ORPHAN MEDICAL INC
Form S-3/A
August 27, 2004

As filed with the Securities and Exchange Commission on August 27, 2004

Registration No. 333-114460

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 3
TO
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:
Philip E. Bauer, 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

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 August 27, 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 August __, 2004, the last sale price of our common stock as reported on the Nasdaq National Market was $ 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 are described beginning on page 27 of our Form 10-K/A (Amendment No. 4) filed with the Securities and Exchange Commission on August 27, 2004.

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 and may supplement 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. The Company markets Xyrem using a 37 person specialty sales force that focuses its selling efforts on physicians specializing in the treatment of sleep disorders. Clinical trials conducted in accordance with United States Food and Drug Administration (FDA) approved protocols have shown that Xyrem consolidates sleep and increases sleep continuity and non-REM sleep, particularly Stages III and IV, which stages are known as slow-wave sleep. Stages III and IV are the stages in which the body experiences the greatest level of restoration. 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. The Company has initiated two Phase III(b) clinical trials to assess the efficacy of Xyrem in the treatment of excessive daytime sleepiness (EDS) and other symptoms of narcolepsy. The first trial is complete and the data was announced on May 19, 2004. The data showed that Xyrem, at certain doses, provides statistically significant improvement in specific measurements of EDS associated with narcolepsy. The second trial is expected to be completed late in the third quarter of 2004. 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 began enrolling patients in late June 2004 in a clinical trial 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. The Company generally seeks to develop products that (1) have some clinical history, (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. We do not conduct extensive basic research to discover new chemical entities. Instead, we generally seek to acquire products that are already in clinical trials. Medicines developed or acquired in the future may hold orphan drug status, although we may develop or acquire products that do not hold such status if we can obtain appropriate proprietary protection through patents or otherwise. A drug that has orphan drug designation and which is the 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.

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. In the second quarter of 2003, we sold all rights to three of these products in order to concentrate resources on Xyrem and enhance our focus on sleep, pain and specialty CNS markets. We currently market the three remaining 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; and Cystadane® (betaine anhydrous for oral solution), for homocystinuria, a genetic disease. We also market a fourth product, Antizol-Vet® (fomepizole) for injection, which is an antidote for ethylene glycol or suspected ethylene glycol ingestion in dogs. This product was approved using a New Animal Drug Application (NADA).

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. Our operations to date have not been profitable and, as of June 30, 2004, we have an accumulated deficit of $65.5 million since inception.

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 to fund clinical trial activities, for certain sales and marketing activities and for general corporate purposes.

Although we believe we have sufficient cash available for currently anticipated clinical trials, proceeds might be used for trials related to products that we may acquire or develop in the future or for trials related to new indications of existing products.

We may also use a portion of the proceeds to fund product acquisition, although we currently have no specific new product acquisition or development plans.

DESCRIPTION OF CAPITAL STOCK

The total number of shares of authorized capital stock of the Company is 25,000,000, of which 14,000 shares are designated Senior Convertible Preferred Stock, $.01 par value, 5,000 shares are designated Series B Convertible Preferred Stock, $.01 par value, 4,000 shares are designated Series C Convertible Preferred Stock, $.01 par value, 1,500,000 shares are designated Series D Non-Voting Preferred Stock, $.01 par value, and the remaining 23,477,000 shares are deemed common stock unless specifically designated otherwise by our board of directors.

Common Stock

As of June 30, 2004, there were 10,900,549 shares of Orphan Medical, Inc. common stock outstanding. The Orphan Medical common stock is listed on the Nasdaq National Market under the symbol ORPH.

Voting and Other Rights

Each share of Orphan Medical common stock is entitled to one vote per share, and, in general, a majority of votes cast with respect to a matter will be sufficient to authorize action upon routine matters. Directors are to be elected by a majority of the votes cast, and shareholders do not have the right to cumulate their votes in the election of directors. For that reason, holders of a majority of the shares of common stock of Orphan Medical entitled to vote in any election of directors may elect all of the directors standing for election. In general, however:

amendments to the certificate of incorporation will be approved if the votes cast within a voting group favoring the action exceed the votes cast within the voting group opposing the action; and

a merger or dissolution of Orphan Medical, or the sale of all or substantially all of its assets, must be approved by the affirmative vote of the holders of a majority of the voting power of the outstanding voting shares and the affirmative vote of the holders of a majority of the outstanding shares of each class entitled to vote on the matter as a class.

No Preemptive or Conversion Rights

Orphan Medical common stock will not entitle its holders to any preemptive rights, redemption privileges, sinking fund privileges or conversion rights.

Assets upon Dissolution

In the event of liquidation, holders of Orphan Medical common stock would be entitled to receive proportionately any assets legally available for distribution to Orphan Medical shareholders with respect to shares held by them, subject to any prior rights of any preferred stock

of Orphan Medical then outstanding.

Distributions

Holders of Orphan Medical common stock will be entitled to receive the dividends or distributions that Orphan Medical s board of directors may declare out of funds legally available for these payments. The payment of distributions by Orphan Medical is subject to the restrictions of Delaware law applicable to the declaration of distributions by a corporation. Under Delaware law, a corporation may not pay a dividend out of net profits if the capital stock of the corporation is less than the stated amount of capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of the corporation s assets. In addition, the payment of distributions to shareholders is subject to any prior rights of outstanding preferred stock.

Preferred Stock

This section describes the general terms and provisions of our preferred stock. We have incorporated by reference our certificate of incorporation as an exhibit to the registration statement. Because this is a summary, it does not contain all of the details found in the full text of our certificate of incorporation. If you would like additional information you should read our certificate of incorporation.

General

Under our articles of incorporation, the Company may issue from time to time shares of preferred stock in one or more series and with such relative rights and preferences and at such times and for such consideration as the board of directors may determine.

The board of directors may determine the following for each series of preferred stock:

the number of shares and designation of the series;

dividend rights;

whether and upon what terms the shares will be redeemable;

whether and upon what terms the shares will have a sinking fund to be used to purchase or redeem the shares of any series;

whether and upon what terms the shares will be convertible;

the restrictions, if any, on the issue or reissue of any additional preferred stock, including increases or decreases in the number of shares of any series subsequent to the issue of shares of that series;

the rights of the holders of the shares of any series upon dissolution or the distribution of our assets; and

the voting rights, if any, which will apply.

Senior Convertible Preferred Stock

On July 23, 1998, the Company issued $7.5 million, or 7,500 shares, of Senior Convertible Preferred Stock. These shares were initially convertible, at the option of the holders, into shares of our common stock at a price equal to $8.50 per share of common stock. The August 1999 issuance of Series B Convertible Preferred Stock, discussed below, triggered antidilution provisions of the Senior Convertible Preferred Stock, which resulted in a decrease in the conversion price of those shares from $8.50 to $8.14 per share. The shares of Senior Convertible Preferred Stock bear a dividend of 7.5% per annum, payable semiannually. During the first two years, these dividends were paid by issuing additional shares of Senior Convertible Preferred Stock, which resulted in a total of 8,706 shares currently outstanding. After July 2000, the Company has the option to pay the dividend either in cash or by issuing our common stock valued at the then current market price. At the Company s option, upon maturity in July 2008, the shares of Senior Convertible Preferred Stock either must be (a) converted into our common stock, subject to a $3.0 million conversion fee payable in cash or by issuing additional shares of common stock, or (b) redeemed for cash at $1,000 per share plus accrued dividends. The holders of the Senior Convertible Preferred Stock are entitled to designate an individual to serve on our board of directors, and Michael Greene serves as that designated board member.

The holders of the Senior Convertible Preferred Stock are entitled to vote on all matters submitted to our stockholders for a vote. The holders of the Senior Convertible Preferred Stock vote with the holders of common stock together as a single class with each share of Senior Convertible Preferred Stock entitled to one vote for each share of common stock issuable upon conversion of the Senior Convertible Preferred Stock. In addition, the Company cannot take any of the following actions without first obtaining the affirmative vote or written consent of holders of a majority of the shares of Senior Convertible Preferred Stock: liquidate, wind up, dissolve, merge or consolidate the Company, sell all or substantially all of the assets of the Company, pay dividends to holders of common stock, incur indebtedness that would cause our aggregate indebtedness (excluding indebtedness that is secured by accounts receivable) to exceed two and one-half times the Company s net income before interest expense, depreciation, amortization and taxes for the preceding four calendar quarters, or issue equity securities for less than the conversion price other in a public offering or certain other permitted issuances.

Series B Convertible Preferred Stock

On August 2, 1999, the Company issued $2.95 million, or 2,950 shares, of Series B Convertible Preferred Stock. These shares are convertible, at the option of the holders, into shares of our common stock at a price equal to $6.50 per share of common stock. The shares of Series B Convertible Preferred Stock bear a dividend of 7.5% per annum, payable semiannually. The Company has the option to pay, and to date has paid, these dividends by issuing additional shares of Series B Convertible Preferred Stock, which resulted in a total of 4,106 shares currently outstanding. At the Company s option, upon maturity in August 2009, the shares of Series B Convertible Preferred Stock either must be (a) converted into our common stock, subject to a $1.2 million conversion fee payable in cash or by issuing additional shares of common stock, or (b) redeemed for cash at $1,000 per share plus accrued dividends.

The holders of the Series B Convertible Preferred Stock are not entitled to any voting rights.

Warrants for the Purchase of Series C Convertible Preferred Stock and Series D Non-Voting Preferred Stock

In connection with the August 1999 issuance of Series B Convertible Preferred Stock, the Company issued two seven-year warrants. One of the warrants entitles the holders to receive, upon payment of a $2.05 million exercise price, either (a) 2,050 shares of Series C Convertible Preferred Stock, or (b) 315,385 shares of Series D Non-Voting Preferred Stock, or (c) a combination of Series C Convertible Preferred Stock or Series D Non-Voting Preferred Stock. The Series C Convertible Preferred Stock is similar to the Series B Convertible Preferred Stock except that it is convertible into shares of the Series D Non-Voting Preferred Stock at a conversion price of $6.50 per share. The Series D Non-Voting Preferred Stock is equivalent to our common stock except that it has no voting rights.

The second warrant entitles the holder to purchase 282,353 shares of Series D Non-Voting Preferred Stock at an exercise price of $4.25 per share.

Both warrants are currently outstanding and neither has been exercised.

Transfer Agent and Registrar

The transfer agent and registrar for the Company is Wells Fargo Bank Minnesota, N.A., Minneapolis, Minnesota.

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/A Amendment No. 4) for the year ended December 31, 2003, have been audited by Ernst & Young LLP, independent registered public accounting firm, 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 from the initial filing date through the termination date of this offering) 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/A (Amendment No. 4), filed August 27, 2004 (Commission File Number 0-24760), for the fiscal year ended December 31, 2003;
- our Quarterly Report on Form 10-Q filed May 10, 2004 (Commission File Number 0-24760), for the period ended March 31, 2004;
- our Quarterly Report on Form 10-Q filed August 9, 2004 (Commission File Number 0-24760), for the period ended June 30, 2004;
- our Current Report on Form 8-K, filed April 20, 2004 (Commission File Number 0-24760); and
- our Current Report on Form 8-K, filed May 24, 2004 (Commission File Number 0-24760).

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 Exhibit 4.1 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 (previously filed).

23.1 Consent of Ernst & Young LLP.

23.2 Consent of Dorsey & Whitney LLP (included in Exhibit 5.1).

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

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 August 27, 2004.

ORPHAN MEDICAL, INC.

By: /s/ John Howell Bullion

John Howell Bullion
Chief Executive Officer

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)*	August 27, 2004
/s/ Timothy G. McGrath Timothy G. McGrath	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	August 27, 2004
* Michael Greene	Director	August 27, 2004
* Julius A. Vida, Ph.D	Director	August 27, 2004
*	Director	August 27, 2004

Name	Title	Date
William M. Wardell, M.D., Ph.D		
*	Director	August 27, 2004
Thomas B. King		
*	Director	August 27, 2004
Farah H. Champsi		
*By: /s/ John Howell Bullion		
John Howell Bullion as attorney-in-fact		

EXHIBIT INDEX

Exhibit No.	Description
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 Exhibit 4.1 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 (previously filed).
23.1	Consent of Ernst & Young LLP.
23.2	Consent of Dorsey & Whitney LLP (included in Exhibit 5.1).
24.1	Power of Attorney from directors of Orphan Medical, Inc. (included on the signature page in the initial filing).