg. hydroxyurea tablet available, which allows for more accurate dosing in 250 mg. increments and offers the possibility of once daily dosing with a single tablet. Mylocel Tablets are designed to simplify drug therapy and enhance patient compliance by eliminating the larger number of doses patients would be required to ingest because the highest dosage strength previously available was 500 mg. Physicians who prescribe the product primarily include oncologists and hematologists. Mylocel Tablets are competitively priced to offer affordable simplicity and convenience for both the physician and the patient.

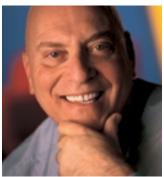
Financial Highlights

| Year Ended December 31, (in thousands, except per share data) | 1996 | 1997 | 1998 | 1999 | 2000 |
|---|-----------------|-----------------|------------|------------|------------|
| REVENUES | | | | | |
| Sales | \$ 6,460 | \$ 9,345 | \$12,945 | \$18,643 | \$ 21,333 |
| Promotion | 4 0, 100 | 4 3,3 13 | 756 | 1,088 | 770 |
| Licensing | 2,335 | 3,275 | 3,342 | 4,955 | 3,109 |
| Lectioning | 8,795 | 12,620 | 17,043 | 24,686 | 25,212 |
| | 3,755 | ,0_0 | ,0.15 | 2 1/000 | |
| COSTS AND EXPENSES | | | | | |
| Cost of sales | 678 | 768 | 939 | 1,209 | 1,627 |
| Selling, general and administrative | 7,659 | 9,339 | 10,989 | 12,713 | 18,295 |
| Research and development | 7,865 | 4,989 | 5,302 | 6,677 | 17,241 |
| Amortization | | | | - | 98 |
| | 16,202 | 15,096 | 17,230 | 20,599 | 37,261 |
| Income (loss) from operations | (7,407) | (2,476) | (187) | 4,087 | (12,049) |
| Interest income | 950 | 876 | 806 | 966 | 2,146 |
| Income (loss) before taxes and cumulative effect | | | | | |
| of change in accounting principle | (6,457) | (1,600) | 619 | 5,053 | (9,903) |
| Provision for income taxes | 165 | 185 | 205 | 321 | 148 |
| Net income (loss) before cumulative effect of change | | | | | |
| in accounting principle | \$(6,622) | \$ (1,785) | \$ 414 | \$ 4,732 | \$(10,051) |
| Cumulative effect of change in accounting principle | | | | - | (9,403) |
| Net income (loss) | \$(6,622) | \$ (1,785) | \$ 414 | \$ 4,732 | \$(19,454) |
| Net income (loss) per common share: | | | | | |
| Basic: | | | | | |
| Income (loss) before effect of accounting change | \$ (0.50) | \$ (0.13) | \$ 0.03 | \$ 0.32 | \$ (0.63) |
| Cumulative effect of accounting change | | | | - | (0.59) |
| Net income (loss) | \$ (0.50) | \$ (0.13) | \$ 0.03 | \$ 0.32 | \$ (1.22) |
| Assuming dilution: | | | | | |
| Income (loss) before effect of accounting change | \$ (0.50) | \$ (0.13) | \$ 0.03 | \$ 0.30 | \$ (0.63) |
| Cumulative effect of accounting change | - | _ | - | - | (0.59) |
| Net income (loss) | \$ (0.50) | \$ (0.13) | \$ 0.03 | \$ 0.30 | \$ (1.22) |
| Weighted average number of common shares outstanding | g: | | | | |
| Basic | 13,179 | 14,116 | 14,368 | 14,742 | 15,990 |
| Assuming dilution | 13,179 | 14,116 | 14,966 | 15,633 | 15,990 |
| | | | | | |
| December 31, (in thousands) | 1996 | 1997 | 1998 | 1999 | 2000 |
| BALANCE SHEET DATA | | | | | |
| Cash and short-term investments | \$17,888 | \$15,056 | \$17,081 | \$24,151 | \$29,899 |
| Working capital | \$15,820 | \$13,981 | \$16,096 | \$23,240 | \$26,042 |
| Total assets | \$20,163 | \$18,191 | \$21,122 | \$28,974 | \$52,744 |
| Total liabilities | \$ 3,796 | \$ 3,172 | \$ 4,011 | \$ 4,329 | \$26,698 |
| Accumulated deficit | \$(72,458) | \$(74,243) | \$(73,828) | \$(69,097) | \$(88,551) |
| Total stockholders' equity | \$16,367 | \$15,019 | \$17,111 | \$24,644 | \$26,046 |

Executive Message

2000 was yet another year of growth and transition for MGI PHARMA as we made substantial progress toward our very ambitious goals of building a balanced oncology product portfolio and establishing our company as a leader in oncology.







CHARLES N. BLITZER
President and
Chief Executive Officer

BUILDING A BALANCED ONCOLOGY PORTFOLIO

A fundamental step toward a first-rate oncology portfolio is optimizing the development of our current product candidates. Irofulven, the lead chemotherapy from our novel family of compounds called the acylfulvenes, is at the heart of our product portfolio enhancement plans. During 2000, we identified pancreatic cancer as the initial registration target for irofulven, with the help of our outside panel of oncology experts and discussions with the U.S. Food and Drug Administration. Given the large unmet medical need and the clear indications of irofulven activity in this area, we decided pancreatic cancer could provide the quickest path to market approval. We are diligently working toward our goal of filing this New Drug Application in 2003. Irofulven has also demonstrated activity as a single agent in other cancers such as ovarian, prostate and sarcoma. Paralleling our work in pancreatic cancer, we will continue to advance irofulven as a single agent in these and other cancers.

Our enthusiasm for initiating a pivotal, Phase 3 trial with irofulven in pancreatic cancer was magnified by the significant improvement in patient tolerability, demonstrated in the

intermittent weekly dose optimization trial reported earlier in the fall of 2000. Intermittent, weekly dosing of irofulven greatly improves the likelihood of patients receiving multiple therapy cycles at dose intensities that are equivalent to those achieved with the initial dosing schedules.

This new once-a-week, every-other-week schedule also accommodates the use of irofulven in combination with approved cancer therapies, a promising development path given additive and synergistic activity in preclinical studies. Our Phase 1 trial, in combination with Camptosar, has already produced an objective response in a refractory, non-small cell lung patient. Other combination trials are planned for 2001 as well.

ADDING TO THE PORTFOLIO

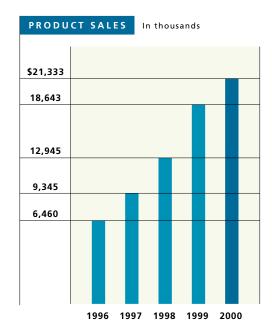
In 2000, we also added a number of products to our oncology portfolio through our aggressive business development and licensing efforts. In August 2000, we licensed North American rights to an exciting DNA methyltransferase inhibitor program. Both MG98 and its complementary small molecule program target the inhibition of the nuclear enzyme, DNA methyltransferase

as a means to allow otherwise inactivated tumor suppressor genes to function, thereby slowing or stopping the growth of tumors. In November 2000, we purchased Hexalen® Capsules (altretamine), an oral chemotherapy for refractory ovarian cancer. The licensing and distribution agreement for Mylocel™ Tablets (hydroxyurea) was completed in January 2001. We began direct promotion of both Hexalen and Mylocel to U.S. oncologists in March 2001. Finally, the in-licensing of palonosetron was completed in the first half of 2001. We licensed exclusive North American rights to this differentiated 5-HT₃ antagonist, which is currently in Phase 3 trials for the treatment of chemotherapy-induced nausea and vomiting. If the trials proceed as planned, a New Drug Application (NDA) for palonosetron could be submitted to the FDA in 2002, meaning that it could be launched prior to irofulven. Today, versus a year ago, we have delivered on our promise of establishing a more meaningful product portfolio, and, I might add, with the addition of palonosetron, we now have a lot more to be proud of than just irofulven. Palonosetron not only represents a major near-term product for MGI and its shareholders, it also moves us into supportive care, another growing segment within oncology.

Obviously, an aggressive business development and licensing effort such as ours requires capital. In May 2000, we raised an aggregate of \$16.4 million through a small "follow-on" offering, in a very difficult market. We are very gratified that a number of larger financial institutions decided to invest their capital in MGI to help fulfill our vision of building an independent, profitable, oncology-focused business.

UNIQUENESS OF THE COMMERCIAL AND R&D ORGANIZATIONS

One of our major corporate assets is our highly experienced, 50-person, dedicated sales organization. This sales force is the primary reason we have successfully attracted and acquired products, especially Hexalen, Mylocel and palonosetron. The quality and size of our commercial organization is a key MGI strength. We are very proud of this accomplished group of people. Early in 2000, we rapidly expanded the sales organization by approximately two-thirds. This extraordinary achievement should be credited to superb leadership, beginning with Al Caplan, vice president of sales, who joined us in February 2000.



The other major corporate asset we have resides in our proven product development team, led by Dr. John MacDonald, senior vice president for research and development. This group already has two NDAs under its belt and has taken irofulven from virtually a "test tube" when first acquired, to a pivotal Phase 3 trial. They are the primary reason MethylGene licensed MG98 and the small molecule inhibitor program to us.

ACHIEVEMENTS OF 2000

Last year, the first challenge for our newly expanded sales and marketing organization was to successfully defend Salagen® Tablets' leading market position, in light of the April 2000 introduction of a competing product in the Sjögren's segment. I am pleased to report that our team met that challenge and U.S. sales of Salagen Tablets grew 14 percent in 2000 to \$21 million. In addition to maintaining our market share of Salagen Tablets, in 2001 we are challenging our sales and marketing organization to successfully launch the direct promotion of Hexalen Capsules and Mylocel Tablets.

MGI'S FUTURE

In the year 2000, we decided to focus our attention almost exclusively on becoming a leader in oncology in the mid- to long-run by aggressively gaining access to a balanced oncology portfolio, and that we have done. Our progress toward building a balanced oncology portfolio is based first on an aggressive targeted business development and licensing strategy, which Lonnie Moulder, our executive vice president, has managed quite well, and second, on our twin pillars for success, a proven product development team and an experienced sales and marketing organization. These skills will remain our key assets as we enthusiastically prepare for and embrace our future challenges. Next year, I look forward to reporting more progress made toward achieving the following major goals for 2001:

- Aggressively enroll patients in the pivotal Phase 3 pancreatic cancer trial of irofulven
- Advance irofulven further as both monotherapy and combination therapy

- Conclude an acylfulvene licensing arrangement with a European partner
- Initiate at least one other Phase 2 trial with MG98
- Add another marketed oncology product to our current portfolio
- Obtain additional capital for continued growth

In closing, let me say thank you for your continued support as MGI PHARMA shareholders. We believe we are taking the right steps toward achieving our goals of building a top-notch, balanced oncology portfolio and establishing our company as a leader in oncology.

Charles N. Blitzer

President and Chief Executive Officer

April 2001



MGI PHARMA OFFICERS

STANDING FROM
LEFT TO RIGHT:
Rob Johnson,
Vice President,
Manufacturing;
Dr. John MacDonald,
Senior Vice President,
Research and Development;
Edgar Timberlake,
Vice President,
Human Resources and
Administration;
and Chuck Blitzer,
President and
Chief Executive Officer.

SEATED FROM
LEFT TO RIGHT:
Dr. Mike Cullen,
Vice President,
Clinical Affairs and
Chief Medical Officer;
Lonnie Moulder,
Executive Vice President;
Bill Brown,
Chief Financial Officer;
and Al Caplan,
Vice President, Sales.

Discussion and Analysis

OVERVIEW

We are an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that meet patient needs. We focus our 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 physicians in the United States using our own specialty sales force. These products include our Salagen® Tablets (pilocarpine hydrochloride), Hexalen® Capsules (altretamine), and Didronel® I.V. Infusion (etidronate disodium), and we co-promote products with other companies. Salagen Tablets are approved in the United States for two indications: symptoms of radiation-induced dry mouth 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 96 percent of our product sales during 2000. Didronel I.V. Infusion is approved for the treatment of hypercalcemia (elevated blood calcium) in late-stage cancer patients. Hexalen Capsules, which we are selling since we acquired the product from MedImmune, Inc. in November 2000, are an orally administered chemotherapeutic agent approved in the United States for the treatment of refractory ovarian cancer in patients. Co-promoted products continue to be owned and distributed by the co-promotion partners, so we recognize promotion fee revenue, rather than product sales revenue, for these products. Outside the United States, we commercialize our products through various alliances from which we recognize licensing revenues. We have licensing agreements with several international pharmaceutical companies to develop and commercialize Salagen Tablets in Europe, Canada and Japan. Exclusive rights in Japan to irofulven and other acylfulvenes were granted to Dainippon Pharmaceutical Co., Ltd., under a development and commercialization agreement in 1995. We rely on third parties to manufacture our commercialized and development stage products.

Our current product development efforts include preclinical studies and clinical trials for irofulven, the lead product

candidate in our novel family of proprietary cancer therapy compounds called the acylfulvenes. During 2000, we broadened the scope of our development activities by licensing exclusive North American development and commercial rights to MG98 and other inhibitors of DNA methyltransferase, an enzyme that has been associated with rapid tumor growth. In addition, in October 2000, we made a \$5 million deposit toward the license of palonosetron, a cancer supportive care product candidate in Phase 3 development for chemotherapy-induced nausea and vomiting. We also provide ongoing clinical support of Salagen Tablets.

RESULTS OF OPERATIONS

REVENUES

Sales: Total sales revenue increased 44 percent from \$12,944,620 in 1998 to \$18,643,168 in 1999, and increased 14 percent to \$21,333,229 in 2000. The increases in sales revenue resulted from higher unit sales derived from an increase in demand for Salagen Tablets, as well as increases in the price of Salagen Tablets. We expect total product sales revenue to increase 10 to 15 percent for 2001.

Sales of Salagen Tablets in the United States provided 95 percent of our product sales in 1998, 97 percent in 1999, and 96 percent in 2000. 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. Growth in sales of Salagen Tablets is moderating due primarily to competition from a new product and moderating growth in the Sjögren's syndrome portion of the market.

Promotion: Promotion revenue increased 44 percent from \$756,326 in 1998 to \$1,087,852 in 1999, but decreased 29 percent to \$769,874 in 2000. These results reflect promotion revenue from different product relationships between 1998 and 2000. In 1998, we were promoting INFeD® under an agreement with Schein Pharmaceutical, which concluded in 1999. In 1999, we entered into promotion agreements with Pharmacia Corporation for Azulfidine EN-tabs® and Connetics Corporation

for Ridaura® and Luxíq™ Foam. The agreements for Ridaura and Luxíq Foam concluded in the third quarter of 2000. Under the INFeD agreement, we recognized promotion revenue of \$756,326 in 1998, and \$337,852 in 1999, based on certain sales call and product sales activity. Under the Ridaura agreement, we recognized \$750,000 in promotion revenue in 1999 and \$750,000 in 2000, based on achieving certain sales call activity. We did not recognize any revenue for Luxíq Foam during the term of the agreement. We expect to conclude the Azulfidine-EN Tabs agreement in the first half of 2001, without the recognition of promotion fee revenue from this agreement.

Licensing: Licensing revenue increased 48 percent from \$3,341,568 in 1998 to \$4,954,468 in 1999, but decreased 37 percent to \$3,109,470 in 2000. The Company adopted Staff Accounting Bulletin No. 101 (SAB 101), "Revenue Recognition in Financial Statements", in the fourth quarter of 2000, and recorded a cumulative effect of this change in accounting principle for previously received, non-refundable licensing payments. This resulted in a \$9.4 million one-time, non-cash charge and a corresponding increase in deferred revenue effective at the beginning of 2000. This amount will be amortized into license revenue over the expected periods of benefit from the related collaborative arrangements.

If SAB 101 had been applied retroactively to the beginning of 1998, licensing revenue would have been \$1,921,111 in 1998 and \$3,384,011 in 1999. The increase in licensing revenue from 1998 to 1999, after applying SAB 101, was a result of an increase of \$1 million in royalties on herbicide resistant crop technology from our former agricultural business, resulting from a broadening of the royalty base, and an increase in revenue from international Salagen Tablets relationships. The decrease in licensing revenue from 1999 to 2000, after applying SAB 101, was a result of a decrease in herbicide royalties, partially reduced by an increase in revenue from international Salagen Tablets relationships.

Total licensing revenue in 2000 is a combination of deferred revenue amortization from multiple element arrangements resulting from adoption of SAB 101 and royalties that are recognized when the related sales activity occurs. In 2000, we received licensing payments of \$830,000 from Kissei Pharmaceutical Co., Ltd. related to the development of Salagen Tablets in Japan, \$750,000 from Novartis Ophthalmics AG related to the licensing of Salagen Tablets in Europe, and \$650,000 from Dainippon related to acylfulvene rights in Japan. In accordance with SAB 101, we recognized \$918,778 related to these three license agreements in 2000. We will recognize the December 31, 2000 unamortized balance of \$10,713,865 from these agreements into licensing revenue over the respective terms of the agreements.

Future licensing revenue will fluctuate from quarter to quarter depending on the level of recurring royalty generating activities, and the initiation of additional licensing arrangements. We expect licensing revenue for 2001 to approximately equal the \$3.1 million recognized in 2000.

COSTS AND EXPENSES

Cost of sales: Cost of sales as a percent of sales was seven percent in 1998, six percent in 1999, and eight percent in 2000. The fluctuations result from a slight change in the product mix from 1998 to 1999, and an increase in production costs for our products from 1999 to 2000. We believe that cost of sales as a percent of product sales for our marketed products for 2001 will range from 10 to 15 percent, as a result of increasing costs and changes in the product mix, including the additions of Hexalen Capsules and Mylocel[™] Tablets to our oncology product portfolio.

Selling, general and administrative: Selling, general and administrative expenses increased 16 percent from \$10,989,017 in 1998 to \$12,713,287 in 1999, and increased 44 percent to \$18,294,757 in 2000. The increase from 1998 to 1999 resulted from increased selling and promotion costs for Salagen Tablets, \$525,000 in expenses associated with non-recurring retirement and separation agreements, expenses related to the relocation

and recruiting for sales, marketing and business development positions, and costs related to our move to a new office location. The increase from 1999 to 2000 resulted primarily from costs associated with the expansion of our U.S. based sales force by approximately two-thirds near the end of the first quarter of 2000. We expect selling, general and administrative expenses for 2001 to range between \$25 to \$27 million to support significant planned increases in the scale of our in-house research and development activities, the launches of Hexalen Capsules and Mylocel Tablets, other new commercial activities, and costs associated with a move to a new office location in the second quarter of 2001.

Research and development: Research and development expense increased 26 percent from \$5,301,578 in 1998 to \$6,677,435 in 1999, and more than doubled to \$17,241,217 in 2000. The increase from 1998 to 1999 reflects increasing costs for the development of irofulven, the lead drug candidate in our novel family of proprietary compounds called acylfulvenes. The increase from 1999 to 2000 reflects expanded development of irofulven, and expenses related to the new license, research and development agreement with MethylGene Inc., including \$5.7 million related to the execution of the MethylGene agreement. Enrollment in a Phase 1 and three Phase 2 clinical trials of irofulven sponsored by us began in 1998 and has increased throughout 1999 and 2000. An additional Phase 1 trial and two additional Phase 2 trials of irofulven were initiated in 2000. Planning and pre-initiation activities for a Phase 3 trial of irofulven in pancreatic cancer patients who are refractory to gemcitabine treatment, that began in early 2001, also contributed to increased expenses in 2000. These trials are designed to evaluate the efficacy and safety of irofulven for the treatment of patients with pancreatic, ovarian, prostate or liver cancer who are generally refractory to current therapies. In addition, we continue to provide clinical supplies of irofulven for clinical trials sponsored by the National Cancer Institute. Conducting these studies is expected to substantially increase research and development costs. Further, emerging data suggests multiple development paths may be warranted for irofulven. We expect research and development expenses to

increase significantly in the next few years as we pursue multiple development paths with irofulven, continue development of the licensed anti-cancer technology from MethylGene, and make development payments under the planned license agreement for palonosetron, a product candidate for the treatment of chemotherapy-induced nausea and vomiting. We expect research and development expenses to range between \$35 to \$45 million for 2001.

Tax expense: Our effective tax rate was 33 percent in the 1998 and six percent in 1999. These tax rates reflect a 10 percent foreign tax rate on Dainippon licensing payments and a two percent tax rate for alternative minimum tax. The tax amount for 2000 reflects the 10 percent foreign tax rate on licensing payments received.

In 2000, we had a net loss of \$19,453,822, and as of December 31, 2000 we had an accumulated deficit of \$88,550,671. Our ability to sustain profitable operations is dependent upon the successful launch of our first significant oncology product, and, therefore, we will continue to maintain a valuation allowance against our deferred tax assets.

INTEREST INCOME

Interest income increased 20 percent from \$805,996 in 1998 to \$966,434 in 1999, and more than doubled to \$2,145,553 in 2000. The increases are a result of a higher average amount of funds available for investment from 1998 to 2000. Funds available in 2000 increased as a result of the sale of stock in the second quarter of 2000. Interest income will fluctuate from 2000 based upon the timing of additional funding.

NET INCOME (LOSS)

We had net income of \$414,287 in 1998 and \$4,731,499 in 1999. We had a net loss of \$19,453,822 in 2000, which includes a non-cash charge of \$9,402,643 relating to the adoption of SAB 101. The increase in net income from 1998 to 1999 reflects an increase in revenues of 45 percent from 1998 to 1999 and an increase in costs and expenses of 20 percent from 1998 to 1999.

The decrease from net income in 1999 to a net loss in 2000 reflects a two percent increase in revenues from 1999 to 2000 and an 81 percent increase in costs and expenses from 1999 to 2000, including a 158 percent increase in research and development expenses. During the next several years, we intend to direct our efforts toward activities intended to grow long-term revenues, including expanded development of irofulven and other product candidates. Increased spending on these initiatives, including development of the recently licensed anti-cancer technology from MethylGene and the planned license of palonosetron, will likely result in substantial net losses until after the launch of our first significant oncology product. We expect our net loss to range between \$35 to \$45 million for 2001.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2000, we had cash and short-term investments of \$29,898,787 and working capital of \$26,041,813, compared with \$24,150,573 and \$23,239,905, respectively, at December 31, 1999. For the year ended December 31, 2000, we received \$16,448,138 in cash from the sale of one million shares in a second quarter follow-on stock offering, \$4,364,412 in cash from the issuance of shares under stock award plans, and \$1,550,000 in cash as a deposit from our international partner, Dainippon. We used \$10,712,233 of cash to fund our operating activities. We also paid \$1,200,000 related to the acquisition of Hexalen Capsules and purchased \$836,248 in equipment and furniture, primarily related to the expansion of our commercial organization.

Significant cash payments for 2001 will be required to fund operating activities, pay \$4,800,000 to MedImmune, Inc. related to the purchase of Hexalen Capsules, pay \$3 million to Methyl-Gene for an additional purchase of common stock, and pay a yet to be finalized amount for the planned license of palonosetron. Substantial amounts of capital are required for pharmaceutical development and commercialization efforts. For continued development and commercialization of our product candidates and Salagen Tablets, and the acquisition and development of

additional product candidates, we plan to utilize cash provided from product sales, collaborative arrangements and existing liquid assets. We will seek other sources of funding, including additional equity or debt issuances.

We have registered for sale on a shelf registration statement that was filed with the Securities and Exchange Commission five million common shares. Under a shelf registration, we may sell securities from time to time in one or more separate offerings in amounts, at prices and on terms to be determined at the time of sale. On February 28, 2001, we entered into a financing facility with Ramius Securities, LLC, and Ramius Capital Group, LLC. Under this facility, Ramius Securities will place up to \$100 million of our common stock over a two-year period, subject to limitations such as a limitation based on the daily trading volumes of our stock. If Ramius Securities fails to sell the requisite amount of shares during any given selling period, Ramius Capital is obligated to purchase the remaining shares. As part of implementing this facility, Ramius Securities was granted an option to purchase 100,000 shares of our common stock for a two-year period at prices ranging from \$16.95 to \$24.72 per share.

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, 2000. 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 and the restatement of licensing revenue for implementation of SAB 101 as if implementation occurred on January 1, 2000) 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.

(In thousands except per share data)

| Three months ended | March 31, | June 30, | Sept. 30, | Dec. 31, | March 31, | June 30, | Sept. 30, | Dec. 31, |
|---|-----------|----------|-----------|----------|-----------|----------|-----------|-------------------|
| | 1999 | 1999 | 1999 | 1999 | 2000 | 2000 | 2000 | 2000 |
| REVENUES: | | | | | | | | |
| Sales | \$4,503 | \$4,754 | \$4,272 | \$5,114 | \$ 4,566 | \$6,134 | \$ 4,860 | \$ 5,773 |
| Promotion | 125 | 250 | 250 | 463 | 250 | 270 | 250 | _ |
| Licensing | 872 | 1,037 | 1,290 | 1,756 | 361 | 897 | 1,219 | 632 |
| | 5,500 | 6,041 | 5,812 | 7,333 | 5,177 | 7,301 | 6,329 | 6,405 |
| COST AND EXPENSES: | | | | | | | | |
| Cost of sales | 308 | 254 | 259 | 387 | 304 | 393 | 332 | 598 |
| Selling, general & administrative | 3,173 | 3,570 | 2,924 | 3,046 | 3,521 | 4,640 | 4,467 | 5,668 |
| Research and development | 1,461 | 1,747 | 1,871 | 1,599 | 1,804 | 2,225 | 8,575 | 4,636 |
| Amortization | _ | _ | _ | _ | _ | _ | _ | 98 |
| | 4,942 | 5,571 | 5,054 | 5,032 | 5,629 | 7,258 | 13,374 | 11,000 |
| Income (loss) from operations | \$558 | \$470 | \$758 | \$2,301 | \$ (452) | \$ 43 | \$(7,045) | \$(4,595) |
| Interest income | 194 | 211 | 270 | 291 | 373 | 539 | 687 | 546 |
| Income (loss) before taxes and cumulative | | | | | | | | |
| effect of change in accounting principle | \$752 | \$681 | \$1,028 | \$2,592 | \$ (79) | \$ 582 | \$(6,358) | \$(4,049) |
| Provision for income taxes | 69 | 70 | 75 | 107 | 61 | 35 | 52 | _ |
| Net income (loss) before cumulative | | | | | | | | |
| effect of change in accounting principle | \$683 | \$611 | \$953 | \$2,485 | \$ (140) | \$ 547 | \$(6,410) | \$(4,049) |
| Cumulative effect of change in | | | | | | | | |
| accounting principle | - | - | - | - | (9,403) | - | - | _ |
| Net income (loss) | \$683 | \$611 | \$953 | \$2,485 | \$(9,543) | \$ 547 | \$(6,410) | \$(4,049) |
| NET INCOME (LOSS) PER COMMON SH | ARE: | | | | | | | |
| Basic | | | | | | | | |
| Income (loss) before accounting change | \$0.05 | \$0.04 | \$0.06 | \$0.17 | \$ (0.01) | \$ 0.03 | \$ (0.39) | \$ (0.25) |
| Cumulative effect of accounting change | _ | _ | _ | _ | (0.62) | _ | _ | _ |
| Net income (loss) | \$0.05 | \$0.04 | \$0.06 | \$0.17 | \$ (0.63) | \$ 0.03 | \$ (0.39) | \$ (0.25) |
| Assuming dilution | | | | | | | | |
| Income (loss) before accounting change | \$0.04 | \$0.04 | \$0.06 | \$0.16 | \$ (0.01) | \$ 0.03 | \$ (0.39) | \$ (0.25) |
| Cumulative effect of accounting change | - | _ | - | _ | (0.62) | - | - | _ |
| Net income (loss) | \$0.04 | \$0.04 | \$0.06 | \$0.16 | \$ (0.63) | \$ 0.03 | \$ (0.39) | \$ (0.25) |
| WEIGHTED AVERAGE NUMBER OF COM | IMON SHAR | ES: | | | | | | |
| Basic | 14,575 | 14,647 | 14,816 | 14,931 | 15,217 | 15,812 | 16,452 | 16,470 |
| Assuming dilution | 15,475 | 15,549 | 15,733 | 15,779 | 15,217 | 17,161 | 16,452 | 16,470 |
| | , | , | , | , | , | , | , | , |

MARKET RISK CONSIDERATIONS

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 short-term 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.

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 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. Factors that might affect our results include, but are not limited to: the ability of irofulven or our other product candidates to be proven safe and effective in humans and to ultimately compete successfully with other therapies; continued sales of our marketed products including Salagen Tablets; continued access to capital for funding our operations; development or acquisition of additional products; reliance on contract manufacturing; changes in strategic alliances; and other risks and uncertainties detailed from time to time in the Company's filings with the Securities and Exchange Commission, included in Exhibit 99 to the Annual Report on Form 10-K for the year ended December 31, 2000. The Company does not intend to update any of the forward-looking statements after the date of this Annual Report to conform them to actual results.

Balance Sheets

| December 31, | 1999 | 2000 |
|--|---------------------|-----------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 8,249,248 | \$ 11,031,714 |
| Short-term investments | 15,901,325 | 18,867,073 |
| Receivables, less allowances of \$128,771 and \$158,579 | 2,427,901 | 2,806,462 |
| Inventories | 836,865 | 1,476,275 |
| Prepaid expenses | 153,923 | 5,826,260 |
| Total current assets | 27,569,262 | 40,007,784 |
| Fixed assets, at cost less accumulated depreciation of \$839,300 and \$1,192,171 | 1,027,482 | 1,510,859 |
| Long-term investments | _ | 3,800,000 |
| Intangible assets, at cost less accumulated amortization of \$0 and \$98,498 | _ | 6,993,372 |
| Other assets | 376,992 | 431,555 |
| Total assets | \$28,973,736 | \$ 52,743,570 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 964,242 | \$ 1,426,828 |
| Accrued expenses | 2,853,794 | 11,785,849 |
| Deferred revenue | 495,000 | 731,883 |
| Other current liabilities | 16,321 | 21,411 |
| Total current liabilities | 4,329,357 | 13,965,971 |
| Noncurrent liabilities: | 4,323,337 | 13,903,971 |
| Long-term deposit payable | _ | 1,550,000 |
| Deferred revenue | _ | 9,981,982 |
| Other noncurrent liabilities | _ | 1,200,000 |
| Total noncurrent liabilities | | 12,731,982 |
| Total liabilities | 4,329,357 | 26,697,953 |
| Stockholders' equity: | 7,323,337 | 20,037,333 |
| Preferred stock, 10,000,000 authorized and unissued shares | _ | _ |
| Common stock, \$0.01 par value, 30,000,000 authorized shares, | _ | _ |
| 14,979,640 and 16,509,008 issued and outstanding shares | 149,796 | 165 000 |
| | 93,591,432 | 165,090 |
| Additional paid-in capital Accumulated deficit | (69,096,849) | 114,431,198 (88,550,671) |
| | | |
| Total stockholders' equity Commitments (Notes 5 and 7) | 24,644,379 | 26,045,617 |
| Commitments (Notes 6 and 7) Total liabilities and stockholders' equity | ¢20 072 72 <i>6</i> | ¢ 52 742 570 |
| Total liabilities and stockholders' equity | \$28,973,736 | \$ 52,743,570 |

Statements of Operations

| Year Ended December 31, | | 1998 | | 1999 | | 2000 |
|--|------|-----------|-------|----------|------|-------------|
| REVENUES | | | | | | |
| Sales | \$13 | 2,944,620 | \$18, | 643,168 | \$ 2 | 1,333,229 |
| Promotion | | 756,326 | 1, | 087,852 | | 769,874 |
| Licensing | : | 3,341,568 | 4, | 954,468 | | 3,109,470 |
| | 1 | 7,042,514 | 24, | 685,488 | 2 | 5,212,573 |
| COSTS AND EXPENSES | | | | | | |
| Cost of sales | | 938,628 | 1, | 208,650 | | 1,626,833 |
| Selling, general and administrative | 10 | 0,989,017 | 12, | 713,287 | 1 | 8,294,757 |
| Research and development | ! | 5,301,578 | 6, | 677,435 | 1 | 7,241,217 |
| Amortization | | - | | _ | | 98,498 |
| | 1 | 7,229,223 | 20, | 599,372 | 3 | 7,261,305 |
| Income (loss) from operations | | (186,709) | 4, | 086,116 | (1 | 2,048,732) |
| Interest income | | 805,996 | | 966,434 | | 2,145,553 |
| Income (loss) before taxes and cumulative effect of change in accounting princip | le | 619,287 | 5, | .052,550 | | (9,903,179) |
| Provision for income taxes | | 205,000 | | 321,051 | | 148,000 |
| Net income (loss) before cumulative effect of change in accounting principle | | 414,287 | 4, | 731,499 | (1 | 0,051,179) |
| Cumulative effect of change in accounting principle | | _ | | _ | | (9,402,643) |
| Net income (loss) | \$ | 414,287 | \$ 4, | 731,499 | \$(1 | 9,453,822) |
| Net income (loss) per common share: | | | | | | |
| Basic | | | | | | |
| Income (loss) before effect of accounting change | \$ | 0.03 | \$ | 0.32 | \$ | (0.63) |
| Cumulative effect of accounting change | | - | | - | | (0.59) |
| Net income (loss) | \$ | 0.03 | \$ | 0.32 | \$ | (1.22) |
| Assuming dilution | | | | | | |
| Income (loss) before effect of accounting change | \$ | 0.03 | \$ | 0.30 | | \$ (0.63) |
| Cumulative effect of accounting change | | _ | | - | | (0.59) |
| Net income (loss) | \$ | 0.03 | \$ | 0.30 | | \$ (1.22) |
| Weighted average number of common shares outstanding: | | | | | | |
| Basic | 14 | 4,367,627 | 14, | 742,151 | 1 | 5,990,459 |
| Assuming dilution | 14 | 4,966,112 | 15, | 633,120 | 1 | 5,990,459 |

Statements of Cash Flows

| Year Ended December 31, | 1998 | 1999 | 2000 |
|--|--------------|---|----------------|
| OPERATING ACTIVITIES | | | |
| Net income (loss) | \$ 414,287 | \$ 4,731,499 | \$(19,453,822) |
| Adjustments for non-cash items: | | | |
| Cumulative effect of change in accounting principle | _ | _ | 9,402,643 |
| Depreciation and asset amortization | 253,685 | 394,201 | 451,369 |
| Benefit plan expense | 314,496 | 362,087 | 315,993 |
| Stock option acceleration | _ | 162,953 | _ |
| Other | 8,293 | 53,791 | 53,802 |
| Changes in operating assets and liabilities: | | | |
| Receivables | (336,546) | (1,017,362) | (378,561) |
| Inventories | (447,310) | 448,503 | (480,584) |
| Prepaid expenses | (145,673) | 176,030 | (5,672,337) |
| Accounts payable and accrued expenses | 785,640 | 343,769 | 4,227,952 |
| Deferred revenue | 45,000 | _ | 816,222 |
| Other current liabilities | 2,995 | 7,071 | 5,090 |
| Net cash provided by (used in) operating activities | 894,867 | 5,662,542 | (10,712,233) |
| INVESTING ACTIVITIES | | | |
| Purchase of investments | (18,699,585) | (22,393,143) | (45,869,003) |
| Maturity of investments | 16,130,356 | 17,059,879 | 39,103,255 |
| Acquisition of Hexalen® Capsules | _ | _ | (1,200,000) |
| Purchase of fixed assets | (174,907) | (783,501) | (836,248) |
| Payments on notes receivable | 45,576 | 56,999 | _ |
| Other | (54,955) | (41,315) | (65,855) |
| Net cash used in investing activities | (2,753,515) | (6,101,081) | (8,867,851) |
| FINANCING ACTIVITIES | | | |
| Proceeds from issuance of shares, net | _ | _ | 16,448,138 |
| Receipt of deposit payable | _ | _ | 1,550,000 |
| Issuance of shares under employee stock plans | 1,314,761 | 2,174,583 | 4,364,412 |
| Net cash provided by financing activities | 1,314,761 | 2,174,583 | 22,362,550 |
| Increase (decrease) in cash and cash equivalents | (543,887) | 1,736,044 | 2,782,466 |
| Cash and cash equivalents at beginning of year | 7,057,091 | 6,513,204 | 8,249,248 |
| Cash and cash equivalents at end of year | \$ 6,513,204 | \$ 8,249,248 | \$ 11,031,714 |
| Supplemental disclosure of cash flow information: | , -,, | , ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | ,, |
| Cash paid for income taxes | \$ 207,000 | \$ 240,000 | \$ 176,975 |
| Supplemental disclosure of non-cash investing activities: | ,, | ,, | ,, |
| Included in accrued liabilities at December 31, 2000, is \$6,000,000 | | | |
| of the \$7,200,000 purchase price for the acquisition of Hexalen Capsules. | | | |

Statements of Stockholders' Equity

| | Common stock | Additional paid-in capital | Notes receivable from officers | Accumulated deficit | Total stockholders' equity |
|---|-----------------|----------------------------------|---|------------------------|----------------------------------|
| BALANCE AT DECEMBER 31, 1997 | \$141,956 | \$ 89,222,575 | \$(102,575) | \$(74,242,635) | \$ 15,019,321 |
| Exercise of stock options, 275,786 shares | 2,758 | 1,184,504 | _ | _ | 1,187,262 |
| Employee stock purchase plan, 31,442 shares | 314 | 135,478 | _ | _ | 135,792 |
| Employee retirement savings plan | | | | | |
| contribution, 39,681 shares | 397 | 308,033 | _ | _ | 308,430 |
| Note payment | - | _ | 45,576 | - | 45,576 |
| Net income | _ | _ | _ | 414,287 | 414,287 |
| BALANCE AT DECEMBER 31, 1998 | \$145,425 | \$ 90,850,590 | \$ (56,999) | \$(73,828,348) | \$ 17,110,668 |
| Exercise of stock options, 386,006 shares | 3,860 | 2,021,544 | _ | _ | 2,025,404 |
| Employee stock purchase plan, 18,189 shares | 182 | 161,704 | _ | _ | 161,886 |
| Employee retirement savings plan | | | | | |
| contribution, 32,973 shares | 329 | 394,641 | _ | _ | 394,970 |
| Note payment | - | _ | 56,999 | _ | 56,999 |
| Stock option acceleration | - | 162,953 | _ | - | 162,953 |
| Net income | _ | _ | | 4,731,499 | 4,731,499 |
| BALANCE AT DECEMBER 31, 1999 | \$149,796 | \$ 93,591,432 | \$ 0 | \$(69,096,849) | \$ 24,644,379 |
| Issuance of 1,000,000 shares | 10,000 | 16,438,138 | _ | _ | 16,448,138 |
| Exercise of stock options, 503,036 shares | 5,030 | 4,046,784 | _ | _ | 4,051,814 |
| Employee stock purchase plan, 25,077 shares | 251 | 312,347 | _ | _ | 312,598 |
| Other issuances, 1,255 shares | 13 | 42,497 | - | _ | 42,510 |
| Net loss | _ | _ | _ | (19,453,822) | (19,453,822) |
| BALANCE AT DECEMBER 31, 2000 | \$165,090 | \$114,431,198 | \$ 0 | \$(88,550,671) | \$ 26,045,617 |

Notes to Financial Statements

NOTE ONE

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

MGI PHARMA, INC. (MGI or the Company) is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that meet patient needs. The Company focuses its sales efforts solely within the United States and creates alliances with other pharmaceutical or biotechnology companies for the commercialization of its products in other countries.

The Company promotes products directly to physicians in the United States using its own specialty sales force. These products include Company owned Salagen® Tablets (pilocarpine hydrochloride), Hexalen® Capsules (altretamine), Didronel® I.V. Infusion (etidronate disodium), and have included co-promoted products. Salagen Tablets are approved in the United States for two indications: symptoms of radiation-induced dry mouth 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 96 percent of product sales during 2000. Didronel I.V. Infusion is approved for the treatment of hypercalcemia (elevated blood calcium) in late-stage cancer patients. Hexalen Capsules, which the Company began selling since it acquired the product from MedImmune, Inc. in November 2000, are an orally administered chemotherapeutic agent approved in the United States for treatment of refractory ovarian cancer. Copromoted products continue to be owned and distributed by the co-promotion partners, so the Company recognizes promotion fee revenues, rather than product sales revenue for these products. Outside the United States, MGI commercializes its products through various alliances and recognizes licensing revenues. MGI has licensing agreements with several international pharmaceutical companies to develop and commercialize Salagen Tablets in Europe, Canada and Japan. Exclusive rights in Japan to irofulven and the other acylfulvene analogs were granted to Dainippon under a development and commercialization agreement in 1995. MGI relies on third parties to manufacture its commercialized and development stage products.

The Company's current product development efforts include preclinical studies and clinical trials for irofulven, the lead product candidate in MGI's novel family of proprietary cancer therapy compounds called the acylfulvenes. During 2000, MGI broadened the scope of its development activities by licensing exclusive North American development and commercial rights to MG98 and other inhibitors of DNA methyltransferase, an enzyme that has been associated with rapid tumor growth. In addition, in October 2000, MGI made a \$5 million deposit toward the license of palonosetron, a cancer supportive care product candidate in Phase 3 development for chemotherapy-induced nausea and vomiting. MGI also provides ongoing clinical support of Salagen Tablets.

CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

The Company considers 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 time of purchase are classified as short-term investments.

Short-term marketable investments are classified as held-tomaturity investments because the Company has the intent and the ability to hold its 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 the Company to significant concentrations of credit risk consist primarily of shortterm marketable investments and trade receivables.

Cash in excess of current operating needs is invested in accordance with the Company's 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.

The Company grants credit primarily to pharmaceutical wholesale distributors throughout the United States in the normal course of business. Five wholesalers accounted for approximately 90 percent of Company sales in 2000. Customer credit-worthiness is routinely monitored and collateral is not normally required.

CONCENTRATION OF SUPPLY RISK

MGI depends on a single supplier to provide the active ingredient for Salagen Tablets, which accounted for 96 percent of the Company's product sales during 2000. If this supplier ends its relationship with MGI, or is unable to meet the Company's demand for the ingredient, MGI may be unable to produce Salagen Tablets 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 INVESTMENTS

MGI purchased a minority interest in MethylGene Inc., a privately held Canadian biopharmaceutical company, in conjunction with the license of North American rights to MG98 and other product candidates in 2000. This minority interest is carried at cost. The valuation of this minority interest is periodically reviewed for impairment based upon the results of operations and financial position of MethylGene.

SALES REVENUE RECOGNITION

Sales and related costs are recognized upon shipment of product to customers. Sales are recorded net of provisions for pricing adjustments, collection discounts and product returns.

PROMOTION REVENUE RECOGNITION

Promotion revenue is recognized when the service has been performed or product sales have occurred which result in a fixed and determinable promotion fee being payable to MGI without a right to refund. Under promotion arrangements, the other party to the agreement recognizes product sales and MGI recognizes promotion revenue.

LICENSING REVENUE RECOGNITION

The Company implemented Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements" (SAB 101), in the fourth quarter of 2000 with retroactive effect to January 1, 2000. Under SAB 101, the Company recognizes revenue from licensing arrangements using a contingencyadjusted 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, starting with the contract's commencement, but not prior to the removal of any contingencies for each individual payment. The Company recognizes 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. The Company recognizes the remaining portion of any milestone payments over the remaining term of the underlying arrangements. Payments received by the Company in excess of amounts earned are classified as deferred revenue. The Company also recognizes licensing revenue to the extent the Company provides support services to strategic partners.

Prior to the implementation of SAB 101, the Company recognized licensing revenue when underlying performance criteria for payment had been met and when the Company had an unconditional right to such payment. Depending on a license agreement's terms, recognition criteria may have been satisfied upon achievement of milestones, passage of time or product sales by the licensee.

The Company recorded a one-time, non-cash charge and corresponding increase in deferred revenue of \$9.4 million as a result of the cumulative effect of the adoption of SAB 101 as of January 1, 2000. Amounts previously recognized as revenue, but deferred as a result of the implementation of SAB 101, will be amortized into future license revenue over the expected period of benefit from these collaborative arrangements. The \$9.4 million increase in deferred revenue as a result of the

cumulative effect of the accounting change as of January 1, 2000 will be amortized into licensing revenue based upon the terms of the underlying arrangements at an estimated rate of approximately \$589,000 in each of the years 2000 through 2014, and approximately \$569,000 in 2015.

STOCK-BASED COMPENSATION

The Company applies the intrinsic value method described in Accounting Principles Board (APB) Opinion No. 25 in accounting for the issuance of stock incentives to employees and directors. Accordingly, no compensation expense has been recognized in the financial statements. In accordance with Statement of Financial Accounting Standards No. (SFAS) 123, "Accounting for Stock-Based Compensation," pro forma information reflecting compensation cost for such issuances is presented in the Stockholders' Equity footnote.

ADVERTISING AND PROMOTION EXPENSE

Costs of advertising and promotion are expensed as incurred and were \$1,617,828, \$1,801,341 and \$2,824,053 in 1998, 1999 and 2000, respectively. The Company does not defer any costs related to direct-response advertising.

DEPRECIATION

Fixed assets consist of equipment, furniture and leasehold improvements. 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.

AMORTIZATION

Amortization of intangible assets relating to the purchase of the business associated with the product Hexalen Capsules is recognized as the greater of the amount computed on a straight-line basis over six years, which is the 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.

INCOME TAXES

Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial 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 based upon the weighted-average fair value of the Company's common shares during the period. During net loss periods, other 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 PRONOUNCEMENT

SFAS 133, "Accounting for Derivative Instruments and Hedging Activities" (as amended), requires all derivatives to be recognized as assets or liabilities on the balance sheet and measured at fair value on a mark-to-market basis. These market value adjustments are to be included either in net earnings or loss in the statement of operations or in other comprehensive

income (and accumulated stockholders' equity), depending on the nature of the transaction. The adoption of SFAS 133, in January 2001, did not have a material impact on the financial position or results of operations of the Company.

NOTE TWO

SHORT-TERM INVESTMENTS

Held-to-maturity investments, stated at amortized cost, which approximates estimated fair value, at December 31, 1999 and 2000 are summarized as follows:

| | 1999 | 2000 |
|-------------------------|--------------|--------------|
| Commercial paper | \$10,747,279 | \$13,333,117 |
| Certificates of deposit | 3,116,817 | 5,533,956 |
| Corporate notes | 2,037,229 | - |
| | \$15,901,325 | \$18,867,073 |

NOTE THREE

INVENTORIES

Inventories at December 31, 1999 and 2000 are summarized as follows:

| | 1999 | 2000 |
|----------------------------|-----------|-------------|
| Raw materials and supplies | \$160,744 | \$ 339,039 |
| Work in process | 153,447 | 699,598 |
| Finished products | 522,674 | 437,638 |
| | \$836,865 | \$1,476,275 |

NOTE FOUR

PREPAID EXPENSES

Prepaid expenses at December 31, 1999 and 2000 are summarized as follows:

| | 1999 | 2000 |
|---------------------------------------|-----------|-------------|
| Palonosetron letter of intent deposit | \$ - | \$5,000,000 |
| Other prepaids | 153,923 | 826,260 |
| | \$153,923 | \$5,826,260 |

NOTE FIVE

ACCRUED EXPENSES

Accrued expenses at December 31, 1999 and 2000 are summarized as follows:

| | | 1999 | 2000 |
|---|--------|-------|--------------|
| Hexalen Capsules business purchase obligation | \$ | _ | \$ 4,800,000 |
| Product development commitments | 86 | 0,981 | 3,500,784 |
| Bonuses | 46 | 7,820 | 889,499 |
| Product return accrual | 34 | 2,648 | 600,768 |
| Other accrued expenses | 1,18 | 2,345 | 1,994,798 |
| | \$2,85 | 3,794 | \$11,785,849 |

NOTE SIX

LEASES

The Company leases office space and computer software under noncancellable lease agreements that contain renewal options and require the Company to pay operating costs, including property taxes, insurance and maintenance. Rent expense was \$437,227, \$408,163 and \$455,364 in 1998, 1999 and 2000, respectively. In January 2001, the Company executed a lease agreement for new office space, beginning in May 2001.

Future minimum lease payments under noncancellable leases, including both the new and existing office spaces, are as follows:

| 2001 | \$1,139,000 |
|------------|-------------|
| 2002 | 1,521,000 |
| 2003 | 1,548,000 |
| 2004 | 1,569,000 |
| 2005 | 1,411,000 |
| Thereafter | 2,791,000 |
| | \$9,979,000 |

LICENSING ARRANGEMENTS

Technology Out-Licensing Arrangements

During 1995, MGI entered into a cooperative development and commercialization agreement with Dainippon Pharmaceutical Co., Ltd., whereby MGI granted Dainippon an exclusive license to develop and commercialize acylfulvenes, including irofulven, in Japan. Dainippon granted MGI an irrevocable, exclusive, royalty-free license allowing MGI to use any technology or data developed by Dainippon relating to the acylfulvenes. If a resulting product has not been launched in Japan by October 2005, MGI may terminate the license unless Dainippon elects to make license continuation payments on a quarterly basis. Under this agreement, Dainippon paid initial and continuing quarterly milestone payments totaling \$11.1 million through April 2000, of which the final \$100,000 was received in April 2000. Dainippon will make a \$1 million milestone payment upon receipt of the approval to market the first acylfulvene product in Japan. From April 2000 through January 1, 2002, \$4.3 million in deposit payments are scheduled to be received from Dainippon. As of December 31, 2000, MGI has received \$1.6 million of these deposits. MGI's repayment of these deposit amounts is due on the later of April 1, 2002, or receipt of marketing approval in Japan. Dainippon may elect to receive the deposit repayment in cash, as a credit toward delivery of bulk drug substance, or in shares of MGI common stock. Dainippon also agreed to pay MGI a portion of any non-royalty payments made by a sublicensee to Dainippon. Unless terminated earlier by the parties for cause or by mutual agreement, the term of the agreement is for the longer of the applicable patents in Japan, or ten years from the date of the last regulatory approval in Japan. Thereafter, the agreement automatically renews for additional one-year periods. Dainippon may terminate the agreement before receipt of marketing authorization upon six months prior written notice, or after receipt of marketing authorization for competitive reasons upon one year prior written notice.

In addition, MGI entered into a supply agreement with Dainippon in October 1995 pursuant to which MGI participates in the commercialization of the product and agrees to supply Dainippon's requirements of the product during the term of the development, marketing and cooperation agreement described above. Dainippon agrees to make certain minimum purchase requirements during the first four years and as agreed upon by the parties thereafter.

Under a November 1994 license agreement with Pharmacia Corporation (formerly The Upjohn Company of Canada), MGI granted an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Canada. Pharmacia granted MGI an irrevocable, non-exclusive, royalty-free license allowing MGI to use any technology or data developed by Pharmacia. Pharmacia paid MGI a \$75,000 initial fee and agreed to pay MGI royalties equal to a percentage of Pharmacia's net Salagen Tablet sales revenues, subject to annual minimum requirements. In addition, MGI agreed to pay Pharmacia royalties if MGI promotes Salagen Tablets in Canada in the first or second year following termination of the agreement. Unless terminated by the parties for cause or by mutual agreement, the term of the agreement is for seven years from the date of first commercial sales of Salagen Tablets in Canada. Thereafter, the agreement continues for an additional two-year period and thereupon automatically expires unless extended by the parties. Sales of Salagen Tablets in Canada began in 1997 and are expected to continue until at least 2004. After the initial commercial period concludes in January 2004, either party may terminate the agreement upon one year prior written notice.

In addition, MGI entered into a supply agreement with Pharmacia in November 1994 pursuant to which MGI agreed to supply Pharmacia's requirement of Salagen Tablets until the termination of the license agreement with Pharmacia, or the termination of MGI's agreement with Merck KgaA, whichever is earlier.

In December 1994, MGI entered into a license agreement with Kissei Pharmaceutical Co., Ltd., a pharmaceutical company in Japan. Under the terms of the agreement, MGI granted an exclusive, royalty-bearing license to develop and commercialize

Salagen Tablets in Japan. Kissei granted back to MGI an irrevocable, non-exclusive, royalty-free license allowing MGI to use any technology or data developed by Kissei related to Salagen Tablets. Kissei paid MGI an initial license fee and subsequent milestone payments that aggregated to \$2.5 million through December 31, 2000. There are no additional milestone payments due under the agreement. In addition, Kissei agreed to pay MGI royalties equal to a percentage of Kissei's Salagen Tablets net sales revenue. 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 launched in Japan. Thereafter, the agreement automatically renews for additional one-year periods.

In April 2000, MGI entered into a license agreement with Novartis Ophthalmics AG (formerly CIBA Vision AG) under which MGI granted Novartis an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Europe, Russia and certain other countries. Novartis granted MGI an irrevocable, non-exclusive, royalty-free license allowing MGI to use any technology developed by Novartis related to Salagen Tablets. In addition, MGI simultaneously entered into a supply agreement with Novartis pursuant to which MGI agreed to supply Novartis' requirements of Salagen Tablets until termination of the license agreement with Novartis. The term of the license 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 in the event of a breach or bankruptcy by the other party. In addition, Novartis may terminate the license agreement if the supply agreement is terminated and Novartis had not been supplied with Salagen Tablets for a period of more than 180 days. Simultaneous with this agreement, the previous agreements with Chiron B.V. for Salagen Tablets rights in Europe were terminated. Sales of Salagen Tablets in Europe began in 1995.

As of December 31, 2000, MGI had recognized license fees, including milestone and royalty fees, in the amount of \$129,325 under this agreement, following implementation of SAB 101. A \$750,000 net license fee was received in June 2000 upon receipt of regulatory qualification for Novartis to sell the

product in the UK and is being amortized to licensing revenue over the 12-year term of the agreement. An additional \$750,000 net license fee would be receivable upon satisfaction of certain regulatory approvals or transfers. 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-Licensing Arrangements

To build its product pipeline, the Company acquires rights to develop and market pharmaceuticals and medical products from others. Under this approach, the Company may be required to pay up-front, development services and milestone fees. In addition, the Company may be required to pay royalties on net sales upon marketing the products. Within a period of time after providing notice, the Company generally may terminate its licenses. All material, noncancellable commitments were recognized as of December 31, 2000.

In August 2000, MGI entered into a License, Research and Development Agreement (License Agreement) and a Stock Purchase Agreement (Purchase Agreement) with MethylGene, Inc. Under the Purchase Agreement, MGI purchased a minority interest in MethylGene for \$3.8 million and agreed to make an additional purchase of MethylGene shares for \$3.0 million by March 31, 2001. Under the License Agreement, MethylGene granted to MGI 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, MGI agreed to make initial payments to MethylGene aggregating \$5.7 million and agreed to purchase up to \$6 million of research services from MethylGene. MGI also agreed to pay royalties on annual net sales revenue related to MG98 and other DNA methyltransferase inhibitors. The term of the License Agreement extends until the later of the expiration of the last-to-expire patent that MGI has 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. In addition, after the

License Agreement has been in effect for two years, MGI may terminate the agreement on a licensed-product-by-licensedproduct basis for any reason upon 90 days notice to MethlyGene.

As of December 31, 2000, MGI had recognized \$5.7 million of expense of initial license fees under the license agreement, of which \$1,175,000 was paid in February 2001. Milestone payments are payable to MethylGene based on achievement of development milestones for MG98 and other DNA methyltransferase inhibitors. Royalty payments are based on a percentage of net sales revenue. The royalty payments continue until the later of the expiration of the last-to-expire patent that MGI has licensed, or ten years after the first commercial sale of any product listed under the agreement.

On October 5, 2000, MGI entered into an exclusive letter of intent with Helsinn Healthcare SA (Helsinn) to negotiate an exclusive license and distribution agreement for palonosetron in North America. Palonosetron is currently under development in Phase 3 clinical trials for the prevention of chemotherapyinduced nausea and vomiting. Upon execution of the letter of intent, MGI paid Helsinn a \$5 million deposit. Upon execution of the license and distribution agreement, an additional license initiation fee would be paid, along with a commitment for future milestone and royalty payments, and a product supply agreement. If a license agreement is not concluded, varying portions of the \$5 million deposit will be returned to MGI under conditions that generally result in \$1 million being retained by Helsinn.

NOTE EIGHT

PROMOTION REVENUE

During 2000, the company continued its co-promotion of Azulfidine EN-tabs® (sulfasalazine delayed release tablets, USP) Enteric-coated under an agreement with Pharmacia. MGI has not recognized promotion revenue under this agreement, because certain sales growth targets were not attained. Pharmacia and MGI have agreed to negotiate early termination of this relationship in the first half of 2001.

In September 2000, MGI concluded its promotion agreements with Connetics Corporation for the promotion of Ridaura® (auranofin) and Luxíq™ (betamethasone valerate) Foam, 0.12%. Under the terms of the Ridaura agreement, MGI recognized \$750,000 in minimum royalties in 2000 for making a minimum number of sales calls. MGI did not recognize promotion revenue under the Luxíq agreement, as a result of MGI not achieving certain sales targets.

In March 1999, MGI and Schein Pharmaceutical, Inc. concluded their agreement for the promotion of INFeD® (iron dextran injection). Under the agreement, the Company recognized a final minimum quarterly promotion fee of \$125,000 in the first quarter of 1999, and smaller promotion fees based upon product sales amounts for the remaining three quarters of 1999.

NOTE NINE

STOCKHOLDER RIGHTS PLAN

Each outstanding share of common stock of the Company has one preferred share purchase right (Right) per share. 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 the Company does not redeem the Rights. The Rights expire on July 14, 2008, if not previously redeemed or exercised.

NOTE TEN

STOCKHOLDERS' EQUITY

Follow-on Stock Offering

On May 25, 2000, the Company issued 1,000,000 shares of common stock at \$18 per share in a public offering and received proceeds of \$16,448,138, net of issuance costs.

Stock Incentive Plans

Under stock incentive plans, designated persons (including officers, employees, directors and consultants) have been or may be granted rights to acquire Company common stock.

These rights include stock options and other equity rights. At December 31, 2000, 4,067,374 shares of common stock remain reserved for issuance, of which 1,803,308 shares remain available for grant.

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-year period ended December 31, 2000 is summarized as follows:

| | Number of Shares | Average Price Per Share |
|----------------------------------|---------------------|----------------------------|
| Outstanding at December 31, 1997 | 2,081,150 | \$ 6.32 |
| Granted | 472,408 | 4.81 |
| Exercised | (275,786) | 4.27 |
| Canceled | (90,296) | 4.43 |
| Outstanding at December 31, 1998 | 2,187,476 | 6.33 |
| Granted | 548,711 | 11.78 |
| Exercised | (386,006) | 5.21 |
| Canceled | (246,047) | 9.77 |
| Outstanding at December 31, 1999 | 2,104,134 | 7.56 |
| Granted | 713,040 | 20.76 |
| Exercised | (503,036) | 8.05 |
| Canceled | (50,372) | 13.08 |
| Outstanding at December 31, 2000 | 2,263,766 | \$11.48 |

The following table summarizes information concerning options outstanding and exercisable at December 31, 2000:

| | | Options Outstandir | ng | Option | s Exercisable |
|-----------------|-------------|---------------------|---------------------|-------------|---------------------|
| Range of | | Weighted Average | Weighted Average | | Weighted Average |
| Exercise | Number | Remaining | Exercise | Number | Exercise |
| Price | Outstanding | Life | Price | Exercisable | Price |
| \$3.38-\$4.00 | 328,752 | 6.76 | \$ 3.85 | 175,497 | \$ 3.82 |
| \$4.13-\$4.75 | 322,500 | 5.32 | \$ 4.65 | 319,303 | \$ 4.65 |
| \$4.81-\$5.25 | 230,723 | 5.94 | \$ 4.86 | 179,322 | \$ 4.87 |
| \$5.38-\$8.75 | 159,845 | 5.77 | \$ 6.69 | 107,357 | \$ 6.30 |
| \$10.06-\$12.00 | 435,496 | 7.79 | \$11.75 | 125,952 | \$11.60 |
| \$12.50-\$16.44 | 535,300 | 8.38 | \$15.96 | 63,927 | \$13.49 |
| \$16.75-\$51.50 | 251,150 | 9.29 | \$29.38 | 15,900 | \$17.31 |
| Total | 2,263,766 | 7.26 | \$11.48 | 987,258 | \$ 6.39 |

Employee Stock Purchase Plan

Under the Company's 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. Shares issued under the plan were 31,422, 18,189 and 25,077 at average prices of \$4.32, \$8.90 and \$12.47

per share in 1998, 1999 and 2000, respectively. At December 31, 2000, 101,901 shares remain reserved for future issuance under the plan.

Fair Value of Stock Plans

The Company applies APB Opinion No. 25 in accounting for its stock incentive plans for designated persons and, accordingly, no compensation cost has been recognized in the financial statements for employee and director stock options granted under its stock plans. Had the Company determined

compensation cost based on the fair value at the grant date for its stock options and the fair value of the discount related to the employee stock purchase plan under SFAS 123, the Company's net income (loss) would have been reported as shown below:

| | | 1998 | | 1999 | | 2000 |
|-----------------------|------|---------|-------|--------|-------|-----------|
| NET INCOME (LOSS): | | | | | | |
| As reported | \$ 4 | 14,287 | \$4,7 | 31,499 | \$(19 | ,453,822) |
| Pro forma | \$(6 | 47,715) | \$2,8 | 53,476 | \$(24 | ,856,197) |
| NET INCOME (LOSS) PER | | | | | | |
| COMMON SHARE: | | | | | | |
| As reported diluted | \$ | 0.03 | \$ | 0.30 | \$ | (1.22) |
| Pro forma diluted | \$ | (0.04) | \$ | 0.18 | \$ | (1.55) |

The per share weighted-average fair value of stock options granted during 1998, 1999 and 2000 was \$2.73, \$6.50 and \$14.03, respectively, on the date of grant, using the Black-Scholes option-pricing model with the following weighted-average assumptions:

| | 1998 | 1999 | 2000 |
|-------------------------|-------|-------|-------|
| Expected dividend yield | 0% | 0% | 0% |
| Risk-free interest rate | 5.00% | 5.00% | 4.80% |
| Annualized volatility | 0.61 | 0.60 | 0.80 |
| Expected life, in years | 5 | 5 | 5 |

Retirement Savings Plan

The Company's retirement savings plan conforms to Section 401(k) of the Internal Revenue Code and participation is available to substantially all employees. Under the savings plan, participants may contribute a percentage of their eligible compensation for investment in Company common stock or other investment vehicles. The Company matches a portion of employees' contributions and may also make discretionary contributions ratably to all eligible employees. Company contributions are made in the form of Company common stock and become fully vested when an employee attains five years of service. Contribution expense was \$314,496, \$362,087 and

\$315,993 in 1998, 1999 and 2000, respectively. The Company had 216,794 shares reserved for future issuance under the savings plan at December 31, 2000.

Preferred Stock

At December 31, 2000, 10,000,000 shares of preferred stock remained issuable. Issuance is subject to board of directors' action.

NOTE ELEVEN

MGI FUNDED RETIREMENT TRUST

The Company sponsors a money purchase retirement plan covering substantially all employees. Under the plan, the Company contributes a percentage of participating employees' eligible compensation. Company contributions resulted in expense of \$198,647, \$203,724 and \$184,634 in 1998, 1999 and 2000, respectively.

NOTE TWELVE

INCOME TAXES

The provision for income taxes differs from statutory federal income tax rates in the years ended December 31, 1998, 1999 and 2000 as follows:

| | 1998 | 1999 | 2000 |
|-------------------------------|------------|--------------|---------------|
| Statutory federal income | | | |
| tax rate | \$ 210,558 | \$ 1,717,867 | \$(3,367,082) |
| Foreign tax | 135,300 | 145,200 | 97,680 |
| Valuation allowance change | (556,081) | (1,833,215) | 3,857,787 |
| Research activities credit | (149,859) | (172,570) | (255,380) |
| Orphan drug credit | (222,155) | (386,357) | (993,878) |
| State income taxes, net of | | | |
| federal benefit | 15,482 | 126,314 | (247,579) |
| Net operating loss expiration | 700,833 | 484,007 | 1,052,891 |
| Other | 70,922 | 239,805 | 3,561 |
| | \$ 205,000 | \$ 321,051 | \$ 148,000 |

Deferred taxes as of December 31, 1999 and 2000 consist of the following:

| | | 1999 | | 2000 |
|------------------------------------|-----|------------|-----|------------|
| DEFERRED TAX ASSETS: | | | | |
| Receivable allowances | \$ | 48,289 | \$ | 59,467 |
| Inventory allowances | | 4,131 | | 7,777 |
| Product return allowance | | 128,493 | | 225,288 |
| Miscellaneous accrued expenses | | 100,085 | | 79,180 |
| Deferred revenue | | - | | 491,708 |
| Amortization of intangibles | | - | | 22,162 |
| Net operating loss carryforward | 20 | 5,605,280 | 32 | 2,046,857 |
| Research credit carryforward | : | 2,345,201 | 2 | 2,600,581 |
| Orphan drug credit | | 1,121,387 | 2 | 2,115,265 |
| Alternative minimum tax | | | | |
| credit carryforward | | 48,295 | | 48,295 |
| | 30 | 0,401,161 | 37 | 7,696,580 |
| Less valuation allowance | (30 | 0,366,162) | (37 | 7,631,803) |
| | \$ | 34,999 | \$ | 64,777 |
| DEFERRED TAX LIABILITIES: | | | | |
| Tax depreciation greater than book | \$ | 34,999 | \$ | 64,777 |

The Company maintains a valuation allowance to fully reserve against its deferred tax assets due to uncertainty over the ability to realize these assets. As of December 31, 1999, and December 31, 2000, the valuation allowances were \$30,366,162 and \$37,631,803, respectively. Of these amounts, \$1,245,124 for the year ended December 31, 1999, and \$4,652,978 for the year ended December 31, 2000 were attributable to increases in the net operating loss carryover resulting from the exercise of stock options. These amounts will be recorded as a credit to paid-in capital if it is determined in the future that this portion of the valuation allowance is no longer required.

At December 31, 2000, the Company had net operating loss carryforwards of approximately \$85,458,000 for federal income tax purposes, which began to expire in 2001. The Company also had a credit for alternative minimum tax of \$48,295 which has no expiration date. Additionally, the Company had research credit carryforwards of approximately \$2,601,000, and orphan drug credit carryforwards of approximately \$2,115,000 which began to expire in 2001.

NOTE THIRTEEN

INCOME (LOSS) PER COMMON SHARE

Income (loss) per share for the years ended December 31, 1998, 1999 and 2000 is based on weighted-average shares outstanding as summarized in the following table:

| Year ended Dec. 31, | 1998 | 1999 | 2000 |
|---|------------|------------|------------|
| Weighted average shares – basic | 14,367,627 | 14,742,151 | 15,990,459 |
| Effect of dilutive stock options | 598,485 | 890,969 | - |
| Weighted average shares – assuming dilution | 14,966,112 | 15,633,120 | 15,990,459 |

The total number of options excluded from the calculation of potentially dilutive securities either because the exercise price exceeded the average market price or because their inclusion in a calculation of net loss per share would have been anti-dilutive were 408,674, 232,087 and 2,263,766 for 1998, 1999 and 2000, respectively.

NOTE FOURTEEN

RELATED PARTY TRANSACTIONS

One of the Company's directors, who became a director in May 1998, is the managing partner of Boston Healthcare Associates, a biotechnology consulting partner for the Company. The Company made payments to Boston Healthcare of \$136,000, \$87,000 and \$172,000 in 1998, 1999, and 2000, respectively. Transactions with Boston Healthcare were in the ordinary course of business at prices comparable to transactions with other companies.

NOTE SEVENTEEN

SEGMENT AND GEOGRAPHICAL INFORMATION

The Company operates in a single operating segment of specialty pharmaceuticals. Essentially all of its long-lived assets are located in the United States. Operating revenues attributable to the U.S. and foreign customers in the years ended December 31, 1998, 1999 and 2000 are as follows:

| | 1998 | 1999 | 2000 |
|---------------|--------------|--------------|--------------|
| United States | \$14,319,608 | \$21,229,185 | \$23,259,190 |
| Japan | 2,100,405 | 2,476,474 | 1,154,315 |
| Other Foreign | 622,501 | 979,829 | 799,068 |
| | \$17,042,514 | \$24,685,488 | \$25,212,573 |

Other foreign areas include Canada, Columbia, Europe, Israel, Korea and Singapore.

NOTE SIXTEEN

PRODUCT ACQUISITION

On November 21, 2000, MGI acquired certain assets and assumed certain liabilities related to the business associated with the product Hexalen Capsules (altretamine) from MedImmune. MGI paid \$1.2 million upon execution of the agreement. Quarterly payments of \$1.2 million each are due over the five quarters following the purchase. The \$7,091,870 excess of the \$7.2 million purchase price over the \$108,130 fair value of the net assets acquired was allocated to intangible assets. Royalties will be due MedImmune on quarterly net sales of Hexalen Capsules for a period of ten years. The results of the operations of the business associated with the product Hexalen Capsules have been included in the accompanying Statement of Operations from November 21, 2000. Net direct revenues of Hexalen Capsules for the period from January 1, 2000, to November 21, 2000 were \$1.4 million (unaudited). No additional information for periods prior to January 1, 2000 or more detailed information during 2000 is available with respect to Hexalen Capsules. Results for this period under MedImmune are not necessarily indicative of results expected for an entire year under MGI ownership.

SUBSEQUENT EVENT

In January 2001, MGI executed a license and distribution agreement with Barr Laboratories for the commercialization in the United States for Mylocel™ Tablets, an FDA-approved oral tablet formulation of hydroxyurea manufactured by Barr Laboratories. Mylocel Tablets are an antineoplastic agent indicated for the treatment of melanoma, resistant chronic leukemia, and recurrent, metastatic, or inoperable carcinoma of the ovary. Under the agreement, Barr granted MGI the right to distribute, market and sell Mylocel Tablets in the United States. MGI will begin marketing and distributing the product late in the first quarter of 2001. Barr will receive royalty payments based upon product contribution derived from MGI's sale of Mylocel Tablets under the agreement. Unless earlier terminated by the parties, the term of the agreement extends for ten years, with automatic annual renewals. MGI may terminate the agreement upon 90 days notice after the first year. Barr may terminate the agreement upon 120 days notice after the second year, or upon 90 days notice if MGI does not meet minimum sales call activity during the first 12 months.

On February 28, 2001, the Company entered into a common stock underwriting agreement with Ramius Securities, LLC (Ramius Securities) and a stand-by purchase agreement with Ramius Capital Group, LLC (Ramius Capital). Under the terms of the underwriting agreement, Ramius Securities is obligated to sell, on a best-efforts basis and at the Company's election from time to time, an aggregate of up to \$100 million of the Company's common stock over a two-year period in individual offerings of \$2 million to \$15 million. Under the terms of the stand-by purchase agreement, if Ramius Securities fails to sell the requisite amount of shares during any given selling period pursuant to the terms of the underwriting agreement, Ramius Capital is obligated to purchase the remaining shares. In connection with these agreements, Ramius Securities was granted an option to purchase an aggregate of 100,000 shares of the Company's common stock for a two-year period at prices ranging from \$16.95 to \$24.72 per share.

Independent Auditors' Report

THE BOARD OF DIRECTORS AND STOCKHOLDERS MGI PHARMA, INC.:

We have audited the accompanying balance sheets of MGI PHARMA, INC. as of December 31, 1999 and 2000, and the related statements of operations, cash flows and stockholders' equity for each of the years in the three-year period ended December 31, 2000. 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, 1999 and 2000, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2000 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the financial statements, the company changed its method of recognizing licensing revenue as a result of the adoption of SEC Staff Accounting Bulletin No. 101.

KPMG LLP

KPMG LLP

Minneapolis, Minnesota

February 5, 2001, except as to Note 17 which is as of February 28, 2001

Officers and Directors

OFFICERS

CHARLES N. BLITZER

President and Chief Executive Officer

WILLIAM C. BROWN

Chief Financial Officer and Secretary

ALAN R. CAPLAN

Vice President, Sales

MICHAEL T. CULLEN JR., M.D.

Vice President, Clinical Affairs and Chief Medical Officer

ROBERT M. JOHNSON

Vice President, Manufacturing

JOHN R. MACDONALD, PH.D.

Senior Vice President, Research and Development

LEON O. MOULDER, JR.

Executive Vice President

EDGAR F. TIMBERLAKE

Vice President, Human Resources and Administration

BOARD OF DIRECTORS

HUGH E. MILLER

Chairman of the Board
Retired Vice Chairman and Director,
ICI Americas Inc.

CHARLES N. BLITZER

President and Chief Executive Officer, MGI

ANDREW J. FERRARA

President and Chief Executive Officer, Boston Healthcare

JOSEPH S. FRELINGHUYSEN

President, J. S. Frelinghuysen & Co.

MICHAEL E. HANSON

Retired President, Internal Medicine Business Unit, Eli Lilly and Company

LEE J. SCHROEDER

President and Director, Lee Schroeder & Associates, Inc.

ARTHUR L. WEAVER, M.D.

Director, Clinical Research, The Arthritis Center of Nebraska Clinical Professor, Department of Medicine, University of Nebraska Medical Center

Shareholder Information

MARKET PRICE AND

RELATED MATTERS



MGI PHARMA INC.'s common stock

trades on The Nasdaq National Market System under the symbol "MOGN." As of March 14, 2001, MGI PHARMA had 767 shareholders of record and 16,553,489 shares of common stock outstanding. 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 | | |
|-------------------|---------|--------|
| 1999 | HIGH | LOW |
| First Quarter | \$13.88 | \$7.00 |
| Second Quarter | 12.13 | 8.25 |
| Third Quarter | 14.75 | 10.00 |
| Fourth Quarter | 14.38 | 9.75 |
| | | |
| 2000 | HIGH | LOW |
| First Quarter | \$54.75 | 11.50 |
| Second Quarter | 42.50 | 14.88 |
| Third Quarter | 35.25 | 25.31 |
| Fourth Quarter | 30.94 | 16.00 |

INDEPENDENT AUDITORS

KPMG LLP

Minneapolis, Minnesota

OUTSIDE LEGAL COUNSEL

Dorsey & Whitney LLP Minneapolis, Minnesota

FORM 10-K

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
Suite 110
6300 West Old Shakopee Road
Bloomington, MN 55438-2318

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 Minnesota, N.A.,

Shareowner Services

P.O. 64854

Saint Paul, Minnesota 55164-0854

Phone: 800-468-9716

Fax: 651-450-4033

FOR MGI PHARMA INQUIRIES

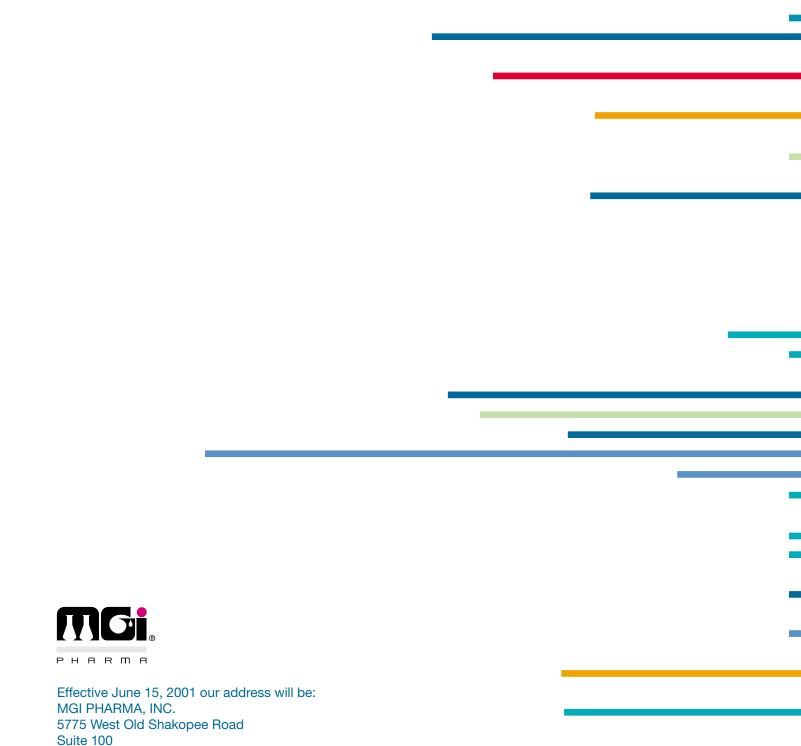
Shareholders and prospective investors seeking information about MGI PHARMA should contact Investor Relations at MGI PHARMA, 952-346-4723, or visit the Company's website at www.mgipharma.com.

PATIENT AND PHYSICIAN

INFORMATION

Patients and health care providers seeking information on irofulven clinical trials may call MGI PHARMA's Medical Communications Help Line at 1-800-562-5580 or the National Cancer Institute at 1-800-4-CANCER.

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Luxíq™ is a trademark of Connetics Corporation;
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