MEDICINES CO/ MA
Form 8-K
June 25, 2002

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): June 20, 2002

The Medicines Company
(Exact Name of Registrant as Specified in Charter)

Delaware	000-31191	04-3324394
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

5 Sylvan Way, Suite 200 Parsippany, New Jersey	07054
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (973) 656-1616

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

ITEM 5. OTHER EVENTS.

On May 1, 2002, the Securities and Exchange Commission (the "SEC") declared effective the Registration Statement on Form S-3 (File No. 333-86762) (the "Registration Statement") of The Medicines Company (the "Company"), which permits the Company to issue up to an aggregate of 4,000,000 shares of its common stock. The prospectus dated May 1, 2002 included in the Registration Statement is referred to herein as the "Prospectus."

On June 20, 2002, the Company issued a press release announcing a public offering of 4,000,000 shares of its common stock at a price to the public of $8.20 per share (the "Shares") pursuant to the Registration Statement. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by this reference.

The Company filed with the SEC on June 21, 2002 the Prospectus together with a supplement to the Prospectus, dated June 20, 2002, relating to the issuance and sale of the Shares (the "Prospectus Supplement"). In connection with the filing of the Prospectus and Prospectus Supplement with the SEC and its offering of the Shares, the Company is filing the underwriting agreement

relating thereto as Exhibit 1.1 to this Current Report on Form 8-K and a legal opinion of Hale and Dorr LLP relating to the Shares as Exhibit 5.1 to this Current Report on Form 8-K.

In connection with the filing of the Prospectus and the Prospectus Supplement with the SEC, the Company is providing below under the caption "Risk Factors," an updated description of the risks and uncertainties which could materially affect the Company's business, financial condition and results of operations, which were included in the Prospectus Supplement.

RISK FACTORS

RISKS RELATED TO OUR BUSINESS

WE HAVE A HISTORY OF NET LOSSES, AND WE EXPECT TO CONTINUE TO INCUR NET LOSSES AND MAY NOT ACHIEVE OR MAINTAIN PROFITABILITY

We have incurred net losses since our inception, including net losses of approximately $11.6 million for the three months ended March 31, 2002. As of March 31, 2002, we had an accumulated deficit of approximately $263.1 million. We expect to make substantial expenditures to develop and commercialize our products further, including costs and expenses associated with clinical trials, regulatory approval and commercialization of products. As a result, we are unsure when we will become profitable, if at all, and if we do become profitable, we may not remain profitable for any substantial period of time. If we fail to achieve profitability within the time frame expected by investors or securities analysts, the market price of our common stock may decline.

OUR BUSINESS IS VERY DEPENDENT ON THE COMMERCIAL SUCCESS OF ANGIOMAX

Other than Angiomax, our products are in clinical phases of development and, even if approved by the FDA, are a number of years away from entering the market. As a result, Angiomax will account for almost all of our revenues for the foreseeable future. The commercial success of Angiomax will depend upon its acceptance by physicians, patients and other key decision-makers as a safe, therapeutic and cost-effective alternative to heparin and other products used in current practice. If Angiomax is not commercially successful, we will have to find additional sources of revenues or curtail or cease operations.

FAILURE TO RAISE ADDITIONAL FUNDS IN THE FUTURE MAY AFFECT THE DEVELOPMENT, MANUFACTURE AND SALE OF OUR PRODUCTS

Our operations to date have generated substantial and increasing needs for cash. Our negative cash flow from operations is expected to continue into the foreseeable future. The clinical development and regulatory approval of Angiomax for additional indications, the development and regulatory approval of our other product candidates and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future capital requirements depend upon many factors and may be significantly greater than we expect.

As of the date hereof, we believe, based on our current operating plan, plus anticipated sales of Angiomax and interest income, that our current cash, cash equivalents and available for sale securities, together with the proceeds from the offering described in the press release attached to this Current Report as Exhibit 99.1, will be sufficient to fund our operations for at least 18 months. If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of Angiomax or otherwise, or if we acquire additional product candidates, we may need to sell additional equity or debt securities or seek additional financing through other

arrangements. The sale of additional equity or debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional public or private financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results. In addition, in order to obtain additional financing, we may be required to relinquish rights to products, product candidates or technologies that we would not otherwise relinquish.

WE CANNOT EXPAND THE INDICATIONS FOR ANGIOMAX UNLESS WE RECEIVE FDA APPROVAL FOR EACH ADDITIONAL INDICATION. FAILURE TO EXPAND THESE INDICATIONS WILL LIMIT THE SIZE OF THE COMMERCIAL MARKET FOR ANGIOMAX

In December 2000, we received approval from the FDA for the use of Angiomax as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. One of our key objectives is to expand the indications for which the FDA will approve Angiomax. In order to do this, we will need to conduct additional clinical trials and obtain FDA approval for each proposed indication. If we fail to expand the approved indications for the use of Angiomax, the size of the commercial market for Angiomax will be limited.

FAILURE TO OBTAIN REGULATORY APPROVAL IN FOREIGN JURISDICTIONS WILL PREVENT US FROM MARKETING ANGIOMAX ABROAD

We intend to market our products in international markets, including Europe. In order to market our products in the European Union and many other foreign jurisdictions, we or our distribution agents must obtain separate regulatory approvals. In February 1998, we submitted a Marketing Authorization Application, or MAA, to the European Agency for the Evaluations of Medicinal Products, or the EMEA, for use of Angiomax in unstable angina patients undergoing angioplasty. Following extended interaction with European regulatory authorities, the Committee of Proprietary Medicinal Products of the EMEA voted in October 1999 not to recommend Angiomax for approval for use in angioplasty. The United Kingdom and Ireland dissented from this decision. We have withdrawn our application to the EMEA and, as of the date hereof, plan to resubmit an MAA with the results of our clinical trial program in angioplasty, the REPLACE-2 program, if positive. We may not be able to obtain approval from any or all of the jurisdictions in which we seek approval to market Angiomax. Obtaining foreign approvals may require additional trials and additional expense.

THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS MAY BE TERMINATED OR DELAYED, AND THE COSTS OF DEVELOPMENT AND COMMERCIALIZATION MAY INCREASE, IF THIRD PARTIES WHO WE RELY ON TO MANUFACTURE AND SUPPORT THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS DO NOT FULFILL THEIR OBLIGATIONS

Our development and commercialization strategy entails entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage our clinical trials, manufacture our products and market and sell our products outside of the United States. Although we manage these services, we do not have the expertise or the resources to conduct these activities on our own and, as a result, are particularly dependent on third parties in most areas.

We may not be able to maintain our existing arrangements with respect to the commercialization of Angiomax or establish and maintain arrangements to develop and commercialize clevidipine or any additional product candidates or

products on terms that are acceptable to us. Any current or future arrangements for the development and commercialization of our products may not be successful. If we are not able to establish or maintain agreements relating to Angiomax, clevidipine or any additional products on terms which we deem favorable, our financial condition would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products may not be within our control. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to conduct its activities in a timely manner, such breach, termination or failure could:

- delay or otherwise adversely impact the development or commercialization of Angiomax, clevidipine, our other product candidates or any additional product candidates that we may acquire or develop;

- require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of our products; or

- result in the termination of the development or commercialization of our products.

WE ARE DEPENDENT ON A SINGLE SUPPLIER FOR THE PRODUCTION OF ANGIOMAX BULK DRUG SUBSTANCE AND A DIFFERENT SINGLE SUPPLIER TO CARRY OUT ALL FILL-FINISH ACTIVITIES FOR ANGIOMAX

We have no experience in manufacturing, and we lack the facilities and personnel to manufacture products in accordance with FDA regulations. As of the date hereof, we obtain all of our Angiomax bulk drug substance from one manufacturer, UCB Bioproducts S.A., and rely on another manufacturer, Ben Venue Laboratories, Inc., to carry out all fill-finish activities for Angiomax, which includes final formulation and transfer of the drug into vials where it is then freeze-dried and sealed.

The FDA requires that all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA's current Good Manufacturing Practice, or cGMP, regulations and guidelines. There are a limited number of manufacturers that operate under cGMP regulations capable of manufacturing Angiomax. As of the date hereof, we do not have alternative sources for production of Angiomax bulk drug substance or to carry out fill-finish activities. If either of our current manufacturers is unable to carry out its respective manufacturing obligations to our satisfaction, we may be unable to obtain alternative manufacturing, or obtain such manufacturing on commercially reasonable terms or on a timely basis. If we were required to transfer manufacturing processes to other third party manufacturers, we would be required to satisfy various regulatory requirements, which could cause us to experience significant delays in receiving an adequate supply of Angiomax. Any delays in the manufacturing process may adversely impact our ability to meet commercial demands for Angiomax on a timely basis and supply product for clinical trials of Angiomax.

IF WE DO NOT SUCCEED IN DEVELOPING A SECOND-GENERATION PROCESS FOR THE PRODUCTION OF BULK ANGIOMAX DRUG SUBSTANCE, OUR GROSS MARGINS MAY BE BELOW INDUSTRY AVERAGES

As of the date hereof, we are developing with UCB Bioproducts a second-generation process for the production of bulk Angiomax drug substance. This process, for which we have received an approvable letter from the FDA, involves changes to the early manufacturing steps of our current process in order to improve our gross margins on the future sales of Angiomax. If regulatory approval of the process is not obtained or is delayed, then our ability to improve our gross margins on future sales of Angiomax may be limited.

CLINICAL TRIALS OF OUR PRODUCT CANDIDATES ARE EXPENSIVE AND TIME-CONSUMING, AND THE RESULTS OF THESE TRIALS ARE UNCERTAIN

Before we can obtain regulatory approvals for the commercial sale of any product that we wish to develop, we will be required to complete pre-clinical studies and extensive clinical trials in humans to demonstrate the safety and efficacy of such product. As of the date hereof, we are conducting clinical trials of Angiomax for use in the treatment of ischemic heart disease and for additional potential hospital applications as a procedural anticoagulant. There are numerous factors that could delay our clinical trials or prevent us from completing our trials successfully. We, or the FDA, may suspend a clinical trial at any time on various grounds, including a finding that patients are being exposed to unacceptable health risks.

The rate of completion of clinical trials depends in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In particular, the patient population targeted by some of our clinical trials may be small. Delays in future planned patient enrollment may result in increased costs and program delays.

In addition, clinical trials, if completed, may not show any potential product to be safe or effective. Results obtained in pre-clinical studies or early clinical trials are not always indicative of results that will be obtained in later clinical trials. Moreover, data obtained from pre-clinical studies and clinical trials may be subject to varying interpretations. As a result, the FDA or other applicable regulatory authorities may not approve a product in a timely fashion, or at all. Even if regulatory approval to market a product is granted, the regulatory approval may impose limitations on the indicated use for which the drug may be marketed.

OUR FAILURE TO ACQUIRE AND DEVELOP ADDITIONAL PRODUCT CANDIDATES OR APPROVED PRODUCTS WILL IMPAIR OUR ABILITY TO GROW

As part of our growth strategy, we intend to acquire and develop additional pharmaceutical product candidates or approved products. The success of this strategy depends upon our ability to identify, select and acquire pharmaceutical products in late-stage development or that have been approved and that meet the criteria we have established. Because we neither have, nor intend to establish, internal scientific research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license product candidates to us.

Any product candidate we acquire will require additional research and

development efforts prior to commercial sale, including extensive pre-clinical and/or clinical testing and approval by the FDA and corresponding foreign regulatory authorities. All of our product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe, non-toxic and effective or approved by regulatory authorities. In addition, we cannot assure you that any approved products that we develop or acquire will be:

- manufactured or produced economically;

- commercialized successfully; or

- widely accepted in the marketplace.

In addition, proposing, negotiating and implementing an economically viable acquisition is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

IF WE BREACH ANY OF THE AGREEMENTS UNDER WHICH WE LICENSE COMMERCIALIZATION RIGHTS TO PRODUCTS OR TECHNOLOGY FROM OTHERS, WE COULD LOSE LICENSE RIGHTS THAT ARE IMPORTANT TO OUR BUSINESS

We license commercialization rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we acquired our first four products through exclusive licensing arrangements. Under these licenses we are subject to commercialization and development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. In addition, upon the termination of the license we may be required to license to the licensor the intellectual property that we developed.

OUR ABILITY TO MANAGE OUR BUSINESS EFFECTIVELY COULD BE HAMPERED IF WE ARE UNABLE TO ATTRACT AND RETAIN KEY PERSONNEL AND CONSULTANTS

The biopharmaceutical industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our ability to attract and retain qualified personnel for the acquisition, development and commercialization activities we conduct or sponsor. If we lose one or more of the members of our senior management, including our executive chairman, Dr. Clive A. Meanwell, or our chief executive officer, David M. Stack, or other key employees or consultants, our ability to implement successfully our business strategy could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in the biotechnology industry with the breadth of skills and experience required to develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

WE FACE SUBSTANTIAL COMPETITION, WHICH MAY RESULT IN OTHERS DISCOVERING, DEVELOPING OR COMMERCIALIZING COMPETING PRODUCTS BEFORE OR MORE SUCCESSFULLY THAN WE DO

The biopharmaceutical industry is highly competitive. Our success will depend on our ability to acquire and develop products and apply technology and

our ability to establish and maintain a market for our products. Potential competitors in the United States and other countries include major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions. Many of our competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do. Accordingly, our competitors may develop or license products or other novel technologies that are more effective, safer or less costly than existing products or technologies or products or technologies that are being developed by us or may obtain FDA approval for products more rapidly than we are able. Technological development by others may render our products or product candidates noncompetitive. We may not be successful in establishing or maintaining technological competitiveness.

BECAUSE THE MARKET FOR THROMBIN INHIBITORS IS COMPETITIVE, OUR PRODUCT MAY NOT OBTAIN WIDESPREAD USE

We have positioned Angiomax as a replacement for heparin, which is widely used and inexpensive, for use in patients with ischemic heart disease. Because heparin is inexpensive and has been widely used for many years, medical decision-makers may be hesitant to adopt our alternative treatment. In addition, due to the high incidence and severity of cardiovascular diseases, competition in the market for thrombin inhibitors is intense and growing. There are a number of thrombin inhibitors currently on the market, awaiting regulatory approval and in development, including orally administered agents.

THE LIMITED RESOURCES OF THIRD-PARTY PAYERS MAY LIMIT THE USE OF OUR PRODUCTS

In general, anticoagulant drugs may be classified in three groups: drugs that directly or indirectly target and inhibit thrombin, drugs that target and inhibit platelets and drugs that break down fibrin. Because each group of anticoagulants acts on different components of the clotting process, we believe that there will be continued clinical work to determine the best combination of drugs for clinical use. We expect Angiomax to be used with aspirin alone or in conjunction with other therapies. Although we are not positioning Angiomax as a direct competitor to platelet inhibitors or fibrinolytic drugs, platelet inhibitors and fibrinolytic drugs may compete with Angiomax for the use of hospital financial resources. Many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform. Because this amount is not based on the actual expenses the hospital incurs, U.S. hospitals may have to choose among Angiomax, platelet inhibitors and fibrinolytic drugs.

FLUCTUATIONS IN OUR OPERATING RESULTS COULD AFFECT THE PRICE OF OUR COMMON STOCK

Our operating results may vary from period to period based on the amount and timing of sales of Angiomax, the availability and timely delivery of a sufficient supply of Angiomax, the timing and expenses

of clinical trials, announcements regarding clinical trial results and product introductions by our competitors, the availability and timing of third-party reimbursement and the timing of approval for our product candidates. If our operating results do not match the expectations of securities analysts and investors as a result of these and other factors, the trading price of our common stock will likely decrease.

WE MAY UNDERTAKE STRATEGIC ACQUISITIONS IN THE FUTURE AND ANY DIFFICULTIES FROM INTEGRATING SUCH ACQUISITIONS COULD DAMAGE OUR ABILITY TO ATTAIN OR MAINTAIN

PROFITABILITY

We may acquire additional businesses and products that complement or augment our existing business. Integrating any newly acquired businesses or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, which may result in dilution for stockholders and the incurrence of indebtedness.

OUR REVENUES ARE SUBSTANTIALLY DEPENDENT ON A LIMITED NUMBER OF WHOLESALERS TO WHICH WE SELL ANGIOMAX, AND SUCH REVENUES MAY FLUCTUATE FROM QUARTER TO QUARTER BASED ON THE BUYING PATTERNS OF THESE WHOLESALERS

We sell Angiomax primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States. During the three months ended March 31, 2002, revenues from the sale of Angiomax to four wholesalers totaled approximately 97% of our net revenues. Our reliance on this small number of wholesalers could cause our revenues to fluctuate from quarter to quarter based on the buying patterns of these wholesalers. In addition, if any of these wholesalers fail to pay us on a timely basis or at all, our financial position and results of operations could be materially adversely affected.

RISKS RELATED TO OUR INDUSTRY

IF WE DO NOT OBTAIN FDA APPROVALS FOR OUR PRODUCTS OR COMPLY WITH GOVERNMENT REGULATIONS, WE MAY NOT BE ABLE TO MARKET OUR PRODUCTS AND MAY BE SUBJECT TO STRINGENT PENALTIES

Except for Angiomax, which has been approved for sale in the United States and New Zealand, we do not have another product approved for sale in the United States or any foreign market. We must obtain approval from the FDA in order to sell our product candidates in the United States and from foreign regulatory authorities in order to sell our product candidates in other countries. We must complete our clinical trials successfully and demonstrate manufacturing capability before we can file with the FDA for approval to sell our products. The FDA could require us to repeat clinical trials as part of the regulatory review process. Delays in obtaining or failure to obtain regulatory approvals may:

- delay or prevent the successful commercialization of any of our product candidates;

- diminish our competitive advantage; and

- defer or decrease our receipt of revenues or royalties.

The regulatory review and approval process is lengthy, expensive and uncertain. Extensive pre-clinical data, clinical data and supporting information must be submitted to the FDA for each additional indication to obtain such approvals, and we cannot be certain when we will receive these regulatory approvals, if ever.

In addition to initial regulatory approval, our products and product candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation. Any approvals, once obtained, may be withdrawn if compliance with regulatory requirements is not maintained or safety problems are identified. Failure to comply with these requirements may also subject us to stringent penalties.

WE MAY NOT BE ABLE TO OBTAIN OR MAINTAIN PATENT PROTECTION FOR OUR PRODUCTS, AND WE MAY INFRINGE THE PATENT RIGHTS OF OTHERS

The patent positions of pharmaceutical and biotechnology companies like us are generally uncertain and involve complex legal, scientific and factual issues. Our success depends significantly on our ability to:

- obtain U.S. and foreign patents;

- protect trade secrets;

- operate without infringing the proprietary rights of others; and

- prevent others from infringing our proprietary rights.

We may not have any patents issued from any patent applications that we own or license. If patents are granted, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We exclusively license U.S. patents and patent applications and corresponding foreign patents and patent applications relating to Angiomax, IS-159 and CTV-05. In all, as of the date hereof, we exclusively license nine issued U.S. patents. The principal U.S. patent that covers Angiomax expires in 2010. The U.S. Patent and Trademark Office has rejected our application for an extension of the term of the patent beyond 2010 because the application was not filed on time. We filed the application in connection with FDA approval of Angiomax. We are exploring an alternative to extend the term of the patent, but we can provide no assurance that we will be successful. We have not yet filed any independent patent applications.

We may not hold proprietary rights to some patents related to our product candidates. In some cases, others may own or control these patents. As a result, we may be required to obtain licenses under third-party patents to market some of our product candidates. If licenses are not available to us on acceptable terms, we will not be able to market these products.

We may become a party to patent litigation or other proceedings regarding intellectual property rights. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. If any patent litigation or other intellectual property proceeding in which we are involved is resolved unfavorably to us, we may be enjoined from manufacturing or selling our products without a license from the other party, and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms, or at all.

IF WE ARE NOT ABLE TO KEEP OUR TRADE SECRETS CONFIDENTIAL, OUR TECHNOLOGY AND INFORMATION MAY BE USED BY OTHERS TO COMPETE AGAINST US

We rely significantly upon unpatented proprietary technology, information, processes and know-how. We seek to protect this information by confidentiality agreements with our employees, consultants and other third-party contractors, as well as through other security measures. We may not have adequate remedies for

any breach by a party to these confidentiality agreements. In addition, our competitors may learn or independently develop our trade secrets.

WE COULD BE EXPOSED TO SIGNIFICANT LIABILITY CLAIMS IF WE ARE UNABLE TO OBTAIN INSURANCE AT ACCEPTABLE COSTS AND ADEQUATE LEVELS OR OTHERWISE PROTECT OURSELVES AGAINST POTENTIAL PRODUCT LIABILITY CLAIMS

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of human healthcare products. Product liability claims might be made by patients in clinical trials, consumers, health care providers or pharmaceutical companies or others that

sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or otherwise possess regulatory approval for commercial sale.

These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. As of the date hereof, we are covered, with respect to our commercial sales in the United States and New Zealand and our clinical trials, by primary product liability insurance in the amount of $20.0 million per occurrence and $20.0 million annually in the aggregate on a claims-made basis. This coverage may not be adequate to cover any product liability claims.

As we commercialize our products, we may wish to increase our product liability insurance. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance on reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims.

OUR ABILITY TO GENERATE FUTURE REVENUE FROM PRODUCTS WILL DEPEND ON REIMBURSEMENT AND DRUG PRICING

Acceptable levels of reimbursement of the cost of developing and manufacturing of drugs and treatments related to those drugs by government authorities, private health insurers and other organizations will have an effect on the successful commercialization of, and attracting collaborative partners to invest in the development of, our product candidates. We cannot be sure that reimbursement in the United States or elsewhere will be available for any products we may develop or, if already available, will not be decreased in the future. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products, and may not be able to obtain a satisfactory financial return on our products.

Third-party payors increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States and the changes in health insurance programs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including any products that may be offered by us in the future. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect our ability to sell any products that are successfully developed by us and approved by regulators. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

RISKS RELATED OWNERSHIP OF OUR COMMON STOCK

VOLATILITY OF OUR STOCK PRICE COULD CAUSE YOU TO LOSE ALL OR PART OF YOUR INVESTMENT

The market price of our common stock, like that of the common stock of many other biotechnology companies, may be highly volatile. The stock market in general has recently experienced extreme price and volume fluctuations, and this volatility has affected the market prices of securities of many biotechnology and pharmaceutical companies for reasons frequently unrelated, or disproportionate, to the operating performance of those companies. The market price of our common stock may fluctuate significantly in response to the following factors, some of which are beyond our control:

- changes in securities analysts' estimates of our financial performance;
- changes in market valuations of similar companies;
- variations in our quarterly operating results;
- acquisitions and strategic partnerships;
- announcements of technological innovations or new commercial products by us or our competitors;
- disclosure of results of clinical testing or regulatory proceedings;
- changes in our management;
- broad fluctuations in stock market prices and volume; and
- general economic conditions, including inflation and unemployment rates.

Investors may not be able to resell their shares of our common stock following periods of volatility because of the market's adverse reaction to the volatility. We cannot assure you that our stock will trade at the same levels as the stock of other companies in our industry or that the market in general will sustain its current prices.

FUTURE SALES OF COMMON STOCK BY OUR EXISTING STOCKHOLDERS COULD CAUSE OUR STOCK PRICE TO FALL

Sales of substantial amounts of our common stock in the public market, or the perception that those sales could occur, could adversely affect the market price of our common stock and could materially impair our future ability to raise capital through offerings of our common stock.

OUR OFFICERS AND DIRECTORS AND THEIR AFFILIATES MAY BE ABLE TO CONTROL THE OUTCOME OF MOST CORPORATE ACTIONS REQUIRING STOCKHOLDER APPROVAL

As of the date hereof, our directors and executive officers and their affiliates beneficially own approximately 35% of our common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

OUR CORPORATE DOCUMENTS AND PROVISIONS OF DELAWARE LAW MAY PREVENT A CHANGE IN CONTROL OR MANAGEMENT THAT STOCKHOLDERS MAY CONSIDER DESIRABLE

Section 203 of the Delaware General Corporation Law and our charter and by-laws contain provisions that might enable our management to resist a takeover of our company. These provisions could have the effect of delaying, deferring, or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock.

ITEM 7. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS.

(c) Exhibits.

Exhibit No.	Description
1.1	Underwriting Agreement, dated as of June 20, 2002, by and between the Registrant and Bear, Stearns & Co. Inc.
5.1	Opinion of Hale and Dorr LLP.
23.1	Consent of Hale and Dorr LLP (included in Exhibit 5.1).
99.1	Press release dated June 20, 2002.

SIGNATURE

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

Date: June 25, 2002 THE MEDICINES COMPANY

By: /s/ Steven H. Koehler
Steven H. Koehler
Vice President and Chief Financial Officer

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