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ORPHAN MEDICAL INC  
Form 10-K  
March 31, 2003

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

Annual Report pursuant Section 13 or 15(d) of the Securities Exchange Act of 1934 [No Fee Required] For the fiscal year ended December 31, 2002

or

Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 [No Fee Required]

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-24760  
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ORPHAN MEDICAL, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

41-1784594

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer Identification Number)

13911 RIDGEDALE DRIVE, SUITE 250,  
MINNETONKA, MN 55305

(952) 513-6900

(Address of principal executive offices  
and zip code)

(Registrant's telephone number,  
including area code)

Securities registered pursuant to Section 12(b) of the Act: NONE

Securities registered pursuant to Section 12(g) of the Act:

COMMON STOCK, \$.01 PAR VALUE

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes  No

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

Aggregate market value of common stock held by non-affiliates of Registrant, based upon the last sale price of the Common Stock reported on the Nasdaq National Market tier of The Nasdaq Stock Market on June 30, 2002 was \$84,190,000 based on approximately 8,909,000 shares held by non-affiliates at that date.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission in connection with the solicitation of

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proxies for the Registrant's Annual Meeting of Shareholders to be held on May 22, 2003 are incorporated by reference in Part III, Items 10, 11, 12 and 13 of this Form 10-K.

### PART I.

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1933, as amended. All forward-looking statements are inherently uncertain as they are based on current expectations and assumptions concerning future events or future performance of the Company. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. Forward-looking statements are not descriptions of historical facts. The words or phrases "will likely result", "look for", "may result", "will continue", "is anticipated", "expect", "project", or similar expressions are intended to identify forward-looking statements, and are subject to numerous known and unknown risks and uncertainties. Actual results could differ materially from those currently anticipated due to a number of factors, including those identified in the "Cautionary Statements" filed as an Exhibit to this Annual Report on Form 10-K, and in the Company's other filings with the Securities and Exchange Commission. The Company undertakes no obligation to update or publicly announce revisions to any forward-looking statements to reflect future events or developments.

Antizol(R), Antizol-Vet(R), Busulfex(R), Cystadane(R), Elliotts B(R) Solution, Sucraid(R), Xyrem(R), MedExpan(TM), "The" Orphan Drug Company(TM), Xyrem Success Program(SM) Orphan Medical, Inc.(R) and Dedicated to Patients with Uncommon Diseases(R) are trademarks of the Company.

#### ITEM 1. BUSINESS

##### OVERVIEW

Orphan Medical, Inc. (the "Company") acquires, develops and markets pharmaceutical products of high medical value for patients within selected therapeutic areas. A pharmaceutical product has high medical value if it offers a major improvement in the safety or efficacy of patient treatment. The Company currently concentrates its efforts on drugs with high medical value that may be marketed within three therapeutic areas: Antidotes, Oncology Support, and Sleep Disorders. Antizol, Busulfex and Xyrem are available commercially and are the Company's lead products in its Antidotes, Oncology Support and Sleep disorders areas, respectively. In addition, the Company manufactures and distributes Cystadane and Sucraid that treat two rare congenital diseases. Antizol-Vet is marketed through separate channels to the veterinary community. Although these products do not fall into the selected therapeutic areas, the Company expects to continue offering Cystadane, Antizol-Vet, and Sucraid because these products have high medical value and require limited resources to market and distribute.

Our corporate offices are located at 13911 Ridgedale Drive, Suite 250, Minnetonka, Minnesota 55305. Our telephone number is 952-513-6900 and our website is [www.orphan.com](http://www.orphan.com). The information on our website is not incorporated into and is not intended to be a part of this report. We make available free of charge on or through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the United States Securities and Exchange Commission.

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Unless the context otherwise indicates, all references to the "Registrant", the "Company", or "Orphan Medical" in this Form 10-K relate to Orphan Medical, Inc.

Each therapeutic area defined by the Company is characterized by a well-defined patient population that is treated by a relatively small number of medical specialists. The Company believes this approach makes a large sales force unnecessary to market the Company's products because marketing efforts can be focused on a limited number of medical specialists or patients. The high medical value of the Company's products is expected to facilitate marketing efforts directed toward users and prescribers. Through its sales force, supported by marketing and sales methods including the use of computer systems and the Internet, the Company intends to promote awareness of the key advantages of Orphan Medical branded products within Antidotes, Oncology Support, and Sleep Disorders. The Company's marketing and sales efforts will differentiate products on the basis of quality, potentially improved medical outcomes, and cost effectiveness. The Company uses established distributors of pharmaceutical products for its currently marketed products in a manner similar to that of most other pharmaceutical companies.

The Company believes its approach to pharmaceutical product development reduces the time, costs and risks traditionally involved in bringing pharmaceutical products to market. In general, the Company does not conduct basic research and does not attempt to discover new drugs. The Company's strategy is to acquire licenses to develop, or develop existing known therapeutic substances for new indications for market products that preferably have existing clinical data that indicate therapeutic value and safety. In addition, the Company considers acquiring

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products that have already received marketing approval from the U.S. Food and Drug Administration (the "FDA"). The Company uses contract development, manufacturing, and consulting companies to assist it in its product development and commercialization activities.

The Company operates within a single industry segment: pharmaceutical product development, marketing and sales. To date, the Company has obtained marketing approval from the FDA on seven New Drug Applications ("NDA"). The Company's products are commercially available in the United States and several foreign countries. Revenues from the Company's approved products outside the United States were approximately 22% of total 2002 revenues.

As an emerging and growing specialty pharmaceutical company, the Company did not achieve profitability in 2002 and does not expect to do so at least through 2003. The Company has significant capital requirements to support product development and marketing efforts until profitability is achieved.

### STRATEGIC BACKGROUND

In the 1950s and early 1960s, drug development was relatively inexpensive and regulatory approval was straightforward. Pharmaceutical companies marketed their products through sales forces directly to physicians who generally had independent responsibility for prescription and purchase decisions. In the 1970s, however, regulatory standards and competition increased, and the price of research and development and manufacturing rose dramatically. In the 1980s and 1990s, prescription decisions by physicians were constrained by managed care entities and drug companies revised their targeted rates-of-return or financial "hurdle rates," as well as other selection criteria, to avoid developing drugs whose incremental profit contributions were considered insufficient to provide acceptable returns on investment. Many of the drugs that did not meet these

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criteria were drugs that treat diseases affecting smaller patient populations. As a consequence, new drugs for such diseases were less likely to be developed by larger companies. Some research institutions, universities and small companies, however, have continued to develop and conduct clinical trials on these types of drugs.

The Company's strategy is based on several factors relating to these and other changes in the health care and pharmaceutical industries:

- o Larger pharmaceutical companies generally have increased their financial return rates, seek new products with annual revenues greater than \$300 million and avoid developing new products that address diseases outside their therapeutic areas of focus. As a result, the Company believes many developmental products of high medical value are available for licensing. If these products are intended to address smaller markets, they may be eligible for orphan drug designation. Many of these products have already been developed to the point where the time and cost required to bring the product to market can be reasonably estimated.
- o The knowledge and skills required to address many aspects of drug development are available on a contract basis from outside companies or individuals.
- o To address rapidly changing market forces, alternative means of marketing and distributing pharmaceuticals have been created. The advent of the Internet has dramatically increased the availability of information, including information related to health and health care products. Many products, particularly those targeted to smaller, well-defined markets, do not require a large, specialized sales force and can be marketed through direct means such as exhibits at professional meetings, direct mailings, telemarketing, continuing medical education programs, and the Internet. In addition, these products can be effectively distributed through companies that are proficient in distribution of pharmaceutical products to smaller patient populations.

In response to these changes, the Company has adopted a business strategy that is centered on products of high medical value within well-defined strategic therapeutic market segments, uses the knowledge and skills available on a contract basis where necessary, and uses alternative marketing and distribution channels, as appropriate.

### BUSINESS STRATEGY

The Company focuses on products of high medical value intended to address inadequately treated or uncommon diseases within selected therapeutic areas. A drug has high medical value if it offers a major improvement in the safety or efficacy of current patient treatments. In addition to products with high medical value, the Company seeks pharmaceuticals that have readily measured clinical endpoints, existing positive clinical data, proprietary attributes, eligibility for insurance reimbursement, and that offer attractive financial returns. The Company generally does not conduct basic research to discover new drugs, but instead seeks to acquire and further develop products that already

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have some data that indicate the presence of therapeutic value and safety. The Company's strategy of developing and marketing high medical value drugs with these clinical characteristics is intended to achieve the following benefits.

- o REGULATORY REQUIREMENTS AND REVIEW - Drugs of high medical value have a greater likelihood of receiving expedited review by the FDA. If such drugs also have smaller patient populations, the number of patients required for

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- clinical trials is generally reduced.
- o PRODUCT DEVELOPMENT TIME AND COST -The Company generally attempts to concentrate resources and project management attention on a single medical indication in order to limit the amount of clinical information required by the FDA to clear a product for marketing. The time and cost of development is directly related to the amount of clinical information required for regulatory approval.
- o LIMITED INFRASTRUCTURE - The Company believes that high quality pharmaceutical products can be developed efficiently and economically using well established independent contractors directed by its experienced staff. Accordingly, the Company uses the available pool of contract development, manufacturing, distribution and consulting companies to assist in product development and marketing activities. This approach allows the Company to avoid the costs, time and financial risks associated with developing an extensive infrastructure to perform these functions internally.
- o MARKETING STRATEGY -To assess the viability of a potential product, the Company considers questions such as these:
  - o Are there unmet therapeutic needs as defined by the customer? (the patient or the health care practitioner)
  - o Are there other product development or product acquisition opportunities that complement the product or does the product fit in the Company's areas of focus?
  - o Can the product's brand be established and command significant market share?
- o DIRECT SALES - The Company has built a small, specialized sales force to promote Antizol and Busulfex. The sales force has extensive knowledge of the Antidote and Oncology Support therapeutic areas, as well as extensive marketing and business experience. The Company has also created a dedicated specialty sales force to support Xyrem in the Sleep Disorders market. Each of the Company's sales forces utilizes a consultative, customer-oriented approach to selling.
- o ALLIANCES - The high medical value of the Company's products has interested other companies seeking to market the Company's products outside the U.S. To date, the Company has agreements with nine companies relating to five of the Company's products. The Company also believes that its relationships with these and other partners may provide strategic benefits, possibly in the area of product acquisition opportunities.
- o ATTRACTION OF POTENTIAL NEW PRODUCTS - As the Company's strategy and focus on pharmaceutical products of high medical value within a selected therapeutic area becomes better known and understood by others in the research and development community and as the Company further proves its ability to market and sell into a therapeutic area, the Company expects more product development or acquisition opportunities will be presented to it in the future.

### RISK MANAGEMENT

The Company's strategy has been designed, in part, to manage its overall business risk. The Company has pursued multiple distinct therapeutic areas rather than concentrating financial, development and marketing resources on a single therapeutic area or a single platform technology. To reduce its product development risk, the Company generally seeks to develop products that (1) are known to the medical community and to the FDA, (2) have a straightforward formulation that can be readily manufactured with established technologies, and (3) do not require excessive specialized processes for development or manufacture. In addition, the Company generally seeks to acquire products that are already in Phase II or Phase III clinical trials, or in an earlier stage of development with proof of concept established. When a product is licensed without the equivalent of Phase II or III data, the Company may conduct one or more "proof of concept" trials to better assess the likelihood of efficacy or safety. Each such pilot trial is narrowly defined. The Company does not conduct extensive basic research to discover new chemical entities. The Company may also purchase rights to approved products. To reduce its marketing risk, the Company

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generally attempts to obtain some form of proprietary protection, such as patent protection, orphan drug status, exclusive licensing agreements, or sole supplier agreements.

### PROPRIETARY RIGHTS

The Company believes it is important that its products receive patent protection or orphan drug status or have other factors that limit potential competition. When available and appropriate, the Company will seek orphan drug status to enhance or provide proprietary protection to a product. A drug that has orphan drug designation and which is the

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first product to receive marketing approval for its product claim, indication or application, receives orphan drug status and is entitled to a seven-year exclusive marketing period in the United States for that product claim and a 10-year exclusive period in Europe for that product claim, indication or application, subject to certain limitations. The Company has six products with orphan drug status. Applications for Orphan Drug designation will be made where appropriate and available for any additional indications or products that may be licensed in the future.

To encourage the continued development of drugs for smaller patient populations, the federal government enacted the Orphan Drug Act of 1983. This Act provides incentives to companies to develop and market drugs for diseases or conditions that are known to affect fewer than 200,000 people in the United States. A company must request orphan drug designation before an NDA is approved, and after the FDA grants orphan drug designation, the generic identity of the therapeutic agent (drug) and its potential orphan use (market) are published by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory approval process. The FDA may grant orphan drug designation to more than one company of an identical drug for the same designated indication, however under current law, orphan drug status is granted to the first company receiving FDA marketing approval for a specific indication of a drug with orphan drug designation. A company receiving orphan drug status for a designated indication is entitled to a seven-year exclusive marketing period in the United States for the drug with the approved indication, subject to certain limitations. Orphan drug status in the United States, however does not prevent subsequent approval of a different drug for the same designated indication, nor subsequent approval of the same drug for a different designated indication, nor provide any marketing exclusivity in foreign markets. Since 1983, the FDA has assigned orphan drug designation to more than 650 potential products.

Orphan drug protection is available in Japan and the European Union under requirements similar to those in the United States. An important distinction in the European Union is the ten-year period of marketing exclusivity for products designated as orphan drugs, compared to seven year of exclusivity in the United States. The period of exclusivity in the European Union also begins upon marketing approval.

The license agreement pursuant to which the Company has acquired rights to develop and market Busulfex provides for an assignment of the licensor's proprietary rights, including patent and technology rights. With respect to additional products it may license in the future, if any, the Company expects that such licenses will include, if such rights are available, an assignment of the licensor's proprietary rights with respect to the licensed product. Foreign patent applications have been filed and some allowed for Busulfex and Xyrem. The

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Company has licensed two patents related to a new potential development opportunity. The Company is evaluating a development program for this product. The Company evaluates the desirability of registering approved patents or other forms of protection for its products in individual foreign markets based on the expected costs and relative benefits of attaining such protection.

### THE REGULATORY PROCESS

Pharmaceutical products intended for therapeutic use in humans are governed by extensive FDA and other federal agencies regulations in the United States and by comparable regulations in foreign countries. The process of seeking and obtaining FDA approval for a previously unapproved new human pharmaceutical product generally takes many years and involves the expenditure of substantial resources and considerable risk.

Before a drug product can be investigated or marketed in the United States, the following general steps are required includes (i) pre-clinical laboratory and animal safety tests, (ii) the submission to the FDA of an IND application, (iii) clinical and other studies to assess safety and parameters of use, (iv) adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug product, (v) the submission to the FDA of an NDA, (vi) FDA approval of the NDA prior to any commercial sale or shipment of the product, (vii) marketing of the drug, and (viii) post-approval safety and risk monitoring.

Upon the successful completion of clinical testing, a marketing application (i.e. NDA) is submitted to the FDA for approval. This application requires detailed data on the results of pre-clinical testing, clinical testing and the composition of the product; proposed labeling to be used with the drug; information on manufacturing methods; and sometimes samples of the product. Since the passage of the Prescription Drug User Fee Act ("PDUFA"), the FDA typically takes from six to eighteen months to review an NDA after it has been accepted for filing. Following its review of a marketing application, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy. Further, there is no assurance that the FDA will ultimately approve an NDA. The FDA can also determine that a drug is "approvable" contingent on satisfactory review of additional information requested by the FDA. We cannot assure you that such requests by the FDA for additional information can be fulfilled in a timely manner, if at all. If the FDA approves the NDA, the new product may be

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marketed for the applications or treatments that have been approved by the FDA. The claims with which a product can be marketed are also subject to review and approval by the Division of Drug Marketing, Advertising and Communications ("DDMAC"), the FDA's marketing surveillance department within the Center for Drugs. The FDA often clears a product for marketing with a modification, or restriction to the proposed label claims or requires that post-marketing surveillance, or Phase IV testing, to be conducted. The method and system of a drug's distribution can also be controlled by the FDA if approved under Subpart H.

### OPERATING FUNCTIONS

The Company has structured each of its operating functions to support its strategy. Following is a general explanation of the typical steps in the Company's processes of product acquisition, development and marketing.

#### PRODUCT ACQUISITION

The Company actively searches for product licensing opportunities. The continual

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acquisition of products for development and/or commercialization is a key element of the Company's growth strategy. The Company attracts product acquisition proposals through a network of customer and industry contacts, licensing brokers and a growing awareness of its activities by governmental, academic and industry sources. Since its inception, the Company has evaluated many product opportunities. To date, seventeen products have been acquired and, of these, seven products are currently under development or being marketed.

The Company seeks to acquire pharmaceutical products within selected therapeutic areas that, in the Company's opinion, generally:

- o Are of high medical value as defined by the customer (physician or patient) within a therapeutic area;
- o Treat diseases that affect distinct patient populations;
- o Are prescribed by physician specialists;
- o Can be marketed with a relatively small, specialized sales team to health care specialists, health care institutions, and patients;
- o Are likely to be eligible for reimbursement by third-party payors;
- o Have or are candidates for patent protection, orphan drug designation or have other characteristics that enhance the Company's competitive position;
- o Treat diseases that have clinical endpoints (i.e., signs or symptoms) that are readily measured;
- o Are conventional pharmaceutical products that are relatively straightforward in formulation and development, and do not involve the application of new technologies;
- o Are in Phase II or Phase III clinical trials and have a relatively high likelihood of obtaining the approval of the FDA within three to five years of acquisition;
- o Offer attractive potential financial returns with relatively inexpensive development costs;
- o Complement other products in an existing therapeutic area or can be grouped with other products to build a new therapeutic area.

In selecting additional products for potential inclusion in its portfolio, the Company generally focuses on acquiring rights to medicines that serve niche or defined patient populations. Major drug companies are less likely to address these niche markets because they do not believe these markets will produce acceptable revenues and returns. This reluctance limits the number of potential sources of competition. In addition, a product designed for smaller patient populations is often eligible for orphan drug designation. By obtaining orphan drug designation, the Company is granted exclusive marketing rights or status in the United States for seven years, subject to certain limitations, after an NDA for a product is approved, if the Company is the first to receive approval for the designated drug and indication.

The Company seeks to acquire potential products that already have, or will not require, a substantial quantity of clinical data to demonstrate their relative efficacy and safety. The Company also searches for product candidates that represent new delivery methods or dosage forms of previously approved or known compounds because the Company believes these types of products are more likely to be quickly approved by the FDA and accepted by the medical community. In addition, the Company attempts to develop medicines where clear clinical endpoints can demonstrate their effectiveness. Generally, the Company seeks to acquire products that can be developed to the point of FDA approval within three to five years of their acquisition. Typically, the Company also focuses its development efforts on one indication and, when possible, one dosage form to minimize development costs. Potential additional indications or dosage forms will only be evaluated after the primary NDA is submitted or approved.



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An additional element of the Company's product development strategy is to acquire products that have or can have a degree of proprietary protection. Generally, this goal is accomplished by selecting products that are covered by patents, are eligible for orphan drug designation, or are the subject of an exclusive license from a sole supplier or a manufacturer with specialized or proprietary processes. The likely availability of adequate levels of reimbursement from third-party payors is also an important factor in product acquisition decisions.

The Company's management reviews new product opportunities and makes recommendations to the Board of Directors of the Company regarding the license or acquisition of any proposed additional products. The product review process involves discussions with customers (physicians and patients) within a given therapeutic area to identify unmet needs, and with the initial product developer and experts in the disease treated by the drug; review of research publications and other databases to gauge competitive activities; market research aimed at identifying potential acceptance by the end user; technical evaluations to determine manufacturability and cost; expected FDA regulatory requirements to obtain acceptable marketing or promotional claims; and a legal review of any relevant proprietary rights. If this review indicates that the proposed product meets the Company's selection criteria, efforts to negotiate a license are initiated. Generally, the Company seeks to obtain licenses that require a minimal signing fees and commercially acceptable royalty levels.

The Company is continually seeking and evaluating additional proposed products within selected therapeutic areas. Should the Company be unsuccessful in acquiring additional proposed products for development and commercialization within a selected therapeutic area, the Company may reassess the viability of a therapeutic area or redefine the area to expand the number of potential products that might satisfy the Company's acquisition criteria for a viable therapeutic area to ensure adequate future growth of the Company.

### PRODUCT DEVELOPMENT

Pharmaceutical product development is one of the Company's principal activities. The Company has incurred \$48.1 million in research and development expense through December 31, 2002. In addition, the Company estimates that it will need to incur at least an additional \$6.0 million in research and development expense relating to the seven products it currently markets, including obtaining any potential additional Xyrem indications.

A major element of the Company's product development strategy is to use third-parties or contract research organizations (CROs) to assist in the conduct of safety and efficacy testing and clinical studies, to assist the Company in guiding products through the FDA review and approval process, and to manufacture and distribute any FDA approved products. The Company believes that maintaining a minimal infrastructure will enable it to develop products efficiently and cost effectively. To facilitate this strategy, the Company uses a team approach to develop its proposed products. A development team is organized and managed by senior staff. The development team is cross-functional and includes in-house experts, as well as appropriate outside consultants, to manage all development activities as well as market planning with respect to a proposed product. A development team designs a development plan, which will support the proposed indication and marketing claims, and creates and manages a financial budget for the proposed product and contracts with outside development agents and consultants to arrange for the necessary clinical and toxicology studies, manufacturing arrangements and FDA filings. Upon approval of the NDA by the FDA, the Company's marketing and sales staff manages marketing and sales of the proposed product.

The Company believes the use of third parties to develop and manufacture its

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products has several advantages. This approach generally allows a greater pool of resources to be concentrated on a product than if these functions were performed by internal personnel who were required to support all of the Company's products. Although this approach will allow the Company to avoid the expense associated with developing a large internal infrastructure to support its product development efforts, it will result in the Company being dependent on the ability of outside parties to perform critical functions for the Company. Over time, the Company expects to build internal capabilities to replace certain functions now contracted to outside parties.

This contract approach to product development requires project management by professionals with substantial industry experience. The Company believes it has in-house experts in areas of critical importance to all of its proposed products who can be consulted by the development teams. These areas include regulatory affairs, marketing and sales, quality assurance, manufacturing, clinical trials management, finance, information systems and general management.

The product development process is designed to identify problems associated with a proposed product's safety and effectiveness. The Company attempts to reduce the risk that a proposed product will not be accepted in the

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marketplace by conducting market research and defining commercial strategy with a product's development. A drug development portfolio cannot be completely insulated from potential clinical and marketing failures. It is likely that some proposed products selected for development by the Company will not produce the clinical or revenue results expected. To date, the Company has discontinued development activities with respect to eleven proposed products because either the products were deemed unapprovable or the estimated financial returns of these proposed products were unacceptable.

### MANUFACTURING

The Company does not have and does not intend to establish any internal product testing, drug or chemical synthesis of bulk drug substance, and manufacturing capability for drug product. Manufacturers of the Company's products are subject to applicable Good Manufacturing Processes ("GMP") as required by FDA regulations, or other rules and regulations prescribed by foreign regulatory authorities. The Company is negotiating or has entered into bulk drug supply and drug product manufacturing agreements with third parties for all of its FDA approved products and is dependent on such third parties for continued compliance with GMP and applicable foreign standards. The Company believes that qualified manufacturers will continue to be available in the future, at a reasonable cost to the Company, although there can be no assurance that this will be the case.

Due to FDA mandated dating requirements and the limited market size for the Company's approved products, the Company may be subject to complex manufacturing logistics, minimum order quantities that could result in excess inventory as determined under the Company's accounting policy, unsalable inventory as a result of product expiring prior to use, and competition with others for manufacturing services when needed or expected. The Company has a production-planning program to assess and manage the manufacturing logistics amongst the vendors supplying the required finished product components of bulk drug substance, drug product and packaging.

The Company is substantially dependent on its contract drug product manufacturers. These manufacturers have been approved by the FDA for the production of the Company's approved products. Following is a listing of the

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Company's contract drug product manufacturers:

Contract Drug Product Manufacturer	Marketed and Proposed Products
----- An affiliate of Boehringer Ingelheim	----- Antizol, Antizol-Vet, Elliotts B Solution, and Busulfex
NutraMax, Inc.	Sucraid
Proclinical, Inc., Ropack, Inc.	Cystadane
DSM/Catalytica Pharmaceuticals, Inc.	Xyrem

In addition to the contract drug product manufacturers, the Company is substantially dependent on Ash Stevens, Inc. ("Ash Stevens") and Lonza, Inc. ("Lonza"). Ash Stevens is the Company's sole supplier of bulk drug substance for the manufacture of Antizol, Antizol-Vet, and Busulfex; while Lonza is the Company's sole supplier of bulk drug substance for the manufacture of Xyrem.

### MARKETING - UNITED STATES

The Company has designed its product selection strategy to maximize the success of its marketing efforts. By having products that current and potential customers have identified as having "high medical value", the Company believes it should be able to more easily attract the attention of targeted segments of the medical community. The Company also believes that its focus on well-defined physician and patient populations will allow the use of a relatively small, focused sales force instead of a large, generalized sales force. Because of the distinct nature of most of its potential markets, the Company expects to be able to concentrate its marketing efforts on a limited number of medical specialists, or on patients themselves.

As part of its marketing efforts, the Company identifies and defines appropriate therapeutic areas, identifies customer needs within each therapeutic area, identifies specific product acquisition candidates within each therapeutic area, works with the development team to insure clinical data are collected that supports the desired indication and marketing claims, and if FDA approval is obtained, designs and implements marketing plans for each of its approved products. Market research is conducted to analyze the potential of products prior to their acquisition. Once a product is acquired and is being developed, further market research is completed and, based on this analysis; the product's marketing plan is developed. Upon submission of the NDA to the FDA, the product management responsibilities transition from the development team to the Company's marketing and sales staff. The development

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group continues to provide support where needed to enhance marketing and sales efforts. This group is responsible for all aspects of a product's marketing and sales, including product forecasting, positioning, price, promotion and physical distribution to successfully launch and commercialize the product. Senior sales and marketing employees lead a cross functional team of internal and external personnel to implement a product's marketing and commercialization plan. In addition, marketing and sales staff also supports the Company's international sales efforts through support of and interfacing with international partners.

### MARKETING - FOREIGN

In general, the Company expects to out-license foreign marketing, sales and distribution rights after an NDA is submitted or approved in the United States.

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The Company contracts with foreign companies (usually pharmaceutical companies) to market and distribute its products. The Company considers Europe and Japan to be its most attractive foreign markets. The Company has entered into marketing, sales and distribution agreements for Antizol, Cystadane and Sucraid in Europe, Cystadane and Sucraid in Australia and New Zealand, Busulfex, Cystadane, Elliotts B Solution and Sucraid in Israel, Antizol and Cystadane in Canada, and Elliotts B Solution in Central America.

In October 1999, the Company signed a definitive agreement with Pierre Fabre Medicament, granting the French company exclusive rights to market and distribute Busulfex in 21 European countries, as well as Argentina and South Africa. Upon approval, Pierre Fabre, a private company with 2002 sales in excess of \$1.3 billion and approximately 9,000 employees, will market Busulfex to transplant centers through its 75 oncology marketing and sales personnel. The Company has an agreement with IDIS World Medicine to distribute Busulfex on a "named patient basis" to requesting physicians outside of the United States, Canada and Israel, and other approved products in territories where the Company's other products are not approved and where the Company does not have a distribution partner. The Company began shipments to IDIS in January 2000.

In December 2000, the Company signed a definitive agreement with Kirin Brewing Co., LTD to market and distribute Busulfex in Asia including Japan, the Peoples Republic of China, South Korea and Taiwan. Kirin is a diversified company with more than \$14 billion worldwide revenues in the food and beverage industry. Kirin expanded into the pharmaceutical business in 1982 and has a strong presence in the fields of nephrology, cancer and cell production, immunology and allergy.

The Company's historical practice is to negotiate contracts with foreign distributors that generally provide for minimum order and sales performance. Minimum fees negotiated with foreign parties to date are not material and are not refundable, nor subject to future performance criteria. The foreign contracting party is responsible for obtaining marketing approval for the Company's product to which the agreement relates and the Company is responsible for providing selected U.S regulatory information to the foreign party on request. The Company cannot unilaterally terminate these agreements without established evidence of default, but these agreements do expire over a defined period of time and the Company may seek other foreign parties to provide comparable services upon expiration if not satisfied with the performance of its partners. The principal benefit a foreign party receives from entering into these agreements with the Company and paying the minimum fees, if any, is a contracted price for acquisition of product from the Company because the Company is the sole supplier of its approved products on a worldwide basis.

The Company is in the process of obtaining a partner for the distribution of Xyrem in the European Union, where it received orphan drug designation in February 2003, and Asia. The commercial agreement with a third party for Xyrem that provides marketing rights outside of the United States may differ from previously executed contracts in that the Company hopes to secure an upfront payment as well as milestone payments for regulatory and/or commercial milestone achievements.

### DISTRIBUTION

In the foreseeable future, the Company does not intend to develop internal physical distribution capabilities because the Company believes its relatively low-volume products can be more economically and efficiently distributed through third party distribution organizations. Cystadane is principally distributed directly to patients through a third party mail order pharmacy, Chronimed, Inc. Elliotts B Solution, Antizol and Busulfex are primarily used in a hospital setting and are distributed by an affiliate of Cardinal Health. This distribution system allows the sale of these products directly into hospitals or, if customers prefer, through their primary wholesaler. Antizol-Vet is a

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product used in veterinary clinics and is distributed by an affiliate of Cardinal Health to individual veterinary clinics and a network of veterinary wholesalers.

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The Company has a contract with a central pharmacy to distribute Xyrem in the United States. Xyrem is classified as a Schedule III controlled substance and approved under Subpart H of the FDA's review and approval process, and distribution will be strictly controlled. The specialty pharmacy will be the only source through which Xyrem can be obtained. Distribution will be governed by the FDA's Subpart H regulations and will fully comply with the risk-management controls jointly developed by Orphan Medical, the Drug Enforcement Agency and law enforcement agencies. Every shipment of Xyrem will be subject to stringent safeguards to ensure it reaches only individuals for whom it has been legitimately prescribed.

### COMPETITION

Potential competitors in the United States are numerous and include pharmaceutical, chemical and biotechnology companies. The Company will experience competition in several specific areas, including, but not limited to, those described below.

- o PRODUCT ACQUISITION -The Company will compete with other entities in acquiring product rights from other companies, universities, other research institutions, as well as from other potential licensors.
- o PRODUCT DEVELOPMENT RESOURCES - The Company will compete for certain resources, such as the services of clinical investigators, contract manufacturers, advisors and other consultants. The Company will generally have little or no control over the allocation of such resources.
- o ORPHAN DRUG DESIGNATION - The Company is aware of two other companies that have filed for and received orphan drug designation on products similar to two of its products. Sparta Pharmaceutical (acquired by SuperGen in 1999) and Teva (formerly Biocraft) have been granted orphan drug designations for their intravenous busulfan and sodium oxybate, respectively. Intravenous busulfan and sodium oxybate are their equivalents of the Company's Busulfex and Xyrem products, respectively. The Company does not believe SuperGen is developing an intravenous busulfan. In 1999, the Company entered into an agreement with Teva that, in effect, transfers Teva's development data to the Company. While the Company is not aware of others holding or seeking orphan drug designations for products that would compete with the Company's products for NDA approval, there can be no assurance that the Company's products will not have such competition from another formulation or drug of materially different composition from being approved, with or without orphan drug status, for the same indication.
- o MARKETING AND SALES - Each of the Company's current products will face competition from other products or from other therapeutic alternatives. The Company's products may compete against products whose marketers have substantially greater resources, including large specialized sales forces, than the Company.
- o MANUFACTURING - The Company may also compete for limited manufacturing capacity or availability.

### GOVERNMENT REGULATION

#### GENERAL

Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental change. Several potential approaches are under consideration, including mandated basic health care

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benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price discounts from drug manufacturers, the creation of large purchasing groups and other significant changes to the health care delivery system. In addition, some states have adopted or are considering price controls and various health care reform proposals. The Company anticipates that Congress and state legislatures will continue to review and assess alternative health care delivery systems and payment methods and that public debate of these issues will likely continue in the future. Because of uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, the Company cannot predict which, if any, of such reform proposals will be adopted, when they may be adopted or what impact they may have on the Company or its prospects.

### REIMBURSEMENT

Employers, through payments to their employee benefit plans, bear a significant share of the health care costs of their employees. These plans are typically administered by insurance companies, health maintenance organizations, preferred provider organizations and other third-party payors. Health care services and products, including pharmaceutical products, are also paid for by government agencies, such as Medicaid. Employers and the payors involved in providing or administering health care benefits are increasingly turning to "managed care" systems to control health care costs. Under these systems, the administrative requirements and standards of care are established by the health care purchasers and providers and the benefit level depends on the negotiated price. Managed care systems usually limit treatment options to approved therapeutic regimens and "formularies," or lists of approved drugs and medical products.

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Inclusion or listing on the formularies of managed care groups is important to the commercial success of most prescription medicines. A pharmaceutical must be included on a third-party payor's formulary or must be deemed "medically necessary" to be eligible for reimbursement by that payor. In deciding whether a drug is to be included on a formulary, payors will generally consider its therapeutic value and cost in comparison to other available treatments. The Company believes that the proprietary nature and medical usefulness of its products should assist it in its efforts to have its products approved for reimbursement. No assurance can be given, however, that the Company's products will be approved for reimbursement by third-party payors at acceptable levels, or at all.

### PRODUCT APPROVALS

The Company's products require FDA approval in the United States and comparable approvals in foreign markets before they can be marketed. The development of investigational products and the marketing and supply of approved products require continuing compliance with FDA regulations on the part of the Company as well as its manufacturers and distributors.

### SCHEDULED PRODUCTS

Products that are designated "controlled" substances also require compliance with regulations administered by the U.S. Drug Enforcement Agency ("DEA"), and similar regulations administered by state regulatory agencies. On February 28, 2000 the President signed PL 106-172, a public law that makes gamma hydroxybutyrate (GHB) a Schedule I substance. Schedule I is the designation by which illegal and non-approved drugs are controlled. The bill further delineates GHB products being studied under Food and Drug Administration (FDA) approved protocols or approved for commercial sale by the FDA as Schedule III substances.

Each state has the ability to schedule products more strictly or equivalent to

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the Federally designated schedule. Most states have adopted, either administratively or legislatively, the bifurcated I/III schedule as described above. The Company continues its efforts to ensure consistency of scheduling across all states.

### MANUFACTURING REGULATION

All facilities and manufacturing processes used to manufacture products for clinical use or sale in the United States must be operated in conformity with Good Manufacturing Practices (GMP). These represent the FDA requirements governing the production of pharmaceutical products. FDA approval is required before a contract manufacturer can implement most changes in manufacturing procedures for any of the Company's approved products. The Company has established a quality assurance program to monitor third-party manufacturers of its products to promote compliance by such manufacturers with domestic and foreign regulations (based on country of use). In addition, FDA approval is required to change contract manufacturers of approved products. Obtaining the FDA's approval for a change in manufacturing procedures or change in manufacturers could cause production delays and loss of revenue.

### FOREIGN REGULATION

Products marketed outside of the United States are subject to regulatory approval requirements similar to those required in the United States, although the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain European countries, the price of a product must also be approved. The pricing review period often begins after market approval is granted. The Company intends to use foreign partners to apply for foreign marketing approvals.

### INSURANCE

Providing health care products entails an inherent risk of liability. In recent years, participants in the health care industry have been subject to a large number of lawsuits alleging malpractice, product liability or related legal theories, many of which involve large claims and significant defense costs. The Company may from time to time be subject to such suits as a result of the nature of its business. The Company carries product liability insurance coverage in the aggregate amount of \$20 million. The Company also carries a \$10 million general business insurance policy. The Company does not carry any insurance to cover the financial risks associated with a potential FDA mandated recall of an approved product. There can be no assurance, however, that such insurance policies will be sufficient to fully indemnify the Company against any asserted claims or that such insurance will continue to be available.

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### HUMAN RESOURCES

The Company has 108 full-time and five part-time employees. The Company believes that its relationship with its employees is good. None of the Company's employees is represented by a labor union.

### TRADE SECRETS

The Company also relies on trade secrets and proprietary know-how to protect certain of its technologies and potential products. The Company requires employees, consultants and advisors to enter into confidentiality agreements that prohibit disclosure to any third party or use of such secrets and know-how for commercial purposes. Company employees also agree to disclose and assign to

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the Company all methods, improvements, modifications, developments, discoveries and inventions conceived during their employment that relate to the Company's business. We cannot assure, however, that these agreements will be observed to prevent disclosure or that they will provide adequate protection for the Company's confidential information and inventions.

### GRANTS

The FDA Office of Orphan Drug Products (Orphan Drug grants) and the Small Business Administration (SBIR grants) offer grants to companies whose efforts meet certain requirements. From July 1, 1995 through December 31, 1998, the Company collected approximately \$1,567,000 in grant proceeds with respect to approximately \$1,567,000 in grant related disbursements for certain products. The grant proceeds collected by the Company are non-refundable. There can be no assurance that Orphan Drug or SBIR grants will be made available to the Company in subsequent periods. The Company currently has no active grants.

### DISCONTINUED DEVELOPMENT PRODUCTS

Through December 31, 2002, the Company discontinued development activities on a total of eleven proposed products. There can be no assurance that the Company's license rights and/or any clinical data related to a discontinued product have any value to a third party and, if such rights or clinical data have value, there can be no assurance that the Company can come to terms with a third party for the sale of such rights or clinical data.

### PRODUCTS

The following tables summarize certain information relating to the Company's products:

#### MARKETED PRODUCTS

Approved Product	Application	NDA Approval Date	U.S. Patent Issued or Applied For
Xyrem(R) (sodium oxybate) oral solution	For the treatment of cataplexy associated with narcolepsy	July 2002	Yes
Antizol(R) (fomepizole) Injection	Antidote for ethylene glycol (antifreeze) or suspected ethylene glycol ingestion in humans	December 1997	No
	Antidote for methanol or suspected methanol ingestion in humans	December 2000	No



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Busulfex(R) (busulfan) Injection	For use in combination with cyclophosphamide as a conditioning regimen prior to allogenic hematopoietic cell transplantation for chronic myelogenous leukemia ("CML")	February 1999	Yes
Cystadane(R) (betaine anhydrous for oral solution)	Homocystinuria, a genetic disease	October 1996	No
Sucraid(R) (sacrosidase) oral solution	Sucrase deficiency, a genetic disease	April 1998	No
Antizol-Vet(R) (fomepizole) for Injection	Antidote for ethylene glycol (antifreeze) or suspected ethylene glycol ingestion in dogs	November 1996	No
Elliotts B(R) Solution (buffered intrathecal electrolyte/dextrose solution)	Diluent for intrathecally administered methotrexate sodium and cytarabine	September 1996	No

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PRODUCTS UNDER DEVELOPMENT

Investigational Product	Proposed Application	Phase of Development *	U.S. Patent Issued or Applied For	Orphan Drug Designation
Xyrem(R) (sodium oxybate) oral solution	Sleep disorders	III (b)		

\* Development Phases are discussed under "Business - The Regulatory Process".

\*\* Orphan Drug Designation and Status are discussed under "Business - Proprietary Rights"

APPROVED PRODUCTS

XYREM (SODIUM OXYBATE) ORAL SOLUTION

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Narcolepsy is a chronic neurologic sleep disorder in which sleep is "fragmented", that is, does not occur in an integrated and cohesive manner. This fragmentation results in excessive daytime sleepiness, unavoidable daytime sleep attacks, cataplexy or sudden loss of muscle control provoked by emotions, sleep paralysis or brief periods of muscle paralysis and hallucinations, or vivid and sometimes frightening dreaming when falling asleep or waking up. Other related symptoms include broken nighttime sleep, disturbances of auditory and visual perception, and lapses of consciousness and memory problems. These symptoms can lead to a variety of complications, such as limitations on education and employment opportunities, driving or machine accidents, difficulties at work resulting in disability, forced retirement or job dismissal, and depression. Narcolepsy is thought to affect approximately 140,000 persons in the United States. Approximately 75,000 of these patients are thought to be diagnosed. Narcolepsy patients usually begin to develop symptoms between the ages of 15-25. Symptoms have been reported in patients as young as five years of age.

The usual treatment for narcolepsy includes symptomatic treatment of excessive daytime sleepiness and sleep attacks with stimulants or wakefulness promoting agents. The symptoms of cataplexy, sleep paralysis and hypnagogic hallucinations are typically treated with tricyclic antidepressants ("TCAs") or selective serotonin reuptake inhibitors ("SSRIs"). These treatment regimens, in addition to limited efficacy, are often unsatisfactory for a number of other reasons. Amphetamines and other stimulants often cause undesirable side effects such as insomnia, hypertension, palpitations, irritability and, at higher doses, may mimic the symptoms of schizophrenia. Patients often build tolerance to the TCAs and SSRIs and doses are increased to obtain clinical effectiveness. These medications can cause the side effects of dry mouth, impotence, loss of libido, and increased heart rate. Clinical results with Xyrem suggest that it is effective in the treatment of narcolepsy symptoms. Administered at night, it is believed to consolidate sleep and has been shown to reduce cataplexy attacks, and to reduce the severity of daytime sleepiness when used in combination with stimulants during the day. More than 500 narcolepsy patients have been exposed to clinical doses with an acceptable side effect profile. Xyrem does not appear to have the side effects associated with TCAs and SSRIs. Narcoleptic patients could be treated with Xyrem at night and, if needed, with stimulants during waking hours.

The Company submitted its NDA for Xyrem on October 2, 2000 and was granted approval on July 17, 2002. The product is indicated for the treatment of cataplexy associated with narcolepsy. The Company began shipping product in September 2002 and the commercial launch commenced on October 7, 2002. Through December 31, 2002 nearly 1000 new prescriptions have been written for Xyrem by approximately 280 physicians.

Gamma hydroxybutyrate (GHB) is the active ingredient in Xyrem. Illicitly produced GHB has been reported to be a drug of abuse. On February 18, 2000, the President signed PL 106-172, a public law that makes GHB a Schedule I substance. Schedule I is the designation by which illegal drugs are controlled. The bill further delineates GHB products being studied under Food and Drug Administration (FDA) approved protocols or approved for commercial sale as Schedule III substances.

Each state has the ability to schedule products more strictly or equivalent to the Federally designated schedule. Most states have adopted, either administratively or legislatively, the I/III schedule as described above. The Company continues its efforts to ensure consistency of scheduling across all states.

Sodium oxybate (GHB), the active ingredient in Xyrem, is a known compound and is not patentable. The Company has received an orphan drug status for its indicated use of Xyrem. There are no license fees or royalty payments

associated with Xyrem revenues. FDA orphan drug status extends through July 17, 2009. The Company has an issued formulation patent, which expires on December 22, 2019. Other patents are pending. The Company has contracted with third party bulk drug and drug product manufacturers for the production of Xyrem under GMP conditions.

#### BUSULFEX (BUSULFAN) INJECTION

Following an accelerated six-month priority review, the Company received regulatory approval from the FDA in February 1999 to market Busulfex in the United States. The FDA approved Busulfex for use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia ("CML"). The first commercial sales of Busulfex occurred in February 1999, within two weeks of FDA approval. Busulfex also received marketing approval in Canada in September 1999, in Israel in February 2000 and in South Korea in December 2001. The indications approved in Canada, Israel and South Korea provide for use of Busulfex as a conditioning regimen prior to bone marrow or hematopoietic progenitor cell transplantation, when used in combination with other chemotherapeutic agents and/or radiotherapy. Included in the Canadian indication are acute lymphocytic leukemia, non-lymphocytic leukemia, acute myeloid leukemia, non-Hodgkin's lymphoma, Hodgkin's disease, multiple myeloma, myelodysplastic syndrome, breast cancer, ovarian cancer and several genetic diseases.

In December 2002, the FDA approved labeling changes for Busulfex with respect to pediatric dosing, but did not award the Company a pediatric indication.

In December 2000, the Company signed a definitive agreement granting Kirin Brewery Co., LTD exclusive rights to market and distribute Busulfex in Asia. Kirin is a diversified company with annual sales of more than \$14 billion worldwide in the food, beverage and pharmaceutical industry. Kirin expanded into the pharmaceutical industry in 1982 and has established a strong presence in the fields of nephrology, cancer and cell production, immunology and allergy. The Company began shipments of clinical trial materials to Kirin in 2001

In October 1999, the Company signed a definitive agreement with Pierre Fabre Medicament, granting the French company exclusive rights to market and distribute Busulfex in 21 European countries, Argentina, and South Africa. Pierre Fabre will market Busulfex to transplant centers through 75 oncology marketing and sales personnel. The Company signed an agreement with IDIS World Medicine in December 1999 to distribute Busulfex on a named patient basis to requesting physicians outside of the United States, Canada and Israel until marketing approvals are granted by the respective regulatory agencies. The Company began shipments to IDIS in January 2000. A marketing application was submitted by Pierre Fabre Medicament in Europe in late 2001. In March 2003 the European Committee for Proprietary Medicinal Products (CPMP) recommended to the European Commission that Busulfex(R) (busulfan) Injection be approved for marketing in Europe as a conditioning treatment prior to haematopoietic progenitor stem cell or bone marrow transplantation in adult patients.

Bone marrow and peripheral stem cell transplants are collectively known as hematopoietic progenitor cell transplants, but are more commonly referred to as stem cell or bone marrow transplants. This year approximately 20,000 stem cell transplants are expected to be performed in the United States, with another 20,000 expected to be performed outside the United States. One of the many complex steps in performing a stem cell transplant includes using high doses of chemotherapeutic drugs, such as Busulfex, and/or radiation as a "conditioning

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regimen" to destroy the abnormal cancer cells in the bone marrow and to create "space" for the engraftment of transplanted stem cells. The stem cell transplant then replaces the diseased or damaged marrow to grow into healthy marrow. Of the 20,000 procedures expected to be performed in the United States, more than 4,000 of these may receive some form of busulfan, as part of the pre-transplantation conditioning regimen. The Company is marketing Busulfex to hematologists and oncologists who perform stem cell transplants at cancer treatment centers.

Adoption of Busulfex into standard busulfan-based regimens has been steady, and several clinicians in leading institutions have initiated new research protocols using Busulfex to enhance the conditioning regimen, based on clinical data and experience with Busulfex. Several leading United States research centers have indicated to the Company that they have initiated or intend to initiate new study protocols specifying the use of Busulfex.

Many other drugs are currently being developed for use in the BMT area. Although most of these new drugs are used for a different purpose during the bone marrow transplant and not in the conditioning regimen, some of them may compete with Busulfex. The Company is aware that SuperGen Inc., which acquired Sparta Pharmaceutical in 1999, now owns rights to another form of intravenous busulfan which was in development by Sparta prior to its acquisition. SuperGen holds orphan drug designation for its intravenous busulfan and could seek orphan drug status for a similar or different indication, if SuperGen were to proceed with development of its intravenous formulation and if the FDA approves an NDA for such a product.

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The Company has obtained orphan drug status for Busulfex for the approved indication, which initially provided marketing exclusivity for that indication to the Company through February 2006. With the addition of pediatric labeling, the FDA granted a six-month extension of exclusivity through August 2006. The Company has contracted with a third party for the production of Busulfex under GMP conditions. In addition, the Company has an exclusive, worldwide license except for Australia from M.D. Anderson Cancer Center, The University of Texas, and The University of Houston (collectively, the "busulfan licensors") to develop and market this intravenous form of busulfan, which is effective for the term of busulfan licensors' patent rights. The busulfan licensors have been granted two U.S. patents covering the licensed product's formulation and its use in bone marrow transplants and other conditions, which expire in September 2016 and July 2015, respectively. The product is distributed for the Company by an affiliate of Cardinal Health.

### ANTIZOL (FOMEPIZOLE) INJECTION

Antizol received marketing clearance from the FDA in December 1997 for suspected or confirmed ethylene glycol poisonings and December 2000 for suspected or confirmed methanol poisonings. The Company commenced shipping Antizol in December 1997. Antizol is primarily used in a hospital setting and is distributed for the Company by an affiliate of Cardinal Health. When ingested by humans, ethylene glycol or methanol (found in antifreeze) and methanol (found in windshield wiper fluid) can lead to death or permanent and serious physical damage. In a survey conducted in 2001 by the American Association of Poison Control Centers, approximately 8,500 cases of ethylene glycol poisoning were reported to United States poison control centers. In the same year, there were approximately 1,100 treatments for such poisonings. The Company believes that hospital pharmacies will continue to stock Antizol because it is important to treat poisoned patients very quickly in order to improve the chances of successful recovery. For 2002, Antizol contributed approximately 39% of the

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Company's total revenues. The Company estimates that over one-third of all hospitals with emergency rooms currently stock the product. Antizol has become the standard of care for toxic alcohol poisoning and guidelines issued by the American Academy of Clinical Toxicologists recommended Antizol as the drug of choice for such poisonings. The Company expects to see limited incremental stocking by hospitals in 2003. Future sales will be based more on usage as stocking levels are expected to plateau. The Company has also received marketing approval for Antizol in Canada for the treatment of suspected or confirmed ethylene glycol poisonings.

The Company has obtained orphan drug status for Antizol as an antidote to treat ethylene glycol and methanol poisonings, which provides marketing exclusivity to the Company through December 2004 for ethylene glycol and December 2007 for methanol. The Company has contracted with a third party for the production of Antizol under GMP conditions. The Company, through a sublicense agreement with Mericon Investment Group, Inc. ("MIG"), has an exclusive, worldwide license to develop and market Antizol, which expires in July 2013, subject to a five year renewal through July 2018 exercisable by MIG at the request of the Company.

### CYSTADANE (BETAINE ANHYDROUS FOR ORAL SOLUTION)

Cystadane received marketing clearance from the FDA in October 1996. The first commercial sales of Cystadane occurred in December 1996. Cystadane is principally distributed on a non-exclusive basis by Chronimed Inc. directly to patients in the United States through its mail order pharmacy. It is the first agent approved by the FDA for the treatment of homocystinuria, an inherited metabolic disease. The clinical consequences are wide-ranging and include dislocation of the ocular lens, early (under age 30) thromboembolism, developmental and mental retardation and reduced life span related to elevated plasma homocysteine levels. It has been estimated that homocystinuria occurs about once in every 200,000 live births worldwide. There are estimated to be 1,000 patients with homocystinuria in the United States. The annual market potential for Cystadane is approximately \$500,000 in the United States. The Company does receive sales revenue generated outside of the United States. Cystadane revenues met the Company's expectations in 2002 and are expected to grow slightly in subsequent periods. The Company believes that the small size of the market and the high medical value of Cystadane justify the limited resources required by the Company to continue making this product available to patients.

The Company has obtained orphan drug status for Cystadane for the treatment of homocystinuria, which provides marketing exclusivity to the Company through October 2003. The Company has contracted with a third party for the production of Cystadane under GMP conditions. No license was required for the Company to develop and market Cystadane.

The Company is not currently sponsoring any clinical trials with/for Cystadane. The Company is aware, however, of clinical trials being conducted by independent investigators to assess the safety and efficacy of Cystadane as a stand alone or adjunctive therapy for the following indications: Non-alcoholic steatohepatitis, Rett syndrome, rheumatoid

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arthritis and hyperhomocystinemia. The Company does not expect that the results of any of these clinical trials will significantly enhance or decrease the current limited market potential for Cystadane in the near future.

### SUCRAID (SACROSIDASE) ORAL SOLUTION

Sucraid received marketing clearance from the FDA in April 1998. The first commercial sales of Sucraid occurred in July 1998. Sucraid is principally

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distributed by an affiliate of Cardinal Health directly to patients in the United States. The FDA approved Sucraid to be used for oral replacement therapy of genetically determined sucrase deficiency, which is part of congenital sucrase isomaltase deficiency (CSID). Sucraid is used as a replacement for an enzyme in the small intestine that is necessary for the digestion of sucrose, which is common table sugar. The Company believes that the small size of the market and the high medical value of Sucraid justify the limited resources required by the Company for making this product available to patients.

Sacrosidase, the active ingredient in Sucraid, is a known compound and is not patentable. The Company has obtained orphan drug status for Sucraid for the approved indication, which provides marketing exclusivity to the Company through April 2005. The Company has contracted with a third party for the production of Sucraid under GMP conditions. In addition, the Company has an exclusive, worldwide license from Hartford Hospital to develop and market Sucraid, which expires in April 2005. The license provides for two five-year extension options, the first through April 2010 and the second through April 2015, unless either party decides to terminate the license within 90 days prior to April 2005 or April 2010.

### ANTIZOL-VET (FOMEPIZOLE) FOR INJECTION

In November 1996, the Center for Veterinary Medicine of the FDA approved Antizol-Vet as a treatment for dogs that have ingested or are suspected of having ingested ethylene glycol. The first commercial sales of Antizol-Vet occurred in January 1997. It is estimated that at least 10,000 cases of ethylene glycol poisoning occur in dogs each year. The earlier an ethylene glycol poisoned dog is treated with Antizol-Vet, the more likely that there will be a positive outcome. The annual market potential for Antizol-Vet is expected to be under \$300,000. The Company has found that stocking of this product has been limited due to its high cost, but it is ordered when a poisoning occurs. Antizol-Vet revenues met the Company's expectations in 2002 and are expected to remain constant or decline in subsequent periods.

Federal law provided the Company with a marketing exclusivity period through November 2001 for the use of Antizol-Vet in dogs for the approved indication. The Company has contracted with a third party for the production of Antizol-Vet under GMP conditions.

The Company has partnered with several leading regional and national veterinary wholesalers to distribute Antizol-Vet to veterinary clinics. It is believed that the current partners effectively and efficiently encompass the entire country with limited sales territory overlap, thus helping prevent downward retail pricing pressures. The Company does not anticipate adding additional distribution partners.

### ELLIOTTS B SOLUTION (BUFFERED INTRATHECAL ELECTROLYTE/DEXTRROSE INJECTION)

Elliotts B Solution received marketing clearance from the FDA in September 1996. The first commercial sales of Elliotts B Solution occurred in December 1996. Elliotts B Solution is primarily used in a hospital setting and is distributed for the Company by an affiliate of Cardinal Health. Elliotts B Solution is a buffered diluent for the intrathecal administration (injection into the fluid space surrounding the central nervous system) of chemotherapeutic agents. Intrathecal injections are most commonly made in treating acute lymphoblastic leukemia ("ALL"). ALL is the most prevalent form of leukemia in children. Due to advances in chemotherapy, the cure rate for ALL has improved dramatically in the past 30 years, going from almost zero to nearly 75% today. As a part of modern chemotherapy, doctors often administer a series of up to 20 injections of methotrexate sodium into the cerebrospinal fluid of patients. Elliotts B Solution is comparable in pH, electrolyte composition, glucose content and osmolarity to cerebrospinal fluid. It is estimated that cerebrospinal injections of methotrexate sodium are administered to about 6,000 people in the United States on an annual basis. Elliotts B Solution revenues have not been material

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nor does the Company expect that revenues to be material to the Company's financial results.

The Company has obtained orphan drug status for the use of Elliotts B Solution as a diluent for methotrexate sodium or cytarabine, which provides marketing exclusivity through September 2003. Elliotts B Solution is a known compound that has been used previously for the intrathecal administration of chemotherapeutic agents and is, therefore, not patentable. The Company has contracted with a third party for the production of Elliotts B Solution under GMP conditions. No license was required for the Company to develop and market Elliotts B Solution.

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The primary symptoms of CSID include severe watery diarrhea, chronic malabsorption and, in infants and toddlers, failure to thrive. Other common symptoms include nausea, vomiting, abdominal cramps and abdominal pain following the consumption of foods containing sucrose. Prior to the approval of Sucraid, the only specific treatment of CSID available to patients was the life-long adherence to a sucrose-free diet. Compliance with a sucrose-free diet is very difficult because sucrose is found in many foods in the typical American diet. Nonspecific symptomatic treatments include antidiarrheal, antispasmodic and antifatulence drugs, all of which are limited in their efficacy. Sucraid is a specific replacement of the missing enzyme responsible for CSID.

### SLEEP DISORDERS - INVESTIGATIONAL PRODUCT XYREM (SODIUM OXYBATE) ORAL SOLUTION

The Company is conducting a Phase III (b) third clinical trial for Xyrem, which the FDA has previously indicated is not required for the Company's NDA submission. This controlled clinical trial assesses the efficacy of Xyrem for treating excessive daytime sleepiness (EDS) related to narcolepsy as its primary endpoint. This trial continues to move forward toward completion in the middle of 2003. A second Phase III(b) trial will begin in early 2003 to assess Xyrem with and without other stimulant medication for the treatment of EDS associated with narcolepsy.

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### ITEM 2. PROPERTIES

The Company currently occupies approximately 15,000 square feet of leased office space at a monthly rent of approximately \$25,000, including operating expenses. This lease expires on October 31, 2003.

### ITEM 3. LEGAL PROCEEDINGS

None.

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

None.

## ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

THIS SECTION NEEDS TO BE UPDSATED TO INCLUDE MARK PERRIN, AND DAVID FULLER The executive officers of the Company and their ages as of March 1, 2003.

Name	Age	Title
John Howell Bullion	51	Chief Executive Officer and Chairman of the Board
William Houghton, M.D.	60	Executive Vice President and Chief Scientific and Medical Officer
Mark Perrin	46	Executive Vice President and Chief Commercial Officer
Timothy G. McGrath	38	Vice President and Chief Financial Officer
Dayton T. Reardan, Ph.D.	47	Vice President of Regulatory Affairs
Pamela J. Stahl	37	Vice President of Commercial Operations
David Fuller, M.D.	39	Vice President of Medical Affairs

Executive officers of the Company serve at the discretion of the Board of Directors with no fixed term. There are no family relationships between or among any of the executive officers or directors of the Company.

Mr. Bullion has been Chief Executive Officer of the Company since June 24, 1994 and Chairman of the Board of Directors since December 30, 1998. Mr. Bullion is a co-founder of Chronimed Inc., the company from which Orphan Medical, Inc. was spun-off in 1994. Prior to joining Orphan Medical, Mr. Bullion served as President of Bluestem Partners, an investment and consulting company; Dahl & Associates, a soil and ground water remediation company; and Concurrent Knowledge Systems, Inc., a software development company. Mr. Bullion also served as partner and Vice President with First Bank System Venture Capital Company for seven years.

Dr. Houghton has been the Company's Executive Vice President, Chief Scientific and Chief Medical Officer since May 2002. Prior to that Dr. Houghton served as the Company's Chief Operating Officer since joining the Company in August 1998. Dr. Houghton's most recent position was Chief Scientific Officer and Vice President of Clinical and Regulatory Affairs at Iotek, Inc. from April 1995 to August 1998. At Iotek, Dr. Houghton was responsible for all research activities, regulatory and clinical research, and served as the medical liaison with Iotek's Medical advisory Board. From February 1984 to March 1995, Dr. Houghton also held a variety of management positions with Abbott Australasia and Abbott Laboratories in the United States.

Mr. Perrin has been the Company's Executive Vice President and Chief Commercial Officer since May 2002. From 1995 to 2001, Mr. Perrin was Executive Vice President, Commercial Operations at COR Therapeutics responsible for all aspects of sales marketing and manufacturing. Prior to that Mr. Perrin held sales, marketing and commercial operations management positions at Burroughs Wellcome Company from 1992 to 1995 and Lederle Laboratories from 1979 to 1992.

Mr. McGrath has been the Company's Vice President and Chief Financial Officer since October 1999. Previously, Mr. McGrath had worked as consultant providing financial services to growing companies in the Minneapolis and Saint Paul area. From 1994 to 1998, he was Vice President of Finance at E. W. Blanch Holdings,



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Inc., a publicly traded provider of integrated risk management and distribution services. Prior to joining E.W. Blanch Holdings, Mr. McGrath was with Ernst & Young LLP in Minneapolis.

Dr. Reardan has been the Company's Vice President of Regulatory Affairs since May 1995 and had been the Director of Regulatory Affairs since joining the Company in 1994. From 1993 to 1994, he was Director of Development at CV Therapeutics. From 1984 to 1993, he held a variety of scientific, development and management positions at Xoma Corporation.

Ms. Stahl has been the Company's Vice President of Commercial Operations since October 2001. Most recently, Ms. Stahl was Vice President of Sales at American TeleCare, Inc. an emerging telemedicine company where she had responsibility for sales, marketing, and distribution. Previously, she held several management positions in sales, managed care, and sales training at AstraZeneca L.P. During her tenure at AstraZeneca L.P., Ms. Stahl was a member of the team that launched Prilosec(R), the leading treatment of acid related disorders. She also worked at Merck & Co., Inc. in sales and training positions supporting Zocor(R) and Pepcid(R). In her position at Orphan Medical, Ms. Stahl manages the Company's U.S. and International sales, distribution, and Patient Affairs functions.

Dr. Fuller has been the Company's Vice President of Medical Affairs since February 2002 and had been the Director of Medical Affairs since joining the Company in July 2001. From February 1999 to July 2001, Dr. Fuller held several management positions at CeNeS Pharmaceuticals. From 1992 through 1999, Dr. Fuller was Managing Director at Spectrum Pharmaceuticals, a consulting firm. Prior to that, Dr. Fuller held various positions at Pfizer Pty Ltd., Bayer Australia Ltd., and Roche Products. Dr. Fuller was also a Resident Medical Officer at Royal Prince Alfred Hospital in Camperdown, Australia.

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### PART II

#### ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

The Company's Common Stock trades on the National Market tier of The Nasdaq Stock Market under the Symbol: ORPH. The following table sets forth the quarterly high and low sales prices for the Company's Common Stock for the years ended December 31, 2002 and December 31, 2001.

	High	Low
-----		
YEAR ENDED DECEMBER 31, 2002		
January 1 through March 31	\$15.000	\$10.310
April 1, through June 30	\$13.060	\$9.000
July 1 through September 30	\$12.200	\$5.950
October 1 through December 31	\$11.350	\$6.960
YEAR ENDED DECEMBER 31, 2001		
January 1 through March 31	\$18.375	\$6.375
April 1 through June 30	\$15.000	\$9.500
July 1 through September 30	\$12.200	\$6.500
October 1 through December 31	\$14.100	\$7.240
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EQUITY COMPENSATION PLAN INFORMATION AS OF DECEMBER 31, 2002

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The following table summarizes information as of December 31, 2002 relating to equity compensation plans of the Company pursuant to which grants of options, restricted stock, or other rights to acquire shares may be granted from time to time. As of December 31, 2002, the Company had no equity compensation plans that were not approved by security holders.

PLAN CATEGORY	NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (1)	WEIGHTED-AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (2)	NUMBER OF SE REMAINING AV FUTURE ISSUA EQUITY COMPE (EXCLUDING S REFLECTED IN
Equity compensation plans approved by security holders	1,997,478	\$7.90	

As of March 15, 2003, the Company's Common Stock was held by approximately 250 shareholders of record and the Company estimates that there were approximately 3,000 beneficial owners of its Common Stock on such date.

The Company has never declared or paid any dividends and does not anticipate paying dividends on its Common Stock in the foreseeable future. The Company currently intends to retain future earnings, if any, for use in the Company's business. The payment of any future dividends on its Common Stock will be determined by the Board of Directors in light of conditions then existing, including the Company's earnings, financial condition and requirements, restrictions in financing agreements, business conditions and other factors.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data of the Company as of December 31, 2002 and 2001 and for the three years ended December 31, 2002, 2001 and 2000, are derived from, and are qualified by reference to, the financial statements of the Company audited by Ernst & Young LLP, independent auditors, included elsewhere in this Form 10-K. The selected financial data as of December 31, 2000, 1999 and 1998 and for each of the two years ending December 31, 1999 and 1998 are derived from financial statements, which are not included herein. The information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," the Financial Statements and Notes thereto and other financial information included elsewhere in this Form 10-K.

FINANCIAL POSITION

December 31,				
2002	2001	2000	1999	1998

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Cash, cash equivalents and available-for-sale securities	\$ 6,920,685	\$ 19,011,245	\$ 11,417,254	\$ 4,032,914	\$ 7,521,000
Working capital	6,672,090	18,010,707	10,266,029	3,161,324	5,274,000
Total assets	13,138,922	22,346,276	15,296,885	6,241,178	9,046,000
Accumulated deficit	(66,388,335)	(54,073,165)	(47,178,667)	(40,243,874)	(34,433,000)
Total shareholders' equity	7,749,794	18,412,707	10,742,927	3,561,208	5,575,000

FINANCIAL RESULTS

	For the Year Ended December 31, 2002	For the Year Ended December 31, 2001	For the Year Ended December 31, 2000	For the Year Ended December 31, 1999	For the Year Ended December 31, 1998
Revenues	\$ 16,130,169	\$ 11,274,110	\$ 11,185,634	\$ 6,457,406	\$ 5,048,000
Cost of sales	2,191,598	1,591,826	1,532,446	803,562	1,118,000
Gross profit	13,938,571	9,682,284	9,653,188	5,653,844	3,929,000
Operating expenses					
Research and development	6,618,091	5,462,336	7,179,605	5,208,099	6,611,000
Sales and marketing	12,518,498	5,729,987	5,259,031	3,198,146	2,739,000
General and administrative	6,458,308	4,807,847	4,094,905	2,756,827	2,994,000
Loss from operations	(11,656,326)	(6,317,886)	(6,880,353)	(5,509,228)	(8,414,000)
Other income, net	255,178	321,315	793,238	287,989	177,000
Net loss	(11,401,148)	(5,996,571)	(6,087,115)	(5,221,239)	(8,237,000)
Less: Preferred stock dividend	922,170	903,053	872,024	682,872	249,000
Net loss applicable to common shareholders	\$ (12,323,318)	\$ (6,899,624)	\$ (6,959,139)	\$ (5,904,111)	\$ (8,486,000)
Basic and diluted loss per common share	\$ (1.19)	\$ (0.80)	\$ (0.86)	\$ (0.90)	\$ (0.90)
Weighted average shares outstanding	10,349,679	8,597,331	8,135,224	6,587,790	6,236,000

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

GENERAL

Since its inception, the activities of the Company have consisted primarily of obtaining the rights for developing and marketing proposed pharmaceutical products, managing the development of these products and preparing for and initiating the commercial introduction of seven products. The Company operates in a single business segment: pharmaceutical products. The Company has experienced recurring losses from operations and has generated an accumulated

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deficit through December 31, 2002 of \$66.4 million. In addition, the Company expects to incur additional losses from operations in 2003.

### RECENT DEVELOPMENTS

On July 17, 2002 the Company announced that the U.S. Food and Drug Administration (FDA) had approved Xyrem(R) (sodium oxybate) oral solution to treat cataplexy, a sudden loss of muscle tone associated with narcolepsy. Xyrem is the first approved medication indicated for the treatment of cataplexy.

Narcolepsy is a chronic neurological disorder affecting approximately 140,000 Americans. An estimated 60-90 percent of narcolepsy patients experience cataplexy. Cataplexy, a sudden partial or total loss of muscle tone, is a debilitating symptom of narcolepsy usually triggered by strong emotions such as laughter, anger, or surprise. In its most severe form, cataplexy can cause a person to collapse during waking hours.

Xyrem (sodium oxybate) is a central nervous system (CNS) depressant and should not be used in conjunction with alcohol or other CNS depressants. Sodium oxybate is GHB (gamma hydroxybutyrate), a known drug of abuse. The abuse of GHB has been associated with a number of important CNS adverse clinical events, including seizure, respiratory depression, and profound decreases in level of consciousness, with instances of coma and death. Even at recommended doses, use has been associated with confusion and other neuropsychiatric events. Reports of respiratory difficulties occurred in clinical trials.

Distribution of Xyrem, a Schedule III controlled substance, is governed by the FDA's Subpart H regulations. To comply with these regulations, the Company has developed a rigorous system that makes Xyrem available to patients from a single, specialty pharmacy. Both physicians and patients must receive educational materials from the Company before obtaining Xyrem. Orphan Medical has worked closely with the FDA, DEA and law enforcement agencies to develop strict distribution and risk-management controls designed to restrict access to Xyrem to the intended patient population. The Company has hired and trained 36 additional sales employees who will call on accredited sleep centers, and other physician specialists treating those with cataplexy. The Company launched Xyrem on October 7, 2002.

The Company has worked with physicians, patients, and FDA for nearly eight years to bring Xyrem to patients with cataplexy. The Company is continuing investigations to fully understand the mechanism of action of Xyrem. The Company also expects to complete by the end of 2003 the clinical portion of the Phase III(b) trial designed to assess the efficacy of Xyrem in reducing excessive daytime sleepiness as a supplement to stimulant therapy. The Company has initiated a second Phase III(b) trial to assess the efficacy of Xyrem in reducing excessive daytime sleepiness both with and without concomitant stimulant therapy.

On March 28, 2003, the Company cancelled its existing line of credit facility and entered into a new facility with a commercial bank. The new line of credit facility, which has a term of one-year, includes a borrowing base equal to 75% of eligible accounts receivable up to a maximum amount of \$3.5 million. Certain other assets have also been pledged as collateral for this facility. The interest rate is equal to two points over the bank's prime rate. The Company will be subject to certain other requirements during the term of the facility, including minimum quarterly net equity amounts.

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### REVENUE RECOGNITION

Sales for all products except Xyrem(R) (sodium oxybate) oral solution are recognized at the time a product is shipped to the Company's customers and are recorded net of reserves for estimated returns of outdated product and for discounts for prompt payment. Sales of Xyrem are recognized at the time product is shipped from the specialty pharmacy to the patient and are recorded net of discounts for prompt payment. Except for Xyrem, the Company is obligated to accept, for exchange, from all domestic customers products that have reached their expiration date. The Company is not obligated to accept exchange of outdated product from its international distribution partners. The Company establishes a reserve for the estimated cost of the exchanges. The Company monitors the return of product and modifies its accrual for outdated product returns as necessary. Management bases these reserves on historical experience and this estimate is subject to change.

### ACCOUNTS RECEIVABLE ALLOWANCE

The Company determines an allowance amount based upon an analysis of the collectibility of specific accounts and the aging of the accounts receivable. There is a concentration of sales to larger medical wholesalers and distributors. The Company performs periodic credit evaluations of its customers' financial condition. Domestic receivables are due within 30 days of the invoice date. International receivables are generally due within 60 to 90 days of invoice date. Credit losses relating to customers have not been material since the Company's inception.

### INVENTORIES

Inventories are valued at the lower of cost or market determined using the first-in, first-out (FIFO) method. The Company's policy is to establish an excess and obsolete reserve for its products in excess of the expected demand for such products.

### RESULTS OF OPERATIONS

TWELVE MONTHS ENDED DECEMBER 31, 2002 VS. TWELVE MONTHS ENDED DECEMBER 31, 2001 Revenues increased to \$16.1 million for the twelve months ended December 31, 2002 from \$11.3 million for the twelve months ended December 31, 2001, an increase of \$4.8 million or 43%. Sales of both Antizol and Busulfex exceeded revenue expectations in 2002. Antizol(R) (fomepizole) Injection performed very well throughout 2002. Sales of the antidote experienced 34% growth as compared to the prior year and Antizol is being stocked in over one-third of all hospitals with emergency departments. Antizol is established as the standard of care for confirmed or suspected ethylene glycol and methanol poisonings. Use of Busulfex(R) (busulfan) Injection in preparative regimens for bone marrow transplantation also continues to realize significant growth in the United States, Canada and other countries. Busulfex continues to advance into new research areas in place of oral busulfan or total body irradiation, and now holds an approximate 55 percent market share of the transplants that include a busulfan-based regimen. The sales of Cystadane, Sucraid Antizol-Vet and Elliotts B met the Company's expectations in 2002 and are not expected to increase significantly in 2003. Revenues will fluctuate from quarter to quarter and from year to year depending on, among other factors, demand for the Company's products, new product introductions and the Company's ability to optimize distribution of its approved products.

Cost of sales increased to \$2.2 million for the twelve months ended December 31, 2002 from \$1.6 million for the twelve months ended December 31, 2001, an increase of \$0.6 million or 38%. The increase is primarily attributable to the increase in sales in 2002. The gross margins for both 2002 and 2001 were 86%. Cost of sales as a percentage of revenues will fluctuate from quarter to quarter and from year to year depending on, among other factors, demand for the Company's products, new product introductions and the mix of approved products

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shipped.

Research and development expense increased to \$6.6 million for the twelve months ended December 31, 2002 from \$5.5 million for the twelve months ended December 31, 2001, an increase of \$1.1 million or 21%. The increase is the result of increased activity in ongoing trials for Xyrem and other development activities related to Xyrem and other products. The two Phase III(b) trials for Xyrem, now underway, will increase research and development spending in subsequent quarters, as will additional trials and data updates requested by the FDA. Clinical spending

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for these activities will be dependent on a number of factors, including among others, the number of human subjects screened and enrolled in the trials, and the number of active clinical sites.

Sales and marketing expense increased to \$12.5 million for the twelve months ended December 31, 2002 from \$5.7 million for the twelve months ended December 31, 2001, an increase of \$6.8 million or 118%. This increase is largely attributable to activities for Xyrem, including the development of marketing materials, the recruitment and training of a dedicated specialty sales force, the implementation of the specialty distribution system and the ongoing activities associated with initial introduction of a new product. Sales and marketing expenses will increase versus historical levels in subsequent quarters to support the sales and marketing efforts related to Xyrem.

General and administrative expense increased to \$6.5 million for the twelve months ended December 31, 2002 from \$4.8 million for the twelve months ended December 31, 2001, an increase of \$1.7 million or 34%. The increase in general and administrative expenses is related to building infrastructure for the launch and subsequent support of Xyrem. General and administrative expenses are expected to increase somewhat above current levels in the next few quarters as additional personnel are added and other support projects are initiated.

Other income consists of interest income from investment activities net of interest expense. Other income was \$0.3 million for the twelve months ended December 31, 2002 and 2001. Even though the equity transaction completed in December 2001 increased the cash available for investment in 2002, the lower interest rates and the cash used to fund development and working capital activities of the Company resulted in no increase in interest income for 2002 over 2001. Other income is expected to decrease in 2003 as a result of cash used to fund development and working capital activities of the Company.

Preferred stock dividends relate to the Senior Convertible Preferred Stock that was issued on July 23, 1998 and Series B Convertible Preferred Stock issued on August 2, 1999. Both have dividend rates of 7.5%. Preferred stock dividends were \$0.9 million for the twelve months ended December 31, 2002 and 2001. Preferred stock dividends, which commenced on February 1, 1999, are payable in arrears on August 1 and February 1 of each year. Prior to February 2001, the Company satisfied its dividend payment obligation by issuing additional preferred stock, as permitted by the terms of the Senior Convertible Stock. Subsequent to February 2001, the Company intends to continue to satisfy its future dividend payment obligations by the issuance of unregistered common shares of stock for the Senior Convertible Preferred Stock and additional preferred stock for the Series B Convertible Preferred Stock, which will cause preferred stock dividends to increase in subsequent quarters.

Net loss applicable to common shareholders was \$12.3 million for the twelve

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months ended December 31, 2002 compared to a net loss of \$6.9 million for the twelve months ended December 31, 2001. Basic and diluted loss per common share for these respective periods were \$1.19 and \$0.80, based on weighted average number of common shares outstanding of 10,349,679 and 8,597,331, respectively.

TWELVE MONTHS ENDED DECEMBER 31, 2001 VS. TWELVE MONTHS ENDED DECEMBER 31, 2000 Revenues increased from \$11.2 million for the twelve months ended December 31, 2000 to \$11.3 million for the twelve months ended December 31, 2001, an increase of \$0.1 million or 1%. Sales of both Antizol and Busulfex exceeded revenue expectations in 2001. International sales of the Company's products decreased in 2001 due primarily to a delay in the shipment of clinical trial supply product requested by an international partner. The sales of Cystadane, Sucraid Antizol-Vet and Elliotts B met the Company's expectations in 2001 and are not expected to increase significantly in 2002.

Cost of sales increased from \$1.5 million for the twelve months ended December 31, 2000 to \$1.6 million for the twelve months ended December 31, 2001, an increase of \$0.1 million or 4%. The increase is primarily attributable to the increase in sales in 2001. The gross margins for both 2001 and 2000 were 86%. Cost of sales as a percentage of revenues will fluctuate from quarter to quarter and from year to year depending on, among other factors, demand for the Company's products, new product introductions and the mix of approved products shipped.

Research and development expense decreased from \$7.2 million for the twelve months ended December 31, 2000 to \$5.5 million for the twelve months ended December 31, 2001, a decrease of \$1.6 million or 23%. The decrease was the result of reduced research and development spending on Xyrem during 2001. The Company's efforts in 2001 were primarily focused on supporting the Xyrem NDA submission. The 2001 spending includes ongoing trials for Xyrem and other development and regulatory activities. Prior year spending included amounts for clinical trials included in the NDA submission.

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Sales and marketing expense increased from \$5.3 million for the twelve months ended December 31, 2000 to \$5.7 million for the twelve months ended December 31, 2001, an increase of \$0.4 million or 9%. This increase was largely attributable to significantly higher spending related to the pre-approval market activities related to Xyrem.

General and administrative expense increased from \$4.1 million for the twelve months ended December 31, 2000 to \$4.8 million for the twelve months ended December 31, 2001, an increase of \$0.7 million or 17%. Approximately 34% of the increase in general and administrative expenses is related to compensation expense associated with stock options. The balance of the increase is related to building infrastructure, including the addition of staff to prepare for the anticipated launch of Xyrem.

Other income consists of interest income from investment activities net of interest expense. Other income decreased from \$0.8 million for the twelve months ended December 31, 2000 to \$0.3 million for the twelve months ended December 31, 2001. This decrease is the result of cash used to fund development and working capital activities of the Company. In addition, interest rates on invested funds declined, reducing the yields received.

Preferred stock dividends relate to the Senior Convertible Preferred Stock that was issued on July 23, 1998 and Series B Convertible Preferred Stock issued on August 2, 1999. Both have dividend rates of 7.5%. Preferred stock dividends were

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\$0.9 million for the twelve months ended December 31, 2001 and 2000. Preferred stock dividends, which commenced on February 1, 1999, are payable in arrears on August 1 and February 1 of each year. The Company previously satisfied its dividend payment obligation by issuing additional preferred stock, as permitted by the terms of the Senior Convertible Stock. The Company intends to continue to satisfy its future dividend payment obligations by the issuance of unregistered common shares of stock for the Senior Convertible Preferred Stock and additional preferred stock for the Series B Convertible Preferred Stock, which will cause preferred stock dividends to increase in subsequent quarters.

Net loss applicable to common shareholders was \$6.9 million for the twelve months ended December 31, 2001 compared to a net loss of \$7.0 million for the twelve months ended December 31, 2000. Basic and diluted loss per common share for these respective periods were \$0.80 and \$0.86, based on weighted average number of common shares outstanding of 8,597,331 and 8,135,224, respectively.

### LIQUIDITY AND CAPITAL RESOURCES

Since July 2, 1994, the effective date the Company was spun-off from Chronimed Inc., it has financed its operations principally from net proceeds from several public and private financings, interest income and product sales. The various public and private placement transactions since inception resulted in aggregate net proceeds, after commissions and expenses, of \$60.5 million. These net proceeds include the private placement of 1.707 million shares of newly issued common stock, resulting in net proceeds of \$13.0 million in December 2001.

Net working capital (current assets less current liabilities) decreased to \$6.7 million at December 31, 2002 from \$18.0 million at December 31, 2001. Cash and cash equivalents decreased to \$6.9 million at December 31, 2002 from \$19.0 million at December 31, 2001. The Company invests excess cash in short-term, interest-bearing, investment grade securities.

The Company has a commercial revolving line of credit facility with a bank, which expires on June 15, 2003. The maximum amount available to the Company under this facility is \$1,000,000, subject to certain limitations based on the Company's cash collateral. The Company intends to renew this line of credit facility. However the Company cannot assure that the bank will do so, or that it would do so on terms acceptable to the Company. In connection with the financing transaction in August 1999, the Company received a \$2.05 million commitment in the form of a line of credit from UBS Capital. This line was eliminated as a provision of the financing transaction in December 2001. The Company had not borrowed under the UBS Capital agreement. In addition, the Company had not borrowed under the bank arrangement.

As discussed previously, the Company entered into a new line of credit facility with a commercial bank on March 27, 2003. The new line of credit facility, which has a term of one-year, includes a borrowing base equal to 75% of eligible accounts receivable up to a maximum amount of \$3.5 million. Certain other assets have also been pledged as collateral for this facility. The interest rate is equal to two points over the bank's prime rate. The Company will be subject to certain other requirements during the term of the facility, including minimum quarterly net equity amounts.

The Company's commitments for outside development spending increased to approximately \$5.7 million at December 31, 2002 from \$4.0 million at December 31, 2001. These commitments are generally for less than one year. The increase is principally attributable to the timing of the initiation of clinical trials



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for Xyrem development activities. The Company expects development spending to increase as the two Xyrem Phase III(b) clinical trials progress and post approval surveillance studies are completed. In addition, the Company continues to look at new product opportunities and any new initiatives will increase development spending. Due to the dependence of this estimate on the results of the studies and other variable components, the actual result of this estimate may be different.

The Company also has future contractual commitments for the following cash obligations

	Total	Less than one year	1-3 Years	4-5 Years
Capital lease obligations	\$ 120,593	\$ 24,119	\$ 48,238	48,2
Operating lease obligations (1)	1,230,300	601,100	629,200	
Outside Development Spending	5,633,000	5,633,000	--	
Total contractual cash obligations	\$6,983,893	\$6,258,219	\$ 677,438	\$ 48,2

(1)-These amounts include both space for facilities and automobiles for the Company's field sales force.

The Company expects spending during 2003 for research and development, sales and marketing, and administration to increase significantly over 2002 levels. Management believes the Company's current working capital and anticipated operating cash flows from product sales will be sufficient to fund its operations at least through December 31, 2003.

For continued listing on the NASDAQ National Market, a company must satisfy a number of requirements, which in the Company's case include either: (1) minimum net equity in excess of \$10.0 million or (2) a market capitalization of at least \$50.0 million. The Company met the market capitalization threshold at December 31, 2002. The Company's minimum net equity at December 31, 2002 equaled approximately \$7.7 million and the Company's market capitalization was approximately \$92.1 million (based on the last sale price of \$8.80 and 10,460,283 shares outstanding as of December 31, 2002). Although the Company does not expect to be profitable in 2003, the Company nevertheless expects to continue to meet the requirements for listing on the NASDAQ National Market. However there can be no assurance that the Company will continue to have adequate capital to meet the requirements through the year 2003 and thereafter.

In connection with the 1998 and 1999 private placements of convertible preferred stock, the Company agreed to certain restrictions and covenants, which could limit its ability to obtain additional financing. The most important of the restrictions are: (1) the Company cannot incur additional indebtedness, except for indebtedness secured solely by the Company's trade receivables, until it has profitable operations, subject to certain limitations and (2) the Company cannot, without the approval of a majority of the preferred stockholders, issue

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additional equity securities unless the selling price per share exceeds the then conversion price of the outstanding convertible preferred stock or the sale of equity is accomplished in a public offering. The present conversion price is \$8.14 for the Senior Convertible Preferred Stock and \$6.50 for the Series B Convertible Preferred Stock. Even without these restrictions, the Company can make no assurances that additional financing opportunities will be available or, if available, on acceptable terms.

### RISK FACTORS

An investment in our common stock involves a number of risks, including among others, risks associated with companies that operate in the pharmaceutical industry. These risks are substantial and inherent in our operations and industry. Any investor or potential investor should carefully consider the following information about these risks before buying shares of common stock.

### WE HAVE A HISTORY OF LOSSES, WHICH WE EXPECT TO CONTINUE.

We have been unprofitable since our inception in January 1993. We expect operating losses at least through 2003 because anticipated gross profits from product revenues will not offset our operating expenses and additional spending to continue drug development activities. The amount of these losses may vary significantly from year-to-year

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and quarter-to-quarter. Our actual losses will depend on, among other factors, the timing of product development, regulatory approval, and market demand for our Food and Drug Administration ("FDA") approved products. We cannot assure you that we will ever generate sufficient product revenues to achieve profitability.

### LIMITATIONS TO SOURCES OF ADDITIONAL CAPITAL - RESTRICTIONS, COVENANTS AND RIGHTS RELATED TO SENIOR CONVERTIBLE PREFERRED STOCK AND SERIES B CONVERTIBLE PREFERRED STOCK.

On July 23, 1998, we completed the private sale to UBS Capital of \$7.5 million of Senior Convertible Preferred Stock. On August 2, 1999, we completed another private sale to UBS Capital of \$2.95 million of Series B Convertible Preferred Stock. In conjunction with the issuance of the preferred shares, we agreed to several restrictions and covenants, and granted certain voting and other rights to the holders of the preferred shares. One of the most important of these restrictions is that we cannot incur additional indebtedness, except for indebtedness secured solely by our trade receivables, until we have profitable operations, subject to certain limitations. Another important restriction is that, without the approval of a majority of the preferred stockholders, we cannot issue additional equity securities unless the selling price per share exceeds the then conversion price of the outstanding convertible preferred stock or the sale of equity is accomplished in a public offering. The present conversion price is \$8.14 per share for the Senior Convertible Preferred Stock and \$6.50 for the Series B Convertible Preferred Stock. These restrictions could make it more difficult and more costly for us to obtain additional capital. We cannot assure you that additional sources of capital will be available to us or, if available, on terms acceptable to us.

### POSSIBLE PRICE VOLATILITY AND LIMITED LIQUIDITY OF STOCK.

There is generally significant volatility in the market prices and limited liquidity of securities of early stage companies, and particularly of early stage pharmaceutical companies. Contributing to this volatility are various factors and events that can affect our stock price in a positive or negative

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manner. These factors and events include, but are not limited to:

- o announcements by us or our competitors of new product developments or clinical testing results;
- o governmental approvals, refusals to approve, regulations or actions;
- o developments or disputes relating to patents or proprietary rights;
- o public concern over the safety of therapies;
- o financial performance;
- o fluctuations in financial performance from period to period; and
- o small float or number of shares of our stock available for sale and trade.

These and other factors and events may have a significant impact on our business and on the market price of the common stock.

WE CANNOT BE SURE THAT FUTURE CAPITAL WILL BE AVAILABLE TO MEET OUR EXPECTED CAPITAL REQUIREMENTS.

Although we believe that we have sufficient capital to meet our current business objectives, if we expand our business plans, we may need additional capital. Adequate funds for our operations, continued development, and expansion of our business plans, whether from financial markets or from other sources, may not be available when needed on acceptable terms, or at all. If we issue additional securities your holding may be diluted.

POSSIBLE VOLATILITY OF STOCK PRICE AND REDUCED LIQUIDITY OF THE MARKET FOR THE STOCK - POSSIBLE LOSS OF NASDAQ NATIONAL MARKET LISTING AND FAILURE TO QUALIFY FOR NASDAQ SMALL CAP MARKET LISTING.

There is a risk that the market value and the liquidity of the public float for our common stock could be adversely affected in the event we no longer meet the Nasdaq's requirements for continued listing on the National Market. For continued listing on the Nasdaq National Market, a company must satisfy a number of requirements, which in our case includes either: (1) minimum net equity in excess of \$10.0 million as reported on Form 10-Q or Form 10-K or (2) a market capitalization of at least \$50.0 million. Market capitalization is defined as total outstanding shares multiplied by the last sales price quoted by Nasdaq. We met the market capitalization criteria as of December 31, 2002, however, we cannot assure you that the market capitalization threshold will continue to be met or that we will be able to generate adequate capital to meet the net tangible asset requirement.

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THERE IS A LIMITED MARKET FOR OUR PRODUCTS.

Most orphan drugs have a potential United States market of less than \$25 million annually and many address annual markets of less than \$1 million. We cannot assure you that sales of our products will be adequate to make us profitable even if the products are accepted by medical specialists and used by patients.

WE RELY ON THE LIMITED PROTECTION OF THE ORPHAN DRUG ACT.

UNITED STATES  
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Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition." The Orphan Drug Act generally defines "rare disease or condition" as one that affects populations of fewer than 200,000 people in the United States. The Orphan Drug Act provides us with

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certain limited protections for our products.

The first step in obtaining the limited protection under the Orphan Drug Act is acquiring the FDA's approval of "orphan drug designation," which must be requested before submitting a New Drug Application ("NDA"). After the FDA grants orphan drug designation, it publishes the generic identity of the therapeutic agent and the potential orphan use specified in the request. Orphan drug designation does not constitute FDA approval. In addition, orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory approval process.

The second step in obtaining the limited protection under the Orphan Drug Act is acquiring the FDA's recognition of "orphan drug status." The Orphan Drug Act confers orphan drug status upon the first company to receive FDA approval to market a drug with "orphan drug designation" for a specific designated indication. Orphan drug status does not protect against another formulation or drug of materially different composition from being approved, with or without orphan drug status, for the same indication. FDA approval also results in United States marketing exclusivity for a period of seven years, subject to certain limitations. Although obtaining FDA approval to market a product with orphan drug status can be advantageous, we cannot assure you that the scope of protection or the level of marketing exclusivity will remain in effect in the future. In addition, United States orphan drug status does not provide any marketing exclusivity in foreign markets. Although certain foreign countries provide development and marketing benefits to orphan drugs, we cannot assure you that such benefits can be obtained or, if obtained, will be of material value to us. The FDA has granted us orphan drug status for Xyrem, Antizol, Elliotts B Solution, Cystadane, Sucraid, and Busulfex.

Even if the FDA approves an NDA for a drug with an orphan drug designation, the FDA may still approve the same drug for a different indication, or a molecular variation of the same drug for the same indication. We are aware that the FDA granted to Sparta Pharmaceutical, which has been acquired by SuperGen Inc., orphan drug designation for an intravenous busulfan for a closely related indication. If the FDA approves an NDA for SuperGen drug for a different indication, SuperGen could seek orphan drug status. In addition, the FDA does not restrict doctors from prescribing an approved drug for uses not approved by the FDA for that drug. Thus, a doctor could prescribe another company's drug for indications for which our product has received FDA approval and orphan drug status. Significant "off label" use, that is, prescribing approved drugs for unapproved uses, could adversely affect the marketing potential of any of our products that have received orphan drug status and NDA approval by FDA.

The possible amendment of the Orphan Drug Act by Congress has been the subject of congressional discussion from time to time over the last ten years. Although Congress has made no significant changes to the Orphan Drug Act for a number of years, members of Congress have from time to time proposed legislation that would limit the application of the Orphan Drug Act. We cannot assure you that the Orphan Drug Act will remain in effect or that it will remain in effect in its current form. The precise scope of protection that orphan drug designation and marketing approval may afford in the future is unknown. We cannot assure you that the current level of exclusivity will remain in effect.

EUROPE

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An orphan drug act was enacted in Europe that provides up to ten years of market exclusivity for a drug that meets the requirements of the act. For a pharmaceutical product to qualify for the benefits of the act, the prevalence or incidence (whichever is greater) must not exceed five patients per 10,000 in the population. Our European partners have obtained orphan drug designation for both

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Busulfex and Cystadane Europe. The Company has obtained orphan drug designation for Xyrem and Antizol, for use in methanol poisonings, in Europe. We cannot provide assurance

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that any of our pharmaceutical products will qualify for orphan drug protection in Europe or that another company will not obtain an approval that would block us from marketing our product in Europe.

THE FDA AND FOREIGN REGULATORY AUTHORITIES MUST APPROVE OUR PRODUCTS FOR SALE.

Government regulation in the United States and abroad is a significant factor in the testing, production and marketing of our current and future products. Each product must undergo an extensive regulatory review process conducted by the United States Food and Drug Administration and by comparable agencies in other countries. We cannot market any medicine we may develop or license as a prescription product in any jurisdiction, including foreign countries, in which the product does not receive regulatory approval. The approval process can take many years and requires the expenditure of substantial resources.

We depend on external laboratories and medical institutions to conduct our pre-clinical and clinical analytical testing in compliance with good clinical and laboratory practices established by the FDA. The data obtained from pre-clinical and clinical testing is subject to varying interpretations that could delay, limit or prevent regulatory approval. In addition, changes in FDA policy for drug approval during the period of development and in the requirements for regulatory review of each submitted NDA could result in additional delays or outright rejection.

We cannot assure you that the FDA or any foreign regulatory authority will approve in a timely manner, if at all, any product we develop. Generally, the FDA and foreign regulatory authorities approve only a very small percentage of newly discovered pharmaceutical compounds that enter pre-clinical development. Moreover, even if the FDA approves a product, it may place commercially unacceptable limitations on the uses, or "indications," for which a product may be marketed. This would result in additional cost and delay for further studies to provide additional data on safety or effectiveness.

FDA APPROVAL DOES NOT GUARANTEE FINANCIAL SUCCESS.

Seven of our products have been approved for marketing by regulatory authorities in the United States and elsewhere. We cannot assure you that any of our products will be commercially successful or achieve the expected financial results. We may encounter unanticipated problems relating to the development, manufacturing, distribution and marketing of our products. Some of these problems may be beyond our financial and technical capacity to solve. The failure to adequately address any such problems could have a material adverse effect on our business and our prospects. In addition, the efforts of government entities and third party payors to contain or reduce the costs of health care may adversely affect our sales and limit the commercial success of our products.

We cannot completely insulate our drug development portfolio from the possibility of clinical or commercial failures. Some products that we have selected for development may not produce the results expected during clinical trials or receive FDA approval. Drugs approved by the FDA may not generate product sales of an acceptable level. We have discontinued the development of eleven products from our portfolio since inception.

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SIGNIFICANT GOVERNMENT REGULATION CONTINUES ONCE A PRODUCT IS APPROVED FOR SALE.

After a reviewing division of the FDA approves a drug, the FDA's Division of Drug Marketing, Advertising and Communication must accept such drug's marketing claims, which are the basis for the drug's labeling, advertising and promotion. We cannot be sure that the Division of Drug Marketing, Advertising and Communication will accept our proposed marketing claims. The failure of the Division of Drug Marketing, Advertising and Communication to accept our proposed marketing claims could have a material adverse effect on our business and prospects.

The FDA can require that a company conduct "post-marketing adverse event surveillance programs" to monitor any side effects that occur after the company's drug is approved for marketing. If the surveillance program indicates unsafe side effects, the FDA may recall the product, and suspend or terminate a company's authorization to market the product. The FDA also regulates the manufacturing process for an approved drug. The FDA may impose restrictions or sanctions upon the subsequent discovery of previously unknown problems with a product or manufacturer. One possible sanction is requiring the withdrawal of such product from the market. The FDA must approve any change in manufacturer as well as most changes in the manufacturing process prior to implementation. Obtaining the FDA's approval for a change in manufacturing procedures or change in manufacturers is a lengthy process and could cause production delays and loss of sales, which would have a material adverse effect on our business and our prospects.

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Certain foreign countries regulate the sales price of a product after marketing approval is granted. We cannot be sure that we can sell our products at satisfactory prices in foreign markets even if foreign regulatory authorities grant marketing approval.

WE RELY ON OTHERS FOR PRODUCT DEVELOPMENT OPPORTUNITIES.

We engage only in limited research to identify new pharmaceutical compounds. To build our product portfolio, we have adopted a license and acquisition strategy. This strategy for growth requires us to identify and acquire pharmaceutical products targeted at niche markets within selected strategic therapeutic market segments. These products usually require further development and approval by regulatory bodies before they can be marketed. We cannot assure you that any such products can be successfully acquired, developed, approved or marketed. We must rely upon the willingness of others to sell or license pharmaceutical product opportunities to us. Other companies, including those with substantially greater resources, compete with us to acquire such products. We cannot assure you that we will be able to acquire rights to additional products on acceptable terms, if at all. Our failure to acquire or license any new pharmaceutical products, or our failure to promote and market any products successfully or products within an existing therapeutic areas, could have a material adverse effect on our business and our prospects.

We have contractual development rights to certain compounds through various license agreements. Generally, the licensor can unilaterally terminate these agreements for several reasons, including, but not limited to the following reasons:

- o for cause if we breach the contract;
- o if we become insolvent or bankrupt;

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- o if we do not apply specified minimum resources and efforts to develop the compound under license; or
- o if we do not achieve certain minimum royalty payments, or in some cases, minimum sales levels.

We cannot assure you that we can meet all specified requirements and avoid termination of any license agreements. We cannot assure you that if any agreement is terminated, we will be able to enter into similar agreements on terms as favorable as those contained in our existing license agreements.

WE DEPEND ON OTHERS TO MANUFACTURE AND SUPPLY THE PRODUCTS WE MARKET.

We do not have and do not intend to establish any internal product testing, synthesis of bulk drug substance, or manufacturing capability for drug product. Accordingly, we depend on others to supply and manufacture the components incorporated into all of our finished drug products. The inability to contract for these purposes on acceptable terms could adversely affect our ability to develop and market our products. Failure by parties with whom we contract to adequately perform their responsibilities may delay the submission of products for regulatory approval, impair our ability to deliver our products on a timely basis or otherwise adversely affect our business and our prospects. The loss of a supply or manufacturing contractor could materially adversely affect our business and our prospects.

The loss of either a bulk drug supplier or drug product manufacturer would require us to obtain regulatory clearance in the form of a "pre-approval submission" and incur validation and other costs associated with the transfer of the bulk drug or drug product manufacturing process. We believe that it could take as long as two years for the FDA to approve such a submission. Because our products are targeted to relatively small markets and our manufacturing production runs are small by industry standards, we have not incurred the added costs to certify and maintain secondary sources of supply for bulk drug substance or backup drug product manufacturers for some products. Should we lose either a bulk drug supplier or a drug product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials, while we wait for the FDA approval of a new bulk drug supplier or drug product manufacturer. We cannot assure you that the change of a bulk drug supplier or drug product manufacturer and the transfer of the processes to another third party will be approved by the FDA, and if approved, in a timely manner. The loss of or the change of a bulk drug supplier or a drug product manufacturer could have a material adverse effect on our business and prospects.

### BULK DRUG SUPPLY

Bulk drug substance is the active chemical compound used in the manufacture of our drug products. We depend

substantially on a single supplier for the supply of bulk drug substance used in Busulfex, Antizol, and Antizol-Vet. If we were to lose this company as a supplier, we would be required to identify a new supplier for the bulk drug substance used in products that provided approximately 88% of our total revenues in 2002, 2001 and 2000, and which are expected to account for approximately 50% of our revenues in 2003. We depend substantially on a different supplier for the supply of bulk drug substance used in Xyrem, which is expected to account for approximately 40% of our revenue in 2003. If we were to lose this company as a

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supplier, we would be required to identify a new supplier. We also cannot assure you that our bulk drug supply arrangements with our current suppliers, or any other future such supplier, might not change in the future. We cannot assure you that any change would not adversely affect production of Busulfex, Antizol, Antizol-Vet, Xyrem, or any other drug the Company might attempt to develop or market.

### DRUG PRODUCT MANUFACTURE

From bulk drug substance, drug product manufacturers formulate a finished drug product and package the product for sale or for use in clinical trials. We depend substantially on a single supplier for drug product manufacturing of Busulfex, Antizol, and Antizol-Vet and a different supplier has been authorized to manufacture Xyrem. If we were to lose either of these companies as a manufacturer, we would be required to identify a new manufacturer for drug products that provided approximately 88% of our total revenues in 2002, 2001 and 2000, and which are expected to account for approximately 50% of our revenues in 2003. We depend substantially on a different supplier for the supply of Xyrem, which is expected to account for approximately 40% of our revenue in 2003. If we were to lose this company as a supplier, we would be required to identify a new manufacturer. We cannot assure you that our drug product manufacturing arrangements with either or both of these suppliers will not change or that the manufacturing services will continue to be available on terms satisfactory to us. Any change in our manufacturing agreements could adversely affect production of Busulfex, Antizol, Antizol-Vet or Xyrem, or any other drug that we might attempt to develop or market, which could have a material adverse effect on our business and prospects.

### WE CANNOT CONTROL OUR CONTRACTORS' COMPLIANCE WITH APPLICABLE REGULATIONS.

The FDA defines and regulates good manufacturing practices to which bulk drug suppliers and drug product manufacturers are subject. The Drug Enforcement Agency (DEA) defines and regulates the handling and reporting requirements for certain drugs which have abuse potential, known as "scheduled drugs". Foreign regulatory authorities prescribe similar rules and regulations. Our supply and manufacturing contractors must comply with these regulatory requirements. Failure by our contractors to comply with FDA or DEA requirements or applicable foreign requirements could result in significant time delays or in our inability to commercialize or continue to market a product. Either result could have a material adverse effect on our business and prospects. Failure to comply with good manufacturing practices or other applicable legal requirements can lead to federal seizure of violative products, injunctive actions brought by the federal government, or potential criminal and civil liability for Orphan, our officers, or our employees. We cannot assure you that we will be able to maintain relationships either domestically or abroad with contractors whose facilities and procedures comply or will continue to comply with FDA or DEA requirements or applicable foreign requirements.

### WE DEPEND UPON OTHERS FOR DISTRIBUTION.

We have an agreement with a specialty pharmacy to distribute Xyrem. Xyrem is classified as a Schedule III controlled substance and approved under Subpart H of the FDA's review process, and distribution will be strictly controlled. The specialty pharmacy will be the only source through which Xyrem can be obtained. Distribution will be governed by the FDA's Subpart H regulations and will fully comply with the risk-management controls jointly developed by Orphan Medical, the FDA, the Drug Enforcement Agency and law enforcement agencies. Every shipment of Xyrem will be subject to stringent safeguards to ensure it reaches only individuals for whom it has been legitimately prescribed.

We have an agreement with a distribution contractor to provide integrated distribution and operations services to support transactions between us and our



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wholesalers, specialty distributors, and direct customers. This contractor also provides reimbursement management, patient assistance and information hotline services and specialty distribution and marketing services to physician practices with respect to our products. The contractor currently distributes Busulfex, Elliotts B Solution, Antizol, Antizol-Vet, and Sucraid. The contractor may also distribute future products should those products receive marketing clearance from the FDA. We are substantially dependent on this contractor's ability to successfully distribute Busulfex, Elliotts B Solution, Antizol, Antizol-Vet, and Sucraid and other potential products.

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A mail order pharmacy is the principal distributor, on a non-exclusive basis, in the United States for Cystadane. The pharmacy distributes this product directly to patients through the mail. We are substantially dependent on this pharmacy's ability to successfully distribute Cystadane directly to patients in the United States.

We cannot assure you that our distribution arrangements with these three entities or other companies would be available, or continue to be available to us on commercially acceptable terms. The loss of a distributor or failure to renew agreements with an existing distributor would have a material adverse effect on our business and prospects.

WE RELY ON FOREIGN MARKETING ALLIANCES AND HAVE NO ASSURANCE OF FOREIGN LICENSEES.

Our strategy to sell our products in foreign markets is to license foreign marketing and distribution rights to a foreign company after a new drug application (referred to in the industry as an "NDA") is submitted or approved in the United States. We consider Europe, Asia, and Canada our most attractive foreign markets. Our current foreign arrangements are:

- o EUROPE. We have licensed the marketing and distribution rights for Busulfex, Antizol, Cystadane and Sucraid in Europe. If our licensees are unsuccessful in their registration and distribution efforts, we may find it difficult to contract with other distributors for these products within Europe. Distribution of all products except Antizol is limited to "named patient" or "emergency use" basis until full regulatory approval is obtained. Antizol has been approved for use in the United Kingdom but is limited to "named patient" basis in other parts of Europe. This distribution of the Company's products is expected to result in a limited contribution to the Company's revenues.
- o AUSTRALIA AND NEW ZEALAND. We have licensed marketing and distribution rights for Cystadane and Sucraid in Australia and New Zealand, but sales of these products have not been material. We do not expect sales to increase in the near future to the point that they become material.
- o ISRAEL. We have licensed marketing and distribution rights for Antizol, Busulfex, Cystadane, Elliotts B Solution and Sucraid in Israel. Full regulatory approval for all products except Antizol was obtained in Israel in February 2000. We do not expect such distribution to result in material revenues.
- o CANADA. We have licensed marketing and distribution rights for Antizol in Canada. For Cystadane we have only licensed the distribution rights in Canada. We do not expect such distribution to result in material

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revenues.

- o CENTRAL AMERICA. We have licensed marketing and distribution rights for Elliotts B Solution in Central America, but sales have not been material. We do not expect domestic or foreign sales of Elliotts B Solution to become material.
- o ASIA. We have licensed marketing and distribution rights for Busulfex in Japan, the Peoples Republic of China, Taiwan and South Korea. Distribution is limited to clinical trial usage until full regulatory approval is achieved. We have also licensed marketing and distribution rights for Busulfex in Turkey.

We depend on our foreign licensees for the regulatory registration of our products in foreign countries. We cannot be sure that our licensees can obtain such registration. In addition, we cannot be sure that we will be able to negotiate commercially acceptable license agreements for our other products or in additional foreign countries. Furthermore, we cannot assure you that these companies will be successful in marketing and selling our products in their respective territories.

### OUR PRODUCTS MIGHT BE RECALLED.

A product can be recalled at our discretion or at the discretion of the FDA, the U.S. Federal Trade Commission, or other government agencies having regulatory authority for marketed products. A recall may occur due to disputed

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labeling claims, manufacturing issues, quality defects, safety issues, or other reasons. We cannot assure you that a product recall will not occur. We do not carry any insurance to cover the risk of a potential product recall. Any product recall could have a material adverse effect on our business and prospects. To date, no recall of products marketed by the Company has occurred.

### WE FACE LIMITS ON PRICE FLEXIBILITY AND THIRD-PARTY REIMBURSEMENT.

The flexibility of prices that we can charge for our products depends on government regulation, both in the United States and abroad, and on other third parties. One important factor is the extent to which reimbursement for our products will be available to patients from government health administration authorities, private health insurers and other third-party payors. Government officials and private health insurers are increasingly challenging the price of medical products and services. We are uncertain as to the pricing flexibility we will have with respect to, and if we will be reimbursed for, newly approved health care products.

In the United States, we expect continuing federal and state proposals to implement greater government control of the pricing and profitability of prescription pharmaceuticals. Cost controls, if mandated by a government agency, could decrease, or limit, the price we receive for our products or products we may develop in the future. We may not be able to recover our development costs, which could be substantial. We may not be able to realize an appropriate profit margin. This could have a material adverse effect on our business. Furthermore, federal and state regulations govern or influence reimbursement of health care providers for medical treatment of certain patients. We cannot assure you that actions taken by federal and/or state governments, if any, with regard to health care reform will not have a material adverse effect on our business and prospects.

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Certain private health insurers and third-party payors may attempt to control costs further by selecting exclusive providers of pharmaceuticals. If such arrangements are made with our competitors, these insurers and third-party payors would not reimburse patients who purchase our competing products. This would diminish the market for our products and could have a material adverse effect on our business and prospects.

### PATENTS AND OTHER PROPRIETARY RIGHTS ARE SIGNIFICANT FACTORS IN THE PHARMACEUTICAL INDUSTRY.

The pharmaceutical industry and the investment community places considerable importance and value on obtaining patent, proprietary, and trade secret protection for new technologies, products and processes. The patent position of pharmaceutical firms is often highly uncertain and generally involves complex legal, technical and factual questions. Our success depends on several issues, including, but not limited to our ability:

- o to obtain, and enforce proprietary protection for our products under United States and foreign patent laws and other intellectual property laws;
- o to preserve the confidentiality of our trade secrets; and
- o to operate without infringing the proprietary rights of third parties.

We evaluate the desirability of seeking patent or other forms of protection for our products in foreign markets based on the expected costs and relative benefits of attaining such protection. We cannot assure you that any patents will be issued from any applications or that any issued patents will afford us adequate protection or competitive advantage. Also, we cannot assure you that any issued patents will not be challenged, invalidated, infringed or circumvented. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to our products. We cannot assure you that patents now in existence or later issued to others will not adversely affect the development or commercialization of our products.

We believe that the active ingredients or compounds in our FDA-approved products, Cystadane, Elliotts B Solution, Antizol, Antizol-Vet, Xyrem and Sucraid, are in the public domain and presently are not subject to patent protection in the United States. However, we have a patent with respect to our formulation of Xyrem oral solution. United States patents issued to the licensor covers our formulation and use of Busulfex. We could, however, incur substantial costs asserting any infringement claims that we may have against others.

We seek to protect our proprietary information and technology, in part, through confidentiality agreements and inventors' rights agreements with our employees. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise be disclosed to or discovered by our competitors. We also cannot assure you that our planned activities will not infringe patents owned by others. We could incur substantial costs in defending infringement suits brought against us. We also could incur substantial costs in connection with any suits relating to matters for which we have agreed to indemnify our licensors

or distributors. An adverse outcome in any such litigation could have a material

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adverse effect on our business and prospects. In addition, we often must obtain licenses under patents or other proprietary rights of third parties. We cannot assure you that we can obtain any such licenses on acceptable terms, if at all. If we cannot obtain required licenses on acceptable terms, we could encounter substantial difficulties in developing, manufacturing or marketing one or more of our products.

### WE FACE INTENSE COMPETITION IN OUR INDUSTRY.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States are numerous and include pharmaceutical, chemical and biotechnology companies. Many of these companies have substantially greater capital resources, marketing experience, research and development staffs and facilities than we do. We seek to limit potential sources of competition by developing products that are eligible for orphan drug status upon NDA approval or other forms of protection. We cannot assure you, however, that our competitors will not succeed in developing similar technologies and products more rapidly than we can. Similarly, we cannot assure you that these competing technologies and products will not be more effective than any of those that we have developed or are currently developing.

### WE EXPECT RAPID TECHNOLOGICAL AND OTHER CHANGE TO BE CONSTANT IN OUR INDUSTRY.

The pharmaceutical industry has experienced rapid and significant technological change as well as structural changes, such as those brought about by changes in health care delivery or in product distribution. We expect that pharmaceutical technology will continue to develop and change rapidly, and our future success will depend, in large part, on our ability to develop and maintain a competitive position. Technological development by others may result in our products becoming obsolete before they are marketed or before we recover a significant portion of the development and commercialization expenses incurred with respect to such products. In addition, alternative therapies, new medical treatments, or changes in the manner in which health care is delivered or products provided could alter existing treatment regimes or health care practices, and thereby reduce the need for one or more of our products, which would adversely affect our business and our prospects.

### WE FACE SUBSTANTIAL PRODUCT LIABILITY AND INSURANCE RISKS.

Testing and selling health care products entails the inherent risk of product liability claims. The cost of product liability insurance coverage has increased and is likely to continue to increase in the future. Substantial increases in insurance premium costs in many cases have rendered coverage economically impractical. We currently carry product liability coverage in the aggregate amount of \$30 million for all claims made in any policy year. Although to date we have not been the subject of any product liability or other claims, we cannot assure you that we will be able to maintain product liability insurance on acceptable terms or that our insurance will provide adequate coverage against potential claims. A successful uninsured product liability or other claim against us could have a material adverse effect on our business and prospects.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK The Company's market risk is not material.

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

The financial statements of the Company as of and for the year ended December 31, 2002 begin on page F-1 of this Annual Report.

### ITEM 9. CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS AND FINANCIAL DISCLOSURE

None.

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PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

(a) DIRECTORS OF THE REGISTRANT.

The information required by this item is incorporated by reference from the information under the caption "Election of Directors" contained in the Company's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the Company's Annual Meeting of Shareholders to be held on May 8, 2002 (the "Proxy Statement").

(b) EXECUTIVE OFFICERS OF THE REGISTRANT.

Information concerning Executive Officers of the Company is included in this Annual Report in Item 4A under the caption "Executive Officers of the Registrant".

(c) COMPLIANCE WITH 16(A) OF THE SECURITIES EXCHANGE ACT OF 1934.

The information required by this item is incorporated by reference from the information under the caption "Section 16(a) Reporting" contained in the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information under the caption "Executive Compensation" contained in the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND  
MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information under the caption "Stock Ownership" contained in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference from the information contained under the caption "Certain Transactions" contained in the Proxy Statement.

ITEM 14. CONTROLS AND PROCEDURES

The Company's Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation within 90 days of the filing date of this report, that the Company's disclosure controls and procedures are adequately designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities and Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in applicable rules and forms. There have not been any significant changes in the Company's internal controls or in other factors that could significantly affect those controls, subsequent to the date of such evaluation, including any corrective actions taken with regard to significant deficiencies and material weaknesses.

PART IV

ITEM 15. FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K  
(a) (1). FINANCIAL STATEMENTS

DESCRIPTION	PAGE NUMBER IN THIS ANNUAL REPORT
-----	
Audited Financial Statements:	
Report of Independent Auditors	F-1
Balance Sheets	F-2
Statements of Operations	F-3
Statements of Cash Flows	F-4
Statement of Changes in Shareholders' Equity	F-5
Notes to Financial Statements	F-6 to F-14

(a) (2). FINANCIAL STATEMENT SCHEDULES

The following financial statement schedule should be read in conjunction with the Audited Financial Statements referred to under Item 15(a) (1) above. Financial statement schedules not included in the Form 10-K have been omitted because they are not applicable or the required information is shown in the Audited Financial Statements or Notes thereto

DESCRIPTION	PAGE NUMBER IN THIS ANNUAL REPORT
-----	
Schedule II - Valuation and Qualifying Accounts: Years Ended December 31, 2002, 2001 and 2000	F-15

(a) (3). LISTING OF EXHIBITS

Exhibit Number	Description
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3.1	Articles of Incorporation of Orphan Medical, Inc. ("OMI")
3.1.1	Certificate of Designation for Senior Convertible Preferred Stock
3.1.2	Certificate of Designation for Series B, C and D Preferred Stock
3.2	Bylaws of OMI, as amended
4.1	OMI 1994 Stock Option Plan
4.2	OMI Employee Incentive Stock Option Agreement
4.3	OMI Non-Incentive Stock Option Agreement
4.4	OMI Non-Incentive Stock Option Agreement for Non-Employee Directors
10.1	Marketing and Distribution Agreement between OMI and Chronimed effective July 2, 1994
10.2	Transfer Agreement between OMI and Chronimed effective July 1, 1994
10.3	Distribution and Spin-off Agreement between OMI and Chronimed effective July 2, 1994
10.4	Administrative Services Agreement between OMI and Chronimed effective July 2, 1994
10.5	Security Agreement between OMI and Chronimed effective July 2, 1994
10.6	Aminocaproic Acid License Agreement between Chronimed and Virginia's Center for

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- Innovative Technology dated September 17, 1993
- 10.7 Patent and Technology License Agreement for Busulfan between Chronimed and The University of Texas M.D., Anderson Cancer Center, the Board of Regents of the University of Texas System and the University of Houston effective February 14, 1994
- 10.8 Letter Agreement regarding L-Cycloserine between Chronimed and Dr. Meier Lev dated December 29, 1993
- 10.9 Sublicense Agreement regarding 4-Methylpyrazole between Chronimed and Mericon Investment Group, Inc. dated December 17, 1993
- 10.10 License Agreement regarding Short Chain Fatty Acids between Chronimed and Richard Breuer dated March 2, 1994
- 10.11.1 Employment Agreement between OMI and John Howell Bullion dated October 29, 1999

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Exhibit Number	Description
10.12	Employment Agreement between OMI and Bertram A. Spilker, Ph.D., M.D. dated August 31, 1994
10.13	Assumption Agreement and Consent to Assignments regarding Short Chain Fatty Acids between OMI and Richard Breuer dated September 30, 1994
10.14	Assumption Agreement and Consent to Assignment regarding Aminocaproic Acid between OMI and Virginia's Center for Innovative Technology dated September 30, 1994
10.15	Assumption Agreement and Consent to Assignment regarding 4-Methylpyrazole between OMI and Mericon Investment Group, Inc. dated October 5, 1994
10.16	License Agreement regarding 4-Methylpyrazole between Kenneth McMartin and Mericon Investment Group, Inc. dated July 6, 1993
10.17	License Agreement regarding Glucaric Acid between OMI and Ohio State University Research Foundation dated December 28, 1994
10.18	Manufacturing Development and Supply Agreement regarding Aminocaproic Acid between OMI and Lifecore Biomedical, Inc. dated December 21, 1994
10.19	Marketing Agreement regarding Cystagon between OMI and Chronimed dated October 19, 1994
10.20	Assumption Agreement and Consent to Assignment regarding Busulfan between OMI and the University of Texas, M.D., Anderson Cancer Center, the Board of Regents of the University of Texas System and the University of Houston dated October 18, 1994
10.21	License Agreement regarding Catrrix between OMI and Lescarden, Inc. dated October 28, 1994
10.22	License Agreement regarding Sucrase between OMI and Hartford Hospital dated December 30, 1994
10.23	Option to Acquire License regarding Tretinoin between OMI and James Hannan dated February 6, 1995
10.24	Consulting Agreement between OMI and William B. Adams dated November 15, 1994
10.27	Agreement regarding Cystagon between Chronimed and Mylan Pharmaceutical dated October 17, 1994
10.29	Agreement between OMI and David A. Feste effective July 1, 1995
10.30	Development and License Agreement regarding Choline Chloride between OMI and Alan Buchman, Donald J. Jenden, Marvin E. Ament and Mark D. Dubin dated May 11, 1995
10.31	Addendum to License Agreement regarding Short Chain Fatty Acids between OMI and Richard Breuer dated May 12, 1995
10.32	Addendum to Administrative Services Agreement between OMI and Chronimed dated August 2, 1995
10.33	Amendment to Aminocaproic Acid License Agreement between OMI and Virginia's Center for Innovative Technology dated September 17, 1993
10.34	Amendment No. 1 to Marketing and Distribution Agreement between OMI and Chronimed dated July 2, 1994
10.35	Amendment to Marketing Agreement regarding Cystagon between OMI and Chronimed dated October 19, 1994

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- 10.36 IRS tax qualification letter dated January 10, 1996 regarding the favorable determination of the tax status of the OMI 401(k) Savings Plan
- 10.38 Form of License Agreement regarding Colloidal Bismuth Subcitrate between OMI and Josman Laboratories, Inc. dated March 4, 1996
- 10.39 Agreement between OMI and Chronimed dated June 3, 1996 to amend Marketing and Distribution Agreement dated July 2, 1996
- 10.40 Cystadane Agreement between the OMI and Chronimed dated October 11, 1996
- 10.41 License Agreement regarding alpha galactosidase A between OMI and Research Corporation Technologies, Inc. Dated March 15, 1996
- 10.42 License Agreement regarding 5-fluorouracil between OMI and the University of Miami and its Department of Ophthalmology dated December 6, 1996
- 10.43 Collaborative Development Agreement regarding Clonidine between OMI and Medtronic, Inc. dated November 27, 1996
- 10.44 Distribution Agreement between OMI and W. A. Butler Company dated November 26, 1996

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Exhibit Number	Description
10.45	Distribution Services Agreement between OMI and Cardinal Health dated June 1, 1997
10.46	Termination Agreement between OMI and Chronimed dated as of June 27, 1997.
10.47	Loan Agreement and Security Agreement between OMI and Riverside Bank dated May 15, 1998.
10.48	Stock Purchase Agreement between OMI and UBS Capital II LLC dated July 23, 1998.
10.49	Supplement to Termination Agreement between OMI and Chronimed dated December 7, 1998.
10.50	Supplement II to Termination Agreement between OMI and Chronimed dated February 9, 1999.
10.51	Purchase Agreement between OMI and UTECH, LLC dated December 30, 1998 regarding the sale and assignment to UTECH LLC of license rights to Colloidal Bismuth Subcitrate.
10.52	Common Stock Purchase Warrant between OMI and R.J. Steichen dated January 1, 1999.
10.53	Purchase Agreement and Letter of Intent between OMI and Caduceus Capital Trust , Caduceus Capital II L.P., PaineWebber Eucalyptus Fund LLC, and PaineWebber Eucalyptus Fund Ltd.
10.54	Purchase Agreement and Letter of Intent between DG LUX LACUNA APO BIOTECH FUND
10.55	Stock Purchase Agreement between OMI and UBS Capital II LLC dated August 2, 1999
10.56	Promissory Note between OMI and UBS Capital II LLC dated August 2, 1999
10.57	Warrant to purchase shares of Series C Convertible Preferred Stock or Series D Non-Voting Preferred Stock
10.58	Warrant to purchase shares Series D Non-Voting Preferred Stock
10.59	Form of Change in Control Agreement to be entered into between the OMI and Certain Executives
23.1	Consent of Ernst & Young LLP
24	Power of Attorney

(1) Incorporated by reference to the corresponding exhibit numbers in OMI's Registration Statement on Form 10 filed on August 31, 1994, Commission File No. 0-24760.

(2) Incorporated by reference to the corresponding exhibit numbers in OMI's Registration Statement on Form S-1 filed on March 3, 1995, Commission File No. 0-24760.

(3) Incorporated by reference to the corresponding exhibit number in OMI's Quarterly Report on Form 10-Q for the quarter ended December 30, 1994, Commission File No. 0-24760.

(4) Incorporated by reference to the corresponding exhibit numbers in



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- OMI's Annual Report on Form 10-K filed for the year ended June 30, 1995, Commission File No. 0-24760.
- (5) Incorporated by reference to the corresponding exhibit numbers in OMI's Registration Statement on Form S-1 filed on March 11, 1996, Commission File No. 0-24760.
- (6) Incorporated by reference to the corresponding exhibit number in OMI's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, Commission File No. 0-24760.
- (7) Incorporated by reference to the corresponding exhibit number in OMI's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996, Commission File No. 0-24760.
- (8) Incorporated by reference to the corresponding exhibit numbers in OMI's Annual Report on Form 10-K filed for the year ended December 31, 1996, Commission File No. 0-24760.
- (9) Incorporated by reference to the corresponding exhibit number in OMI's Quarterly Report on Form 10-Q for the quarter ended March 31, 1997, Commission File No. 0-24760.
- (10) Incorporated by reference to the corresponding exhibit numbers in OMI's Annual Report on Form 10-K filed for the year ended December 31, 1997, Commission File No. 0-24760.
- (11) Incorporated by reference to the corresponding exhibit numbers in OMI's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998, Commission File No. 0-24760.
- (12) Incorporated by reference to the similarly described exhibit included with OMI's Current Report on Form 8-K dated December 7, 1998, Commission File No. 0-24760.
- (13) Incorporated by reference to the similarly described exhibit included with OMI's Current Report on Form 8-K dated February 9, 1999, Commission File No. 0-24760.

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- (14) Incorporated by reference to the similarly described exhibit included with OMI's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-24760.
- (15) Incorporated by reference to the similarly described exhibit included with OMI's Current Report on Form 10-Q for the quarter ended June 30, 1999, Commission File No. 0-24760.
- (16) Incorporated by reference to the similarly described exhibit included with OMI's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-24760.

### (b). REPORTS ON FORM 8-K

None.

### (c). EXHIBITS

See Item 15(a) (3) above.

### (d). FINANCIAL STATEMENT SCHEDULES

See Item 15(a) (2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized, in the City of Minnetonka, Minnesota, on the 31st day of March, 2003.

ORPHAN MEDICAL, INC.

By:

/s/ John Howell Bullion

-----  
John Howell Bullion  
Chief Executive Officer

/s/ Timothy G. McGrath

-----  
Timothy G. McGrath  
Chief Financial Officer

Pursuant to the requirements of the Securities Act of 1934 this report has been signed by the following persons on behalf of the Registrant and in the capacities indicated as of March 31, 2003.

SIGNATURE	TITLE
----- /s/ John Howell Bullion ----- John Howell Bullion	----- Chief Executive Officer (Principal Executive Officer) and a Director
* ----- Michael Greene	Director
* ----- Julius A. Vida	Director
* ----- Farah Champsi	Director
* ----- William M. Wardell, Ph.D., M.D.	Director
* ----- Thomas King	Director

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By: /s/ John Howell Bullion

-----  
John Howell Bullion, Attorney-In-Fact

- o John Howell Bullion, pursuant to the Powers of Attorney executed by each of the officers and directors above whose name is marked by a "\*", by signing his name hereto, does hereby sign and execute this Annual Report on behalf of each of the officers and directors in the capacities in which the name of each appears above.

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### CERTIFICATIONS

I, John H. Bullion, President and Chief Executive Officer of Orphan Medical, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Orphan Medical, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have

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identified for the registrant's auditors any material weaknesses in internal controls; and

- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/S/ John H. Bullion

-----  
President and Chief Executive Officer

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I, Timothy G. McGrath, Vice President and Chief Financial Officer of Orphan Medical, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Orphan Medical, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the

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equivalent function):

- a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/S/ Timothy G. McGrath

-----  
Vice President and Chief Financial Officer

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### REPORT OF INDEPENDENT AUDITORS

Board of Directors and Shareholders  
Orphan Medical, Inc.

We have audited the accompanying balance sheets of Orphan Medical, Inc. as of December 31, 2002 and 2001, and the related statements of operations, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. Our audits also included the financial statement schedule listed in Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Orphan Medical, Inc. at December 31, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States. Also in our opinion, the financial statement schedule referred to above, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

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Minneapolis, Minnesota

Ernst & Young LLP

February 11, 2003, except for Note 13, as to which the date is March 28, 2003

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ORPHAN MEDICAL, INC.  
BALANCE SHEETS

	DECEMBER 31,	
	2002	2001
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 6,920,685	\$ 19,011,245
Restricted cash	251,144	--
Accounts receivable, less allowance for doubtful accounts of \$25,000 for 2002 and 2001	2,215,462	1,645,749
Inventories	2,019,758	1,242,120
Prepaid expenses and other	576,156	63,662
<b>Total current assets</b>	<b>11,983,205</b>	<b>21,962,776</b>
<b>Property and equipment:</b>		
Property and equipment	2,096,618	1,056,642
Accumulated depreciation	(940,901)	(673,142)
	1,155,717	383,500
<b>Total assets</b>	<b>\$ 13,138,922</b>	<b>\$ 22,346,276</b>
<b>Liabilities and shareholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,379,790	\$ 1,152,426
Accrued royalties	234,688	204,790
Accrued compensation	1,795,410	1,065,662
Deferred revenue	--	431,310
Accrued expenses	1,901,227	1,097,881
<b>Total current liabilities</b>	<b>5,311,115</b>	<b>3,952,069</b>
Capital lease obligation-less current maturities	78,013	--
<b>Commitments</b>		
<b>Shareholders' equity:</b>		
Senior Convertible Preferred Stock, \$.01 par value; 14,400 shares authorized 8,706 shares issued and outstanding	87	87
Series B Convertible Preferred Stock, \$.01 par value; 5,000 shares authorized; 3,677 and 3,417 shares issued and outstanding	37	34

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Series C Convertible Preferred Stock, \$.01 par value; 4,000 shares authorized; 0 shares issued and outstanding	--	--
Series D Convertible Preferred Stock, \$.01 par value; 1,500,000 shares authorized; 0 shares issued and outstanding	--	--
Common stock, \$.01 par value; 25,000,000 shares authorized; 10,460,283 and 10,263,961 issued and outstanding	104,602	102,639
Additional paid-in capital	74,033,403	72,364,612
Accumulated deficit	(66,388,335)	(54,073,165)
Total shareholders' equity	7,749,794	18,394,207
Total liabilities and shareholders' equity	\$ 13,138,922	\$ 22,346,276

SEE ACCOMPANYING NOTES.

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ORPHAN MEDICAL, INC.  
STATEMENTS OF OPERATIONS

	FOR THE YEAR ENDED DECEMBER 31, 2002	FOR THE YEAR ENDED DECEMBER 31, 2001	FOR THE YEAR ENDED DECEMBER 31, 2000
Revenues	\$ 16,130,169	\$ 11,274,110	\$ 11,274,110
Cost of sales	2,191,598	1,591,826	1,591,826
Gross profit	13,938,571	9,682,284	9,682,284
Operating expenses:			
Research and development	6,618,091	5,462,336	7,462,336
Sales and marketing	12,518,498	5,729,987	5,729,987
General and administrative	6,458,308	4,807,847	4,807,847
Loss from operations	(11,656,326)	(6,317,886)	(6,317,886)
Other income:			
Interest, net	255,178	321,315	321,315
Net loss	(11,401,148)	(5,996,571)	(6,317,886)
Less: Preferred stock dividends	922,170	903,053	903,053
Net loss applicable to common shareholders	\$ (12,323,318)	\$ (6,899,624)	\$ (6,899,624)
Basic and diluted loss per common share applicable to common shareholders	\$ (1.19)	\$ (0.80)	\$ (0.80)

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	=====	=====	=====
Weighted average number of shares outstanding	10,349,679	8,597,331	8,
	=====	=====	=====

SEE ACCOMPANYING NOTES.

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ORPHAN MEDICAL, INC.  
STATEMENTS OF CASH FLOWS

	FOR THE YEAR ENDED DECEMBER 31, 2002	FOR THE YEAR ENDED DECEMBER 31, 2001	FOR E DECE
	-----	-----	-----
<b>OPERATING ACTIVITIES</b>			
Net loss	\$ (11,401,148)	\$ (5,996,571)	\$ (6
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	267,759	168,955	
Compensatory options	--	239,887	
Changes in operating assets and liabilities:			
Accounts receivable and prepaid expenses	(1,082,207)	103,340	
Inventories	(777,638)	360,829	(1
Accounts payable	227,364	(606,381)	1
Accrued expenses and deferred revenue	1,116,895	4,492	
	-----	-----	-----
Net cash used in operating activities	(11,648,975)	(5,725,449)	(5
<b>INVESTING ACTIVITIES</b>			
Purchase of property and equipment	(947,176)	(88,524)	
Increase in restricted cash	(251,144)	--	
Purchase of short-term investments	--	--	(27
Maturities of short term investments	--	10,314,277	21
	-----	-----	-----
Net cash (used in) provided by investing activities	(1,198,320)	10,225,753	(6
<b>FINANCING ACTIVITIES</b>			
Proceeds from common stock offering	(8,102)	12,994,122	10
Proceeds from the issuance of shares under the Employee Stock Purchase Plan	61,466	134,288	
Proceeds from stock options and warrants	704,449	267,414	1
Preferred stock dividend	(1,078)	(202)	
	-----	-----	-----
Net cash provided by financing activities	756,735	13,395,622	13
	-----	-----	-----



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(Decrease) increase in cash and cash equivalents	(12,090,560)	17,895,926	
Cash and cash equivalents at the beginning of year	19,011,245	1,115,319	
	-----	-----	-----
Cash and cash equivalents at the end of year	\$ 6,920,685	\$ 19,011,245	\$ 1
	=====	=====	=====

SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES

Issuance of stock for preferred stock dividends	\$ 912,944	\$ 897,725	\$
Capital lease for equipment	92,800	--	

SEE ACCOMPANYING NOTES.

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ORPHAN MEDICAL, INC.  
STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

	PREFERRED STOCK		COMMON STOCK	
	SHARES	AMOUNT	SHARES	AMOUNT
	-----	-----	-----	-----
Balance at December 31, 1999	11,038	\$ 111	6,606,207	\$
Net proceeds from private offering of 1,365,000 shares of Common Stock	--	--	1,365,000	
Options and warrants exercised	--	--	384,746	
Proceeds from Employee Stock Purchase Plan	--	--	86,806	
Options issued for services	--	--	--	
Preferred stock dividends	842	8	--	
Comprehensive loss:				
Net loss	--	--	--	
Unrealized loss on available-for-sale securities	--	--	--	
Subtotal - comprehensive loss				
	-----	-----	-----	-----
Balance at December 31, 2000	11,880	119	8,442,759	
Net proceeds from private offering of 1,706,999 shares of Common Stock	--	--	1,706,999	
Options and warrants exercised	--	--	41,700	
Proceeds from Employee Stock Purchase Plan	--	--	19,210	
Compensatory options	--	--	--	
Preferred stock dividends	243	2	53,293	

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Comprehensive loss:			
Net loss	--	--	--
Unrealized loss on available-for-sale securities	--	--	--
Subtotal - comprehensive loss			
Balance at December 31, 2001	12,123	121	10,263,961
Offering costs from December 2001 private offering	--	--	--
Options and warrants exercised	--	--	125,950
Proceeds from Employee Stock Purchase Plan	--	--	8,338
Preferred stock dividends	260	3	62,034
Net loss	--	--	--
Balance at December 31, 2002	12,383	\$ 124	10,460,283

[WIDE TABLE CONTINUED FROM ABOVE]

	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE LOSS	TOTAL
Balance at December 31, 1999	\$ (40,243,874)	\$ (4,755)	\$ 3,561,208
Net proceeds from private offering of 1,365,000 shares of Common Stock	--	--	10,692,154
Options and warrants exercised	(2,647)	--	1,992,313
Proceeds from Employee Stock Purchase Plan	--	--	398,596
Options issued for services	--	--	196,390
Preferred stock dividends	(845,031)	--	(3,032)
Comprehensive loss:			
Net loss	(6,087,115)	--	(6,087,115)
Unrealized loss on available-for-sale securities	--	(7,587)	(7,587)
Subtotal - comprehensive loss			(6,094,702)
Balance at December 31, 2000	(47,178,667)	(12,342)	10,742,927
Net proceeds from private offering of 1,706,999 shares of Common Stock	--	--	12,994,122
Options and warrants exercised	--	--	267,414

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Proceeds from Employee			
Stock Purchase Plan	--	--	134,288
Compensatory options	--	--	239,887
Preferred stock dividends	(897,927)	--	(202)
Comprehensive loss:			
Net loss	(5,996,571)	--	(5,996,571)
Unrealized loss on			
available-for-sale			
securities	--	12,342	12,342
			-----
Subtotal - comprehensive			(5,984,229)
loss			-----
Balance at December 31, 2001	(54,073,165)	--	18,394,207
Offering costs from			
December 2001 private			
offering	--	--	(8,102)
Options and warrants exercised	--	--	704,449
Proceeds from Employee			
Stock Purchase Plan	--	--	61,466
Preferred stock dividends	(914,022)	--	(1,078)
Net loss	(11,401,148)	--	(11,401,148)
	-----	-----	-----
Balance at December 31, 2002	\$ (66,388,335)	\$ --	\$ 7,749,794
	=====	=====	=====

SEE ACCOMPANYING NOTES.

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ORPHAN MEDICAL, INC.  
NOTES TO FINANCIAL STATEMENTS  
DECEMBER 31, 2002

1. BUSINESS ACTIVITY

Orphan Medical, Inc. (the "Company") acquires, develops and markets pharmaceutical products of high medical value for patients within selected therapeutic areas. A pharmaceutical product has high medical value if it offers a major improvement in the safety or efficacy of patient treatment. The Company currently concentrates its efforts on drugs with high medical value that may be marketed within three therapeutic areas: Antidotes, Oncology Support, and Sleep Disorders. Antizol, Busulfex and Xyrem are available commercially and are the Company's lead products in its Antidotes, Oncology Support and Sleep disorders areas, respectively. In addition, the Company manufactures and distributes Cystadane and Sucraid that treat two rare congenital diseases. Antizol-Vet is marketed through separate channels to the veterinary community. Although these products do not fall into the selected therapeutic areas, the Company expects to continue offering Cystadane, Antizol-Vet, and Sucraid because these products have high medical value and require limited resources to market and distribute. The Company's NDA for Xyrem was approved on July 17, 2002.

The Company has experienced losses from operations since inception and has an

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accumulated deficit of \$66 million at December 31, 2002. The Company anticipates the revenue from its existing products, including Xyrem, will be adequate to fund operations in the future. However, in the event that revenue from any of the products is lower than anticipated, management believes it can reduce operating expenses to manage its cash flow.

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### USE OF ESTIMATES

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

#### REVENUE RECOGNITION

Sales for all products, except Xyrem(R) (sodium oxybate) oral solution, are recognized at the time a product is shipped to the Company's customers and are recorded net of reserves for discounts for prompt payment. Sales of Xyrem are recognized at the time product is shipped from the specialty pharmacy to the patient and are recorded net of discounts for prompt payment. Except for Xyrem, the Company is obligated to accept, for exchange, from all domestic customers products that have reached their expiration date. The Company is not obligated to accept exchange of outdated product from its international distribution partners. The Company establishes a reserve for the estimated cost of the exchanges. The Company monitors the exchange of product and modifies its reserve as necessary. Management bases these reserves on historical experience and these estimates are subject to change.

Deferred revenue represents prepayment from customers for products not yet shipped.

#### CASH EQUIVALENTS AND AVAILABLE-FOR-SALE SECURITIES

The Company considers all highly liquid investments with remaining maturities of 90 days or less when purchased to be cash equivalents. The Company considers all highly liquid investments with remaining maturities of more than 90 days when purchased to be available-for-sale securities. Cash equivalents are carried at cost plus accrued interest, which approximates market value. There were no available-for-sale securities at December 31, 2002 or 2001.

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### ORPHAN MEDICAL, INC. NOTES TO FINANCIAL STATEMENTS (CONTINUED)

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

#### CONCENTRATION OF CREDIT RISK

The Company invests its excess cash in U.S. government agency securities, investment grade commercial paper, and other money market instruments and has established guidelines relative to diversification and maturities in an effort to maintain safety and liquidity. These guidelines are periodically reviewed to take advantage of trends in yields and interest rates. The Company has not experienced any significant losses on its cash equivalents or available-for-sale securities.

There is a concentration of sales to larger medical wholesalers and distributors. The Company performs periodic credit evaluations of its customers' financial condition. Domestic receivables are due within 30 days of the invoice date. International receivables are generally due within 60 to 90 days of

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invoice date. Credit losses relating to customers have not been material since the Company's inception.

### INVENTORIES

Inventories are valued at the lower of cost or market determined using the first-in, first-out (FIFO) method. The Company's policy is to establish an excess and obsolete reserve for its products in excess of the expected demand for such products.

	DECEMBER 31,	
	2002	2001
Raw materials and packaging	\$ 1,023,256	\$ 981,583
Finished goods	996,502	260,537
	\$ 2,019,758	\$ 1,242,120

### PROPERTY AND EQUIPMENT

Property and equipment are stated at cost. Maintenance and repairs are expensed as incurred. Depreciation is computed using the straight-line method over the assets' estimated useful lives of three to seven years.

### LONG-LIVED ASSETS

The Company performs reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount.

### RESEARCH AND DEVELOPMENT COSTS

All research and development costs are charged to operations as incurred. Research and development costs consist principally of preclinical and clinical testing costs, certain salary and related expenses, bulk drug and drug product costs incurred in support of clinical testing and for validation lots required by the FDA, toxicology studies and various technical consulting costs.

### STOCK-BASED COMPENSATION

At December 31, 2002 the Company has a stock-based employee compensation plan, which is described more fully in Note 8. The Company accounts for this plan under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees", and related interpretations. No stock-based compensation cost is reflected in the net loss for 2002 or 2000, as all options granted under this plan had an exercise price equal to market value of the underlying common stock on the date of grant. In 2001, the Company modified the terms of options granted to an employee. As a result, the Company recognized compensation expense of \$239,887. The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation", to stock-based employee compensation.

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ORPHAN MEDICAL, INC.  
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

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### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

	YEAR ENDED DECEMBER 31,		
	2002	2001	2000
	----	----	----
Net loss as reported	\$ (12,323,318)	\$ (6,899,624)	\$ (6,959,139)
Add stock-based employee compensation included in net loss	--	239,887	--
Deduct total stock-based employee compensation expense determined under fair value-based method for all awards	(1,975,676)	(1,273,156)	(728,809)
Pro forma net loss	(14,298,994)	(7,932,893)	(7,687,948)
Loss per share			
Basic and diluted - as reported	\$ (1.19)	\$ (0.80)	\$ (0.86)
Basic and diluted - as pro forma	\$ (1.38)	\$ (0.92)	\$ (0.95)

#### INCOME TAXES

The Company accounts for income taxes using the liability method. Deferred income taxes are provided for temporary differences between the financial reporting and tax bases of assets and liabilities. A valuation allowance is provided against the deferred tax assets to the extent management believes that the deferred tax assets may not be realized.

#### LOSS PER SHARE

Basic and diluted loss per common share applicable to common shareholders are based upon the weighted average number of Common Stock shares outstanding during the respective period. Basic and diluted loss per share are the same for the reported periods because the effect of stock options, warrants, and convertible securities is anti-dilutive.

#### RECLASSIFICATIONS

Certain prior year balances have been reclassified in order to conform with the current year presentation. These reclassifications have no impact on net loss or shareholders' equity as previously reported.

### 3. LEASES

The Company has a non-cancelable operating lease for office space that expires on October 31, 2003. The Company also has operating leases for certain office equipment expiring at various times through August 2005. The Company also leases vehicles for the Company's sales force. The term of this lease runs through October 2005. The number of vehicles leased may increase as the sales force expands. The vehicle lease requires the Company to maintain \$251,144 in an account securing a letter of credit. This cash has been disclosed as restricted in the balance sheet. In December 2002, the Company entered into a capital lease for phone equipment that expires in December 2007. The lease contains a bargain purchase option.

Future minimum lease payments, including current real estate taxes and operating expenses under the facility lease, the auto lease, and the equipment leases are as follows:

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ORPHAN MEDICAL, INC.  
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

3. LEASES (CONTINUED)

	CAPITAL LEASE	OPERATING LEASE
	-----	-----
2003	\$ 24,119	\$ 601,100
2004	24,119	352,100
2005	24,119	277,100
2006	24,119	--
2007	24,117	--
	-----	-----
Minimum lease payments	120,593	\$ 1,230,300
		=====
Amounts representing interest	27,793	
	-----	
Present value of net minimum lease payments	92,800	
Less current maturities	14,787	
	-----	
	\$ 78,013	
	=====	

Total rent expense was approximately \$476,000, \$302,900, and \$239,100 for the years ended December 31, 2002, 2001, and 2000, respectively.

4. BORROWINGS

The Company has a commercial revolving line of credit with a bank, which expires in June 2003. The maximum amount available to the Company under this arrangement is \$1,000,000, subject to certain limitations. The Company's indebtedness to the bank may not exceed the lesser of (1) 75 percent of the Company's trade accounts receivable that have been outstanding for 90 days or less or (2) \$1,000,000. Advances are charged a variable rate of interest equal to the prime rate plus one half of a percent. Through December 31, 2002, the Company has not borrowed under this arrangement.

5. INCOME TAXES

As of December 31, 2002, the Company had net operating loss (NOL) carryforwards of approximately \$52,255,000, credit for increasing research activities (the "R&D credit") carryforwards of approximately \$359,000 and orphan drug credit carryforwards of approximately \$10,309,000, available to reduce its future tax liabilities. These carryforwards will begin expiring after 2010. No current income taxes have been provided for the years ended December 31, 2002, 2001 and 2000 as the Company had a loss for both financial reporting and tax purposes.

Significant components of the Company's net deferred tax assets are as follows:

DECEMBER 31,	DECEMBER 31,
2002	2001
-----	-----

Deferred tax assets:

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Net operating loss carryforwards	\$ 17,767,000	\$ 14,361,000
R&D and orphan drug credit carryforwards	10,668,000	9,274,000
Inventory reserves	48,000	168,000
All other reserves	127,000	154,000
Deferred tax liabilities:		
Depreciation	(77,000)	(3,000)
Valuation allowance for deferred tax assets	(28,533,000)	(23,954,000)
	-----	-----
Net deferred tax assets	\$ --	\$ --
	=====	=====

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### ORPHAN MEDICAL, INC. NOTES TO FINANCIAL STATEMENTS (CONTINUED)

#### 5. INCOME TAXES (CONTINUED)

As a result of the 1995 public stock offering, the Company exceeded the limits allowable under Section 382 of the Internal Revenue Code related to changes in ownership percentage which governs future utilization of NOL, R&D credit, and orphan drug credit carryforwards (collectively, "tax benefit carryforwards"). The effect of this occurrence is to limit the annual utilization of a portion of the Company's tax benefit carryforwards attributable to the period prior to the change in ownership. Should another change in ownership occur, future utilization of the Company's tax benefit carryforwards may be subject to additional limitations under Section 382.

#### 6. EMPLOYEE BENEFIT PLANS

The Company maintains a 401(k) Savings Plan, which is funded by elective salary deferrals by employees. The Plan covers substantially all employees meeting minimum eligibility requirements. The Plan does not require mandatory contributions by the Company, but discretionary contributions may be made at the election of the Company. No such discretionary contributions to the Plan have been made to date.

The Company has a stock purchase plan that is funded by employee contributions, generally through payroll deductions. All employees are eligible subject to certain requirements. The purchase price is 85% of the lower of the average of the high and the low trade on the first and last trading day of each purchase period, defined as each calendar quarter. The Company reserved 200,000 shares of its common stock for future issuance at the Plan's inception. From the Plan's inception through December 31, 2002, there have been 114,354 shares issued under the Plan.

#### 7. STOCK OPTIONS

The Company has a stock option plan for employees and non-employees, the 1994 Stock Option Plan (the "Plan"). The Plan provides that the Company may grant employee incentive stock options and non-qualified stock options at an exercise price of not less than 100% of fair market value. Options are exercisable as prescribed by the Plan and expire up to fifteen years from the grant date for non-qualified stock options and up to ten years from the grant date for employee incentive stock options. At December 31, 2002, the Plan has 2,675,000 shares of Common Stock reserved for issuance.

Options outstanding were granted as follows:



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	PLAN ----- OPTIONS OUTSTANDING -----	WEIGHTED AVERAGE EXERCISE PRICE -----
Balance at December 31, 1999	1,471,618	5.85
Options granted	40,750	11.08
Options canceled	(15,300)	10.85
Options exercised	(179,010)	5.10
Balance at December 31, 2000	1,318,058	6.05
Options granted	259,883	11.49
Options canceled	(9,263)	5.82
Options exercised	(41,700)	6.52
Balance at December 31, 2001	1,526,978	6.97
Options granted	652,050	9.78
Options canceled	(55,600)	9.31
Options exercised	(125,950)	5.59
Balance at December 31, 2002	1,997,478	\$ 7.90

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ORPHAN MEDICAL, INC.  
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

7. STOCK OPTIONS (CONTINUED)

The following table summarizes information about the stock options outstanding at December 31, 2002:

RANGE OF EXERCISE PRICES -----	OPTIONS OUTSTANDING -----		WEIGHTED AVERAGE EXERCISE PRICE -----	OPTIONS E ----- NUMBER EXERCISABLE -----
	NUMBER OUTSTANDING -----	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE -----		
\$ 4.19 - \$ 5.00	478,500	1.86 years	\$5.00	478,500
\$ 5.38 - \$ 6.75	451,025	5.86 years	6.12	325,875
\$ 6.83 - \$11.30	745,833	7.95 years	8.73	408,783
\$11.31 - \$18.31	322,070	8.79 years	12.75	89,210
\$ 4.19 - \$18.31	1,997,478		\$7.90	1,302,368

Fully vested and exercisable options were 1,302,368, 1,251,772, and 1,098,258, as of December 31, 2002, 2001, and 2000, respectively. The weighted average exercise prices for the fully vested and exercisable options as of December 31, 2002, 2001, and 2000 were \$6.86, \$6.24, and \$5.85 respectively.

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The Company applies the intrinsic-value method in accounting for stock issued to employees and directors. Accordingly, compensation expense is recognized only when options are granted with a discounted exercise price. Any such compensation expense is recognized ratably over the associated service period, which is generally the option vesting period.

Pro forma net loss and loss per share information, as required by Statement of Financial Accounting Standards No. 123, "Accounting for Stock Based Compensation" (SFAS 123), has been determined as if the Company had accounted for employee stock options under the fair value method. The fair value of these options was estimated at grant date using a Black-Scholes option pricing model with the following assumptions for 2002, 2001, and 2000, respectively

	2002	2001	2000
Expected dividend yield	0.00%	0.00%	0.00%
Expected stock price volatility	70%	73%	72%
Risk-free interest rate	4.00%	5.75%	6.00%
Expected life of options	10 years	10 years	10 years

The weighted average fair value of the options granted in 2002, 2001, and 2000 was \$7.62, \$9.33, and \$9.13, respectively, as computed as described above.

The Company granted 15,000 options to purchase unregistered common stock to a consultant in December 2000. These options were granted at \$13.6875, the closing price of the Company's common stock on the date of grant. The options vest under certain conditions. The fair value of these options was being charged to expense over the vesting period of the options.

### 8. SHAREHOLDERS' EQUITY

On July 23, 1998 the Company issued \$7.5 million of Senior Convertible Preferred Stock (the "Preferred Shares") in a private placement. The Company realized net cash proceeds of \$7.1 million from the sale of the Preferred Shares after the payment of related offering expenses. The Preferred Shares were initially convertible, at the option of the holders, into shares of the Company's Common Stock at a price equal to \$8.50 per share. The August 1999 financing, as discussed in the following paragraph, triggered antidilution provisions relating to the \$8.1 million of the Senior Convertible Preferred Stock held as of August 1, 1999 (after giving effect to the semi-annual in-kind dividend distributions),

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### ORPHAN MEDICAL, INC. NOTES TO FINANCIAL STATEMENTS (CONTINUED)

### 8. SHAREHOLDERS' EQUITY (CONTINUED)

which resulted in a decrease in the conversion price of those shares from \$8.50 to \$8.14 per share. The Preferred Shares have anti-dilution protection and bear a dividend of 7.5% per annum, payable semi annually, which during the first two years may be paid either in cash or by issuing additional Preferred Shares. In the third year and thereafter, the dividend may be paid either in cash or by issuing Common Stock valued at the then current market price. At the Company's option upon their maturity in July 2008, the Preferred Shares must be (a) converted into Common Stock, subject to a \$3.0 million conversion fee payable in cash or by issuing additional Common Shares, or (b) redeemed for cash at \$1,000 per share plus accrued dividends. The holders of the Preferred Shares are

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entitled to and have exercised their right to designate an individual to serve on the Company's Board of Directors.

On August 2, 1999, the Company completed a \$5.0 million financing transaction in a private placement. The funding consisted of a purchase of 2,950 shares of the Company's Series B Convertible Preferred Stock for an aggregate purchase price of \$2.95 million and a commitment of \$2.05 million of debt in the form of a line of credit. The Company had not borrowed on this line of credit and it was eliminated as a part of the December 2001 financing transaction. The Series B Convertible Preferred Stock ("Series B Preferred Shares") may be converted prior to August 2, 2009 into shares of the Company's Common Stock at a price of \$6.50 per share. The Series B Preferred Shares have anti-dilution protection and bear a dividend of 7.5% per annum, payable semi annually, which during the first two years may be paid either in cash or by issuing additional Series B Preferred Shares. In the third year and thereafter, the dividend may be paid either in cash or by issuing Common Stock valued at the then current market price. At the Company's option upon their maturity in August 2009, the Series B Preferred Shares must be (a) converted into Common Stock, subject to a \$1.2 million conversion fee payable in cash or by issuing additional Common Shares, or (b) redeemed for cash at \$1,000 per share plus accrued dividends.

In conjunction with the issuance of the preferred shares, the Company agreed to several restrictions and covenants, and granted certain voting and other rights to the holders of the preferred shares. One of these restrictions is that the Company cannot incur additional indebtedness, except for indebtedness secured solely by our trade receivables, until the Company has profitable operations, subject to certain limitations. Another important restriction is that, without the approval of a majority of the preferred stockholders, the Company cannot issue additional equity securities unless the selling price per share exceeds the then conversion price of the outstanding convertible preferred stock or the sale of equity is accomplished in a public offering.

On February 23, 2000, the Company completed the sale of 1,265,000 shares of its Common Stock at a price of \$8.00 per share. The Company received net proceeds of \$9.7 million from the transaction and registered the shares under the Securities Act of 1933, as amended.

On February 25, 2000, the Company completed the sale of 100,000 shares of its Common Stock at a price of \$10.00 per share. The Company received proceeds of \$1.0 million from the transaction and registered the shares under the Securities Act of 1933, as amended.

On December 6, 2001, the Company completed the sale of 1,706,999 shares of its Common Stock at a price of \$8.25 per share. The Company received net proceeds of \$13.0 million from the transaction and registered the shares under the Securities Act of 1933, as amended.

### 9. STOCK WARRANTS

At December 31, 2002, the Company had warrants outstanding to purchase 5,000 shares of Common Stock at \$8.50, all of which are currently exercisable.

In connection with the August 1999 financing, the Company issued two seven-year warrants. One of the warrants entitles the holder to receive, upon payment of the \$2.05 million exercise price, either 2,050 shares of Series C Convertible Preferred Stock (which is similar to the Series B Convertible Preferred Stock and which is convertible to shares of the Company's Series D Non-Voting Preferred Stock at a conversion price of \$6.50 per share) or 315,385 shares of Series D Non-Voting Preferred Stock (which is equivalent to common stock except that it has no voting rights) or a combination of Series C Convertible Preferred Stock and Series D Non-Voting Preferred Stock, so long as the combined purchase price for the shares does not exceed \$2.05 million. The second warrant, issued

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in relation to the line of credit, entitled the holder to purchase 282,353 shares of Series D Non-Voting Preferred Stock at an

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### ORPHAN MEDICAL, INC. NOTES TO FINANCIAL STATEMENTS (CONTINUED)

#### 9. STOCK WARRANTS (CONTINUED)

exercise price of \$4.25 per share. The value of the warrants was \$82,000 and was amortized over the term of the line of credit to interest expense. All of these warrants are outstanding and exercisable at December 31, 2002.

#### 10. RESEARCH AND DEVELOPMENT COMMITMENTS

The Company has various commitments under agreements with outside consultants, contract drug developers and manufacturers, technical service companies, and drug distributors. In addition, the Company has commitments under license and research agreements. The Company does not have any joint venture agreements nor does it have any arrangements to perform research and development for other parties. The Company recognizes the costs associated with these commitments as incurred based on the accrual method of accounting. Expenditures associated with these commitments totaled approximately \$3,900,000, \$3,000,000, and \$4,900,000 for the years ended December 31, 2002, 2001, and 2000, respectively. The Company's commitment to incur additional expenditures in subsequent periods for development activities totaled approximately \$5,676,000 \$4,045,000, and \$3,907,000 at December 31, 2002, 2001, and 2000, respectively. Commitments for research and development expenditures will likely fluctuate from year to year depending on, among other factors, the timing of new product development, if any, and clinical trial activity.

#### 11. GEOGRAPHIC INFORMATION

The Company operates in two geographic regions, domestic and international. The Company has no assets outside of the United States. The following is a summary of net sales by geographic region for the years ended December 31, 2002, 2001 and 2000, respectively.

	2002	2001	2000
	-----	-----	-----
Domestic	\$ 12,553,434	\$ 9,566,099	\$ 9,226,618
International			
Japan	799,942	24,570	--
United Kingdom	915,084	620,790	801,698
All other	1,861,709	1,062,651	1,157,368
	-----	-----	-----
Total	\$ 16,130,169	\$ 11,274,110	\$ 11,185,634
	=====	=====	=====

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## ORPHAN MEDICAL, INC. NOTES TO FINANCIAL STATEMENTS (CONTINUED)

### 12. QUARTERLY FINANCIAL INFORMATION

The following are unaudited quarterly results of operations for the years ended December 31, 2002 and 2002.

	March 31, 2002	Quarter ended		Decem 2
		June 30, 2002	September 30, 2002	
Revenues	\$ 3,681,638	\$ 3,505,639	\$ 4,155,061	\$ 4,7
Gross profit	3,148,362	2,980,344	3,546,435	4,2
Net loss	(932,707)	(1,458,570)	(4,104,231)	(4,9
Less: Preferred stock dividends	225,730	226,683	235,668	2
Net loss attributable to common shareholders	(1,158,437)	(1,685,253)	(4,339,899)	(5,1
Basic and diluted loss per common share	(0.11)	(0.16)	(0.42)	
	March 31, 2001	Quarter ended		Decem 2
		June 30, 2001	September 30, 2001	
Revenues	\$ 2,341,510	\$ 2,424,843	\$ 2,940,438	\$ 3,5
Gross profit	2,051,844	1,990,264	2,531,306	3,1
Net loss	(1,390,474)	(1,709,289)	(1,833,281)	(1,0
Less: Preferred stock dividends	221,129	224,383	228,366	2
Net loss attributable to common shareholders	(1,611,603)	(1,933,672)	(2,061,647)	(1,2
Basic and diluted loss per common share	(0.19)	(0.23)	(0.24)	

### 13. SUBSEQUENT EVENTS

On March 28, 2003, the Company cancelled its existing line of credit facility and entered into a new facility with a commercial bank. The new line of credit facility, which has a term of one-year, includes a borrowing base equal to 75% of eligible accounts receivable up to a maximum line of credit of \$3.5 million. Certain other assets have also been pledged as collateral for this facility. The interest rate is equal to two points over the bank's prime rate. The Company will be subject to certain other requirements during the term of the facility, including minimum quarterly net equity amounts.

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ORPHAN MEDICAL, INC.

Description	Balance at Beginning of Period	Additions	
		Charged to Costs and Expenses	Charged to Other Accounts - Describe
YEAR ENDED DECEMBER 31, 2002			
Reserves and allowances deducted from asset accounts:			
Allowance for doubtful accounts	\$25,000	\$107,400	
Allowance for excess inventory	492,997	11,363	
YEAR ENDED DECEMBER 31, 2001			
Reserves and allowances deducted from asset accounts:			
Allowance for doubtful accounts	\$116,200	\$56,408	
Allowance for excess inventory	334,602	158,395	
YEAR ENDED DECEMBER 31, 2000			
Reserves and allowances deducted from asset accounts:			
Allowance for doubtful accounts	\$113,000	\$3,200	
Allowance for excess inventory	376,593	-	

(1) Recovery of amounts previously reserved.

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