ORPHAN MEDICAL INC
Form S-3
April 14, 2004

As filed with the Securities and Exchange Commission on April 14, 2004

Registration No. 333-_____

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT
Under The Securities Act of 1933

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 No.)

John Howell Bullion
Chief Executive Officer
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 250
Minnetonka, MN 55405
(952) 513-6900

Copies to:
John T. Kramer, Esq.
Dorsey & Whitney LLP
50 South Sixth Street, Suite 1500
Minneapolis, Minnesota 55402
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Approximate date of commencement of proposed sale to the public: As soon as practicable after the Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price per Share(1)	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Common Stock, $.01 par value	4,000,000 Shares	$11.80	$47,200,000	$5,980.24

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457 under the Securities Act of 1933, as amended, based upon the average of the high and low sales prices of the common stock reported on the Nasdaq National Market on April 7, 2004.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **Subject to Completion, dated April 14, 2004**

ORPHAN MEDICAL, INC.

4,000,000 Common Shares

We may from time to time sell up to 4,000,000 shares of our common stock through public or private transactions, on or off the Nasdaq National Market, at prevailing market prices or at privately negotiated prices.

This prospectus describes the general manner in which our common stock may be offered using this prospectus. We will provide the specific terms of the offering in supplements to this prospectus. This prospectus may not be used to offer and sell our common stock unless accompanied by a prospectus supplement.

Our common stock is traded on the Nasdaq National Market under the symbol ORPH. On April 12, 2004, the last sale price of our common stock as reported on the Nasdaq National Market was $11.25 per share.

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.

The shares of common stock we offer may involve a high degree of risk. The risks associated with an investment in our shares will be described in a prospectus supplement.

The date of this prospectus is , 2004.

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PROSPECTUS SUMMARY

This prospectus is part of a registration statement that we filed with the SEC using a shelf registration process. Under this shelf process, each time we sell shares of our common stock using this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read this prospectus and the applicable prospectus supplement together with the additional information described under the heading Where You Can Find More Information.

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, even if this prospectus is delivered to you after that date or you buy shares of our common stock after that date. Our business, financial condition, results of operations and prospects may have changed since that date. Information contained on our website does not constitute part of this prospectus. In this prospectus, references to Orphan, we, us and our refer to Orphan Medical, Inc.

The registration statement that contains this prospectus (including the exhibits filed with and incorporated by reference to the registration statement) contains additional information about us and the shares of our common stock offered under this prospectus. That registration statement can be read at the SEC web site or at the SEC offices mentioned under the heading Where You Can Find More Information.

ORPHAN MEDICAL, INC.

Orphan Medical, Inc. is a specialty pharmaceutical company focused primarily on sleep disorders, pain and other central nervous system (CNS) disorders. We seek to acquire, develop and market pharmaceutical products that are prescribed by physician specialists and offer a major improvement in the safety or efficacy of patient treatment and have no substantially equivalent substitute. The Company s lead product, Xyrem® (sodium oxybate) solution is approved for the treatment of cataplexy, a debilitating symptom of narcolepsy, a sleep disorder and is marketed by

a 37 person specialty sales force.

In addition to reducing cataplexy in narcolepsy, Xyrem has a direct effect on sleep architecture and may be relevant to treatment of other indications as well. It consolidates sleep and, in fact, increases sleep continuity and non-REM sleep particularly Stage III and IV, or slow-wave sleep which is considered the restorative stage of sleep. Although currently available hypnotics facilitate sleep onset and maintenance, they tend to reduce rather than increase slow-wave sleep. The active ingredient of Xyrem, sodium oxybate or gamma hydroxybutyrate, has also been shown to have other activity that may have therapeutic significance.

Recognizing the significant long-term potential of Xyrem, the Company has initiated a range of clinical development and product development programs. Two clinical trials that are near completion may demonstrate that Xyrem treats excessive daytime sleepiness (EDS) and other symptoms of narcolepsy. If the results of these trials are positive, Xyrem could be marketed to the entire narcolepsy market, which is estimated to affect approximately .05% of the population or 100,000 to 140,000 persons in the United States. We also expect to begin a clinical trial in the first half of 2004 to assess Xyrem in treating the symptoms of Fibromyalgia Syndrome (FMS). FMS is a chronic condition characterized by widespread muscular pain, musculoskeletal discomfort, fatigue, and systemic symptoms. FMS is estimated to affect over 4 million Americans. If Xyrem demonstrates efficacy in treating certain FMS symptoms, additional trials will be conducted in order to obtain FDA approval to market Xyrem to physicians treating this condition. We are also assessing development of an unrelated product, Butamben (butyl-p-amino benzoate), for the treatment of cancer pain.

In addition to expanding the labeling of Xyrem and developing Butamben, we plan to build our presence in specialty CNS markets through the acquisition of both development stage compounds and marketed products. In 2003, we sold all rights to three of our products in order to concentrate resources on Xyrem and enhance our focus on sleep, pain and specialty CNS markets. Medicines developed or acquired in the future may hold orphan drug status, although such status is not central to the Company s strategy.

Since its inception, the Company has obtained New Drug Application (NDA) approvals from the United States Food and Drug Administration (FDA) for six specialty pharmaceutical products. Each of the NDAs was granted Orphan Drug Status by the FDA. We currently market four NDA approved drugs: Xyrem® (sodium oxybate) oral solution, for the treatment of cataplexy associated with narcolepsy; Antizol® (fomepizole) Injection, an antidote for ethylene glycol or suspected ethylene glycol ingestion in humans and an antidote for methanol or suspected methanol ingestion in humans; Cystadane® (betaine anhydrous for oral solution), for homocystinuria, a genetic disease; and Antizol-Vet® (fomepizole) for injection, an antidote for ethylene glycol or suspected ethylene glycol ingestion in dogs. The Company continues to market the three products that treat conditions outside of CNS disorders to help reduce losses since they have attractive gross and operating margins.

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 these products and raising capital to support our business operations.

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. The business was reincorporated as a Delaware corporation on September 1, 2000. 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. We expect operating losses to continue at least through 2004. As of the first quarter of 1999, we no longer considered the Company to be in the development stage.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this prospectus constitute forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by that statute. In some cases, you can identify forward looking statements by terminology such as expects, anticipates, intends, may, should, plans, believes, seeks, estimates, could, would such terms or other comparable terminology. Such forward-looking statements are based upon current expectations and beliefs and involve numerous risks and uncertainties, both known and unknown, that could cause actual events or results to differ materially from these forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable as of the date of this prospectus, we cannot guarantee future results, levels of activity, performance or achievements. We undertake no duty to update any of the forward-looking statements after the date of this prospectus.

USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we will use the net proceeds from the sale of common stock hereunder for general corporate purposes.

DESCRIPTION OF COMMON STOCK

A description of our common stock is included in our Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on November 26, 1999, including any amendment or report filed for the purpose of updating such description, which is incorporated by reference. You may request a copy in the manner described under the heading Where You Can Find More Information.

PLAN OF DISTRIBUTION

We may sell or distribute some or all of our respective shares of common stock from time to time in one or more transactions:

- directly to purchasers in transactions (which may involve crosses and block transactions) on the Nasdaq National Market, in privately negotiated transactions or in the over-the-counter market;
- through dealers, brokers or other agents;
- through underwriters; or
- through a combination of any of the above.

Such transactions may be effected:

- at a fixed price or prices, which price or prices may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Brokers, dealers or other agents participating in such transactions as agents may receive compensation in the form of discounts, concessions or commissions from us (and, if they act as agent for the purchaser of the shares, from the purchaser). Such discounts, concessions or commissions as to a particular broker, dealer or other agent might be in excess of those customary in the type of transaction involved.

Any such brokers, dealers or other agents that participate in such distribution may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, and any discounts, commissions or concessions received by any such brokers, dealers or other agents might be deemed to be underwriting discounts and commissions under the Securities Act.

We will provide a supplement to this prospectus to disclose the specific shares to be sold, the public offering price of the shares to be sold, the names of any underwriters, brokers, dealers or other agents employed by us in connection with such sale, and any underwriting commissions or discounts paid by us.

Any person engaged in a distribution of the shares of common stock offered by this prospectus may not simultaneously engage in market activities with respect to our common stock for the applicable period under Regulation M under the Securities Exchange Act of 1934, as amended. These provisions may affect the marketability of the shares offered by this prospectus.

Any underwriter may engage in over-allotment, stabilizing and syndicate short covering transactions and penalty bids in accordance with Regulation M. Over-allotment involves sales in excess of the offering size, which creates a short position. Stabilizing transactions involve bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate short covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the underwriters to reclaim selling concessions from dealers when the securities originally sold by such dealers are purchased in covering transactions to cover syndicate short positions. These transactions may cause the price of the offered common stock to be higher than it would otherwise be. These transactions, if commenced, may be discontinued by the underwriters at any time.

Underwriters, dealers and agents may be entitled, under agreements entered into with us, to indemnification against and contribution toward certain civil liabilities, including liabilities under the Securities Act of 1933, as amended, and to reimbursement by us for expenses.

Certain of any such underwriters, dealers or agents and their associates may engage in transactions with and perform services for us in the ordinary course of business.

In connection with the offer and sale of the shares of common stock by us, various state securities laws and regulations require that any such offer and sale should be made only through the use of a broker-dealer registered as such in any state where we engage such broker-dealer and in any state where such broker dealer intends to offer and sell shares.

Any common stock sold pursuant to this prospectus will be listed on the Nasdaq National Market, subject to official notice of issuance.

LEGAL MATTERS

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

EXPERTS

The financial statements of Orphan Medical, Inc. included in Orphan Medical, Inc. s Annual Report (Form 10-K) for the year ended December 31, 2003, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Federal securities law requires us to file information with the Securities and Exchange Commission concerning our business and operations. We file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read and copy these documents at the public reference facility maintained by the SEC at Judiciary Plaza, 450 Fifth Street, NW, Room 1024, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public on the SEC s web site at http://www.sec.gov. You can also inspect our reports, proxy statements and other information at the offices of the Nasdaq National Market.

We have filed with the SEC a registration statement on Form S-3 to register the common stock to be sold in connection with this prospectus. This prospectus, which forms a part of the registration statement, does not contain all of the information included or incorporated in the registration statement. The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information that we incorporate by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC (including all filings prior to the effectiveness of this registration statement) under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended:

- our Annual Report on Form 10-K and 10-K/A for the fiscal year ended December 31, 2003; and
- the description of our common stock contained in our Proxy Statement on Schedule 14A filed November 26, 1999, including any amendment or report filed for the purpose of updating such description.

Upon written or oral request, we will provide to each person to whom a copy of this prospectus is delivered, at no cost, a copy of any of the documents that are incorporated by reference into this prospectus. You may request a copy of any of the above filings by writing or telephoning us at the following address:

Timothy G. McGrath,
Chief Financial Officer
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 250
Minnetonka, Minnesota 55318
(952) 513-6900

PART II.

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

SEC Registration Fee	$	5,980
Accounting Fees and Expenses		25,000
Legal Fees and Expenses		75,000
Miscellaneous		14,020
Printing Expenses		25,000
Nasdaq Filing Fee		5,000
Total	$	150,000

All fees and expenses other than the SEC registration fee are estimated. The expenses listed above will be paid by Orphan Medical, Inc. (the Company).

Item 15. Indemnification of Officers and Directors

Section 145 of the Delaware General Corporation Law contains detailed provisions for indemnification of directors and officers of Delaware corporation against expenses, judgment, fines and settlements in connection with litigation. Reference is made to Section 145, which is incorporated herein by reference. The following summary is qualified in its entirety by that reference.

Delaware law permits a corporation to indemnify officers and directors against expenses and other liabilities arising out of legal actions brought or threatened against them, provided that the officer or director each acted in good faith and did not involve a knowing violation of the law. Delaware law does not allow indemnification for directors in cases brought against a director by the corporation or its stockholders unless indemnification is ordered by a court. Delaware law also permits a corporation to enter into agreement with officers and directors providing for indemnification against certain liabilities in addition to indemnification rights permitted by law or in the corporation s certificate of incorporation or bylaws.

Our bylaws provide that we shall indemnify officers and directors under such circumstances and to the extent permitted by Section 145 of the Delaware General Corporation Law as now enacted or hereafter amended.

The Company has entered into agreements with its directors and executive officers which provide that the Company shall indemnify such persons to the fullest extent authorized by the Delaware General Corporation Law. Such agreements also set forth certain procedures with regard to advances, settlement, maintenance of insurance, notification of claims and defense of claims.

The Company maintains a standard policy of directors and officers liability insurance.

Item 16. List of Exhibits

1.1 Form of Underwriting Agreement (to be filed by amendment or by Current Report on Form 8-K pursuant to Item 601(b) of Regulation S-K).

4.1 Specimen of Common Stock Certificate (incorporated by reference to the Company s Registration Statement on Form S-3 (No. 333-51287), filed with the Commission on April 29, 1998, as amended through the date hereof).

5.1 Opinion of Dorsey & Whitney LLP regarding legality.

23.1 Consent of Ernst & Young LLP.

23.2 Consent of Dorsey & Whitney LLP (included in Exhibit 5.1 to this Registration Statement).

24.1 Power of attorney from directors of Orphan Medical, Inc. (included on the signature page).

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change to such information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) under the Securities Act if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change in the information set forth in the registration statement;

provided, however, that paragraphs (1)(i) and (1)(ii) do not apply if the registration statement is on Form S-3 or Form S-8, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the

matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Minnetonka, State of Minnesota, on April 13, 2004.

ORPHAN MEDICAL, INC.

By: /s/ John Howell Bullion

John Howell Bullion
Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints John Howell Bullion and Timothy G. McGrath, or either of them (with full power to act alone), as the undersigned s true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for the undersigned and in his or her name, place and stead, in any and all capacities, to sign the Registration Statement on Form S-3 of Orphan Medical, Inc., and any or all amendments (including post-effective amendments or a related Registration filed pursuant to rule 462(b)) thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the date indicated.

Name	Title	Date
/s/ John Howell Bullion John Howell Bullion	Chief Executive Officer, Director and Chairman of the Board *(Principal Executive Officer)*	April 13, 2004
/s/ Timothy G. McGrath Timothy G. McGrath	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	April 13, 2004

Name	Title	Date
/s/ Michael Greene Michael Greene	Director	April 13, 2004
/s/ Julius A. Vida, Ph.D Julius A. Vida, Ph.D	Director	April 13, 2004
/s/ William M. Wardell, M.D., Ph William M. Wardell, M.D., Ph.D	Director	April 13, 2004
/s/ Thomas B. King Thomas B. King	Director	April 13, 2004
/s/ Farah H. Champsi Farah H. Champsi	Director	April 13, 2004

EXHIBIT INDEX

Exhibit No.	Description
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5.1	Opinion of Dorsey & Whitney LLP regarding legality.
23.1	Consent of Ernst & Young LLP.
23.2	Consent of Dorsey & Whitney LLP (included in Exhibit 5.1 to this Registration Statement).
24.1	Power of Attorney from directors of Orphan Medical, Inc. (included on the signature pages).