BIGMAR INC
Form 10KSB40
April 02, 2001

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549
FORM 10-KSB

/X/ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000.

OR

/ / TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

COMMISSION FILE NO. 1-14416
BIGMAR, INC.
(Name of Small Business Issuer in its charter)

DELAWARE	31-1445779
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
9711 SPORTSMAN CLUB ROAD JOHNSTOWN, OHIO	43031
(Address of principal executive offices)	(Zip Code)

Issuer's telephone number, including area code: (740) 966-5800

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT:

Common Stock, par value $.001 per share
(Title of class)

Check whether the issuer : (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

Yes X No

Issuer's revenues for its most recent fiscal year were $7,650,665.

The aggregate market value of Common Stock held by non-affiliates is $3,996,416 based on a closing sale price of $1.625 per share on March 30, 2001. As of March 30, 2001, 10,168,973 shares of $.001 par value Common Stock were issued and outstanding.

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PART I

ITEM 1. BUSINESS

GENERAL

BIGMAR. Bigmar, Inc. ("the Company") was incorporated in Delaware in September 1995. It has three wholly owned subsidiaries: Bioren SA ("Bioren"), Bigmar Pharmaceuticals SA ("Pharmaceuticals"), and Bigmar Therapeutics ("Therapeutics"). Bioren, a Swiss corporation, was formed in July 1986. Pharmaceuticals, also a Swiss corporation, was formed in January 1992 under the name BVI, SA. Therapeutics, a Delaware corporation, was formed in September 1995 under the name Bioren, Inc. but its name was subsequently changed in November 1995. The Company consummated its initial public offering in June 1996.

The Company's corporate headquarters, located in Johnstown, Ohio, includes research and development laboratories used for testing of generic oncology pharmaceuticals and related products ("Oncology Products") to be marketed in the United States.

The Company manufactures generic pharmaceutical Oncology Products and intravenous infusion solutions through its Swiss subsidiaries and markets these products in Europe, the United States and other countries primarily through pharmaceutical distributors. At December 31, 2000, the Company employed 82 full-time and 12 part-time associates in the following functional areas: manufacturing and quality control-69; marketing and sales-8; research and development, including regulatory affairs-11; and administration-6. All but three of the Company's employees are located in Switzerland and none of the employees are a party to any collective bargaining agreements. Financial information relating to the Company's business segments and operations in various geographic areas of the world is provided in the accompanying Notes to the Consolidated Financial Statements.

BIOREN. Bioren is engaged in manufacturing and marketing various pharmaceutical products in Switzerland. Current products include 22 types of intravenous infusion solutions and other related products ("IV Solutions"). Bioren's strategy is to expand its current IV Solutions product line and its market penetration in Switzerland and Europe. Bioren's manufacturing facility (the "Bioren Facility") is located in Couvet, Switzerland.

PHARMACEUTICALS. Pharmaceuticals manufactures and markets Oncology Products, such as Calcium Leucovorin, Sodium Folinate, Dacarbazine, Doxorubicin, Etoposide, Fluorouracil, Daunorubicin, Methotrexate, and Cisplatin. The Oncology Products are currently marketed in the United States, Italy, Germany, Switzerland, Brazil, Greece and Spain. Pharmaceuticals' primary strategy is to supply world markets with a full line of high-quality, affordably priced generic pharmaceutical products focusing on oncology. The products are manufactured in its state-of-the-art facilities in Switzerland and marketed through pharmaceutical company partners in Europe. The products have been marketed in the United States since the end of October 1999. Pharmaceuticals has received regulatory approval to manufacture and market certain Oncology Products from the United States Food and Drug Administration ("FDA") and Switzerland's Intercantonal Office for the Control of Medications ("IKS"). Pharmaceuticals' manufacturing facility (the "Pharmaceuticals Facility") is located in Barbengo, Switzerland.

THERAPEUTICS. Therapeutics is essentially a shell company and has no significant business operations as of December 31, 2000.

PRODUCTS

IV SOLUTIONS. Bioren's Facility manufactures and markets IV Solutions. The IV Solutions generally consist of different chemical entities, such as sodium chloride, electrolytes, carbohydrates and other nutrients and antibiotic solutions such as Metronidazole, which are administered to patients

intravenously. The Company markets IV Solutions through its own sales force to hospitals, clinics, retirement homes,

nursing homes, managed health care organizations, home infusion providers and other health care providers in Switzerland. The Company intends to continue manufacturing and marketing IV Solutions and is seeking to penetrate additional markets in Switzerland and the United Kingdom.

In March 1995, Bioren and PLM Langeskov A/S ("PLM") entered into an agreement, which grants Bioren the exclusive right to distribute its IV Solutions throughout Switzerland and Liechtenstein in PLM's collapsible containers. The agreement expires in the year 2005, unless it is terminated earlier. Under the terms of the agreement, PLM is entitled to terminate the exclusive right contained in the agreement if, among other things, Bioren does not purchase a minimum number of intravenous solution containers each year. In addition, either party may terminate the agreement upon the occurrence of certain specified conditions. The termination of the agreement would have a material adverse effect on the Company. In early 1999, PLM was acquired by Rexam ("Rexam"). Rexam operates in the packaging sector and supplies packaging solutions to the beauty, food, beverages and healthcare industries.

ONCOLOGY PRODUCTS. The Company currently markets various generic Oncology Products in the United States and Europe. The Company received a total of eight Abbreviated New Drug Application ("ANDAs" or "ANDA") approvals from the FDA for:

- Methotrexate for Injection USP, 1g vial (Preservative-free)
- Methotrexate Injection USP, 50 mg and 250 mg vial (Preserved)
- Methotrexate Injection USP, 50 mg, 100 mg, 200 mg and 250 mg vial (Preservative-free)
- Leucovorin Calcium for Injection USP, 200 mg vial (Preservative-free)
- Leucovorin Calcium for Injection USP, 500 mg vial (Preservative-free)
- Fluorouracil Injection USP, 250 mg and 500 mg vial
- Fluorouracil Injection USP, 5 g vial
- Daunorubicin Hydrochloride for Injection USP, 20mg vial

The Methotrexate products are indicated in the treatment of various neoplastic diseases. The Leucovorin products diminish toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of folic acid antagonists. Leucovorin Calcium for Injection, 500mg is also indicated in combination with 5-Fluorouracil in the palliative treatment of patients with advanced colorectal cancer, carcinoma of the colon, rectum, breast, stomach and pancreas. The approval of Leucovorin Calcium for Injection USP, 500 mg provided the Company with a unique proprietary position, since it was the first to offer this configuration in the United States. Approval of this product represents an important step in addressing the specific dosage needs of the patient population who depend on them. The estimated combined total for the 1998 domestic market for all seven approved products was approximately $170 million. Competition in generic oncology drugs for the U.S. market is limited to only one or two suppliers. The strong demand for Daunorubicin Hydrochloride for Injection should

enable the Company to establish a strong market presence for this product and result in an increase in overall Company sales.

The Company has already received a total of four registrations in Switzerland for the following products:

- Methotrexate Injection USP, 50 mg and 200 mg vial
- Calcium Folinate for Injection USP, 50 mg vial
- Doxorubicin for Injection 10 mg, 20 mg and 50 mg vial
- Etoposide Injection 100 mg, 500 mg and 1000 mg vial

With its strong experience in the Swiss marketplace and close relationships with Swiss hospitals, Bioren began to launch its first oncology pharmaceuticals during 2000.

PROPOSED PRODUCTS. Most of the off-patent multi-source drugs (meaning all drugs for which the patent has expired and which are available from more than one supplier in one country) are cytotoxic drugs, which are exclusively sold to the hospital market in the form of injectables. The Company has identified approximately 30 oncological drugs that are currently off-patent and sold in generic form and 15 additional oncological drugs that the Company believes will become generic in the next few years. Generic drugs are the chemical and therapeutic equivalents of brand name drugs and generally are marketed once the patent on the proprietary drug has expired.

There can be no assurance that the Company will manufacture or market any of the foregoing products. The commercialization of these products will depend on a number of factors including, but not limited to, the successful results of the Company's clinical toxicity studies and obtaining regulatory approval. Although the Company believes that these proposed products have commercial value, the Company may choose not to manufacture or market some or all of these products.

COMPETITION

The pharmaceutical industry is subject to intense competition and rapid and significant technological change. Competitors of the Company are numerous and include United States and international companies. In the intravenous infusion market, the Company faces competition from Braun and Fresenius, and in the oncological markets, the Company faces competition from Bedford Laboratories, Bristol-Myers Squibb Co., Pharmachemie, BV, Pharmacia & Upjohn, Inc., and Gensia-Sicor. Furthermore, in oncological markets the Company may face competition from alternative methods of treatment such as surgical procedures, radiation treatments and other treatments.

Many of the Company's competitors, including all of the companies referred to above, have substantially greater financial and technical resources, and production and marketing capabilities than the Company. The Company believes that the principal competitive factors affecting its products and proposed products are timing of product introduction, price, quality, and service. The Company believes that quality and service continue to be an advantage in the sale of IV Solutions. It also believes that the price, timing, quality, customer service and breadth of its product line are all important competitive factors for its oncological products and proposed oncological products. However, the competitor's ability to introduce generic versions of products promptly after a drug's patent expires and the breadth of their product lines may give them a competitive advantage over the Company.

MARKETING AND SALES

Pharmaceutical products are generally sold directly to distributors, wholesalers, health care facilities, and government agencies. Primary marketing efforts for pharmaceutical products are directed toward securing the prescription or recommendation of a product by physicians or other health care professionals. For example, in the United States health maintenance organizations ("HMOs") and pharmacy benefit managers are becoming increasingly important marketing channels for distributing pharmaceutical products. The increasing pressures to contain health care costs have accelerated the use of lower priced generic pharmaceutical products. The substitution of generic drugs for the brand drug has increased competitive pressures on pharmaceutical products.

The Company finalized a five year distribution and marketing agreement with American Pharmaceutical Partners ("APP") as the exclusive distributor of certain generic oncology products, manufactured by the Company, in North America. The agreement includes three market-ready generic Oncology Products on an exclusive basis: Methotrexate for Injection, 1gr; Calcium Leucovorin for Injection, 500mg; Daunorubicin Hydrochloride for Injection, 20mg, along with several Oncology Products on a non-exclusive basis. The products involved under this arrangement are produced at Pharmaceuticals' FDA-inspected Barbengo manufacturing facility that utilizes barrier isolation technology to manufacture FDA-

approved parenteral drug products. By using this technology for the first time in the production of generic oncology drugs, the Company increases the assurance of the sterility of oncology drugs resulting in a higher quality product with reduced manufacturing costs.

The Company has given other companies the exclusive right to market and distribute, in various territories, its oncological products as well as the right of first refusal to market and distribute other products in such areas. As a result Bigmar:

- cannot independently market products that are covered under these agreements;
- does not have control of marketing abilities or strategies; and
- cannot make any other strategic alliances or collaborative arrangements regarding a product that is covered by an exclusive deal or right of first refusal.

The acceptance of the Company's product in the marketplace is dependent upon these exclusive distributors' ability to demonstrate the benefits of our products to the medical and health care communities and to sell commercial quantities of our products at acceptable costs.

In the second quarter of 2000, the Company entered into an exclusive, five-year distribution and supply agreement with Indena S.p.A., a world leader in processing capacity of pharmaceutical extracts, to develop, manufacture and distribute a generic version of Taxol(R), one of the leading oncology drugs on the market with annual sales of approximately $1.5 billion worldwide according to a Datamonitor report published in September 2000. Taxol(R) is currently available in generic form and, widely used in the treatment of ovarian and breast cancer, as well as some forms of leukemia and currently marketed by Ivax.

The Company signed a licensing and supply agreement with Graminex, L.L.C. to develop a new prostatitis therapy, BGM-24, and plans to file an Investigational

New Drug Application with the FDA for this therapy. Cynthia R. May and John G. Tramontana, Directors and officers of the Company, are currently Members of Graminex, L.L.C., a manufacturer and supplier of botanical raw materials containing proprietary active pharmaceutical substances.

Bioren markets IV Solutions through its own sales force to health care providers and third-party payors in Switzerland. Bioren has entered into exclusive arrangements with non-affiliated pharmaceutical companies to market certain IV Solution products in Switzerland and the United Kingdom.

Pharmaceuticals markets its registered products to pharmaceutical companies. Pharmaceuticals does not market its other products directly to the public. Pharmaceuticals has entered into exclusive arrangements with various non-affiliated pharmaceutical companies to market certain Oncology Products, manufactured or licensed by the Company in the United States, Germany, Italy, Spain and Brazil. The amount of resources and time that any of these collaborators devote towards marketing and sales of the Company's products are not within the Company's control. The termination of any of these agreements would have a material adverse effect on the Company.

The Company's sales are not subject to significant variations due to seasonal changes.

RESEARCH AND DEVELOPMENT

The Company's research and development activities focus on three areas:

- Formulating raw materials into finished products;
- Scaling up the development from the laboratory phase to the production phase; and
- Conducting stability and bio-equivalency testing of the finished products.

During 1999, the Company received approvals for seven ANDA's from the FDA. The approved ANDA's are for certain Oncology Products manufactured by Pharmaceuticals (see "Manufacturing and Suppliers" below).

During 2000, the Company received approval from FDA for the 5-Fluorouracil 5 gr, an antineoplastic agent used in combination with other drugs to treat ovarian and breast cancer.

The Brazil's Agencia Nacional de Vigilancia Sanitaria ("ANVS") also approved 5-Fluorouracil in Brazil. The Company will market the product as "Bigmar 5FU".

The Company also received approval from the IKS to market Etoposide in Switzerland. Etoposide is an oncological drug used in the treatment of a wide array of solid tumors and hematologic malignancies. Etoposide is Bigmar's fourth chemotherapy agent approved for use in Switzerland, joining Calcium Leucovorin, Methotrexate and Doxorubicin.

IKS approved Bupivacaine Hyperbar as well, a long-acting local anesthetic recommended for local or regional anesthesia. Bupivacaine's onset of action is rapid and its duration is significantly longer than other commonly used local anesthetics.

In July 2000, the Company received licenses from the UK Medicines Control Agency granting authorization to market two dosage strengths of Bupivacaine Hydrochloride Solution in the United Kingdom. Bupivacaine HCl is a long-acting

local anesthetic used for caudal, epidural or peripheral nerve block. Although injectable Bupivacaine was approved by the FDA in 1972, Bioren's easy-to-use premix solution delivered in the intravenous bag is the first such formulation of the drug.

The Company also received approval from Switzerland's IKS to utilize IV bags as a drug delivery system for Metronidazole, an antibiotic used in the treatment of serious infections caused by anaerobic bacteria. This approval allows the Company to manufacture and market IV bags within Switzerland.

The Company also filed for approval from the IKS for the formulation of Nitroglycerin and Bupivacaine in IV bags. Nitroglycerin is used in treating patients with heart disease.

The Company's research and development human resources were also dedicated to formulate the generic version of Taxol(R) (paclitaxel). The FDA received the Company's filing in September 2000. Sales of the prescription oncology agent are growing rapidly, with reported 1999 worldwide sales of approximately $1.5 billion according to a Datamonitor report published in September 2000.

In May 2000, the Company was awarded a one-year contract by Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., an Italian company, to determine the feasibility of L-Carnitine infusion treatments in various new dosages, volumes and combinations with other ingredients. Sigma-Tau, a privately held company based in Rome, is a major leader in the Italian pharmaceutical market and devotes nearly 20% of its annual revenues to research and development investments. Sigma-Tau is the worldwide leader in L-Carnitine and the owner of several key related patents in the field. Under the terms of the agreement, the Company will conduct detailed studies in determining the feasibility of manufacturing IV infusions of L-Carnitine.

The Company's research and development expenditures totaled $2,375,034 and $2,758,372 for the years ending December 31, 1999, and 2000, respectively.

To the Company's knowledge, there are no claims against it for infringement of any third party intellectual property. However, the Company's ability to sell its products and proposed products depends on not infringing the proprietary rights of competitors. Patents concerning pharmaceutical products are often uncertain and involve complex legal, scientific and factual questions. Laws regarding the enforceability of intellectual property also vary from country to country. The Company has no assurance that such

intellectual property issues will be uniformly resolved or that local laws will provide consistent rights and benefits.

MANUFACTURING AND SUPPLIERS

The Company has two production facilities, the Bioren Facility and the Pharmaceuticals Facility. The Bioren Facility is a 57,000 square foot facility in Couvet, Switzerland, where the Company manufactures and markets IV Solutions and plans to manufacture non-toxic pharmaceutical products. The Company has dedicated approximately 25,000 square feet of the Bioren Facility to the testing and manufacturing certain oncological products such as calcium leucovorin. The Pharmaceuticals Facility is a 25,000 square foot, state-of-the-art facility in Barbengo, Switzerland, where the Company manufactures Oncology Products.

The capital costs associated with equipping a facility and manufacturing Oncology Products are substantial and the manufacturing process is complex. The FDA and foreign regulatory authorities regulate facilities in which Oncology

Products are manufactured and the method of manufacture, as well as the employees' working conditions. Because the manufacturing of cytotoxic Oncology Products is expensive and complex, only a few companies throughout the world engage in their manufacture.

The majority of raw materials needed to manufacture the Company's products and proposed products generally are not readily available and must be purchased from limited sources. In addition, the Company obtains containers for IV Solutions from a sole supplier. The Company's reliance on a sole or a limited number of suppliers involves several risks, including the inability to obtain an adequate supply of required raw materials and components, increased raw material or component costs and reduced control over quality and timely delivery.

GOVERNMENTAL REGULATIONS

UNITED STATES. The Company's research and development activities and the production and marketing of the Company's licensed and owned products and proposed products are subject to compliance with a wide range of regulatory requirements by numerous governmental authorities in the United States and in other countries. In the United States, drugs are subject to rigorous review by the FDA. The Federal Food, Drug, and Cosmetic Act and other Federal statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, distribution, reporting, advertising and promotion of such products.

Non-compliance with applicable requirements can result in recall, injunction or seizure of products; imposition of import restrictions; refusal of the government to approve new product applications; prevention from entering into government supply contracts; withdrawal of previously approved applications and, in certain circumstances, criminal prosecution.

In order to obtain FDA approval of a drug, companies must generally submit proof of safety and efficacy. In some cases such proof entails extensive clinical and pre-clinical laboratory tests. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive and may take several years to complete. There is no assurance that the FDA will act favorably or in a timely manner in reviewing submitted applications, and the Company may encounter significant difficulties or costs in its efforts to obtain FDA approvals, which could delay or preclude the Company from marketing any products it may develop. The FDA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could make it more difficult or expensive to sell the products, and therefore could restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. For patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which the Company will have the exclusive right to exploit such technologies; however, an additional period of up to five years may be added to the term of the patent in such circumstance.

Generally, with respect to drugs with active ingredients not previously approved by FDA, a prospective manufacturer must conduct and submit to the FDA adequate and well-controlled clinical studies to prove that drug's safety and efficacy. Currently, FDA approval of a New Drug Application ("NDA") takes approximately two to three years on average after its initial submission to FDA, based on information published by the FDA. Following drug discovery, the steps required before a new pharmaceutical product may be marketed in the United States include:

- Pre-clinical laboratory and animal tests;
- Submission to the FDA of an application for an Investigational New Drug ("IND");
- Clinical and other studies to assess safety and parameters of use;
- Adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug;
- Submission of a NDA to the FDA; and
- FDA approval of the NDA prior to any commercial sale or shipment of the drug.

Typically, pre-clinical studies are conducted in the laboratory and in animal model systems to gain preliminary information on the drug's pharmacology and toxicology and to identify any potential safety problems that would preclude testing in humans. The results of these studies are submitted to the FDA as part of the IND application. Testing in humans may commence 30 days after submission of the IND unless the FDA places the IND on "clinical hold." A three-phase clinical trial program is usually required for FDA approval of a pharmaceutical product.

Phase I clinical trials are designed to determine the metabolism and pharmacological effects of the drug in humans, the side effects associated with increasing doses, and, possibly, to obtain early indications of efficacy. These studies generally involve a small number of healthy volunteer subjects, but may be conducted in people with the disease the drug is intended to treat. Phase II studies are conducted to evaluate the effectiveness of the drug for a particular indication and thus involve patients with the disease under study. These studies also provide evidence of the short-term side effects and risks associated with the drug. Phase III studies are generally designed to provide the substantial evidence of safety and effectiveness of a drug required to obtain FDA approval. They often involve a substantial number of patients in multiple study centers and may include chronic administration of the drug in order to assess the overall benefit-risk relationship of the drug.

Upon completion of clinical testing that demonstrates that the product is safe and effective for a specific indication, a NDA may be submitted to the FDA. This application includes details of the manufacturing and testing processes, pre-clinical studies and clinical trials. The FDA closely monitors the progress of each of the three phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based on the data that has been accumulated to that point and its assessment of the risk/benefit ratio to the patient. Typical estimates of the total time required for completing such clinical testing vary between four and ten years. The clinical testing and FDA review process for new drugs are likely to require substantial time, effort and expense. The Company anticipates that all of its proprietary Oncological Products will be required to be approved through the NDA process.

There can be no assurance that any approval will be granted to the Company on a timely basis, if at all. The FDA may refuse to approve a NDA if applicable statutory and/or regulatory criteria are not satisfied, or may require additional testing or information. There can be no assurance that such additional testing or the provision of such information, if required, will not have a material adverse effect on the Company. Congress or the FDA can modify the regulatory process in specific situations.

The Drug Price Competition and Patent Term Restoration Act of 1984 ("Drug Price Act") established a new abbreviated procedure for obtaining FDA approval for those generic drugs that are equivalents of brand name drugs. For drugs that contain the same active ingredient as drugs already approved for use in the United States, the FDA ordinarily requires bioequivalence data illustrating that the generic drug formulation is, within an acceptable range, equivalent to a previously approved drug. A generic drug manufacturer is not required to submit the clinical data to establish the safety and effectiveness of the product. Instead, the Drug Price Act allows the FDA to rely on bioequivalence data to approve (ANDAs). "Bioequivalence" compares the bioavailability of one drug product with another and, when established, indicates that the rate of absorption and the levels of concentration of a generic drug in the body are substantially equivalent to those of the previously approved drug. The Company anticipates that it will submit ANDAs to the FDA for approval of those generic Oncological Products that are intended to be marketed in the United States. According to information published by the FDA, it currently takes approximately one to three years on average to obtain FDA approval of an ANDA following the date of its first submission to the FDA. Due to the experience of its senior management in submitting ANDAs to the FDA, the Company believes that it will be able to obtain FDA approval for each of its proposed Oncological Products well below the industry average of approximately 27 months.

The Drug Price Act, in addition to establishing a new ANDA procedure, created new statutory protection for approved brand name drugs. Prior to enactment of the Drug Price Act, the FDA gave no consideration to the patent status of a previously approved drug in deciding whether to approve an ANDA. Under the Drug Price Act, however, the effective date of approval of an ANDA can depend, under certain circumstances, on the patent status of the brand name drug. Additionally, the Drug Price Act, in certain circumstances, provides for an extension of the term of certain patents to cover a drug for up to an additional five years to compensate the patent holder for the reduction of the effective market life of a patent due to the time involved in federal regulatory review.

The Company is subject to the FDA's Good Manufacturing Practices ("GMPs"), Good Laboratory Practices ("GLPs") and extensive record keeping and reporting requirements for manufacturing products for sale in the United States. As a result, the Company's manufacturing facilities are subject to periodic inspections by the FDA and other United States federal agencies when the Company's products are offered for sale in the United States. The Company has retained independent consultants to assist it in complying with FDA standards, including the GMP requirements. Failure to comply with applicable regulatory requirements can result in, among other things, import detentions, fines, civil penalties, suspensions or losses of approvals, recalls or seizures of products, operating restrictions and criminal prosecutions.

GERMANY. In Germany, drugs for human use can be marketed only if they are approved in advance either by the Federal Institute for Medicinal Products and Medical Devices ("BfArM") in Berlin or by the European Union ("EU") Commission after a substantive review of all safety, quality and efficacy data. The application for a marketing authorization requires the preparation and submission of extensive data and files. The applicant must produce the results of analytical, pharmacological/toxicological and clinical studies and related experts' opinions. The production of these data usually requires a long-term pre-clinical examination phase. The details of the requirements are prescribed in administrative regulations such as the Medicinal Products Guidelines. Clinical trials in Germany are monitored by the state authorities. In theory, once a complete application has been submitted to the BfArM, a decision must be issued within four months, in exceptional cases within seven months. In practice, however, a term of review by the BfArM generally takes three to five years. The marketing authorization of a new substance triggers fees to the BfArM, the amount of which varies, depending on the amount of work required of the authority, the kind of procedure and the result of such procedure.

SWITZERLAND. In Switzerland, approval of the production and sale of drugs for human use is regulated on a cantonal level rather than a federal level. The cantons of Switzerland have organized the IKS as an authority for the approval of pharmaceuticals. Based on approval by the IKS, the cantons then grant permission for the production and sale of such approved pharmaceuticals. Theoretically, each canton is

still entitled to deny approval of a particular medication. However, cantons generally follow the decision of the IKS.

The IKS reviews all applicable safety, quality and effectiveness data, as well as data relating to the cost effectiveness of the product. To obtain approval from the IKS, the manufacturer must submit analytical, chemical, pharmacological and toxicological data based on animal trials and human clinical studies. The IKS approves the manufacturing of products only after having checked the conformity to applicable standards of the World Health Organization or the Pharmaceutical Inspection Convention. The IKS also will inspect the manufacturing facility to determine if the manufacturer is complying with good manufacturing practices before approval is granted to produce the drug product. For generic products, pharmacological and toxicological data are not required to be submitted to the IKS. To date, all of the Company's pharmaceutical products that have been approved by the IKS are generic products.

EUROPEAN UNION. On January 1, 1995, the EU established new procedures for the approval of pharmaceuticals and created a new coordinating body, the European Agency for the Evaluation of Medical Products ("EMEA"). Germany is a member of the EU; Switzerland is not. Under the new procedures, which are optional for certain other pharmaceutical products, in particular those with new chemical agents, applications are filed with the EMEA and are evaluated scientifically by the Committee for Proprietary Medicinal Products ("CPMP"). The CPMP consists of representatives of the national registration authorities. For each application, a Rapporteur, (i.e. one of the national authorities), is appointed and has the overall responsibility for the review of the application. The Rapporteur prepares an assessment report for the CPMP. The EU Commission will generally follow the CPMP's scientific evaluation. If one or more member states objects, the EU Council will decide the matter; otherwise, the decision is rendered by the EU Commission on the basis of the CPMP evaluation. This is known as the "centralized procedure."

A decentralized approval procedure is used for most other marketing authorization applications. The applicant submits the application to one member state where the application is reviewed. Once the first marketing authorization is obtained, the company files identical applications in the other EU member states. The marketing authorities of such other member states are supposed to approve or disapprove the first decision within 90 days. If there is disagreement between the authorities that cannot be resolved, the CPMP will be involved and will issue a scientific evaluation. If this scientific evaluation is not further disputed, the EU will render a decision on this basis. If the disagreement continues, the EU will vote to decide the matter.

Because the EMEA guidelines have been in effect for a limited period of time, the Company is unable to reliably predict how long it will take on average for drugs to be approved under these new procedures.

THIRD-PARTY REIMBURSEMENT

UNITED STATES. The Company's revenues and profitability may be affected by the ongoing efforts of third-party payors to contain or reduce the costs of

healthcare by lowering reimbursement payment rates, increasing case management review of services and negotiating reduced contract pricing and reimbursement caps. In the event any of the Company's products become subject to a maximum reimbursement rate, the Company's revenues may be adversely affected.

Successful commercialization of the Company's owned or licensed products may depend in part on the availability of adequate reimbursement from third-party health care payors such as Medicare, Medicaid, and private insurance plans. Reimbursement rules vary from payor to payor, and reimbursement also may depend upon the setting in which a particular item or service is furnished.

In general, payors exclude payment for items and services that are deemed to be not medically "reasonable and necessary," or which are considered to be unsafe and ineffective, experimental or investigative, or not medically appropriate for the patient. In making these determinations, payors typically rely on studies published in peer-reviewed medical journals, the opinions of recognized medical specialty societies, and the practices of physicians in the local medical community. Some payors are also beginning to consider

the cost of a new item or service in comparison to existing alternatives in determining whether and how much they will reimburse for a new technology. FDA clearance or approval to begin marketing a drug generally is required by payors as a condition of coverage, but such clearance or approval alone does not assure that the payor will reimburse for the drug treatment.

Most medical procedures involve payment for the physician service and, in cases where the service is provided outside of the physician's office, payment for the facility costs, including supplies furnished in connection with the procedure. Medicare, which is a federal government program that primarily reimburses health care furnished to the elderly and disabled, pays for physician services based on a physician fee schedule, which assigns a payment weight for each covered physician procedure.

The trend towards managed health care and the concurrent growth of HMOs which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care, may all result in lower prices for the Company's products. There can be no assurance that the Company's products will be considered cost-effective by third-party payors, that reimbursement will be available or, if currently available, will continue to be available, or that payors' reimbursement policies will not adversely affect the Company's ability to sell products on a profitable basis, if at all. The cost containment measures that health care providers are instituting in the face of the uncertainty and the ultimate effect of any health care reform could have an adverse effect on the Company's ability to sell its products and may have a material adverse effect on the Company.

Virtually every state as well as the District of Columbia has enacted legislation permitting the substitution of equivalent generic prescription drugs for brand name drugs where authorized or not prohibited by the prescribing physician. Currently 13 states mandate generic substitution in Medicaid programs.

GERMANY. About 90% of Germans are members of statutory health insurance programs. These health insurance providers are public bodies independent from the government and are funded equally by employers and employees. Their catalogue of services for which they will provide reimbursement is widely influenced by government regulations. Managed Care and HMOs are still unknown in Germany although various elements of these systems will probably be adopted in the future. The economic success of a drug product in Germany is widely

dependent upon acceptance of the drug by the statutory health insurance providers.

Certain drugs are generally excluded from reimbursement, however. These include medications to treat minor diseases like colds and influenza and drugs that have been determined by the Federal Ministry of Health ("FMH") to be "uneconomical", (e.g., medicinal products with more than three active ingredients). The FMH is authorized to amend this "negative list" at any time. Health insurance providers generally deny reimbursement for drugs used in clinical trials. Although drugs can generally be prescribed by a doctor "off label" (i.e., beyond their approved indication) and still be reimbursed, there have been cases where the reimbursement of oncological drugs off-label was denied on the basis that the treatment was experimental.

The health insurance providers are also authorized to set maximum reimbursement levels for generic drugs. As soon as two products with identical or chemically similar ingredients or similar therapeutic effects are on the market, the health insurance providers may set a maximum reimbursement amount. This amount will usually be an average of the lowest and the highest price. Typically, the maximum reimbursement is fixed on the basis of the lowest price plus 1/3 of the price range to the most expensive product. About 70% of drugs sold in Germany are subject to maximum reimbursement. So far, no Oncological Products have been affected by a maximum reimbursement cap. This may, however, change at any time. A manufacturer is legally free to continue to sell its products at higher than the maximum reimbursement rate, but patients must then pay the difference. So far, the Company believes that no manufacturer has tried to sell its products at prices exceeding the maximum reimbursement. If the products of the Company become subject to a maximum reimbursement rate, this may adversely affect the prices that the Company will be able to charge.

In addition to maximum reimbursement caps, pharmaceutical prices are subject to statutory limitations on the amounts that can be spent on drugs by the statutory health insurance providers. As a consequence, pharmaceutical prices decreased in the last several years and may decrease further in the future.

SWITZERLAND. In Switzerland, reimbursement for pharmaceuticals is federally regulated. There are two categories of drugs subject to reimbursement. The first category consists of medications that are required to be reimbursed by private health insurers. The second category contains specialty medications for which reimbursement is recommended. In practice, private health insurers grant reimbursement for the specialty products on the recommended list.

ENVIRONMENTAL REGULATIONS

In Switzerland, Pharmaceuticals and Bioren are subject to applicable environmental laws such as the Environment Protection Act of 1983, the Water Protection Act of 1991 and the Toxic Substance Act of 1969, as well as all applicable regulations. Swiss environmental protection laws govern, among other things, all emissions to the air, soil and water, waste-water discharge and solid and hazardous waste disposal. Pharmaceuticals and Bioren are subject periodically to environmental compliance reviews by various Swiss regulatory offices.

The Company believes all of its facilities are in compliance with applicable environmental laws. However, environmental laws have changed in recent years and the Company may become subject to increasingly stringent environmental standards in the future. While the Company anticipates that it may from time to time incur expenditures in connection with environmental matters, it does not anticipate making substantial expenditures for those matters within the next twelve months. Beyond that, the Company is unable to predict the extent or timing of future

expenditures that may be required in connection with complying with environmental laws.

PRODUCT LIABILITY AND INSURANCE

The testing, clinical trials, manufacturing, and marketing of the Company's products involve inherent risks of product liability claims against the Company. The Company currently maintains product liability insurance coverage on European territories in the amount of approximately $6.2 million and on US territories in the amount of approximately $3.1 million. Such insurance is expensive, subject to various exclusions and may not be obtainable or maintainable by the Company in the future on terms acceptable to the Company. There can be no assurance that the amount and scope of any coverage will be adequate to protect the Company in the event that a product liability claim is successfully asserted against the Company. Products, such as those sold or proposed to be sold by the Company, may be subject to recall for unforeseen reasons. A recall of the Company's products could have a material adverse effect on the Company and its reputation.

ITEM 2. PROPERTIES

BIOREN FACILITY

The Bioren Facility is a 57,000 square foot facility in Couvet, Switzerland that houses manufacturing operations, laboratory facilities for quality assurance and quality control activities (including batch testing and multiple-batch stability testing operations), labeling and packaging operations, warehousing and storage operations, administrative and record-keeping areas. The two story building was completed in 1987 on an industrial freehold site. It is of solid concrete construction and well insulated. A 25,000 square foot area in the Bioren Facility is used as a dedicated area for scaling up the development and manufacturing supporting non-toxic products, such as Leucovorin Calcium (rescue therapy). A 21,000 square foot area in the Bioren Facility is used for manufacturing and marketing IV Solutions. A portion of the Bioren Facility was leased to an unaffiliated third party until April 15, 1998. This portion is now vacant. The Company believes that the Bioren Facility is sufficient for Bioren's current and reasonably anticipated operations.

PHARMACEUTICALS FACILITY

The Pharmaceuticals Facility, a 25,000 square foot facility in Barbengo, Switzerland, is used for developing and manufacturing oncological products. This Facility also houses warehousing and storage, manufacturing, labeling and packaging, quality control and research and development laboratories and administrative areas. The Company believes that the Pharmaceuticals Facility is sufficient for Pharmaceuticals' current and reasonably anticipated operations. The two story building was completed in 1997 on an industrial freehold site. It is a solid metallic construction.

CORPORATE HEADQUARTERS

On December 31, 1996, the Company entered into a lease with JTech Laboratories, Inc. ("Jtech") relating to approximately 8,600 square feet of space located at 9711 Sportsman Club Road, Johnstown, Ohio 43031. This space is being utilized by the Company as its principle corporate headquarters and research and development laboratory for Oncology Products marketed in the U.S. The lease for this space expires in June 2002, five years from the occupancy date. John G. Tramontana, Chief Executive Officer and Chairman of the Board of Directors of the Company, is the President and a Director of JTech. Mr. Tramontana shares ownership in JTech with a company owned by certain stockholders of the Company. Management

believes that its corporate headquarters will meet its operational needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

There are no pending legal proceedings to which the Company or any of is subsidiaries is a party or to which any of their respective properties are subject, except routine legal proceedings to which they are parties incident to their respective businesses. None of such proceedings are considered by the Company to be material.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the last quarter of the fiscal year ended December 31, 2000.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS
MARKET INFORMATION

The Company's Common Stock was delisted from the Nasdaq SmallCap Market on October 5, 2000, and is currently traded under the symbol "BGMR.OB" on the OTC Bulletin Board. The high and low sales prices for the Company's Common Stock during each quarter in the years ended December 31, 2000, and 1999, as derived from information provided by the Nasdaq SmallCap Market and OTC Bulletin Board System, were as follows:

	2000		1
COMMON STOCK MARKET PRICES	HIGH	LOW	HIGH
QUARTERS:			
First	$ 3.62	$ 2.62	$ 4.06
Second	$ 3.06	$ 1.50	$ 5.12
Third	$ 2.44	$ 1.62	$ 5.06
Fourth	$ 2.19	$ 1.06	$ 3.87

HOLDERS

As of March 30, 2001, as reported by the Company's transfer agent, 10,168,973 shares of Common Stock were held of record by approximately 745 persons.

DIVIDENDS

The Company has paid no dividends, cash or otherwise, subsequent to the date of the initial public offering of the Common Stock in June 1996. Although it is not currently anticipated that any cash dividends will be paid on the Common Stock in the foreseeable future, the Board of Directors may review the Company's dividend policy from time to time. In determining whether to declare dividends and the amount of dividends to be declared, the Board will consider relevant factors, including the Company's earnings, its capital needs and its general financial condition. In addition, the Swiss Federal Code of Obligations provides further restrictions on the Company's ability to pay dividends to its stockholders.

In March 2000, the Company issued 500,000 shares of Common Stock to Banca del Gottardo via a private placement offering. The Company also issued to Banca del Gottardo 2-year warrants to purchase 150,000 shares of Common Stock at $4.00 per share. Proceeds from the sale of the shares and warrants totaled $1,375,000 and were applied to working capital and general corporate purposes. The offering of such shares of Common Stock and warrants was made pursuant to an exemption from registration under Regulation S of the Securities Act as private transactions not involving a public distribution.

In June 2000, the Company issued 300,000 shares of Common Stock to Banca del Gottardo via a private placement offering. Proceeds from the sale of the shares totaled $637,200 and were applied to working capital and general corporate purposes. The offering of such shares of Common Stock was made pursuant to an exemption from registration under Regulation S of the Securities Act as a private transaction not involving a public distribution.

In August 2000, the Company issued 375,000 shares of Common Stock to Banca del Gottardo via a private placement offering. Proceeds from the sale of shares totaled $750,000 and were applied to working capital and general corporate purposes. The offering of such shares of Common Stock was made pursuant to an exemption from registration under Regulation S of the Securities Act as a private transaction not involving a public distribution.

In December 2000, the Company issued 1,000 shares of Series B Convertible Preferred Stock, $0.001 par value per share to Banca del Gottardo via a private placement offering. Proceeds from the sale of the shares, after payment of a bank commission of 5% and satisfaction of an October 31, 2000 loan in the amount of $475,000, plus accrued interest from Banca del Gottardo, totaled $468,943.75 and were applied to working capital and general corporate purposes. The offering of such shares of Preferred Stock was made pursuant to an exemption from registration under Regulation S of the Securities Act as private transactions not involving a public distribution.

In February 2001, the Company issued 7,000 shares of Series B Convertible Preferred Stock, $0.001 par value per share and warrants for the purchase of 1,400,000 shares of the Company's Common Stock, $0.001 par value per share to Banca del Gottardo via a private placement offering. Proceeds from the sale of the shares, after payment of a bank commission of 2.5%, totaled $6,850,000 and were applied: to repay $4 million convertible notes and related interest and to repurchase 1,000 shares of Series B Convertible Preferred Stock, $0.001 par value per share including accrued dividends. Net proceeds of $1,651,766.67 will be applied to working capital and general corporate purposes. The offering of such shares of Preferred Stock and warrants was made pursuant to an exemption from registration under Regulation S of the Securities Act as private transactions not involving a public distribution.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Certain statements under this caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding future cash requirements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: delays in product development; problems or delays in clinical testing; failure or delays in receiving regulatory approvals; lack of

proprietary rights; or, change in business strategy or development plans.

OVERVIEW

The Company's first ANDA approvals from the FDA for injectable forms were received in 1999. The Company launched its Oncology Products into the U.S. market during the fourth quarter of 1999, through APP. The approved ANDA's enhance the Company's business model, which focuses on achieving a global marketing presence, as U.S. distribution efforts complement sales activities already realized throughout Europe.

YEAR ENDED DECEMBER 31, 2000 COMPARED TO YEAR ENDED DECEMBER 31, 1999

Sales. Total sales were $7.65 million for the year ended December 31, 2000, as compared to $7.73 million for the corresponding period of 1999. Year 2000 revenues were adversely affected by the increase of the U.S. Dollar exchange rate against the Swiss Franc. The exchange ratio of Swiss Francs to U.S. Dollars at December 31, 2000, was .621 as compared to .626 in 1999. This change, which was 0.8%, affected numerous financial balances including property, plant and equipment and long-term debt. Revenues and expenses were translated at the monthly average exchange rates for the periods (see item e of the summary of significant accounting policies and practices in audited financial statements). The weighted average exchange ratio of Swiss Francs to U.S. Dollars at December 31, 2000, was .591 as compared to .666 in 1999. This change, which was 11.3%, affected numerous financial positions

including sales, gross margin and operating expenses. Without taking into account the exchange rate increase, sales levels would have increased from $7.73 million in 1999, to $8.84 million in 2000, a 14.4% increase or $1.11 million.

Pharmaceuticals' sales of Oncology Products increased $41,000, or 2.4%, to $1.72 million for the year ended December 31, 2000, as compared to $1.68 million for the same period in 1999. Without taking into account the exchange rate increase, sales levels would have increased from $1.68 million in 1999, to $2.16 million in 2000, a 28.6% increase or $0.48 million. This increase was primarily the result of cytotoxic sales in Europe and Brazil as well as sales of 5-Fluorouracil. The Company anticipates that Pharmaceuticals' sales will continue to increase based upon increases in levels forecast under the APP arrangement as well as other distribution channels that the Company is developing. The Company intends to devote additional capital resources, if available, to increase the production capacity in the next 12 months, especially in the field of lyophilized products.

Bioren's sales of IV Solutions decreased by $115,000, or 1.9%, to $5.93 million for the year ended December 31, 2000, as compared to $6.05 million for 1999. Without taking into account the exchange rate increase, sales levels would have increased from $6.05 million in 1999, to $6.68 million in 2000, a 10.4% increase or $0.63 million. Sales of infusion bags increased by $0.24 million, whereas contract manufacturing and new products such as Metronidazole increased by $0.39 million. The average selling price of infusion bags remained stable in 2000. The Company anticipates that Bioren's sales will continue to increase mainly with new products such as Nitroglycerin and Bupivacaine.

Costs of Goods Sold and Gross Margins. Cost of goods sold for the year ended December 31, 2000 was $6.27 million, which yielded a product gross margin of 18.1%, compared to a cost of goods sold of $6.45 million for the same period of 1999, which yielded a gross margin of 16.4%. The lower cost of goods sold in 2000, and increase in margins, resulted from lower production costs at Pharmaceuticals due to management efforts to reduce raw material purchase prices

and optimize the production cycle. Without taking into account the exchange rate increase, cost of goods sold would have increased from $6.45 million in 1999, to $7.07 million in 2000, a 9.6% increase or $0.62 million. As a result, gross margin would have increased from $1.27 million in 1999, which yielded a product gross margin of 16.4%, as compared to $1.77 million in 2000, which yielded a gross margin of 20%.

Pharmaceuticals' cost of goods sold in 2000 was $1.79 million, which yielded a product gross margin of -3.7%, compared to cost of goods sold of $1.8 million in 1999, which yielded a gross margin of -7.6%. Production cost efficiencies explained the gross margin increase in 2000. The Company anticipates that gross margin levels should improve as Pharmaceuticals increases manufacturing levels.

Bioren's cost of goods sold in 2000 was $4.48 million, which yielded a product gross margin of 24.4%, compared to cost of goods sold of $4.65 million in 1999, which yielded a gross margin of 23%. The lower cost of goods sold and increase in gross margin was primarily due to the stabilization in the average selling price of infusion bags and production cost reductions related to higher manufacturing levels.

Operating Expenses. Total operating expenses decreased slightly from $5.89 million in 1999 to $5.83 million in 2000.

Research and development expenses increased by 16%, or $383,000, from $2,375,000 in 1999 to $2,758,000 in 2000. This increase resulting of the Company's commitment to not increase the number of employees but to maintain a significant level of research and development investment in support of its line of pharmaceutical products focusing in Oncology Products. Most of the research and development expenditures were incurred at Pharmaceuticals. The Company will continue to devote substantial resources to research and development during the next several years and does not anticipate significant decreases in research and development spending.

Selling, general and administrative expenses decreased by 12.5%, or $441,000, from $3.51 million in 1999, to $3.07 million in 2000. The decrease is primarily due to a reduction in personnel at both Swiss plants.

Operating Loss. Operating loss, as a result of the foregoing, was $4.45 million and $4.62 million in 2000 and 1999, respectively, a decrease of 3.6%. Without taking into account the exchange rate increase, operating loss would have been unchanged at $4.62 million, as a result of higher gross margins in both companies and higher research and development expenses at Pharmaceuticals.

Other Expense. Other expense amounted to a net expense of $0.8 million for 2000, as compared to a net expense of $1.7 million in 1999. The decrease of $0.9 million, or 53%, included fluctuations in three significant areas: gain/loss on foreign currency transactions, interest expense, and other income. In 1999, the Company incurred a loss on foreign currency transactions of $836,600 whereas it incurred a loss in 2000 of $6,980. Effective January 1, 2000, $7.14 million of the intercompany debt was no longer considered short-term as repayment is not expected in the foreseeable future. Accordingly, the gain or loss on translating such debt was included in the cumulative translation adjustment as a separate component of stockholders' equity. As a consequence, the remaining amount of $6,980 was related to the short-term part of the intercompany debt. Interest expense increased $56,500, or 6.3%, from $0.89 million in 1999, to $0.95 million in 2000. The increase is due to higher interest rates on various Swiss notes payable and lines of credit that are adjustable with the money market increase and due to an overall increase in notes payable and long-term debt of $0.85

million. The increase of other income increased $114,500 from $19,500 in 1999, to $134,000 in 2000. This increase is attributable to the sale of fully depreciated equipment to a third party during the second quarter of 2000.

Income Taxes. Income tax expense was zero for both 2000 and 1999, due to sustained losses and net operating loss carryforwards from prior years.

Net Loss. For the fiscal year ended December 31, 2000, the Company reported a net loss of $4.89 million. For the same period of 1999, net loss was $6.32 million. The corresponding basic and diluted loss per share was $0.50 in 2000, versus $0.73 in 1999.

Pharmaceuticals' net loss in 2000 amounted to $0.33 million, compared to $1.06 million in 1999, a decrease of $0.73 million or 69%. The decrease in net loss resulted from increases in margins due to production efficiencies and reductions in operating expenses. Bioren's net loss in 2000 amounted to $24,500, compared to $229,600 in 1999, a decrease of $205,100 or 89%. The decrease at Bioren is primarily due to reductions in research and development expenses as well as a non-recurring income related to the sale of a fully depreciated equipment.

YEAR ENDED DECEMBER 31, 1999 COMPARED TO YEAR ENDED DECEMBER 31, 1998

Sales. Total sales were $7.73 million for the year ended December 31, 1999, as compared to $6.38 million for 1998. The increase of 21%, or $1.35 million, is due to the first deliveries of Oncology Products shipped under the APP arrangement, which occurred during the fourth quarter 1999, resulting in sales of $1.0 million.

Pharmaceuticals' sales of Oncology Products increased $1.28 million, or 318%, to $1.68 million for the year ended December 31, 1999, as compared to $401,000 for the same period in 1998. This increase was primarily the result of cytotoxic sales to APP in the United States ($1.0 million) and Europe ($0.2 million).

Bioren's sales of IV Solutions increased by $70,000, or 1%, to $6.05 million for the year ended December 31, 1999, as compared to $5.98 million for 1998. Sales of infusion bags increased by $400,000, whereas contract manufacturing decreased by $300,000. During 1999, Bioren ceased contract manufacturing for one third-party product to optimize its production capacity and relaunch a new product in year 2000. The average selling price of infusion bags decreased by 4% in 1999, compared to the prior year due to the high level of competition in the Swiss marketplace. Nevertheless, Bioren succeeded in increasing its infusion bag market share by 5% in Switzerland due to better customer support, offsetting the impact of price reductions.

Costs of Goods Sold and Gross Margins. Cost of goods sold for the year ended December 31, 1999, was $6.45 million, which yielded a product gross margin of 16.5%, compared to a cost of goods sold of $4.81 million for the same period of 1998, which yielded a gross margin of 24.5%. The higher cost of goods sold in 1999, and reduction in margins, is primarily due to high production costs related to the first production batches of Pharmaceuticals and price pressure at Bioren.

Pharmaceuticals' cost of goods sold in 1999 was $1.80 million, which yielded a product gross margin of -7.6%, compared to cost of good sold of $391,000 in 1998, which yielded a gross margin of 2.6%. The increase in cost of goods sold is due to fourth quarter sales to APP. The decrease in gross margin is due to high production costs related to the first production batches for APP at the Pharmaceuticals Facility.

Bioren's cost of goods sold in 1999 was $4.65 million, which yielded a product gross margin of 23%, compared to cost of goods sold of $4.42 million in 1998, which yielded a gross margin of 26%. The higher cost of goods sold and decrease in gross margin is primarily due to the decrease in the average selling price of infusion bags by 4% in 1999, compared to 1998, due to the high level of competition in the Swiss marketplace. The decrease in selling price was offset by Bioren succeeding in increasing its infusion bag market share by 5% in Switzerland due to better customer support.

Operating Expenses. Total operating expenses decreased by 17%, or $1.23 million, from $7.12 million in 1998 to $5.89 million in 1999.

Research and development expenses decreased by 13%, or $366,000, as a result of the Company's commitment to reducing the number of employees but maintaining a significant level of research and development investment in support of its line of pharmaceutical products focusing in Oncology Products. Most of the Company's reduction in research and development occurred at its U.S. facility where total research and development expenses decreased approximately $959,000. This decrease was offset by increases at the operating segments. The Company will continue to devote substantial resources to research and development during the next several years and does not anticipate significant decreases in research and development spending.

Selling, general and administrative expenses decreased by 20%, or $864,000, from $4.38 million in 1998 to $3.51 million in 1999. The decrease is primarily due to a reduction in personnel at the Company's U.S. facility and at each of the operating segments.

Operating Loss. Operating loss, as a result of the foregoing, was $4.62 million and $5.55 million in 1999, and 1998, respectively, a decrease of 17%. Pharmaceuticals' operating loss was $1.98 million in 1999, as compared to $408,000 in 1998, an increase of 385%. The Phamaceuticals' increased operating loss is primarily a result of decreases in margins due to the first production batches and higher research and development costs incurred prior to reaching full production. Bioren's operating income was $65,000 in 1999, compared to a $158,000 operating loss in 1998. The change in Bioren's operating income is primarily due to reductions in personnel resulting in decreased selling, general and administrative expenses. In addition to the two segments, operating loss also includes $2.70 million of general corporate expenses in 1999, and $5.8 million in 1998, a decrease of 53%. The reduction in general expenses is a reduction in personnel in both research and development and general, selling and administrative.

Other Expense. Other expense amounted to a net expense of $1.71 million for 1999, as compared to a net expense of $1.67 million in 1998. The increase of $40,000, or 2%, included fluctuations in three significant areas: interest expense, issuance of preferred stock warrants for a loan guarantee, and gain/loss on foreign currency transactions. Interest expense decreased $170,000, or 16%, from $1.06 million in 1998, to $892,000 in 1999. The decrease is due to the Company's efforts to obtain lower interest rates on various notes payable and lines of credit and due to an overall decrease in notes payable and long-term debt of $2.2 million. In the prior year, the Company incurred a non-recurring non-cash charge of $958,000 related to preferred stock warrants issued in consideration to obtain a guarantee to renew and increase a line of credit. There was no such charge in 1999. These decreases were offset by a change in gain/loss in foreign currency transactions. In 1998, the Company incurred a gain on foreign currency

transactions of $332,000 whereas it incurred a loss in 1999 of $837,000. The

loss in 1999, which arises for the most part from the translation of intercompany balances that are considered short-term, is primarily due to the increase of the U.S. Dollar exchange rate against the Swiss Franc combined with an increase of intercompany borrowing of $657,000. The exchange ratio of Swiss Francs to U.S. Dollars at December 31, 1999, was .626 as compared to .708 in 1998. This 12% change affected numerous financial balances including property, plant and equipment, and long-term debt.

Income Taxes. Income tax expense was zero for both 1999 and 1998, due to sustained losses and net operating loss carryforwards from prior years.

Net Loss. For the fiscal year ended December 31, 1999, the Company reported a net loss of $6.32 million. For the same period of 1998, net loss was $7.22 million. The corresponding basic and diluted loss per share was $0.73 in 1999, versus $1.46 in 1998.

Pharmaceuticals' net loss in 1999 amounted to $1.06 million compared to $820,000 in 1998, an increase of $240,000, or 29%. The increase in net loss is due to decreases in margins due to the first production batches and higher research and development costs incurred prior to reaching full production, offset by certain intercompany charges. Bioren's net loss in 1999 amounted to $230,000, compared to $315,000 in 1998, a decrease of $86,000, or 27%. The decrease at Bioren is primarily due to reductions in personnel resulting in decreased selling, general and administrative expenses.

Fourth Quarter. Net sales for the fourth quarter of 1999 amounted to $3.1 million, as compared to $1.5 million in 1998. The increase in 1999 is due to the APP sales during the fourth quarter.

LIQUIDITY AND CAPITAL RESOURCES

Operating Activities. The Company's working capital at December 31, 2000, was a $3.6 million deficit, and at December 31, 1999, was a $2.3 million deficit. The biggest factors influencing working capital were the increase in inventories of $0.2 million for anticipated year 2001 deliveries, general increases in business levels, and the increase in notes payable to related parties of $1.2 million. Working capital was also influenced by accounts payable increasing by $0.7 million, notes payable decreasing $0.9 million, prepaid expenses decreasing $0.1 million, and accrued expenses increasing $0.1 million.

Net cash used in operating activities during 2000 was $2.3 million, a decrease from the previous year's cash used of $5.3 million. Net loss, less non-cash items used, was $3.3 million in 2000, and $3.5 million in 1999, while working capital provided was $1.0 million in 2000, and used was $1.8 million in 1999. The increase with respect to working capital is principally due to increases in accounts payable and notes to related parties for Pharmaceuticals' growth.

The Company has incurred, and will continue to incur, substantial expenditures for research and development activities related to bringing its products to the commercial market. The Company intends to devote significant additional funds to product development, formulation, clinical testing, product registration, and other activities required for regulatory review of generic Oncological Products. The amount required to complete such activities depends upon the outcome of regulatory reviews. The regulatory bodies may require more testing than is currently planned by the Company. There can be no assurance that the Company's generic Oncological Products will be approved for marketing by the FDA or any foreign government agency or that any such products will be successfully introduced or achieve market acceptance. Although the Company expects that cash flows from operating activities will continue to improve in the future, the Company expects that additional funds will be needed from financing activities.

Investing Activities. The Company's investing activities in 2000 involved the

purchase of property, plant and equipment. Capital expenditures for 2000 were $0.6 million, a $0.1 million increase from $0.5 million in 1999. The higher expenditures reflect the completion in 2000 of the Pharmaceuticals' Facility

packaging area. The Company anticipates higher levels of investing activities in the short-term due to planned equipment purchases to increase manufacturing capacity.

Financing Activities. Net cash provided by financing activities was $2.8 million in 2000, and $5.8 million in 1999.

Early in 2000, the Company extinguished $4.3 million of its long-term debt. The Company paid $3.9 million and the bank forgave $0.4 million. The amount that was repaid was financed by loans of $2.7 million from Credit Suisse, a $1.1 million loan from a stockholder, and cash of $0.1 million.

In December 2000, the Company issued 1,000 shares of Series B Convertible Preferred Stock to Banca del Gottardo via a private placement offering. The proceeds of this Preferred Stock issuance was used primarily for working capital. The offering of such shares of Preferred Stock was made pursuant to an exemption from registration under Regulation S of the Securities Act as a private transaction not involving a public distribution.

During 2000, the Company also received $2.8 million in proceeds from issuance of Common Stock. The Company sold 1,175,000 shares of Common Stock, at $2.00 to $2.75 per share. These shares were exclusively issued to Banca del Gottardo. The proceeds of this Common Stock issuance were used primarily for working capital. The offering of such shares of Common Stock was made pursuant to an exemption from registration under Regulation S of the Securities Act as a private transaction not involving a public distribution.

Subsequent to December 31, 2000, the Company issued 7,000 shares of Series B Convertible Preferred Stock, $0.001 par value per share, and warrants at $2.00 for the purchase of 1,400,000 shares of the Company's Common Stock, $0.001 par value per share, to Banca del Gottardo via a private placement offering. The proceeds of this Preferred Stock issuance will be used for repayment of the $4,000,000 convertible notes issued in 1997 and related interest, and for repurchase of the above 1,000 Preferred Shares including accrued dividends. Net proceeds of $1,651,776.67 will be applied primarily to working capital. The offerings of such shares of Preferred Stock and warrants was made pursuant to an exemption from registration under Regulation S of the Securities Act as private transactions not involving a public distribution.

In addition to the first quarter 2001 activity described above, the Company anticipates that additional capital funding together with cash from operations will be required to sustain operations through 2001. However, there can be no assurance that events affecting the Company's operations will not result in the Company depleting its funds before that time. Management is currently discussing additional financing with a number of financial institutions and investors, but there are no assurances that the Company will be able to obtain additional financing or that such financing, if available, will be on acceptable terms.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In December 1999, the SEC issued Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements". SAB 101 was also amended by SAB 101A and 101B. SAB 101, 101A and 101B summarize the staff's views in applying generally accepted accounting principles to revenue recognition in financial

statements. The Company adopted SAB 101 during the fourth quarter of 2000. SAB 101 did not have a material impact on the Company's results of operations or financial position.

In June 1999, the Statement of Financial Accounting Standards No. 137 ("SFAS No. 137"), "Accounting for Derivative Instruments and Hedging Activities - Deferral of Effective Date of FASB Statement No. 133" was issued. Statement No. 137 deferred the effective date of Statement No. 133 to all fiscal quarters of fiscal years beginning after June 15, 2000. Statement No. 133 requires that all derivatives be recorded in the balance sheet as either assets or liabilities and be measured at fair value. Management has evaluated

this standard and this statement will not have a material impact on the Company's financial position or result of operations.

RISK FACTORS

Limited Operating History; History of Operating Losses; Uncertainty of Future Profitability; Going Concern Qualification. The Company has a limited operating history and is in the early stage of commercializing its products. As of December 31, 2000, the Company had incurred an operating loss of approximately $4.5 million. Losses to date have resulted principally from research and development costs and low margins due to first production batches. There can be no assurance that the Company will ever generate sufficient revenues to attain operating profitability. In addition, the Company may experience fluctuations in revenues and operating results based on such factors as the demand for the Company's products; the timing, costs and acceptance of product introductions; levels of third-party payment; alternative treatments currently existing or which may be introduced in the future; comparative conditions; regulatory announcements; and changes affecting the Company's products and general economic conditions.

Future Capital Needs. The Company's future capital requirements will depend on many factors, including its ability to generate revenues through its ability to market its products successfully, the cost of manufacturing, the size of its research and development programs, the length of time required to collect accounts receivable, competition, regulatory announcements, and costs associated with and the timing relating to the implementation of the Company's business strategy. The Company's ability to satisfy future capital needs will depend on conditions in the generic pharmaceuticals market and the market for the securities of small capitalization companies and pharmaceutical companies in particular.

Uncertainties Regarding Patents and Proprietary Rights. As a manufacturer of off-patent, generic pharmaceuticals, the Company's success will depend upon its ability to operate without infringing the proprietary rights of third parties. Although the Company only manufactures pharmaceuticals for which it believes the patent has expired, there can be no assurance that the "expiration" will not be challenged or denied by either the U.S. Patent and Trademark Office, any of its foreign counterparts or by courts inside or outside the United States. In some cases, litigation or other proceedings may be necessary to defend against claims of infringement and to determine the validity of the proprietary rights of third parties. Such litigation could result in substantial costs to and diversion of resources by the Company. An adverse outcome in any such litigation or proceeding could subject the Company to significant liabilities, require the Company to obtain alternative non-infringing alternatives, require the Company to cease producing the particular drug or require the Company to license the manufacture of the drug from the third party, all of which could have a material adverse effect upon the Company's business, financial condition and results of

operations. If any licenses are required, there can be no assurance that the Company will be able to obtain any such license on commercially reasonable terms, if at all, and if these licenses are not obtained, the Company might be prevented from manufacturing some of its pharmaceuticals.

Dependence upon Collaborative Arrangement with Distributors. One of the Company's strategies to penetrate the generic oncology pharmaceuticals and related products market is to enter into various collaborative arrangements with established pharmaceutical distribution companies. The Company recently entered into such an arrangement with APP, giving it exclusive distribution rights for certain oncology drugs. The Company has entered into a number of exclusive marketing agreements, which have provided the Company with sales, but also limits the Company's control over its marketing abilities and strategies. The acceptance of the Company's products in the market place is dependent upon the exclusive distributor's ability to demonstrate the benefits of the Company's products to the medical and health care communities and to sell commercial quantities at acceptable costs. There is no assurance that the third party distributors will be able to provide adequate sales for the Company to become profitable nor is there any assurance the Company will be able to continue building successful distribution relationships with further distributors.

Competition. Competition in the pharmaceutical industry is intense and subject to rapid technological change. Competitors of the Company are numerous and include United States and international companies. See "Item 1 - Competition." In addition, the Company may face competition from alternative methods of treatment such as surgery, radiation and other new oncology treatments. Many of the Company's competitors may have substantially greater financial and technical resources, production and marketing capabilities and experience in the generic oncology pharmaceutical field. There can be no assurance that the Company will be able to compete favorably in the pharmaceutical market.

Fluctuations in Operating Results. The Company's operating results may vary significantly from quarter to quarter or year to year, depending on factors such as timing of product development, the timing and terms of collaborative distribution agreements, the timing of increased research and development and sales and marketing expenses, the timing and size of orders and the introduction of new products by the Company and by competitors. The Company's current and planned expense levels are based in part on its expectations as to future revenue. Consequently, revenue and operating results may vary significantly from quarter to quarter or year to year, and revenue and operating results in any period will not necessarily be predictive of results in subsequent periods.

Dependence on Outside Suppliers. Although the Company manufacturers its pharmaceutical products at its own manufacturing facilities, a majority of raw materials the Company uses to manufacturer its products are generally not readily available and are purchased from limited sources. Although the Company believes that alternative sources for such raw materials and components are available, an interruption in the supply of the raw materials or components would have a material adverse affect on the Company's ability to manufacture its products until a new source of supply was qualified. In addition to the risk exposure that the Company may be unable to obtain adequate supplies of required raw materials and components, the Company is also exposed to the risk that the cost of the raw materials and components may rise but its control over the timely delivery and quality of the products is reduced.

Dependence on Key Employees. Competition among pharmaceutical companies for qualified employees is intense, and the loss of any such qualified employees, or an inability to attract, retain and motivate any additional highly skilled employees necessary for the maintenance and expansion of the Company's activities, could have a material adverse effect on the Company. There can be no

assurance that the Company will be able to retain its existing key personnel or to attract additional qualified employees. A loss of the services of one or more of the members of the senior management group or the Company's inability to hire additional personnel, could have an adverse effect on the Company's business, financial condition and results of operations.

Product Liability; Availability of Insurance. Although the Company has obtained product liability insurance, there can be no assurance that it will be able to maintain such insurance on acceptable terms or that insurance will provide adequate coverage against potential liabilities.

Limitations On Third Party Payments; Uncertain Effects Of Managed Care. The Company's ability to commercialize its products successfully in the United Sates and other countries will depend in part on the extent to which acceptance of payment for such products will continue to be available from government health administration authorities, private health insurers and other payors. Cost control measures adopted by third party payors in recent years have had, and may continue to have, a significant affect on the purchasing patterns of many health care providers. This could work to the benefit of the Company in its sale of generic oncology pharmaceuticals. However, payors are increasingly challenging the prices and clinical efficacy of medical products. Significant uncertainty exists as to the reimbursement status of newly improved health care products, including pharmaceuticals, and there can be no assurance that adequate third party coverage will continue to be available to the Company at current or increased levels.

Uncertainty and Potential Negative Effects of Health Care Reform. The health care industry is undergoing

fundamental changes resulting from political, economic and regulatory influences. The Company anticipates that the United States Congress and state legislatures will continue to review and assess alternative health care delivery systems and methods of payment. Due to uncertainties regarding the outcome of reform initiatives, the Company cannot predict which proposals will be adopted and when they might be adopted. Other countries are also considering health care reform. The Company's plan for its international sales are largely dependent upon other countries adopting managed care systems that will provide adequate reimbursement through third party payors, which will have a positive affect on the Company's sales. Significant changes and health care systems are likely to have a substantial impact over time on the manner in which the Company conducts it business and could have a material adverse affect on the Company's business, financial conditions and results of operations and its ability to market its products as currently contemplated.

Government Regulation. The Company's current and future products and manufacturing activities will be regulated by a number of governmental regulations involving the production and sale of pharmaceuticals. The FDA and comparable agencies in many foreign countries may impose substantial limitations on the introduction of foreign manufacturers of pharmaceuticals. The Company is also required to adhere to extensive recordkeeping reporting and inspections by government agencies. Failure to comply with these and other applicable regulatory requirements could result in significant fines, suspensions, seizures and recalls of products or operating restrictions and even criminal prosecutions. Changes in existing regulations or interpretations of existing regulations could prevent the Company from obtaining future regulatory approvals. If the Company experiences a delay in receiving or fails to obtain any governmental approval for any of its current or future products, or fails to comply with any regulatory requirements, the Company's business, financial condition and results of operations could be materially adversely affected.

ITEM 7. FINANCIAL STATEMENTS

The Consolidated Financial Statements of the Company, together with the report thereon of KPMG LLP ("KPMG"), dated March 12, 2001, are set forth on pages F-2 through F-27.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK. On January 1, 1999, 11 member countries of the EU (Switzerland excluded) established fixed conversion rates between their existing sovereign currencies, and adopted the Euro as their own common legal currency. The Euro is currently trading on currency exchanges and the legacy currencies will remain legal tender in the participating countries for a transition period between January 1, 1999, and December 31, 2001. Between January 1, 2002, and July 1, 2002, the participating countries will introduce Euro notes and coins and withdraw all legacy currencies so that they will no longer be available. Based on current information and management's current assessment, the Company does not expect that Euro conversion will have a material adverse effect on its business or financial condition.

In the normal course of business, operations of the Company are exposed to fluctuations in currency values. These fluctuations can vary the costs of financing, investing, and operating activities. The Company does not have any programs in place to control these risks.

The Company's foreign currency risk exposure results from fluctuating currency exchange rates, primarily the fluctuation of the U.S. Dollar against the Swiss Franc ("Sfr"). The Company faces transactional currency exposures that arise when its foreign subsidiaries (or the Company itself) enter into transactions denominated in currencies other than their local currency. The Company also faces currency exposure that arises from translating the results of its Swiss operations to the U.S. Dollar at exchange rates that have fluctuated from the beginning of the period. The Company does not have any programs in place to control these risks. Effective January 1, 2000, $7.14 million of the outstanding intercompany debt was no longer considered short-term as repayment was not expected in the foreseeable future. Accordingly, the gain or loss on translating such debt was included in the cumulative translation adjustment as a separate component of stockholders' equity.

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The table below provides information about the Company's debt instruments (not including lines of credit) by functional currency and presents such information in U.S. dollar equivalents:

	Expected Maturity Date			
	2001	2002	2003	2004
(US$ Equivalent) except average interest rate				
Long-Term Debt:				
Fixed Rate ($US)	$ --	4,000,000	--	--
Average interest rate	--	8.0%	--	--
Fixed Rate (Sfr)	$ 1,055,245	--	1,862,197	--
Average interest rate	5.0%	--	4.0%	--
Variable rate ($US)	$ 127,000	--	--	--
Average interest rate	9.5%	--	--	--

Variable Rate (Sfr)	$ 626,940	564,867	378,647	254,500
Average interest rate	5.9%	5.9%	5.6%	5.2%

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

The names of the directors and certain executive officers of the Company, and certain information about them, are set forth below.

Name	Age	Recent History
Bernard Kramer	47	In 2001, Mr. Kramer was elected Chief Operating Officer and h Director of the Company since April 1996. From January 1988, 1996, Mr. Kramer worked at Bioren SA, a wholly-owned subsidia where he was a manager, responsible for quality control and b development of pharmaceutical products.
Cynthia R. May	49	Ms. May has served as a member of the Board of Directors sinc 2001, Ms. May was elected President of the Company. Ms. May h by Saginaw Control & Engineering Corp., a private manufacturi 1981, most recently as Vice President. Ms. May has been Memb Investments, L.L.C. since 1994, a Member of GRQ, L.L.C. since Managing Member of Jericho II, L.L.C. since September 1997, e privately-owned entity involved in investment and financing. L.L.C. is a principal shareholder of the Company.
Massimo Pedrani	46	In 2001, Mr. Pedrani was elected Executive Vice-President of Development. Mr. Pedrani was elected to the Board of Director Since January 1997, Mr. Pedrani has been Managing Director of pharmaceutical consulting company involved in chemical, pharm development and regulatory affairs. From September 1992 to A Pedrani was Managing Director of Applied Analytical Industrie subsidiary of Applied Analytical Industries, Inc. Mr. Pedran the American Association of Pharmaceutical Scientists.
Philippe J.H. Rohrer	44	Mr. Rohrer was appointed to the Board of Directors in June 19 1999, he was appointed as Treasurer of the Company. He is Ch Officer of Bigmar Inc., Bioren SA and Bigmar Pharmaceuticals wholly-owned Swiss subsidiaries of Bigmar, Inc. He joined Bi 1990, as Finance and Administration Manager with responsibili computerization and administration of Bioren.
John G. Tramontana	55	Mr. Tramontana served as Chairman of the Board, President and Officer of the Company since its inception in September 1995. Tramontana resigned as President of the Company. From Novembe 1996, Mr. Tramontana was the Chief Operating Officer and a Di Chemholding, a holding company for five pharmaceutical compan the development, manufacture, and commercialization of active

ingredients and finished pharmaceutical products. He held ex
at Adria Laboratories (now Pharmacia & Upjohn) from 1974 to 1
Laboratories from 1985 to 1989.

ITEM 10. EXECUTIVE COMPENSATION

SUMMARY COMPENSATION TABLE

The following table sets forth information regarding compensation paid by the Company for the last three fiscal years to its Chief Executive Officer and the other most highly compensated executive officers whose annual compensation exceeded $100,000 for the year ended December 31, 2000:

		ANNUAL COMPENSATION			LONG-TE COMPENSA AWARD
NAME AND PRINCIPAL POSITION	YEAR	SALARY ($)	BONUS ($)	OTHER ANNUAL COMPENSATION ($)	SECURIT UNDERLY OPTIONS/ (#)(2
John G. Tramontana Chairman of the Board of Directors, President, and Chief Executive Officer	2000	200,000	0	0	0
	1999	200,000	0	0	0
	1998	200,000	0	0	125,00
Peter P. Stoelzle (3) Executive Vice President	2000	0	0	0	0
	1999	140,000	0	0	0
	1998	140,000	0	0	10,00

(1) Amounts relate to annual auto allowance.

(2) Shares of common stock underlying options issued pursuant to the 1997 Stock Option Plan.

(3) Mr. Stoelzle's employment with the Company was terminated in December 1999.

OPTION/SAR GRANTS IN LAST FISCAL YEAR

No options or stock appreciation rights were granted during the fiscal year ended December 31, 2000.

AGGREGATED OPTION/SAR EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR END OPTION/SAR VALUES

No options were exercised during the fiscal year ended December 31, 2000. The Company has no outstanding stock appreciation rights. The following table lists the value of unexercised options for the named executive officers as of December 31, 2000.

	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT FY-END (#)		VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS AT FY-END ($)	
NAME	EXERCISABLE	UNEXERCISABLE	EXERCISABLE	UNEXERCISABLE
John G. Tramontana	250,000(1)	0	0	0
Peter P. Stoelzle (2)	0	0	0	0

(1) Includes 125,000 stock options originally granted under the 1996 Stock Option Plan repriced under the 1997 Stock Option Plan and 125,000 new stock options granted under the 1997 Stock Option Plan.

(2) Mr. Stoelzle's employment with the Company was terminated in December 1999.

COMPENSATION OF DIRECTORS

Directors who are not employees of the Company receive $500 per meeting attended as a Director. Committee members receive $500 per committee meeting attended. In addition, all directors are reimbursed for their reasonable out-of-pocket expenses in connection with attending meetings of the Board or any committee thereof. The Board of Directors met five times in 2000. Each Director attended at least 75% of the meetings. The directors waived their fees and out-of-pocket expense reimbursements for the meetings held in fiscal 2000.

EMPLOYMENT AGREEMENTS

In April 1996, the Company entered into an employment agreement with Mr. Tramontana to serve as the Company's President and Chief Executive Officer. The employment agreement is for a five-year term commencing June 19, 1996, and is subject to automatic annual renewal unless earlier terminated. Pursuant to the terms of this employment agreement, Mr. Tramontana is required to devote his full business time and attention to fulfill his duties and responsibilities to the Company. Mr. Tramontana's initial base salary was $200,000 subject to annual cost of living increases at the discretion of the Company's Board of Directors. Mr. Tramontana's based salary for fiscal 2000 has been set at $200,000. In addition to his base salary, Mr. Tramontana is entitled to receive an annual bonus, at the discretion of the Board of Directors, provided such bonus is equal to at least 25% of his base salary. For 1999 and 2000, Mr. Tramontana agreed to waive the minimum bonus of 25% of his base salary.

Mr. Tramontana's employment agreement provides that the Company is required to provide Mr. Tramontana with an automobile allowance of $6,000 per annum and the Company is required to obtain life insurance coverage on the life and for the benefit of Mr. Tramontana in an amount equal to $500,000, assuming he is insurable. Mr. Tramontana also has the right to participate in all benefit plans afforded or which may be afforded to other executive officers during the term of the agreement including, without limitation, group insurance, health, hospital, dental, major medical, life and disability insurance, stock option plans and other similar fringe benefits. If Mr. Tramontana dies or is unable to perform his duties on account of illness or other incapacity and the agreement is terminated, he or his legal representative shall receive from the Company the base salary that would otherwise be due to the end of the month during which the termination of employment occurred plus three additional months of base salary in the event of death and six additional months of base salary in the event of illness or other incapacity.

The agreement further provides that if the Company terminates Mr. Tramontana's employment for cause or if Mr. Tramontana voluntarily leaves the employment of the Company, Mr. Tramontana shall receive his salary through the end of the month in which the termination occurred. If Mr. Tramontana's employment is terminated by the Company without cause, Mr. Tramontana shall receive from the Company the base salary that would otherwise be due to the end of the month during which the termination of employment occurred, plus four additional months. Mr. Tramontana's employment agreement contains certain confidentiality and non-competition provisions. The Company has obtained $2,000,000 of key-person life insurance for the benefit of the Company on the life of Mr. Tramontana.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of the Company's Common Stock at March 30, 2001, with respect to (i) each person known to the Company to own beneficially more than five percent of the outstanding shares of the Company's Common Stock, (ii) each director of the Company, (iii) each of the named executive officers and (iv) all directors and executive officers of the Company as a group.

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	SHARES BENEFICIALLY OWNED (1)	
IDENTITY OF STOCKHOLDER OR GROUP	NUMBER	PERCENT
Bernard Kramer (2)	35,000	*
Cynthia R. May (3)	6,607,805	56.6
Massimo Pedrani	0	0
Philippe J.H. Rohrer (4)	35,000	*
John G. Tramontana (5)	1,285,800	12.3
Jericho II, LLC (6) 13260 Spencer Road Hemlock, Michigan 48626	6,607,805	56.6
Banca del Gottardo Viale Stefano Franscini 8 CH-6901 Lugano Switzerland	1,245,000	12.2
All directors and executive Officers as a group (6 persons) (7)	8,048,605	67.1

Less than 1%

(1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission ("SEC") and generally includes voting or investment power with respect to securities. In accordance with SEC rules, shares that may be acquired upon exercise of stock options that are currently exercisable or that become exercisable within 60 days of the date of the table are deemed beneficially owned by the optionee. Except as indicated by footnote, and subject to community property laws where applicable, the persons or entities named in the table above have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them.

(2) Includes 35,000 shares subject to options.

(3) Includes 6,423,539 shares of Common Stock held by Jericho II, LLC (of which 1,500,000 shares issuable upon exercise of warrants) and 184,266 shares of Common Stock held by GRQ, LLC.

(4) Includes 35,000 shares subject to options.

(5) Includes 250,000 shares subject to options.

(6) Includes 1,500,000 shares issuable upon exercise of warrants and 184,266 shares of Common Stock held by GRQ, L.L.C.

(7) Includes 1,905,000 shares directors and executive officers have a right to acquire upon exercise of stock options.

CHANGES IN CONTROL

In May 1998, in consideration of a guarantee of an increased line of credit from a commercial institution, the Company delivered to Jericho II, L.L.C. ("Jericho") warrants to purchase 1,000,000 shares of convertible Preferred Stock (the "Preferred Stock") at a price per share equal to $2.5625 and having a term of 10 years (the "Warrants"). The Preferred Stock is convertible to Common Stock on a one-to-one basis, subject to adjustment to reflect dilutive issuances of equity securities by the Company and stock splits,

dividends, combinations and similar events. The Preferred Stock is entitled to five votes per share and votes together with the Common Stock in addition to having certain special approval rights. The Preferred Stock has a liquidation preference equal to the purchase price per share. The Warrants include a net exercise clause (to permit the conversion of the Warrants into shares having a fair market value equal to the spread between the exercise price and the then fair market value) and the shares issuable on exercise shall be entitled to piggyback registration rights, subject to certain restrictions.

Jericho holds other warrants to purchase up to 500,000 shares of the Company's Common Stock.

In October 1998, Jericho acquired 3,692,308 shares of newly issued Common Stock for a purchase price of $6,000,000.

In January 1999, pursuant to a Debt Repayment Agreement, 1,231,231 shares of Common Stock were transferred to Jericho from John G. Tramontana in satisfaction of a debt incurred by a third party holder of the Company's Common Stock. Mr. Tramontana, Chief Executive Officer and Chairman of the Board of Directors of the Company, has a 50% ownership interest in Jericho. Cynthia R. May, President and a Director of the Company, is the Managing Member of Jericho and as such, has sole voting and investment power over shares of the Company's Common Stock owned by Jericho.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In 1998, the Company effected several transactions with Jericho involving securities of the Company. See "Changes in Control". John G. Tramontana owns a 50% interest in Jericho, and Cynthia R. May has sole voting and investment power over shares of the Company's Common Stock owned by Jericho.

In December 1998, pursuant to promissory notes, the Company borrowed an aggregate amount of $185,000 from Jericho. The principal sum, together with interest at the prime rate, was repaid in full in February 1999. Also, in

December 1998, the Company borrowed $100,000 from GRQ, L.L.C., an affiliate of Cynthia R. May, which sum together with interest at the prime rate was repaid in full in March 1999.

In December 1996, the Company entered into a lease agreement with JTech Laboratories, Inc. ("JTech"). The lease commenced on the completion of construction of an approximately 8,600 square foot office and laboratory facility. The lease is at a rental of approximately $120,000 per annum. Mr. Tramontana is the President and a Director of JTech.

Pursuant to the terms of the $4.0 million Note Purchase, Paying and Conversion Agency Agreement with Banca del Gottardo (the "Bank"), the Bank, at its option, may appoint two members of its choice to the Company's Board of Directors. As of March 15, 2001, the Bank has not exercised its option to appoint board members.

PART IV

(a) EXHIBITS:

NUMBER	DESCRIPTION OF EXHIBIT
3.1	Restated and Amended Certificate of Incorporation
3.1(a)	Certificate of Correction to Restated and Amended Certificate of Incorporation the Registrant
3.1(b)	Certificate of Amendment of Amended and Restated Certificate of Incorporation Bigmar, Inc.
3.2	Restated By-Laws of the Registrant
3.2(a)	Amendment to Restated By-Laws of the Registrant
4.1	Specimen Stock Certificate
4.2	Form of Representatives Warrant
4.3	Registrant's 1996 Stock Option Plan
4.4	Form of Non-qualified Stock Option Agreement under the 1996 Stock Option Plan
4.5	Form of Incentive Stock Option Agreement under the 1996 Stock Option Plan
4.6	Form of Registrant's Director Option Plan
4.7	Registrant's 1997 Stock Option Plan
4.8	Form of Non-qualified Stock Option Agreement under the 1997 Stock Option Plan
4.9	Form of Incentive Stock Option Agreement under the 1997 Stock Option Plan
10.1	Sublease Agreement dated as of March 1, 1996 between the Registrant and Cernit America, Inc.
10.2	Form of Indemnification Agreement

10.3	Employment Agreement dated as of April 15, 1996 between the Registrant and Joh G. Tramontana
10.4	Form of Medical Advisory Agreement
10.5	Form of Scientific Advisory Agreement
10.6	Exclusive Distribution and Supply Agreement dated November 5, 1995 between Bigmar Pharmaceuticals SA and AB Cernelle
10.7	Technical Services Agreement dated November 5, 1995 between Bigmar Pharmaceuticals SA and AB Cernelle
10.8	Stock for Stock Exchange Agreement dated April 9, 1996 between the Registrant and its stockholders
10.9	Contribution Agreement dated April 8, 1996 between the Registrant and it's stockholders
10.10	Exclusive Distribution Agreement dated December 22, 1995 between Bigmar Pharmaceuticals SA and Boehringer Mannheim Italia S.p.A.

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NUMBER	DESCRIPTION OF EXHIBIT
10.11	International Activities Agreements dated March 3, 1994 between Bigmar Pharmaceuticals SA and Medac GmbH
10.12	Distribution Agreement dated October 10, 1994 between Bigmar Pharmaceuticals S and Pharma Stroschein GmbH
10.13	Distribution Agreement dated July 31, 1995 between Bigmar Pharmaceuticals SA a Laboratorios Vita S.A.
10.14	Supply and Collaboration Agreement dated March 8, 1995 between Bioren SA and P Langeskov A/S10.22
10.15	Agreement dated December 21, 1995 between Laevosan international AG and Bigmar Pharmaceuticals SA
10.16	Loan documentation between Bioren SA and Union Bank of Switzerland
10.17	Loan documentation between Bigmar Pharmaceuticals SA and Union Bank of Switzer
10.18	Acquisition Agreement dated June 22, 1995 between Galenica Holding AG and the Registrant
10.19	Extension of Licensing Agreement dated October 27, 1995 between Dr. F. Messi Cella Culture Technologies and Bigmar Pharmaceuticals SA
10.20	Lease Agreement dated as of December 31, 1996 between the Registrant and JTech Laboratories, Inc.
10.21	Cancellation Agreement dated as of March 27, 1997

10.22	Release dated March 27, 1997 issued by Cerbios-Pharma in favor of the Registra
10.23	Cancellation Agreement dated as of March 27, 1997 between the registrant and Cerbios-Pharma
10.24	Cancellation Agreement dated as of March 27, 1997 between the Registrant and Cerbios-Pharma
10.25	Libor Mortgage Loan Agreement dated February 26, 1997 between the Union Bank o Switzerland and the Registrant
10.26	Credit Contract and Libor Loan Contract dated December 13, 1996 between Union Bank of Switzerland and the Registrant
10.27*	Employment Agreement dated as of July 1, 1996 between the Registrant and Albe Z. Hodge
10.28*	Employment Agreement dated as of April 15, 1996 between the Registrant and Pe P. Stoelzle
21.10	Subsidiaries of the Registrant
23.01	Consent of KPMG LLP

* Includes compensatory plan or arrangements required to be filed pursuant to Item 13 of this Form 10-KSB.

(A) Incorporated by reference to the Company's Registration Statement No. 333-3830, declared effective by the Securities and Exchange Commission on June 19, 1996.

(B) Incorporated by reference to the Company's Form 10-K for the year ended December 31, 1996.

(C) Incorporated by reference to the Company's Form 10-K for year ended December 31, 1998.

(b) REPORTS ON FORM 8-K.

On October 10, 2000, the Company filed a Form 8-K announcing under item 5 disclosure the delisting of the Company's Common Stock from the Nasdaq Small Cap Market.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 30, 2001 BIGMAR, INC.

By: /s/ JOHN G. TRAMONTANA

John G. Tramontana

CHAIRMAN OF THE BOARD OF DIRECTORS AND
CHIEF EXECUTIVE OFFICER

(PRINCIPAL EXECUTIVE OFFICER)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

SIGNATURE	CAPACITY
/s/ JOHN G. TRAMONTANA John G. Tramontana	Chairman of the Board of Directors and Chief Executive Officer (Principal Executive Officer)
/s/ CYNTHIA R. MAY Cynthia R. May	President and Secretary Director
/s/ PHILIPPE J.H. ROHRER Philippe J.H. Rohrer	Chief Financial Officer Treasurer and Director (Principal Financial Officer)
/s/ BERNARD KRAMER Bernard Kramer	Vice President and Chief Operating Officer Director
/s/ MASSIMO PEDRANI Massimo Pedrani	Executive Vice President Resear and Development Director

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BIGMAR, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders
Bigmar, Inc.:

We have audited the accompanying consolidated financial statements of Bigmar, Inc. and subsidiaries as listed in the accompanying index. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Bigmar, Inc. and subsidiaries as of December 31, 2000 and 1999, and the results of their operations and their 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.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1(c) to the consolidated financial statements, the Company has suffered recurring losses from operations, and anticipates it will require additional financing in order to fund its operations during 2001. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1(c). The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Columbus, Ohio
March 12, 2001

BIGMAR, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2000, AND 1999

	2000
ASSETS	
Current assets:	
Cash and cash equivalents	$ 72,971
Accounts receivable third parties	1,872,657
Accounts receivable related parties (Note 12)	141,107
Inventories (Note 2)	2,638,999
Prepaid expenses and other current assets	119,792
Total current assets	4,845,526
Property, plant and equipment, net (Note 3)	13,387,698
Intangible and other assets, net	283,617
Total	$18,516,841
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	3,023,463
Notes payable (Note 4)	2,481,301
Current portion of long-term debt (Note 5)	626,940
Short-term borrowings due to related parties (Note 12)	1,238,781
Accrued expenses and other current liabilities (Note 7)	1,060,965
Total current liabilities	8,431,450
Long-term debt, excluding current portion (Note 5)	9,642,459
Total liabilities	18,073,909
Stockholders' equity (Note 8, 9 and 10):	
Preferred stock ($.001 par value; 5,000,000 shares authorized) 1,000,000 designated as Series A and 10,000 designated as Series B	--
Series B Preferred Stock, 1,000 shares issued and outstanding at December 31, 2000	1
Common stock ($.001 par value; 30,000,000 shares authorized; 10,168,973 shares and 8,993,973 issued and outstanding at December 31, 2000 and 1999 respectively)	10,169
Additional paid-in capital	29,023,791
Retained earnings (deficit)	(27,448,377)
Cumulative translation adjustment	(1,142,652)
Total stockholders' equity	442,932
Commitments (Note 13)	
Total	$18,516,841

See accompanying notes to consolidated financial statements.

BIGMAR, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

	2000	1999
Net sales (Note 11)	$ 7,650,665	$ 7,725,362
Cost of goods sold	6,268,559	6,453,581
Gross margin	1,382,106	1,271,781
Operating expenses:		
Research and development	2,758,372	2,375,034
Selling, general and administrative	3,072,747	3,514,003
Total operating expenses	5,831,119	5,889,037
Operating loss	(4,449,013)	(4,617,256)
Other income (expense) :		
Interest income	19,189	2,403
Interest expense	(948,894)	(892,388)
Issuance of preferred stock warrants for loan guarantee	--	--
Gain (loss) on foreign currency transactions	(6,984)	(836,601)
Other, net	134,099	19,563
Other income (expense), net	(802,590)	(1,707,023)
Loss before extraordinary items	(5,251,603)	(6,324,279)
Extraordinary item - gain on extinguishment of debt net of income taxes of $0	361,837	--
Net loss	$ (4,889,766)	$ (6,324,279)
Basic and diluted loss per share from continuing operations	$ (0.54)	$ (0.73)
Basic and diluted extraordinary gain per share	$ 0.04	$ --
Basic and diluted net loss per share	$ (0.50)	$ (0.73)
Weighted average shares outstanding	9,687,445	8,659,398

See accompanying notes to consolidated financial statements

BIGMAR, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

YEARS ENDED DECEMBER 31, 2000, AND 1999 AND 1998

	SERIES B PREFERRED STOCK		COMMON STOCK			
	NUMBER OF SHARES	AMOUNT	NUMBER OF SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	RETAIN EARNIN (DEFIC
BALANCE--DECEMBER 31, 1997			4,185,000	$ 4,185	15,063,166	(9,012
Issuance of common stock warrants to Jericho II, LLC (Note 9)					958,000	
Issuance of common stock to Banca del Gottardo			150,000	$ 150	$ 299,850	
Issuance of common stock to Jericho II, LLC			3,692,308	$ 3,692	$ 5,996,308	
Net (loss) for the year ended December 31, 1998						(7,22
Translation adjustment						
BALANCE--DECEMBER 31, 1998	--	$ --	8,027,308	$ 8,027	$22,317,324	$(16,23
Issuance of common stock warrants for consulting contract (Note 9)					$ 106,149	
Issuance of common stock to accredited investors						
Issuance of common stock to Banca del Gottardo			70,000	$ 70	$ 209,930	
Issuance of common stock GRQ, LLC			166,666	$ 167	$ 499,833	
Net (loss) for the year ended December 31, 1999						(6,32
Translation adjustment						
BALANCE-- DECEMBER 31, 1999	--	$ --	8,993,973	$ 8,994	$25,312,467	$(22,55
Issuance of common stock to Banca del Gottardo			1,175,000	$ 1,175	$ 2,761,325	
Issuance of preferred stock to Banca del Gottardo net of offering costs of $50,000 ..	1,000	$ 1			$ 949,999	
Net (loss) for the year ended December 31, 2000						(4,889
Translation adjustment						
BALANCE-- DECEMBER 31, 2000	1,000	$ 1	10,168,973	$10,169	$29,023,791	(27,448

See accompanying notes to consolidated financial statements

BIGMAR, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

	2000	1999
Cash flow from operating activities:		
Net loss	(4,889,766)	(6,324,
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,532,739	1,737,
Issuance of warrants	--	106,
Unrealized foreign exchange (gains) losses	19,850	995,
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	263,672	(1,337,
Increase in inventories	(181,126)	(1,110,
(Increase) decrease in prepaid expenses and other current assets	119,269	(33,
Increase (decrease) in due to related parties	--	(312,
Increase (decrease) in accounts payable	653,407	792,
Increase in accrued expenses and other current liabilities	136,703	200,
Net cash used in operating activities	(2,345,252)	(5,285,
Cash flows from investing activities :		
Purchase of property, plant and equipment	(575,372)	(530,
Net cash used in investing activities	(575,372)	(530,
Cash flows from financing activities :		
Proceeds from short-term borrowings	--	1,837,
Proceeds from short-term borrowing from related party	1,131,728	
Repayment of short and long-term debt	(4,503,762)	(552,
Long-term borrowings	2,525,047	1,770,
Debt and equity issuance costs	--	(107,
Proceeds from issuance of common stock	2,762,500	2,889,
Proceeds from issuance of preferred stock, net	950,000	
Net cash provided by financing activities	2,865,512	5,838,
Effect of exchange rate changes on cash	(27,772)	(7,
Net increase (decrease) in cash and cash equivalents	(82,883)	15,

Cash and cash equivalents, beginning of year	155,854	140,
Cash and cash equivalents, end of year	72,971	$ 155,
Supplemental disclosures of cash flow information :		
Cash paid during the period for :		
Interest	$ 653,566	$ 783,

See accompanying notes to consolidated financial statements.

BIGMAR, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

	2000	1999	
Net loss	$ (4,889,766)	$ (6,324,279)	$ (
Other comprehensive income (loss), net of tax:			
Foreign currency translation adjustments, net of income taxes of $0 in 2000, 1999 and 1998	(115,603)	(168,996)	
Comprehensive loss (Note 1m)	$ (5,005,369)	$ (6,493,275)	$ (

See accompanying notes to consolidated financial statements.

BIGMAR, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2000, 1999 AND 1998

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND PRACTICES

(a) BUSINESS AND RECENT TRANSACTIONS

Bigmar, Inc. (the "Company"), a Delaware corporation, was formed in September 1995 by Chemholding SA, Chemholding's principal stockholders and John G. Tramontana for the purpose of manufacturing and distributing various oncological and biotechnical products. Certain stockholders of the Company owned 100% of Bigmar Pharmaceuticals SA ("Pharmaceuticals") and 50% of Bioren SA ("Bioren"), two Swiss corporations. The other 50% is owned by Pharmaceuticals. In April 1996, the Company acquired 100% of Pharmaceuticals and 50% of Bioren in a stock for stock exchange. Since there was a high degree of common ownership, the acquisition was accounted for as a reorganization of companies under common control.

Pharmaceuticals is currently engaged in the development, manufacture, and distribution of injectable oncological products ("Oncology Products") in various countries in Europe. In February 1999, Pharmaceuticals received approval from the United States Food and Drug Administration ("FDA") to market certain injectable forms of Methotrexate and Leucovorin Calcium. Both are generic products used for the treatment of various forms of cancer. Bioren is primarily a manufacturer and distributor of intravenous infusion solutions ("IV Solutions") in Switzerland. The Company's headquarters, located in Johnstown, Ohio, include a research and development laboratory used for the testing of Oncology Products to be marketed in the United States.

In May 1997, Mr. Tramontana, the Company's Chairman of the Board, President and Chief Executive Officer ("CEO"), pursuant to privately negotiated transactions in Switzerland, acquired 1,293,663 additional shares of the Company's Common Stock from the Chemholding shareholders.

In May 1998, the Company, in consideration of a guarantee to renew and increase a line of credit from $3.5 million to $6.0 million from a commercial institution, delivered to Jericho II, L.L.C. ("Jericho"), a related party, warrants to purchase 1,000,000 shares of Convertible Preferred Stock (the "Preferred Stock") at a price equal to $2.5625 per share and having a term of 10 years (the "Warrants"). The Company renegotiated the terms of the line of credit in December 1998, and reduced the line of credit from $6.0 million to $0.5 million. This line was subsequently increased to $2.0 million (see U.S. line of credit at Note 4).

In August 1998, the Company, issued 150,000 shares of Common Stock to Banca del Gottardo, a Swiss bank, for $2.00 per share via a private placement. The proceeds were used for working capital and other general corporate purposes.

In October 1998, the Company issued 3,692,308 shares of Common Stock to Jericho for $1.625 per share via a Stock Purchase Agreement dated October 20, 1998. Proceeds from the sale of shares totaled $6,000,000, and were used to repay debt and for working capital.

In February 1999, the Company issued 216,666 shares of Common Stock to accredited investors, including 166,666 shares to GRQ, L.L.C. (a company owned by certain stockholders of the Company) for prices ranging from $2.00 to $3.00 per share via private placement offerings. The proceeds were used for working capital and other general corporate purposes.

DECEMBER 31, 2000, 1999 AND 1998

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND PRACTICES (CONTINUED)

(a) BUSINESS AND RECENT TRANSACTIONS (CONTINUED)

In March 2000, the Company issued 500,000 shares of Common Stock to Banca del Gottardo via a private placement offering. The Company also issued 2-year warrants to purchase 150,000 shares of Common Stock at $4.00 per share. Proceeds from the sale of shares and warrants totaled $1,375,000 and were applied to working capital and general corporate purposes.

In June 2000, the Company issued 300,000 shares of Common Stock to Banca del Gottardo via private placement offering. Proceeds from the sale of shares totaled $637,500 and were applied to working capital and general corporate purposes.

In August 2000, the Company issued 375,000 shares of Common Stock to Banca del Gottardo via a private placement offering. Proceeds from the sale of shares totaled $750,000 and were applied to working capital and general corporate purposes.

In December 2000, the Company issued 1,000 shares of Series B Convertible Preferred Stock, $0.001 par value per share to Banca del Gottardo via a private placement offering. Proceeds from the sale of shares totaled $500,000 and were applied to working capital, to repay debt and general corporate purposes.

In February 2001, the Company issued 7,000 shares of Series B Convertible Preferred Stock, $0.001 par value per share and warrants at $2.00 for the purchase of 1,400,000 shares of the Company's Common Stock, $0.001 par value per share, to Banca del Gottardo via a private placement offering. Proceeds from the sale of shares after bank commission of 2.5% totaled $6,850,000 and were applied: to repay $4 million convertible notes and related interest; to repurchase 1,000 shares of Series B Convertible Preferred Stock, including accrued dividends; and to pay a $175,000 bank fee. Net proceeds of $1,501,767 will be applied to working capital and general corporate purposes.

(b) CONSOLIDATION

The consolidated financial statements include the financial statements of the Company, its wholly owned Swiss subsidiaries, Pharmaceuticals and Bioren, and Bigmar Therapeutics, Inc. ("Therapeutics"), a Delaware corporation. All significant intercompany balances and transactions have been eliminated in consolidation.

(c) BASIS OF PRESENTATION

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

BIGMAR, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000, 1999 AND 1998

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND PRACTICES (CONTINUED)

(c) BASIS OF PRESENTATION (CONTINUED)

The accompanying consolidated financial statements also have been prepared assuming that the Company will continue as a going concern. The construction of the Company's pharmaceutical manufacturing plant in Barbengo, Switzerland and the process for obtaining regulatory approvals has consumed a substantial amount of the Company's resources. In February 1999, the manufacturing plant received regulatory approval from the FDA and the Intercantonal Office for the Control of Medications ("IKS") in Switzerland to manufacture and sell certain injectable pharmaceutical products in the U.S. and Switzerland.

As a result, the Company anticipates that these operations will begin to generate cash to help fund its expansion and further planned research and development activities. During 2000, the Company has received approximately $3.7 million in proceeds from the sale of shares of Preferred and Common Stock. In addition, the Company's current business plan calls for raising additional funds during 2001 through other private stock offerings and through additional bank borrowings. However, there can be no assurance that the Company will be successful in these efforts.

(d) USE OF ESTIMATES

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities 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.

(e) FOREIGN CURRENCY

Assets and liabilities of foreign operations are translated at the exchange rates in effect at the balance sheet date and revenues and expenses are translated at the monthly average exchange rates for the period. Net gains and losses arising from translation are accumulated in a separate component of stockholders' equity. Gains and losses resulting from foreign currency transactions are included in income or expense. The Company recognized foreign currency gains (losses) of $(6,984), $(836,601), and $332,377 primarily related to translation of intercompany balances that are considered short-term in 2000, 1999, and 1998, respectively. Effective January 1, 2000, $7.14 million of the intercompany debt was no longer considered short-term as repayment was not expected in the foreseeable future. Accordingly, the gain or loss on translating such debt was included in the cumulative translation adjustment as a separate component of stockholders' equity.

(f) CASH EQUIVALENTS

All highly liquid investments with original maturities of three months or less are considered to be cash equivalents.

(g) INVENTORY

Inventory is stated at the lower of cost or market using the first-in, first-out (FIFO) method.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000, 1999 AND 1998

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND PRACTICES (CONTINUED)

(h) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are stated at cost. Upon retirement or other disposition of property, plant and equipment, the cost and related accumulated depreciation and amortization are removed from the accounts and the resulting gain or loss is reflected in earnings. Maintenance and repairs are expensed as incurred. Depreciation and amortization are calculated on a straight-line basis utilizing the assets' estimated useful lives.

(i) INTANGIBLE AND OTHER ASSETS

Intangible assets consist of goodwill, which represents the excess of purchase price over fair value of net assets acquired, amortized on a straight-line basis over 10 years. Other assets consist of debt issuance costs, which are amortized using the effective interest method over the life of the related debt. The Company assesses the recoverability of goodwill by determining whether the amortization of the goodwill balance over its remaining life can be recovered through undiscounted future operating cash flows of the acquired operation. The amount of goodwill impairment, if any, is measured based on projected discounted future operating cash flows using a discount rate reflecting the Company's average cost of funds. The assessment of the recoverability of goodwill will be impacted if estimated future operating cash flows are not achieved. No such losses have been recorded through December 31, 2000.

(j) IMPAIRMENT OF LONG-LIVED ASSETS AND LONG-LIVED ASSETS TO BE DISPOSED OF

The Company records impairment losses on long-lived assets used in operations, including intangible assets, when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. No such losses have been recorded through December 31, 2000.

(k) FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying value of cash and cash equivalents, accounts receivable and accounts payable, accrued expenses and other current liabilities, and due to related parties, approximates the fair value because of the short maturity of those instruments. For long-term debt, the carrying value approximates the fair value because interest is either variable based upon prevailing market rates or approximates market rates.

(l) REVENUE RECOGNITION

The Company derives revenue from the sale of Oncology Products and IV solutions. The Company recognizes revenue when the products are shipped and the earnings process is complete.

(m) COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) consists of net income and foreign currency translation adjustments and is presented in the consolidated statements of comprehensive income (loss).

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND PRACTICES (CONTINUED)

(n) INCOME TAXES

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

(o) STOCK-BASED COMPENSATION

The Company continues to follow the intrinsic value method set forth in Accounting Principles Bulletin Opinion No. 25, Accounting for Stock Issued to Employees ("APB No. 25"), and provides pro forma net income and pro forma earnings per share disclosures for employee stock option grants as if the fair-value-based method defined in SFAS No. 123 had been applied.

(p) PER SHARE DATA

Net loss per share is based on the weighted average number of shares outstanding during each period. Common Stock equivalents are anti-dilutive and have not been included in the weighted average number of shares outstanding.

(q) DERIVATIVE FINANCIAL INSTRUMENTS

In 1998, the Company had only limited involvement with derivative financial instruments and did not use them for trading purposes. They were used to manage well-defined interest rate risks. An interest rate cap agreement was used to reduce the potential impact of increases in interest rates on floating-rate long-term debt. The premium paid for the purchased interest rate cap agreement was amortized to interest expense over the terms of the cap. The unamortized premium was included in other assets in the consolidated 1998 balance sheet. Any amounts receivable under the cap agreement were recorded as a reduction of interest expense. As of December 31, 2000, the Company has no derivative financial instruments.

(2) INVENTORIES

Company's inventory consists of IV Solutions and Oncology Products. Components of inventory are as follows:

	DECEMBER 31,	
	2000	1999

Raw materials	$ 1,169,320	1,362,439
Finished goods	1,469,679	1,107,795
Total	$ 2,638,999	2,470,234

BIGMAR, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000, 1999 AND 1998

(3) PROPERTY, PLANT AND EQUIPMENT, NET

The components of property, plant and equipment, net are as follows:

	DECEMBER 31,		
	2000	1999	Estimated lif in years
Land	$ 1,186,568	1,196,969	--
Building and building improvements	11,031,293	11,343,487	10-40
Machinery	4,711,900	4,480,567	3-10
Equipment	1,943,514	1,826,064	3-10
	18,873,275	18,847,087	
Less accumulated depreciation	5,485,577	4,466,210	
Total	$ 13,387,698	14,380,877	

(4) NOTES PAYABLE

Notes payable consists of the following:

	DECEMBER 31,	
	2000	1999
Bank lines of credit	$ 2,481,301	2,109,689
Short-term bank loan	--	1,252,349
Total	$ 2,481,301	3,362,038

Under a Swiss bank line of credit, Bioren may borrow up to Sfr 500,000

($310,366) with quarterly interest payments due based on 5.875% variable interest plus 1/4% commission paid quarterly on outstanding balances resulting in an annualized rate of 6.875%. At December 31, 2000, $171,043 was outstanding. As of January 2001, the above line of credit was increased to Sfr 1,200,000 ($744,879).

Under another Swiss bank line of credit, Pharmaceuticals may borrow up to Sfr 500,000 ($310,366) with quarterly interest payments due based on 5.75% variable interest plus 1/4% commission paid quarterly on outstanding balances resulting in an annualized rate of 6.75%. At December 31, 2000, $310,366 was outstanding.

Under a U.S. bank line of credit, the Company may borrow up to $2,000,000 with monthly interest payments due based upon the prime rate (9.5% at December 31, 2000). The credit line, which is subject to re-negotiation on June 30, 2001, is secured by a guaranty of Jericho and certain shareholders and officers of the Company. At December 31, 2000, $1,999,892 was outstanding.

Substantially all of the Company's assets are pledged as collateral under its various debt agreements. The weighed-average interest rate on notes payable was 8.9% and 8.2% at December 31, 2000 and 1999, respectively.

(5) LONG TERM DEBT

The Company's long-term debt consists of the following:

	DECEMBER 2000
Bank loan collateralized by mortgage on Bioren building; principal payable in installments of $62,073 paid annually until full repayment; interest at 3.5% per annum through May 2002, adjustable thereafter; subject to certain restrictive covenants and subject to renegotiation by the bank after May 2002.	$1,707,014
Bank loan collateralized by mortgage on Bioren building; principal payable in installments of $248,293 paid annually until full repayment; interest at 5.875% per annum through Dec. 2000, adjustable thereafter; subject to certain restrictive covenants and subject to renegotiation by the bank after December, 2000.	434,513
Bank loan partially secured by the Pharmaceuticals building, subject to certain restrictive covenants; principal payable in installments of $62,073 paid annually until full repayment; interest at 4.25% per annum, adjustable.	1,179,392
Bank loan collateralized by mortgage on Pharmaceuticals building, subject to certain restrictive covenants; principal payable in installments of $248,293 paid annually until full repayment; interest at 6% per annum, adjustable.	869,026

Bank loan collateralized by mortgage on Pharmaceuticals warehouse building; payable in installments of $6,207 per year, for thirty eight years, beginning December 31, 1998 at an interest rate of 4.875% per year.	217,256
Convertible notes issued by the Company, due August 29, 2002; 8% interest payable semi-annually on February 27 and on August 29 of each year; subject to certain restrictive covenants and repayable in US dollars.	4,000,000
Convertible notes issued by the Company, due October 22, 2003; 4% interest payable semi-annually on April 29 and on October 29 of each year; subject to certain restrictive covenants and repayable in Swiss Francs.	1,862,198
Total long-term debt	10,269,399
Less current portion	626,940
Long-term, excluding current portion	$ 9,642,459

In August 1997, the Company entered into a Note Purchase, Paying, and Conversion Agency Agreement (the "1997 Note Agreement") with Banca del Gottardo, a bank organized under the laws of Switzerland ("Banca del Gottardo").

(5) LONG TERM DEBT (CONTINUED)

Under the 1997 Note Agreement, the Company issued 8% notes, due August 29, 2002, with interest payable semi-annually in February and August. After January 1, 1998, the notes are convertible into 761,905 shares of the Company's Common Stock at an initial conversion price of $5.25 per share. Net proceeds from the notes were $3,670,000 after deductions of commissions and related expenses. The notes can be repaid at the option of the Company before the due date at 110% of the principal amount due.

In October 1999, the Company entered into a Note Purchase, Paying, and Conversion Agency Agreement (the "1999 Note Agreement") with Banca del Gottardo. Under the 1999 Note Agreement, the Company issued 4% notes, due October 22, 2003, with interest payable semi-annually in April and October. After March 1, 2000, the notes are convertible into 528,000 shares of the Company's Common Stock at an initial conversion price of $3.75 per share. Net proceeds from the notes were approximately $1,700,000 after deductions of commissions and related expenses. The notes can be repaid at the option of the Company before the due date at 110% of the principal amount due.

FUTURE MATURITIES OF LONG-TERM DEBT ARE AS FOLLOWS:

YEAR ENDED DECEMBER 31:	PHARMACEUTICALS	BIOREN	CORPORATE	TOTAL LONG-TERM DEBT

2001	$ 316,574	310,366	--	626,940
2002	316,574	248,293	--	564,867
2003	316,574	62,073	4,000,000	4,378,647
2004	192,427	62,073	1,862,198	2,116,698
2005	68,281	62,073	--	130,354
Thereafter	1,055,245	1,396,648	--	2,451,893
	$ 2,265,675	2,141,526	5,862,198	10,269,399

Substantially all of the Company's assets are pledged as collateral under its various debt agreements.

In January and March 2000, the Company settled the following outstanding bank loans and accrued interest to the Union Bank of Switzerland, which amounted to $4.3 million:

- approximately $1.3 million secured by the Pharmaceuticals building.
- approximately $1.6 million collaterized by Pharmaceuticals building and equipment.
- approximately $1.3 million from the unsecured short-term bank loan.
- approximately $0.1 million from the bank line of credit and accrued interest.

The Company paid $3.9 million and Union Bank of Switzerland forgave $0.4 million. The amount that was paid was financed by loans of $2.7 million from Credit Suisse, a loan of $1.1 million from the CEO of the Company, and cash of $0.1 million.

(5) LONG TERM DEBT (CONTINUED)

The following new loans have been executed:

- $1.3 million bank loan from Credit Suisse collaterized by mortgage on Pharmaceuticals building and certain receivables; variable interest at 4.25% per annum.
- $1.1 million bank loan from Credit Suisse collaterized by mortgage on Pharmaceuticals building and certain receivables; variable interest at 6% per annum.
- Bank line of credit up to $ 0.3 million collaterized by mortgage on Pharmaceuticals building with quarterly interest payments due based on 5.75% variable interest.
- $1.1 loan from the CEO with quarterly interest payments due based on 5%

fixed interest (see Note 12).

Pursuant to this new financing, the current portion of long-term debt remained the same, long-term debt exluding current portion decreased from $11.4 million to $10.2 million and notes payable decreased from $3.4 million to $2.5 million.

(6) INCOME TAXES

The sources of income (loss) before income taxes is as follows:

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
Source of Loss			
United States	$ (4,417,345)	(5,299,396)	(6,086,322)
Switzerland	(522,421)	(1,024,883)	(1,135,380)
	$ (4,939,766)	(6,324,279)	(7,221,702)

Income tax benefit differed from the amounts computed by applying the U.S. federal income tax rate of 34 percent to pretax loss as a result of the following :

	2000	1999	
Computed income rate taxes benefit at 34%	$ (1,679,520)	(2,150,255)	(2,4
Impact of difference between Swiss effective rate and U.S effective tax rate	60,078	40,995	
Increase in valuation allowance on deferred tax assets	943,674	1,462,668	2,0
Impact of change in Swiss effective tax rate	594,442	--	
Non-deductible stock warrant expense	--	39,032	3
Non-deductible foreign exchange (gain) loss	1,797	284,436	(1
Expiration of net operating loss carryforward	67,093	113,269	
Other	12,436	209,855	1
	$ --	--	

(6) INCOME TAXES (CONTINUED)

The tax charge in Switzerland is an accumulation of city, canton (state) and federal taxes. Therefore, the tax burden varies from one entity to another depending upon its location. While the actual tax rate is a function of the percentage of profitability in relation to the taxable entity, the Company believes that 23% is a fair approximation of the effective tax rates for Pharmaceuticals and Bioren in 2000, and 30% in 1999, and 1998. In addition, as Swiss tax laws do not permit consolidated tax filings, possible tax losses in one entity do not offset taxable income in another entity.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities are presented below:

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
Deferred tax assets:			
Benefit of net operating loss carryforwards:			
United States	$ 7,283,915	5,343,836	4,019,
Switzerland	1,544,987	2,023,896	2,192,
Loss on forgiveness of debt due from Swiss subsidiary	--	510,000	510,
Intangible and other assets	275,557	307,614	278,
Accrued expenses and other current liabilities	112,640	88,079	99,
Total deferred tax assets	9,217,099	8,273,425	7,100,
Valuation allowance	(9,217,099)	(8,273,425)	(7,100,
Net deferred tax assets	$ --	--	

Bioren and Pharmaceuticals have net operating loss carryforwards of approximately $5,357,000 and $1,509,000, respectively, expiring through December 31, 2007. The Company has net operating loss carryforwards of approximately $21,422,000 expiring through December 31, 2020. The net change in the total valuation allowance for the years ended December 31, 2000, 1999, and 1998, was an increase of $944,000, $1,173,000 ($1,462,000 impact of 1999 loss net of $289,000 currency translation adjustment), and $2,076,000, respectively.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based upon the historical losses of the Company and its subsidiaries, the total deferred tax assets have been fully reserved.

Under Sections 382 and 383 of the Internal Revenue Code (IRC) of 1986, as amended, the utilization of U.S. net operating loss carryforwards may be limited under the change in stock ownership rules of the IRC. As a result of ownership

changes as defined by Sections 382 and 383, which have occurred at various points in the Company's history, management believes utilization of the Company's net operating loss carryforwards may be limited under certain circumstances such as a change in control of the Company.

(7) ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other current liabilities consisted of the following at December 31, 2000 and 1999:

	Year Ended December 31,	
	2000	1999
Accrued salaries	$478,532	$492,878
Accrued interest	133,408	169,413
Accrued professional fees	203,088	123,664
Taxes payable	80,462	109,431
Other	165,475	90,000
	$1,060,965	$985,386

(8) STOCK OPTIONS

Effective November 4, 1997, the Board of Directors approved an option plan, which was approved by Shareholders on June 30, 1998, that provides for the grant of incentive stock options and nonqualified stock options to directors, officers, employees, agents and consultants of the Company to purchase up to 600,000 shares of the Company's Common Stock, with exercise terms not to exceed ten years. In addition, the Company adopted a director option plan providing for awards of up to 50,000 shares of Common Stock to directors who are not otherwise affiliated with the Company. Stock options have various vesting terms and are granted with an exercise price equal to the Company's stock price at the date of grant.

At December 31, 2000, options for 580,000 shares of Common Stock were available

for future grant under the 1997 Plan and 50,000 shares of Common Stock were available for future grant under the director option plan. No options were granted in 2000, 1999 or 1998.

The Company applies APB Opinion No. 25 in accounting for options and, accordingly, no compensation cost has been recognized for its stock options in the financial statements. Had the Company determined compensation cost based on the fair value at the grant date for its stock options under SFAS No. 123, the Company's net loss would have increased the pro forma amounts indicated below:

At December 31, 2000, the range of exercise prices and weighted-average remaining contractual life of outstanding options was $5.09 - $5.60 and 1.23 years, respectively.

		2000	1999	1998
Net Loss	As reported	$ (4,889,766)	(6,324,279)	(7,221,702)
	Pro forma	$ (4,912,835)	(6,439,079)	(7,807,202)
Loss per share	As reported	$ (0.50)	(0.73)	(1.46)
	Pro forma	$ (0.51)	(0.74)	(1.58)

(8) STOCK OPTIONS (CONTINUED)

Stock option activity during the years indicated is as follows:

	Number of shares	Weighted-average exercise price
Balance, December 31, 1997	512,000	$ 5.20
Forfeited	(97,000)	$ 5.09
Balance, December 31, 1998	415,000	$ 5.23
Forfeited	(10,000)	$ 5.09
Balance, December 31, 1999	405,000	$ 5.22
Forfeited	(85,000)	$ 5.09
Balance, December 31, 2000	320,000	$ 5.26

At December 31, 2000, 1999, and 1998, the number of options exercisable was 320,000, 353,335 and 305,003, respectively, and the weighted-average exercise price of those options was $5.26, $5.21 and $5.21, respectively.

(9) WARRANTS

On April 15, 1999, the Company entered into a consulting contract for public relations and investor relations services. A portion of the consideration paid for this contract included the Company granting warrants to purchase 45,000 shares of its Common Stock. These warrants are exercisable for a period of five years at an exercise price of $3.88 per share. The Company estimated the fair value of these warrants to be $106,144 (using the Black-Scholes option pricing model) and has recorded that amount as an expense and an increase to additional paid-in capital in 1999.

As described in Note 1, on May 28, 1998, the Company, in consideration of a guarantee to obtain a $6.0 million line of credit from a commercial institution, delivered warrants to Jericho to purchase 1,000,000 shares of convertible Preferred Stock at a price equal to $2.5625 per share and having a term of 10 years (the "Warrants"). The Preferred Stock is convertible to Common Stock on a one-to-one basis, with such conversion rate to adjust to reflect dilutive issuances of equity securities by the Company and also to adjust for stock splits, dividends, combinations and similar events. The Preferred Stock votes together with the Common Stock and outstanding shares of Preferred Stock carry a vote equal to five times the number of shares of Common Stock into which the Preferred Stock is then converted. The Preferred Stock has a liquidation preference equal to the purchase price per share. The Warrants include a net exercise clause and the shares issuable on exercise shall be entitled to piggyback registration rights, subject to standard underwriter's cutback. The line of credit is in the form of a demand note payable. Accordingly, the fair value of the warrants of $958,000, determined using the Black-Scholes model, has been recognized in the accompanying consolidated statements of operations for the year ended December 31, 1998.

(9) WARRANTS (CONTINUED)

On July 24, 1997, the Company granted warrants to Protyde to purchase 500,000 shares of its Common Stock. These warrants are exercisable for a period of four years at an exercise price of $5.00 per share. The Company estimated the fair value of the warrants as of the issuance date to be approximately $800,000 (using the Black-Scholes option pricing model) and recorded that amount as expense and as an increase to additional paid-in capital in 1997.

(10) LEGAL RESERVE

The Swiss Federal Code of Obligation provides that at least 5% of a company's net income each year must be appropriated to a legal reserve until such time as this reserve equals 20% of a company's share capital. In addition, 10% of any distribution in excess of a 5% dividend also must be appropriated to the legal reserve. The legal reserve of up to 5% of the share capital is not available for

distribution.

(11) SIGNIFICANT CUSTOMERS AND SUPPLIERS

Sales to significant customers were as follows:

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
Oncology Products (one customer)	$ 672,398	1,005,514	412,701
IV Solutions (three customers)			
Customer 1	771,517	790,368	751,461
Customer 2	572,762	667,854	602,366
Customer 3	519,601	625,858	590,503

The Company obtains containers for IV Solutions from a sole supplier. The Company's reliance on a sole or a limited number of suppliers involves several risks including, among others, the inability to obtain an adequate supply of required raw materials and components in order to manufacture or market a product or proposed product, increased raw material or component costs and reduced control over pricing, quality and timely delivery.

(12) RELATED PARTY TRANSACTIONS

The Company has $1.1 million short-term loan from the CEO of the Company with quarterly interest payments due based on 5% fixed interest. The Company also has $127,000 in notes payable with interest at prime outstanding to various related parties. All notes are payable on demand.

	DECEMBER 31,	
	2000	1999
Sales to related parties	$ 327,721	--
Purchase from related parties	9,244	--
Selling, general and administrative expenses paid to related party	390,000	300,000
Accrued interest to related parties	56,535	11,789
Accounts receivable related parties	141,107	
Short-term borrowings due to related parties	1,238,781	

(13) COMMITMENTS

The Company leases office space in the United States from a related party and has various leases in Switzerland. Rent expense amounted to $216,993 in 2000, $173,968 in 1999, and $143,638 in 1998. Rent paid to a related party amounted to $90,000 in 2000, $120,000 in 1999, and $100,000 in 1998.

Minimum future rental payments under the Company's noncancelable operating leases are as follows:

YEAR ENDED DECEMBER 31 :	Third Parties	Related Parties
2001	$ 54,864	120,000
2002	--	50,000
2003	--	--
Total	$ 54,864	170,000

In December 1996 the Company entered into an agreement to lease real property, including an office/laboratory building from a company owned by the Company's President and a company owned by certain stockholders of the Company. The lease is for a term of five years from commencement date (June 1, 1997), with an option to renew for an additional five years, and provides for rent of $120,000 per annum.

Bioren leased part of its Couvet Facility to a third party pursuant to a year to year lease which ended April 15, 1998. The rental income for the year ended December 31, 1998 was $23,281.

(13) COMMITMENTS (CONTINUED)

In March 1995, Bioren and PLM Langeskov A/S ("PLM") entered into an agreement (the "PLM Agreement"), which grants Bioren the exclusive right to distribute its IV Solutions throughout Switzerland and Liechtenstein in PLM's collapsible containers. Under the terms of the agreement, PLM is entitled to terminate the exclusive right contained in the agreement if, among other things, Bioren does not purchase a minimum of 2 million containers each year.

The total purchase commitment is as follows:

YEAR ENDED DECEMBER 31 :	PURCHASE VALUE

2001	$ 890,824
2002	890,824
2003	890,824
2004	890,824
2005	890,824
Afterward	--
Total	$4,454,120

Bioren purchased $1.6 million in 2000, $1.4 million in 1999 and $1.6 million in 1998

(14) SEGMENT DATA

The Company manages its business segments primarily on a geographic basis with each location representing a distinct segment. The Company's reportable segments are comprised of Bioren, located in Couvet, Switzerland; Pharmaceuticals, located in Barbengo, Switzerland; and the Company's Corporate Headquarters, located in Johnstown, Ohio, U.S.A.

The accounting policies of the various segments are the same as those described in the Summary of Significant Accounting Policies and Practices in Note 1. The Company evaluates the performance of its segments based on segment profit/(loss). Segment profit/(loss) for each segment includes sales and marketing, certain research and development, and overhead charges directly attributable to the segment and excludes certain expenses that are managed outside the reportable segments. Costs excluded from segment profit primarily consist of corporate expenses, as well as other research and development charges for testing of products targeted for U.S. markets, and other general and administrative expenses which are separately managed.

The Company does not include intercompany transfers between segments for management reporting purposes. Segment assets exclude corporate assets. Corporate assets include cash and cash equivalents, short-term investments, a laboratory facility, and intangible assets.

(14) SEGMENT DATA (CONTINUED)

Summary information by segment as of and for the years ended December 31, 2000, 1999 and 1998 is as follows:

	DECEMBER 31,		
	2000	1999	1998
BIOREN:			
Sales:			

IV Solutions	$ 5,930,870	$ 6,046,311	$ 5,976,369
Gross Margin:			
IV Solutions	1,449,408	1,400,034	1,555,138
Segment Income (Loss)	(24,547)	(229,617)	(315,394)
Interest Expense	104,039	135,528	150,624
Depreciation and Amortization	261,967	267,044	578,694
Segment Assets	6,376,467	6,565,840	7,401,168
PHARMACEUTICALS:			
Sales:			
Oncology Products	$ 1,719,795	$ 1,679,051	$ 401,453
Gross Margin:			
Onclology Products	(67,302)	(128,235)	10,394
Segment Income (Loss)	(333,654)	(1,059,606)	(819,986)
Interest Expense	210,016	262,423	278,736
Gain on extinguishment of debt	361,837	--	--
Depreciation and Amortization	1,230,296	1,089,586	1,069,707
Segment Assets	11,194,644	11,481,742	12,407,223

(14) SEGMENT DATA (CONTINUED)

A reconciliation of the Company's segment gross margin, segment profit, and segment assets to the corresponding consolidated amounts as of and for the years ended December 31, 2000, 1999, and 1998 is as follows:

	DECEMBER 31,		
	2000	1999	1998
Segment gross margin	$ 1,382,106	$ 1,271,781	$ 1,565,532
Non-Segment gross margin	--	--	--
Total gross margin	1,382,106	1,271,781	1,565,532
Segment profit (loss)	$ (358,201)	$ (1,289,223)	$ (1,135,380)
Corporate expenses, net	(4,531,565)	(5,035,056)	(6,086,322)
Loss before provision for income taxes	(4,889,766)	(6,324,279)	(7,221,702)
Segment assets	$ 17,571,111	$ 18,047,582	$ 19,808,391
Corporate assets	945,730	1,751,170	900,791

Total assets	18,516,841	19,798,752	20,709,182
Sales :			
U.S.	$ 791,810	$ 1,005,514	$ --
Other foreign countries	6,858,855	6,719,848	6,377,822
Total revenue	7,650,665	7,725,362	6,377,822
Property, plant and equipment:			
U.S.	$ 321,667	$ 321,631	$ 608,746
Other foreign countries	13,066,031	14,059,246	16,741,258
Total property, plant and equipment	13,387,698	14,380,877	17,350,004

(15) SUBSEQUENT EVENTS

In February 2001, the Company issued 7,000 shares of Series B Convertible Preferred Stock, $0.001 par value per share and warrants at $2.00 for the purchase of 1,400,000 shares of the Company's Common Stock, $0.001 par value per share, to Banca del Gottardo via a private placement offering. Proceeds from the sale of shares after bank commission of 2.5% totaled $6,850,000 and were applied : to repay $4 million convertible notes and related interest; to repurchase 1,000 shares of Series B Convertible Preferred Stock including accrued dividends; and to pay a $175,000 bank fee. Net proceeds will be applied to working capital and general corporate purposes.

EXHIBIT INDEX

NUMBER	DESCRIPTION OF EXHIBIT
3.1	Restated and Amended Certificate of Incorporation
3.1(a)	Certificate of Correction to Restated and Amended Certificate of Incorporation of the Registrant
3.1(b)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Bigmar, Inc.
3.2	Restated By-Laws of the Registrant
3.2(a)	Amendment to Restated By-Laws of the Registrant
4.1	Specimen Stock Certificate
4.2	Form of Representatives Warrant
4.3	Registrant's 1996 Stock Option Plan
4.4	Form of Non-qualified Stock Option Agreement under the 1996 Stock Option Plan

4.5 Form of Incentive Stock Option Agreement under the 1996 Stock Option Plan

4.6 Form of Registrant's Director Option Plan

4.7 Registrant's 1997 Stock Option Plan

4.8 Form of Non-qualified Stock Option Agreement under the 1997 Stock Option Plan

4.9 Form of Incentive Stock Option Agreement under the 1997 Stock Option Plan

10.1 Sublease Agreement dated as of March 1, 1996 between the Registrant and Cernitin America, Inc.

10.2 Form of Indemnification Agreement

10.3 Employment Agreement dated as of April 15, 1996 between the Registrant and John G. Tramontana

10.4 Form of Medical Advisory Agreement

10.5 Form of Scientific Advisory Agreement

10.6 Exclusive Distribution and Supply Agreement dated November 5, 1995 between Bigmar Pharmaceuticals SA and AB Cernelle

10.7 Technical Services Agreement dated November 5, 1995 between Bigmar Pharmaceuticals SA and AB Cernelle

10.8 Stock for Stock Exchange Agreement dated April 9, 1996 between the Registrant and its stockholders

10.9 Contribution Agreement dated April 8, 1996 between the Registrant and it's stockholders

10.10 Exclusive Distribution Agreement dated December 22, 1995 between Bigmar Pharmaceuticals SA and Boehringer Mannheim Italia S.p.A.

10.11 International Activities Agreements dated March 3, 1994 between Bigmar Pharmaceuticals SA and Medac GmbH

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10.12 Distribution Agreement dated October 10, 1994 between Bigmar Pharmaceuticals SA A and Pharma Stroschein GmbH

10.13 Distribution Agreement dated July 31, 1995 between Bigmar Pharmaceuticals SA and Laboratorios Vita S.A.

10.14 Supply and Collaboration Agreement dated March 8, 1995 between Bioren SA and PLM Langeskov A/S10.22

10.15 Agreement dated December 21, 1995 between Laevosan international AG and Bigmar Pharmaceuticals SA

10.16 Loan documentation between Bioren SA and Union Bank of Switzerland

10.17 Loan documentation between Bigmar Pharmaceuticals SA and Union Bank of Switzerland

10.18 Acquisition Agreement dated June 22, 1995 between Galenica Holding AG and the Registrant

10.19 Extension of Licensing Agreement dated October 27, 1995 between Dr. F. Messi Cella Culture Technologies and Bigmar Pharmaceuticals SA

10.20 Lease Agreement dated as of December 31, 1996 between the Registrant and JTech Laboratories, Inc.

10.21 Cancellation Agreement dated as of March 27, 1997

10.22 Release dated March 27, 1997 issued by Cerbios-Pharma in favor of the Registrant

10.23 Cancellation Agreement dated as of March 27, 1997 between the registrant and Cerbios-Pharma

10.24 Cancellation Agreement dated as of March 27, 1997 between the Registrant and Cerbios-Pharma

10.25 Libor Mortgage Loan Agreement dated February 26, 1997 between the Union Bank of Switzerland and the Registrant

10.26 Credit Contract and Libor Loan Contract dated December 13, 1996 between Union Bank of Switzerland and the Registrant

10.27* Employment Agreement dated as of July 1, 1996 between the Registrant and Albert Z. Hodge

10.28* Employment Agreement dated as of April 15, 1996 between the Registrant and Peter P. Stoelzle

21.10 Subsidiaries of the Registrant

23.01 Consent of KPMG LLP Fi

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* Includes compensatory plan or arrangements required to be filed pursuant to Item 13 of this Form 10-KSB.

(A) Incorporated by reference to the Company's Registration Statement No. 333-3830, declared effective by the Securities and Exchange Commission on June 19, 1996.

(B) Incorporated by reference to the Company's Form 10-K for the year ended December 31, 1996.

(C) Incorporated by reference to the Company's Form 10-K for the year ended December 31, 1998.