ORPHAN MEDICAL INC
Form 424B3
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ORPHAN MEDICAL, INC.

1,706,999 SHARES

COMMON STOCK

This prospectus covers the sale of up to 1,706,999 shares of common stock of Orphan Medical, Inc. offered for the account of certain selling stockholders. We will not receive any part of the proceeds from the sale and will bear all expenses and fees of registration of the shares.

Our common stock is traded on the Nasdaq National Market under the symbol "ORPH." The closing sale price of the common stock reported by the Nasdaq National Market on February 19, 2002 was $11.85 per share.

SEE THE SECTION TITLED "RISK FACTORS" BEGINNING ON PAGE 4 TO READ ABOUT CERTAIN FACTORS YOU SHOULD CONSIDER BEFORE BUYING SHARES OF COMMON STOCK.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

ORPHAN MEDICAL, INC.
13911 RIDGEDALE DRIVE, SUITE 250
MINNETONKA, MINNESOTA 55305
(952) 513-6900

The date of this prospectus is February 20, 2002

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the "SEC"). The prospectus relates to 1,706,999 shares of our common stock which the selling stockholders named in this prospectus may sell from time to time. We will not receive any of the proceeds from these sales. We have agreed to pay the expenses incurred in registering these shares, including legal and accounting fees.

These shares have not been registered under the securities laws of any state or other jurisdiction as of the date of this prospectus. The selling

stockholders should not make an offer of these shares in any state where the offer is not permitted. Brokers or dealers should confirm the existence of an exemption from registration or effect a registration in connection with any offer and sale of these shares.

You should read this prospectus together with the additional information described under the heading "Where You Can Find More Information."

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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. You should carefully consider the following information about these risks, together with the information in the rest of this prospectus, before buying shares of common stock.

WE HAVE A HISTORY OF LOSSES.

We have been unprofitable since our inception in 1994. We expect operating losses in 2002 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 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.

THERE ARE RESTRICTIONS ON OUR ABILITY TO RAISE ADDITIONAL CAPITAL. IF WE ARE UNABLE TO OBTAIN ADDITIONAL FINANCING, WE MAY NOT BE ABLE TO SUPPORT OUR CURRENT OR FUTURE BUSINESS OPERATIONS.

On July 23, 1998, we completed the private sale to UBS Capital II, LLC of $7.5 million of Senior Convertible Preferred Stock. On August 2, 1999, we completed another private sale to UBS Capital II of $3.0 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. On December 7, 2001, we completed the private sale of 1.7 million shares of common stock to a group of investors led by Alta BioPharma Partners II, L.P. In connection with this sale, UBS Capital II agreed to forfeit its right as a preferred stockholder to enforce the restrictions and covenants relating to our ability to incur additional indebtedness and issue additional equity securities. However, we are still subject to other restrictions and covenants relating to the preferred stock, and these restrictions could make it more difficult and more costly for us to obtain additional capital.

We expect our spending for research and development and sales and marketing to increase significantly in fiscal 2002. Although we believe that we have sufficient capital to meet our business objectives in fiscal 2002, if we expand our business plan, or unanticipated events occur, we may need additional capital. We cannot assure you that additional sources of capital will be available to us, or if available, on terms acceptable to us. If we issue additional equity securities, your ownership interest may be diluted.

THE MARKET PRICE OF OUR COMMON STOCK COULD FLUCTUATE IN RESPONSE TO QUARTERLY OPERATING RESULTS AND OTHER FACTORS.

The market price of our common stock could fluctuate significantly in response to a number of factors, including:

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

The market value and 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) net tangible assets in excess of $4.0 million as reported on Form 10-Q or Form 10-K or (2) a market capitalization of at least $50.0 million. Net tangible assets are defined as total assets less the sum of total liabilities and intangible assets. Market capitalization is defined as total outstanding shares multiplied by the last sales price quoted by Nasdaq. Although we currently meet the requirements for listing on the Nasdaq National Market, we cannot assure you that we will continue to meet these requirements. The Nasdaq National Market has issued new listing qualifications which will become effective November 2002, and which will replace the net tangible asset requirement with a minimum net equity requirements of $10.0 million. At September 30, 2001, we met the new listing qualifications with respect to market capitalization. We cannot assure you that we will continue to meet the new listing qualification requirements.

The market price of our common stock may also fluctuate significantly in response to other factors over which we have no control and that may not be directly related to us. Fluctuations or decreases in the trading price of our

common stock may adversely affect your ability to trade your shares and you may lose all or a part of your investment. In addition, fluctuations and decreases in our stock price could adversely impact our business and our ability to raise capital through additional equity financings.

THERE IS A LIMITED MARKET FOR OUR PRODUCTS.

While we will seek to obtain and market products that address diseases that affect patient populations larger than those affected by orphan diseases (200,000 or fewer patients in the United States), many of our opportunities will address orphan diseases. 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

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 a "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 certain limited protections for our products.

The first step in obtaining the limited protection under the Orphan Drug Act is obtaining "orphan drug designation" for a product from the FDA. 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, nor does it provide any advantage in, or shorten the duration of, the regulatory approval process.

The second step in obtaining limited protection under the Orphan Drug Act for a specific product is acquiring the FDA's recognition of "orphan drug status." This step involves submission of a New Drug Application ("NDA") to the FDA containing all clinical study results, safety and manufacturing information and requesting approval to market a drug for the designated indication. The FDA will grant orphan drug status to the first company to receive approval of an NDA for the designated indication. Orphan drug status gives a company the exclusive right to market the approved product in the United States for a period of seven years, subject to certain limitations. Obtaining orphan drug status for a particular product may not, however, prevent another company from developing or marketing the same drug having a different formation or composition for the same or different indication. In addition, orphan drug status does not provide any marketing exclusivity in foreign markets. While 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 or will have meaningful or material value to us. Although certain foreign countries provide exclusivity, development and marketing

benefits for orphan drugs, we cannot assure you that such benefits can be obtained or, if obtained, will be of material value to us.

We have obtained orphan drug status for Antizol, Elliotts B Solution, Cystadane, Sucraid, and Busulfex. We have obtained orphan drug designation for Xyrem, our narcolepsy drug and our NDA requesting orphan drug status for Xyrem is currently under review by the FDA. If the FDA approves another company's NDA for sodium oxybate (the generic identity of the therapeutic agent for Xyrem) for

the same indication as Xyrem prior to approving our NDA for Xyrem, that company will be entitled to exclusive marketing rights for sodium oxybate, and the FDA would not approve our application to market Xyrem for seven years, if at all. We are aware that the FDA has granted Teva (formerly Biocraft) orphan drug designation for the use of sodium oxybate to treat the symptoms of narcolepsy, however, we have obtained the exclusive right to use Teva's data for one controlled study included in our NDA submission. While we are not aware of any activities to develop sodium oxybate by any other U.S. company, we cannot assure you that such activities are not being conducted, or that the FDA will approve our NDA for Xyrem first for the designated indication. We also cannot assure you that the FDA will not grant orphan drug designation and orphan drug status to other competing products before or after approving our NDA for Xyrem.

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 has granted Sparta Pharmaceutical, which was acquired by SuperGen Inc., orphan drug designation for an intravenous busulfan with an indication closely related to the indication for our product Busulfex. If the FDA approves an NDA for SuperGen's product for a different indication, SuperGen could seek orphan drug status for that product, which competes with Busulfex. In addition, the FDA does not restrict doctors from prescribing an approved drug for uses not approved by the FDA. 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 the 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

The European orphan drug act provides for up to ten years of market exclusivity for a pharmaceutical product that meets the requirement of the European orphan drug act. For a pharmaceutical product to qualify under the act, the prevalence (or incidence), of the condition being treated must not exceed five patients per 10,000 population. Our European partners have submitted and obtained orphan drug designation under the act for Busulfex and Cystadane, and in May 2001 we were granted orphan drug designation under the act for Antizol for use in methanol poisonings. While these products are currently designated as orphan drugs, we cannot assure you that these products will continue to qualify for orphan drug protection in Europe or that we will be able to obtain orphan drug protection in Europe for other or future products. We also cannot provide you any assurance that another company will not obtain an approval which would block us from marketing our products in Europe.

THE SALE OF OUR PRODUCTS IS DEPENDENT UPON GOVERNMENTAL APPROVAL.

Government regulation in the United States and abroad is a significant factor in the testing, production and marketing of our products. Each product must undergo an extensive regulatory review

process conducted by FDA and by comparable agencies in other countries. We cannot market any pharmaceutical product we develop or license as a prescription product in any jurisdiction, including foreign countries, without 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 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.

GOVERNMENTAL APPROVAL OF OUR PRODUCTS DOES NOT GUARANTEE FINANCIAL SUCCESS.

Six of our products have been approved for marketing by regulatory authorities in the United States or elsewhere. Even if we obtain FDA approval to market Xyrem, we cannot assure you that Xyrem or our other 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, primarily to focus our development efforts and resources on those products that fit within our three selected strategic therapeutic market segments: Antidote; Oncology Support; and Sleep Disorders or for which we believe there is an opportunity for growth or profitability. We cannot assure you that any of these discontinued products currently, or may in the future, have any value. Depending on available financing, we may develop one or more of these discontinued products in the future. We cannot assure you that we will continue development of our current or any proposed products, or that we will continue marketing all of our FDA approved products.

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

After the FDA's Division of Drug Marketing approves a drug, the FDA's Advertising and Communication division must accept the drug's marketing claims, which are the basis for the drug's labeling, advertising and promotion. We cannot assure you that the FDA will approve our proposed marketing claims. Failure to obtain approval of our proposed marketing claims could have a

material adverse effect on our business and prospects.

The FDA requires that we conduct "post-marketing adverse event surveillance programs" to monitor any side effects that occur after any of our drug products are approved for marketing. If the surveillance program indicates unsafe side effects, the FDA may recall the product, and suspend or terminate our 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. To date, none of our products have been subject to an FDA recall. We cannot assure you that our products will not be subject to an FDA recall in the future.

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

WE DEPEND ON OTHERS FOR PRODUCT DEVELOPMENT OPPORTUNITIES.

We engage only in limited research to identify new pharmaceutical compounds. To build our product portfolio, we utilize 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 or will be successfully developed, approved or marketed. We 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 license or acquire new pharmaceutical products, or to promote and market products successfully, would 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:

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

We cannot assure you that we will meet, or continue to meet, the requirements specified in our current or any future license agreements. We cannot assure you that if any agreement is terminated, we will be able to enter

into a similar agreement on terms as favorable as those contained in our existing license agreement.

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 products. The inability to secure contracts for these components 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 our 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 either a 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 drug supply or manufacturing process to a new supplier or manufacturer. We believe

that it could take as long as one year 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 undertaken to certify and maintain secondary sources of supply for drug substances or backup drug manufacturers for some products. If we lose either a supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we locate and then wait for FDA approval of a new drug supplier or manufacturer. We cannot assure you that any change in drug supplier or manufacturer or the transfer of a drug manufacturing processes to another third party would be approved by the FDA, or approved in a timely manner. The loss of, or change in, drug supplier or a drug 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 Ash Stevens, Inc. for the supply of bulk drug substance used in Busulfex, Antizol, and Antizol-Vet. If we were to lose Ash Stevens 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 2000 and 90% of our total revenues in 1999, and which are expected to account for approximately 85% of our revenues in 2001. We depend substantially on Lonza, Inc. for the supply of bulk drug substance used in Xyrem. If we were to lose Lonza as a supplier, we would be required to identify a new supplier before an NDA is submitted for Xyrem. We also cannot assure you that our bulk drug supply arrangements with Ash Stevens and Lonza, 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 an affiliate of Boehringer Ingelheim for drug product manufacturing of Busulfex, Antizol, and Antizol-Vet. Upon FDA approval of Xyrem, an affiliate of DSM, N.V. has been authorized to manufacture Xyrem. If we were to lose Boehringer as a manufacturer, we would be required to identify a new manufacturer for drug products that provided approximately 88% of our total revenues in 2000 and 90% of our total revenues in 1999, and which are expected to account for approximately 85% of our total revenues in 2001. We cannot assure you that our drug product manufacturing arrangements with Boehringer and DSM, N.V. will not change or that the manufacturing services will continue to be available on terms satisfactory to us. Any change in our manufacturing agreements with Boehringer and DSM, N.V 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 prescriptions. Failure by our contractors to comply with FDA or DEA requirements or applicable foreign requirements could significantly delay our ability to commercialize or continue to market our products. Either result could have a material adverse effect on our business and prospects. Our contractors failure to comply with good marketing practices or other legal requirements could also result in seizure of violative products, injunctive actions brought by the federal government or 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 with, or will continue to comply with, FDA or DEA requirements or applicable foreign requirements.

WE DEPEND UPON OTHERS FOR DISTRIBUTION OF OUR PRODUCTS.

We have an agreement with CORD Logistics, Inc., a subsidiary of Cardinal Health, Inc., to provide integrated distribution and operations services to support transactions between us and our wholesalers, specialty distributors, and direct customers. CORD also provides reimbursement management, patient assistance and information hotline services and specialty distribution and marketing services to physician practices with respect to our products. CORD currently distributes Busulfex, Cystadane, Elliotts B Solution, Antizol, Antizol-Vet, and Sucraid. CORD may also distribute future products should those products receive marketing clearance from the FDA. We are substantially dependent on CORD's ability to successfully distribute Busulfex, Elliotts B Solution, Antizol, Antizol-Vet, and Sucraid and other potential products.

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

We cannot assure you that our distribution arrangements with CORD, Chronimed 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 DEPEND ON FOREIGN COMPANIES TO SELL OUR PRODUCTS OUTSIDE OF THE UNITED STATES AND OUR INABILITY TO ESTABLISH AND MAINTAIN MARKETING ALLIANCES WITH FOREIGN COMPANIES COULD ADVERSELY AFFECT OUR BUSINESS.

Our strategy to sell our products outside of the United States is to license foreign marketing and distribution rights to a foreign company after a NDA is submitted to, or approved by, the FDA in the United States. We consider Europe, Asia and Canada our most attractive foreign markets. Our current foreign developments are:

- Europe. We have licensed the marketing and distribution rights for Busulfex, Antizol, Cystadane and Sucraid in Europe. If our licensees' registration and distribution efforts are not successful, it may be difficult for us to contract with other distributors in Europe for these products. 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" or "emergency use." Emergency use distribution of our products is expected to result in limited revenues for us.

- Asia. We have licensed marketing and distribution rights for Busulfex in Japan, the Peoples Republic of China, Taiwan and South Korea. Use and distribution of all products in these countries, except South Korea, is limited to clinical trials until full regulatory approval is obtained. Revenues prior to full approval are not expected to be material. Full regulatory approval for marketing of these products in South Korea was obtained in late 2001. We do not expect to generate material revenues from our South Korean marketing and distribution activities.

- Canada. We have licensed marketing and distribution rights for Antizol. We do not expect to generate material revenues from these marketing and distribution activities.

- Australia and New Zealand. We have licensed marketing and distribution rights for Cystadane and Sucraid in Australia and New Zealand. We do not expect to generate material revenues from these marketing and distribution activities.

- Central America. We have licensed marketing and distribution rights for Elliotts B Solution in Central America. We do not expect to generate material revenues from these marketing and distribution activities.

- 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 February 2000. Antizol has been submitted for approval. We do not expect to generate material revenues from these marketing and distribution activities.

- Turkey. We have licensed marketing and distribution rights for Busulfex in Turkey. We do not expect to generate material revenues from these marketing and distribution activities.

We depend on our foreign licensees for the regulatory registration of our products in foreign countries. We cannot assure you that our licensees will

obtain such registration. In addition, we cannot assure you 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 our foreign licensees 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 labeling claims, manufacturing issues, quality defects, 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, none of our products have been subject to an FDA recall. We cannot assure you that our products will not be subject to an FDA recall in the future.

THE PRICES WE CHARGE FOR OUR PRODUCTS ARE SUBJECT TO GOVERNMENTAL REGULATION WHICH COULD ADVERSELY AFFECT OUR ABILITY TO RECOVER OUR PRODUCT DEVELOPMENT COSTS AND OUR FINANCIAL PERFORMANCE.

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 cannot predict the level of pricing flexibility we will have with respect to our products or whether we, or users of our products, will be reimbursed for newly approved health care products.

In the United States, we expect continuing federal and state proposals to implement government control of the pricing and profitability of prescription pharmaceuticals. Cost controls could decrease, or limit, the price we receive for our current and future products. 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 and prospects. 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 or state governments, if any, with regard to health care reform will not have a material adverse effect on our business and prospects.

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.

WE MAY BE UNABLE TO PROTECT OUR PROPRIETARY INFORMATION, WHICH COULD NEGATIVELY AFFECT OUR ABILITY TO COMPETE IN THE PHARMACEUTICAL INDUSTRY.

The pharmaceutical industry and the investment community place considerable importance and value on obtaining patent 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:

- to obtain, and enforce proprietary protection for our products under United States and foreign patent laws and other intellectual property laws;

- to preserve the confidentiality of our trade secrets; and

- 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 patents issued to us 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 and proposed products, Cystadane, Elliotts B Solution, Antizol, Antizol-Vet, Xyrem and Sucraid, are in the public domain and are not currently subject to patent protection in the United States. However, we have filed a patent application with respect to our formulation of Xyrem oral solution. A United States patents issued to The University of Texas System and The University of Houston-University Park, the group from whom we license the formulation for Busulfex, 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 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 THE PHARMACEUTICAL 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 designation and 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.

IF WE ARE UNABLE TO RESPONSE TO RAPIDLY CHANGING TECHNOLOGIES AND OTHER DEVELOPMENTS, WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY.

The pharmaceutical industry has experienced rapid and significant technological change as well as structural changes, such as those brought about by changes in heath 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 $20 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.

This prospectus, any applicable prospectus supplement and the documents incorporated by reference in this prospectus contain forward-looking statements based on our current expectations, assumptions, estimates and projections about our business and our industry. These forward-looking statements involve risks and uncertainties. These statements may be identified by the use of words such as "expects," "anticipates," "intends," "plans" and similar expressions. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, as more fully described above and elsewhere in this prospectus. We undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

ABOUT ORPHAN MEDICAL, INC.

Orphan Medical, Inc. was incorporated on June 17, 1994 as a Minnesota corporation to carry on the business previously conducted by the Orphan Medical Division of Chronimed, Inc. We reincorporated as a Delaware corporation on November 24, 1999. We acquire, develop, and market products of high medical value intended to address inadequately treated or uncommon diseases within selected strategic therapeutic market segments. A drug has high medical value if it offers a major improvement in the safety or efficacy of patient treatment and

has no substantial equivalent substitute. Our activities have consisted primarily of obtaining the rights for pharmaceutical products, hiring the personnel required to implement our business plan, managing the development of these products, preparing for the commercial introduction of six products and raising capital to support our business operations. At December 31, 2001, six of our products, Busulfex, Elliotts B Solution, Cystadane, Antizol-Vet, Antizol and Sucraid have been approved by the FDA for marketing and are commercially available. One product, Xyrem, is currently under review by the FDA. We expect to seek additional products for development. We have not generated sufficient levels of revenue from our approved products to date to fund our operating activities and have sustained significant operating losses each year since inception. In addition, we expect operating losses to continue through at least 2002. As of the first quarter of 1999, we no longer considered our company to be in the development stage.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's web site at "http://www.sec.gov." You may also read and copy any document we file with the SEC at the SEC's public reference rooms in Washington, D.C., New York, N.Y. and Chicago, Illinois. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms and their copy charges. Our common stock is listed on the Nasdaq national market, and you may also inspect the information we file with the SEC at the offices of the National Association of Securities Dealers, 1735 K. Street N.W., Washington, D.C. 20006.

The SEC allows us to incorporate by reference the information that we file with them, which means that we can disclose important information to you by referring to those filed documents. We have previously filed the following documents with the SEC and are incorporating them by reference into this prospectus:

- Annual Report on Form 10-K for the year ended December 31, 2000;
- Quarterly Reports on Form 10-Q for the quarters ended March 31 , June 30, and September 30 2001;
- Current Report on Form 8-K filed on December 17, 2001; and
- the description of the common stock contained in our Registration Statement on Form S-1, dated March 11, 1996 (File No. 333-2200), and any amendment or report filed to update such description filed subsequent to the date of this prospectus and prior to the termination of the offering of the shares.

You can obtain a copy of any documents which are incorporated by reference in this prospectus or any prospectus supplement at no cost by writing or telephoning us at:

Orphan Medical, Inc.
13911 Ridgedale Drive, Suite 250
Minnetonka, Minnesota 55305
Attn: Timothy G. McGrath
(952) 513-6900

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement to this prospectus. We have not

authorized anyone else to provide you with different information. The selling stockholders will not make an offer of the shares in any state where the offer is not permitted. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front of those documents.

SELLING STOCKHOLDERS

We have agreed to register 1,706,999 shares for resale by the selling stockholders. This number does not include an indeterminate number of shares that may be registered and issued in accordance with Rule 416 under the Securities Act of 1933, as amended, to prevent dilution of the common stock resulting from stock splits, stock dividends or other events, or changes in the exercise price of warrants.

The following table lists the selling stockholders and the number of shares they beneficially own as of February 1, 2002 and the number of shares that they may sell upon registration. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission.

NAME	NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED PRIOR TO THE OFFERING	MAXIMUM NUMBER OF SHARES TO BE ISSUED PURSUANT TO THIS PROSPECTUS	NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED AFTER THE OFFERING(1)	B
Alta BioPharma Partners II, L.P. (2)	1,169,113	1,169,113	0	
Alta Embarcadero BioPharma Partners II, LLC (3)	43,008	43,008	0	
Medical BioHe@lth-Trends Funds	110,061	110,061	0	
Pharm/wHealth Funds	27,515	27,515	0	
Caduceus Capital Trust	537,302	137,302	400,000	
Caduceus Capital II, L.P.	300,000	120,000	180,000	
PW Eucalyptus Fund LLC	690,000	40,000	650,000	
PW Eucalyptus Fund Ltd	75,000	40,000	35,000	
William Hyman	55,500	20,000	35,500	
TOTAL	3,007,499	1,706,999	1,300,500	

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* Shares represent less than 1% of total common stock outstanding.

(1) Assumes the sale of all shares offered by this prospectus.

(2) Alta BioPharma Partners II, L.P. is managed by Alta BioPharma Management Partners II, LLC. Director Farah Champsi is a managing director of Alta BioPharma Management Partners II, LLC.

(3) Director Farah Champsi is a manager of Alta Embarcadero BioPharma Partners II, LLC.

PLAN OF DISTRIBUTION

We are registering the shares on behalf of the selling stockholders. As used in this prospectus, the term "selling stockholders" includes donees and pledgees selling shares received from a named selling stockholder after the date of this prospectus. The selling stockholders will offer and sell the shares to which this prospectus relates for their own accounts. We will not receive any proceeds from the sale of the shares. We will bear all fees and expenses in connection with the registration of the shares. The selling stockholders shall bear any fees and expenses of any attorneys or other advisors retained by the selling stockholders in connection with the registration.

The selling stockholders may offer and sell the shares from time to time in one or more types of the following transactions at prevailing market prices or at negotiated prices:

- block transactions

- on the Nasdaq National Market

- directly with market makers or in privately negotiated transactions

- through put or call option transactions

- through short sales, or

- a combination of these methods of sale.

Sales may be made to or through brokers or dealers who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders or the purchasers of the shares. As of the date of this prospectus, we are not aware of any agreement, arrangement or understanding between any broker or dealer and the selling stockholders regarding the sale of their shares. In addition, we are not aware of any underwriter or coordinating broker acting in connection with the proposed sale of shares by the selling stockholders. The selling stockholders may also resell all or a portion of these shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, as amended, provided they meet the criteria and conform to the requirements of that Rule. We cannot assure you that the selling stockholders will sell any or all of the shares that they offer.

The selling stockholders and any brokers or dealers who participate in the sale of the shares may be deemed to be "underwriters" within the meaning of the Securities Act and any commissions received by them and any profits realized by them on the resale of shares may be deemed to be underwriting discounts or commissions under the Securities Act. Because the selling stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, the selling stockholders will be subject to the prospectus delivery requirements of the Securities Act. We have informed the selling stockholders that their sales in the market must comply with the requirements of the rules and regulations of the Securities and Exchange Act of 1934, as amended.

Upon notification to us by a selling stockholder that any material arrangement has been entered into with a broker or dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing:

(i) the name of each such selling stockholder and of the participating brokers or dealers,

(ii) the number of shares involved,

(iii) the price at which such shares were sold,

(iv) the commissions paid or discounts or concessions allowed to such brokers or dealers, where applicable,

(v) that such brokers or dealers did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and

(vi) other facts material to the transaction.

In addition, upon notification to us by a selling stockholder that a donee or pledgee intends to sell more than 500 shares, a supplement to this prospectus will be filed if required.

LEGAL MATTERS

The validity of the shares offered in this prospectus has been passed upon by Dorsey & Whitney LLP, Minneapolis, Minnesota.

EXPERTS

Ernst and Young LLP, independent auditors, have audited our financial statements and financial schedule included in our Annual Report on Form 10-K for the year ended December 31, 2000, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and financial schedule are incorporated by reference in reliance upon Ernst and Young LLP's report, given on their authority as experts in accounting and auditing.