

CURIS INC  
Form S-3  
September 05, 2003  
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As filed with the Securities and Exchange Commission on September 5, 2003

Registration Statement No. 333-

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM S-3**  
**REGISTRATION STATEMENT**

*UNDER*  
*THE SECURITIES ACT OF 1933*

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**CURIS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of incorporation or organization)

61 Moulton Street

Cambridge, Massachusetts 02138

617-503-6500

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**04-3505116**  
(I.R.S. employer identification number)

**Daniel R. Passeri**

**President and Chief Executive Officer**

**61 Moulton Street**

**Cambridge, Massachusetts 02138**

**(617) 503-6500**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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*Copy to:*

**Steven D. Singer, Esq.**

**Hale and Dorr LLP**

**60 State Street**

**Boston, Massachusetts 02109**

**Telephone: (617) 526-6000**

**Telecopy: (617) 526-5000**

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**Approximate date of commencement of proposed sale to public:** As soon as practicable after this 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. "

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. " 333- .

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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. " 333- .

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

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### CALCULATION OF REGISTRATION FEE

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| Title of Each Class of Securities to be Registered | Amount to be Registered | Proposed Maximum Offering Price Per Share(1) | Proposed                            | Amount of Registration Fee |
|--|-------------------------|--|-------------------------------------|----------------------------|
|  |                         |  | Maximum Aggregate Offering Price(1) |                            |
| Common Stock, \$0.01 par value per share           | 8,525,807               | \$3.44                                       | \$29,328,776                        | \$2,373                    |

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- (1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act and based upon the average of the high and low prices on the NASDAQ National Market on August 29, 2003.
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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), shall determine.

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**The information in this prospectus is not complete and may be changed. The selling stockholders named in this prospectus 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 the selling stockholders named in this prospectus are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED SEPTEMBER 5, 2003**

**PROSPECTUS**

# **CURIS, INC.**

## **8,525,807 SHARES OF COMMON STOCK**

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This prospectus relates to resales of common stock, including shares of common stock underlying warrants and a convertible promissory note, that we issued and sold to the selling stockholders listed on page 15. We will not receive any of the proceeds from the sale of the shares by the selling stockholders.

The selling stockholders identified in this prospectus, or their pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

Our common stock is traded on the NASDAQ National Market under the symbol CRIS. On September 4, 2003, the closing sale price of the common stock on NASDAQ was \$3.97 per share. You are urged to obtain current market quotations for the common stock.

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**Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 4.**

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**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 date of this prospectus is \_\_\_\_\_, 2003.**

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**PROSPECTUS SUMMARY**

*This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under Risk Factors.*

**WHO WE ARE**

Curis, Inc. ( we , our , us or the Company ) is a therapeutic drug discovery and development company. Our technology focus is on regulatory signaling pathways that control repair and regeneration of human tissue and organs. Our product development approach involves using proteins or small molecules to modulate these regulatory signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive. We have successfully used this product discovery and development approach to produce several promising protein and small-molecule based product candidates in the fields of kidney disease, neurological disorders, cancer and hair loss.

Each cell in our body is programmed during fetal development to respond to a specific set of signals. These signaling pathways act like switches to determine how the cells will behave. The signaling pathways in our cells that are active during early human development are often the same pathways the body calls on in adulthood to maintain physiological balance and to repair and regenerate tissue. Through our research we have developed an understanding of the biological signaling pathways that the body uses to promote repair and regeneration. We have used this information to find ways of modulating and controlling these signals to promote therapeutic benefit.

We have developed a significant intellectual property portfolio related to several major signaling pathways, including the Hedgehog, or Hh, pathway and the Bone Morphogenetic Protein-7, or BMP-7, pathway. Both of these pathways are prominent regulators of cell tissue and organ formation throughout human development and adulthood.

We currently are a party to collaborations and strategic relationships with Ortho Biotech, a subsidiary of Johnson & Johnson, and Genentech. We have also outlicensed certain of our technologies to Amylin Pharmaceuticals and ES Cell International. We have also established a broad intellectual property position relating to our technology, as well as our therapeutic product candidates.

We were organized in 2000 and are incorporated in Delaware. Our principal executive office is located at 61 Moulton Street, Cambridge, Massachusetts, 02138 and our telephone number is (617) 503-6500. We maintain a website with the address [www.curis.com](http://www.curis.com). We are not including the information contained in our website as part of, or incorporating it by reference into, this prospectus. Our web site address is included in this prospectus as an inactive textual reference only.

Curis is our trademark. This prospectus and the documents we incorporate by reference into this prospectus also contain trademarks and trade names of others.

**THE OFFERING**

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Common Stock offered by selling stockholders

8,525,807 shares

Use of proceeds

Curis will not receive any proceeds from the sale of shares by the selling stockholders in this offering

NASDAQ National Market symbol

CRIS



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**RISK FACTORS**

*If you purchase shares of our common stock, you will assume a high degree of risk. In deciding whether to invest, you should carefully consider the following risk factors, as well as the other information contained in this prospectus and in the documents we incorporate by reference into this prospectus. Any of the following risks as well as other risks and uncertainties discussed in this prospectus and in the documents we incorporated by reference into this prospectus could have a material adverse effect on our business, financial condition, results of operations or prospects and cause the value of our stock to decline, which could cause you to lose all or part of your investment. The risks and uncertainties described below are also not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that are currently deemed immaterial, also may become important factors that affect us.*

**RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING**

**We have incurred substantial losses, we expect to continue to incur substantial losses and we may never achieve profitability.**

We expect to incur substantial operating losses for the foreseeable future and we have no current sources of material ongoing revenue. It is uncertain when, if ever, we will develop significant sources of ongoing revenue or achieve profitability, even if we are able to develop and commercialize products.

We expect to spend significant capital to fund our research and development programs for the foreseeable future. As a result, we will need to generate significant revenues in order to achieve profitability. We cannot be certain whether or when this will occur because of the significant uncertainties that affect our business.

**We may require additional financing, which may be difficult to obtain and may dilute your ownership interest in us.**

We will require substantial funds to continue our research and development programs. Our future capital requirements will depend on many factors, including the following:

continued progress in our research and development programs, as well as the magnitude of these programs;

the cost of additional facilities requirements, if any;

the timing, receipt and amount of milestone and other payments, if any, from collaborative partners;

the timing, payment and amount of milestone license, royalty payments, research funding and royalties due to licensors of patent rights and technology used to make, use and sell our product candidates, if any;

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the timing, receipt and amount of sales revenues and royalties, if any, from our product candidates in the market;

the cost of manufacturing and commercialization activities; and

the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and technology license fees.

In 2003, we expect to seek additional funding through collaborative arrangements with strategic partners and may seek additional funding through public or private financings. The biotechnology market, however, is highly volatile and, depending on market conditions and the status of our development pipeline, additional

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funding may not be available to us on acceptable terms, if at all. If we fail to obtain such additional financing on a timely basis, our ability to continue all of our research, development, commercialization, manufacturing and marketing activities will be adversely affected.

If we raise additional funds by issuing equity securities, dilution to our stockholders will result. In addition, the terms of such a financing may adversely affect other rights of our stockholders. We also could elect to seek funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain technologies, product candidates or products.

If the estimates we make, and the assumptions on which we rely, in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. There can be no assurance, however, that our estimates, or the assumptions underlying them, will be correct. Our actual financial results may vary significantly from the estimates contained in our financial statements.

## **RISKS RELATING TO OUR COLLABORATIONS**

**We are dependent on collaborative partners for the development and commercialization of many of our product candidates. Any failure or delay by these partners in developing or commercializing our product candidates could eliminate significant portions of our anticipated product pipeline.**

The success of our strategy for development and commercialization of product candidates depends upon our ability to form productive strategic collaborations. We currently have strategic collaborations with Genentech, Inc., Ortho Biotech, Products, L.P., a Johnson & Johnson company, ES Cell International Pte Ltd., and Amylin Pharmaceuticals, Inc. and we expect to enter into additional collaborations in the future. Our existing and any future alliances may not be scientifically or commercially successful.

The risks that we face in connection with these alliances include the following:

Each of our collaborators has significant discretion in determining the efforts and resources that they will apply to the collaboration. The timing and amount of any future royalty and milestone revenue that we may receive under such collaborative arrangements will depend on, among other things, such collaborator's efforts and allocation of resources.

All of our strategic alliance agreements are for fixed terms and are subject to termination under various circumstances, including in some cases, on short notice without cause. If any collaborative partner were to terminate an agreement we may be required to undertake product development, manufacturing and commercialization and we may not have the funds or capability to do this, which could result in a discontinuation of such program.

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Our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products and services that are the subject of the alliance with us.

Our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of certain of our product candidates to reach their potential could be limited if our collaborators decrease or fail to increase spending related to such product candidates.

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**We may not be successful in establishing additional strategic alliances, which could adversely affect our ability to develop and commercialize products and services.**

As an integral part of our ongoing research and development efforts, we periodically review opportunities to establish new collaborations, joint ventures and strategic alliances for the development and commercialization of products in our development pipeline. We face significant competition in seeking appropriate collaborators. Moreover, these alliance arrangements are complex to negotiate and time-consuming to document. We may not be successful in our efforts to establish additional strategic alliances or other alternative arrangements. The terms of any additional alliances or other arrangements that we establish may not be favorable to us. Moreover, such strategic alliances or other arrangements may not be successful.

## **RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS**

**We have not commercialized any products to date. If we are not able to commercialize any products, we will not be profitable.**

All of our product opportunities are in various stages of preclinical development. Because our product opportunities have several years of development prior to reaching commercialization, there is a substantial risk that none of our current product opportunities will ever be commercialized. If none of our product opportunities are commercialized, we will not be profitable.

**We face substantial competition, which may result in our competitors discovering, developing or commercializing products before or more successfully than we do.**

Our product candidates face competition with existing and new products being developed by biotechnology, medical device and pharmaceutical companies, as well as universities and other research institutions. Many of our competitors have substantially greater capital resources, research and development staffs and facilities than we have. Efforts by other biotechnology, medical device and pharmaceutical companies could render our programs or products uneconomical or result in therapies superior to those that we and our collaborative partners develop. Furthermore, many of our competitors are more experienced in product development and commercialization, obtaining regulatory approvals and product manufacturing. As a result, they may develop competing products more rapidly and at a lower cost. These competitors may discover, develop and commercialize products which render the products that we or our collaborative partners are seeking to develop and commercialize non-competitive or obsolete.

For example, research in the fields of regulatory signaling pathways and functional genomics, which includes our work in oncology and renal disease, is highly competitive. A number of entities are seeking to identify and patent randomly sequenced genes and gene fragments, typically without specific knowledge of the function that such genes or gene fragments perform. Our competitors may discover, characterize and develop important inducing molecules or genes in advance of us. We also face competition from these and other entities in gaining access to DNA samples used in our research and development projects. We expect competition to intensify in genomics research and regulatory signaling pathways as technical advances in the field are made and become more widely known.

**Since our technologies have many potential applications and we have limited resources, our election to focus on a particular application may result in our failure to capitalize on other potentially profitable applications of our technologies.**

We have limited financial and managerial resources. These limitations require us to focus on a select group of product candidates in specific therapeutic areas and to forego the exploration of other product opportunities. For example, a decision to concentrate on a particular indication within our neurology program may mean that

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we will not be able to allocate sufficient resources to fully exploit several different indications within our neurology program. While our technologies may permit us to work in both areas, resource commitments may require trade-offs resulting in delays in the development of certain programs or research areas, which may place us at a competitive disadvantage. Our decisions as to resource allocation may not lead to the development of viable commercial products and may divert resources away from other market opportunities which ultimately proved to be more profitable.

**If any of our product candidates ever receive regulatory approval for commercialization, the market may not be receptive to such products due to their use of new technologies or cost. Such a lack of reception would adversely affect expected revenues.**

If any of our product opportunities ever receive regulatory approval, the commercial success of these products will depend upon their acceptance by patients, the medical community and third-party payors. Our future products, if any are successfully developed, may not gain commercial acceptance among physicians, patients and third-party payors, even if necessary marketing approvals have been obtained. We believe that recommendations and endorsements by physicians will be essential for market acceptance of our products. If we are not able to obtain a positive reception for our products, our expected revenues from sales of these products would be adversely affected.

**We could be exposed to significant risk from liability claims if we are unable to obtain insurance at acceptable costs or otherwise protect ourselves against potential product liability claims.**

We may be subjected to product liability claims arising from the testing, manufacturing, marketing and sale of human health care products. Product liability claims, inherent in the process of researching and developing human health care products, could expose us to significant liabilities and prevent or interfere with the development or commercialization of our product candidates. Product liability claims would require us to spend significant time, money and other resources to defend such claims and could ultimately lead to our having to pay a significant damage award. Product liability insurance is expensive to procure for biopharmaceutical companies such as ours. Although we maintain product liability insurance coverage for the clinical trials of our products under development, it is possible that we will not be able to obtain additional product liability insurance on acceptable terms, if at all, and that our product liability insurance coverage will not prove to be adequate to protect us from all potential claims.

**Our growth could be limited if we are unable to attract and retain key personnel and consultants.**

Our success depends on the ability to attract, train and retain qualified scientific and technical personnel to further our research and development efforts. The loss of services of one or more of our key employees or consultants could have a negative impact on our business and operating results. Competition for hiring personnel in the biotechnology industry is intense and locating candidates with the appropriate qualifications can be difficult. Although we expect to be able to attract and retain sufficient numbers of highly skilled employees for the foreseeable future, we may not be able to do so.

Any growth and expansion into areas and activities that may require additional human resources or expertise, such as regulatory affairs, compliance, manufacturing and marketing, would require us to hire new key personnel. The pool of personnel with the skills that we require is limited. Competition to hire from this limited pool is intense, and we may not be able to hire, train, retain or motivate such additional personnel.

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**RISKS RELATING TO CLINICAL AND REGULATORY MATTERS**

**We expect to rely heavily on third parties for the conduct of clinical trials of our product candidates. If these clinical trials are not successful, or if we are not able to obtain the necessary regulatory approvals, we will not be able to complete development and commercialization of our product candidates.**

In order to obtain regulatory approval for the commercial sale of our product candidates, we will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our product candidates are safe and effective. We have limited experience in conducting clinical trials and expect to rely primarily on contract research organizations and collaborative partners for their performance and management of clinical trials of our product candidates.

Clinical development, including preclinical testing, is a long, expensive and uncertain process. Accordingly, clinical trials, if any, of our product candidates under development may not be successful. We could experience delays in preclinical or clinical trials of any of our product candidates, obtain unfavorable results in a development program, or fail to obtain regulatory approval for the commercialization of a product. Furthermore, the timing and completion of clinical trials, if any, of our product candidates depend on, among other factors, the numbers of patients required for approval and the rate at which those patients are enrolled. Any increase in the required number of patients or decrease in recruitment rates may result in increased costs, program delays or both. Also, our products under development may not be effective in treating any of our targeted disorders or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use. Any of these events would adversely affect our ability to market a product candidate.

**The development process necessary to obtain regulatory approval is lengthy, complex and expensive and we may not obtain necessary regulatory approvals.**

We and our collaborative partners are required to obtain regulatory approval for our development activities and, in the future, our marketing and selling efforts. If we are unable to navigate the complexities of dealing with the several interested regulatory agencies, we and our collaborative partners may not receive the necessary approvals to conduct clinical trials of our product candidates or to market and sell our product candidates. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals. Delays in obtaining, or failure to obtain, necessary approvals could adversely affect our ability to market and sell our products and our ability to generate product revenue.

The process of obtaining FDA and other required regulatory approvals is lengthy and expensive. The time required for FDA and other approvals is uncertain and typically takes a number of years, depending on the complexity and novelty of the product. The process of obtaining FDA and other required regulatory approvals for many of our products under development is further complicated because some of these products use non-traditional or novel materials in non-traditional or novel ways, and the regulatory officials have little precedent to follow. We have only limited experience in filing and prosecuting applications for the conduct of clinical studies and for obtaining marketing approval. Any delay in obtaining or failure to obtain required clearance or approvals would reduce our ability to generate revenues from the affected product. We also plan to rely significantly on contract research organizations and collaborative partners as we build internal capabilities.

Our analysis of data obtained from preclinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may restrict the size of the market for the product and affect reimbursement by third party payors.



We also are subject to numerous foreign regulatory requirements governing the design and conduct of the clinical trials and the manufacturing and marketing of our potential future products outside of the United States.

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The approval procedure varies among countries and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries, and vice versa.

**Even if we obtain marketing approval, our products will be subject to ongoing regulatory oversight which may affect our ability to successfully commercialize any products we may develop.**

Even if we receive regulatory approval of a product candidate, the approval may be subject to limitations on the indicated uses for which the product is marketed or require costly post-marketing follow-up studies. After we obtain marketing approval for any product, the manufacturer and the manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA and other regulatory agencies. The subsequent discovery of previously unknown problems with the product, or with the manufacturer or facility, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

**We are subject to governmental regulations other than those imposed by the FDA. We may not be able to comply with these regulations, which could subject us to penalties and otherwise result in the limitation of our operations.**

In addition to regulations imposed by the FDA, we are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, as well as regulations administered by the Nuclear Regulatory Commission, national restrictions on technology transfer, import, export and customs regulations and certain other local, state or federal regulation. From time to time, other federal agencies and congressional committees have indicated an interest in implementing further regulation of biotechnology applications. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we would be able to comply with any applicable regulations.

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for handling and disposing of such materials comply with all applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury caused by these materials.

## **RISKS RELATING TO PRODUCT MANUFACTURING AND SALES**

**We will depend on third-party manufactures to produce most, if not all, of our products under development, and if these third parties do not successfully manufacture these products our business will be harmed.**

If we receive the necessary regulatory approvals for our products under development, we expect to rely upon third parties, including our collaborative partners, to produce materials required for commercial production. We may not be able to enter into commercial-scale manufacturing contracts on a timely or commercially reasonable basis, if at all. To the extent that we enter into manufacturing arrangements

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with third parties, we will be dependent upon these third parties to perform their obligations in a timely and effective manner. If third-party manufacturers with whom we contract fail to perform their obligations our competitive position and ability to generate revenue may be adversely affected in a number of ways, including;

we may not be able to initiate or continue clinical trials of products that are under development;

we may be delayed in submitting applications for regulatory approvals for our product candidates; and

we may not be able to meet commercial demands for any approved products.

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**We have no sales and marketing experience and, as such, will depend significantly on third parties who may not successfully sell our products.**

We have no sales, marketing and product distribution experience. We plan to rely solely on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, as part of our agreements with Genentech and Ortho Biotech, we have granted our collaborators exclusive rights to distribute certain products resulting from such collaborations, if any are ever successfully developed. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these additional arrangements on terms which are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

We may seek to independently market products that are not already subject to marketing agreements with other parties. If we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

we may not be able to attract and build a significant and skilled marketing staff or sales force;

the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular product; and

our direct sales and marketing efforts may not be successful.

**If we fail to obtain an adequate level of reimbursement for our future products from third-party payors such as Medicare or insurance companies, there may be no commercially viable markets for our products.**

The availability of reimbursement by governmental and other third-party payors for future products affects the market viability of any pharmaceutical product. These governmental and third-party payors persistently try to limit the costs of healthcare by exerting downward pressure on the prices for pharmaceutical products. The net effect of this downward pressure can be reduced availability of reimbursement by governmental and other third-party payors. In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. We or our partners may not be able to sell our products profitably if reimbursement is unavailable or limited in scope or amount.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system. Further proposals are likely. The potential for adoption of some or all of these proposals affects or will affect our ability to raise capital, obtain additional collaborative partners and to market our products.

If we or our collaborative partners obtain marketing approval for our products, we expect to experience pricing pressure due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

**RISKS RELATING TO INTELLECTUAL PROPERTY**

**We may not be able to obtain patent protection for our discoveries and our technologies may be found to infringe patent rights of third parties.**

The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions.

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The long-term success of our enterprise depends in significant part on our ability to:

- obtain patents to protect our discoveries;
- protect trade secrets from disclosure to third-party competitors;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

Patents may not issue from any of the patent applications that we own or license. If patents do issue, the allowed claims may not be sufficiently broad to protect our technology from exploitation by our competitors. 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 are maintained in secrecy until 18 months after filing, it is possible that third parties have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our knowledge.

We may not have rights under patents which may cover one or more of our product candidates. In some cases, these patents may be owned or controlled by third party competitors and may impair our ability to exploit our technology. As a result, we or our collaborative partners may be required to obtain licenses under third-party patents to develop and commercialize some of our product candidates. If we are unable to secure licenses to such patented technology on acceptable terms, we or our collaborative partners will not be able to develop and commercialize the affected product candidate or candidates.

### **If we are unable to keep our trade secrets confidential, our technology and information may be used by others to compete against us.**

We also rely significantly upon unpatented proprietary technology, information, processes and know-how. We seek to protect this information through confidentiality agreements with our employees, consultants and other third-party contractors as well as through other security measures. These confidentiality agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

### **We may become involved in expensive patent litigation or other intellectual property proceedings which could result in liability for damages or stop our development and commercialization efforts.**

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

Situations which may give rise to patent litigation or other disputes over the use of our intellectual property include:

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initiation of litigation or other proceedings against third parties to enforce our patent rights;

initiation of litigation or other proceedings against third parties to seek to invalidate the patents held by these third parties or to obtain a judgment that our product candidates or proposed services do not infringe the third parties' patents;

participation in interference or opposition proceedings to determine the priority of invention if our competitors file patent applications that claim technology also claimed by us;

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initiation of litigation by third parties claiming that our processes or product candidates or the intended use of our product candidates infringe their patent or other intellectual property rights; and

initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property which may be important to our business.

The costs associated with any patent litigation or other proceeding, even if resolved favorably, likely would be substantial. Some of our competitors may be able to sustain the cost of such litigation or other proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved unfavorably, we or our collaborative partners may be enjoined from manufacturing or selling our products and services without a license from the other party and be held liable for significant damages. Moreover, we may not be able to obtain required licenses on commercially acceptable terms or any terms at all. In addition, we could be held liable for lost profits if we are found to have infringed a valid patent, or liable for treble damages if we are found to have willfully infringed a valid patent. Litigation results are highly unpredictable and we or our collaborative partners may not prevail in any patent litigation or other proceeding in which we may become involved.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could damage our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time and expense.

**If we breach any of the agreements under which we license or have acquired intellectual property from others, we could lose intellectual property rights that are important to our business.**

We are a party to intellectual property licenses and agreements that are important to our business and expect to enter into similar licenses and agreements in the future. These licenses and agreements impose various research, development, commercialization, sublicensing, royalty, indemnification, insurance and other obligations on us. If we fail to perform under these agreements or otherwise breach obligations thereunder, we could lose intellectual property rights that are important to our business.

**If licensees or assignees of our intellectual property rights breach any of the agreements under which we have licensed or assigned our intellectual property to them, we could be deprived of important intellectual property rights and future revenue.**

We are a party to intellectual property out-licenses, collaborations and agreements that are important to our business and expect to enter into similar agreements with third parties in the future. Under these agreements, we license or transfer intellectual property to third parties and impose various research, development, commercialization, sublicensing, royalty, indemnification, insurance, and other obligations on them. If a third party fails to comply with these requirements, we generally retain the right to terminate the agreement, and to bring a legal action in court or in arbitration. In the event of breach, we may need to enforce our rights under these agreements by resorting to arbitration or litigation. During the period of arbitration or litigation, we may be unable to effectively use, assign or license the relevant intellectual property rights and may be deprived of current or future revenues that are associated with such intellectual property.

## **RISKS RELATED TO OUR SECURITIES**

**We expect that our stock price will fluctuate significantly and the market price of our common stock could fall significantly.**



The trading price of our common stock has been volatile and may continue to be volatile in the future. For example, our stock price has traded as high as \$5.60 and as low as \$0.76 in the quarter ended June 30, 2003. The stock market, particularly in recent years, has experienced significant volatility particularly with respect to

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biopharmaceutical- and biotechnology-based company stocks. The volatility of biopharmaceutical- and biotechnology-based company stocks often does not relate to the operating performance of the companies represented by the stock. Prices for our stock will be determined in the market place and may be influenced by many factors, including:

announcements regarding new technologies by us or our competitors;

market conditions in the biotechnology sectors;

rumors relating to us or our competitors;

litigation or public concern about the safety of our potential products;

actual or anticipated variations in our quarterly operating results;

deviations in our operating results from the estimates of securities analysts;

adverse results or delays in clinical trials;

FDA or international regulatory actions; and

general market conditions.

While we cannot predict the individual effect that these factors may have on the price of our common stock, these factors, either individually or in the aggregate, could result in significant variations in price during any given period of time. Moreover, in the past securities class action litigation has often been instituted against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources.

**Our common stock may be delisted from The NASDAQ National Market, which could reduce the liquidity of our common stock and adversely affect our ability to raise additional necessary capital.**

In order to continue trading on The NASDAQ National Market, we must comply with The NASDAQ National Market's continued listing requirements, which require that we either maintain a minimum stockholders' equity of \$10.0 million and a minimum closing bid price of \$1.00 per share or, if we fall below the minimum stockholder's equity requirement, maintain a minimum closing bid price of \$3.00 per share.

We currently are in compliance with The NASDAQ National Market's continued listing requirements. However, if in the future we fail to satisfy The NASDAQ National Market's continued listing requirements, our common stock may be delisted from The NASDAQ National Market. The delisting of our common stock may result in the trading of the stock on the NASDAQ SmallCap Market or the OTC Bulletin Board.

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Consequently, a delisting of our common stock from The NASDAQ National Market may reduce the liquidity of our common stock and adversely affect our ability to raise capital.

**We have anti-takeover defenses that could delay or prevent an acquisition that our stockholders may consider favorable and the market price of our common stock may be lower as a result.**

Provisions of our certificate of incorporation, our bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing changes in control of our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. For example, we have divided our board of directors into three classes that serve staggered three-year terms, we may issue shares of our authorized blank check preferred stock and our stockholders are limited in their ability to call special stockholder meetings.

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In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our class A common stock. These provisions may also prevent changes in our management.

### **SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION**

This prospectus includes and incorporates forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical facts, included or incorporated in this prospectus regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included or incorporated in this prospectus, particularly under the heading **Risk Factors**, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements.

### **USE OF PROCEEDS**

We will not receive any proceeds from the sale of shares by the selling stockholders.

The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, NASDAQ National Market listing fees and fees and expenses of our counsel and our accountants.

**Table of Contents****SELLING STOCKHOLDERS**

We are registering for resale on behalf of the selling stockholders named below 8,525,807 shares of common stock. Of these shares, 4,666,610 shares of common stock, including 1,076,910 shares of common stock underlying warrants, were issued in a private placement in August 2003. The remaining 3,859,197 shares of common stock, including 50,000 shares of common stock underlying a warrant and 383,967 shares of common stock underlying a convertible promissory note, were issued in connection with the formation and subsequent dissolution of a corporate joint venture transaction with Elan Corporation plc and its affiliates, as further described below. Beneficial ownership is determined in accordance with the rules of the SEC, and includes voting or investment power with respect to shares. Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the person named below.

We do not know when or in what amounts a selling stockholder may offer shares for sale. The selling stockholders might not sell any or all of the shares offered by this prospectus. Because the selling stockholders may offer all or some of the shares pursuant to this offering, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, we cannot estimate the number of the shares that will be held by the selling stockholders after completion of the offering. However, for purposes of this table, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders.

The following table sets forth, to our knowledge, certain information about the selling stockholders. To our knowledge, except as noted on this paragraph, none of the selling stockholders has held any position or office with or, has otherwise had a material relationship with us within the past three years. Elan International Services, Ltd. is an affiliate of Elan Corporation, plc. In May 2003, we terminated a joint venture with Elan and its affiliates which we had previously entered into in July 2001.

| Name of Selling Stockholder              | Shares of Common Stock Beneficially Owned Prior to Offering |  |       | Number of Shares of Common Stock Being Offered |   |            |                                  |           | Shares of Common Stock to be Beneficially Owned After Offering |   |
|--|---|--|-------|--|---|------------|----------------------------------|-----------|--|---|
|  | Common Stock  | Common Stock Issuable Upon Exercise of Warrants or Notes | % (4) | Common Stock                                   | Common Stock Issuable Upon Exercise of Warrants |            | Total Common Stock Being Offered | Number    | % (4)  |   |
|  |   |  |       |  | (+)   | (=)        |                                  |           |  |   |
| CLSP II, LP                              | 275,151   | 82,545   | *     | 275,151  |   | 82,545     |                                  | 357,696   | 0  | * |
| CLSP Overseas, Ltd.                      | 229,775   | 68,933   | *     | 229,775  |   | 68,933     |                                  | 298,708   | 0  | * |
| CLSP SBS-I, LP                           | 119,744   | 35,923   | *     | 119,744  |   | 35,923     |                                  | 155,667   | 0  | * |
| CLSP SBS-II, LP                          | 41,186  | 12,356   | *     | 41,186   |   | 12,356     |                                  | 53,542    | 0  | * |
| CLSP, LP                                 | 320,994   | 96,298   | 1.0%  | 320,994  |   | 96,298     |                                  | 417,292   | 0  | * |
| Cougar Trading, LLC                      | 70,800  | 19,740   | *     | 65,800   |   | 19,740     |                                  | 85,540    | 0  | * |
| Elan International Services, Ltd.        | 3,425,230   | 433,967  | 9.7%  | 3,425,230                                      |   | 433,967(1) |                                  | 3,859,197 | 0  | * |
| Mainfield Enterprises, Inc. (2)          | 806,875   | 240,000  | 2.6%  | 800,000  |   | 240,000    |                                  | 1,040,000 | 0  | * |
| Portside Growth and Opportunity Fund (3) | 164,400   | 49,320   | *     | 164,400  |   | 49,320     |                                  | 213,720   | 0  | * |
| Proximity Fund, LP                       | 100,000   | 30,000   | *     | 100,000  |   | 30,000     |                                  | 130,000   | 0  | * |
| Proximity Partners, LP                   | 100,000   | 30,000   | *     | 100,000  |   | 30,000     |                                  | 130,000   | 0  | * |
| RHP Master Fund, Ltd.                    | 65,800  | 19,740   | *     | 65,800   |   | 19,740     |                                  | 85,540    | 0  | * |
| SDS Merchant Fund, LP                    | 328,950   | 98,685   | 1.1%  | 328,950  |   | 98,685     |                                  | 427,635   | 0  | * |

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|   |         |        |      |         |        |         |   |   |
|---|---------|--------|------|---------|--------|---------|---|---|
| Smithfield Fiduciary LLC                    | 328,950 | 98,685 | 1.1% | 328,950 | 98,685 | 427,635 | 0 | * |
| UBS O Connor LLC                            |         |        |      |         |        |         |   |   |
| f/b/o PIPES Corporate<br>Strategies Limited | 170,000 | 51,000 | *    | 170,000 | 51,000 | 221,000 | 0 | * |

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| Name of Selling<br>Stockholder        | Shares of<br>Common Stock<br>Beneficially Owned<br>Prior to Offering |  |       | Number of Shares of<br>Common Stock Being Offered |     |  |     | Shares of<br>Common Stock<br>to be Beneficially<br>Owned After<br>Offering |        |       |
|---------------------------------------|--|--|-------|---|-----|--|-----|--|--------|-------|
|                                       | Common<br>Stock  | Common<br>Stock Issuable<br>Upon Exercise<br>of Warrants<br>or Notes | % (4) | Common<br>Stock                                   | (+) | Common<br>Stock Issuable<br>Upon Exercise<br>of Warrants<br>or Notes | (-) | Total<br>Common<br>Stock Being<br>Offered                                  | Number | % (4) |
|                                       |  |  |       |   |     |  |     |  |        |       |
| URSUS Capital, L.P.                   | 89,500   | 26,850   | *     | 89,500  |     | 26,850   |     | 116,350  | 0      | *     |
| URSUS Offshore Ltd.                   | 60,500   | 18,150   | *     | 60,500  |     | 18,150   |     | 78,650   | 0      | *     |
| Vertical Ventures<br>Investments, LLC | 328,950  | 98,685   | 1.1%  | 328,950   |     | 98,685   |     | 427,635  | 0      | *     |

\* Less than one percent.

- (1) These shares of common stock are issuable upon the conversion of a \$3 million convertible promissory note held by Elan Pharma International, Ltd., or EPIL, an affiliate of Elan Corporation, plc. This note is convertible, at the option of EPIL, into a number of shares of our common stock that is obtained by dividing the outstanding principal and accrued interest under the note by \$10.00 per share, at any time from July 17, 2003 until its maturity date of July 17, 2007. On the maturity date of the note, unless earlier converted or repaid, we have the option of converting the outstanding principal and any accrued interest into a number of shares of our common stock equal to the outstanding principal and accrued interest divided by the then fair market value of our common stock, determined in accordance with the provisions of the note. EPIL has transferred its right to receive these shares upon conversion to Elan International Services, Ltd., an affiliate of EPIL.
- (2) Pursuant to an investment management agreement, Avi Vigder has voting discretion and investment control over the shares held by Mainfield Enterprises, Inc. Avi Vigder disclaims beneficial ownership of such shares.
- (3) The Investment Advisor to Portside Growth and Opportunity Fund is Ramius Capital Group, LLC. The Managing Member of Ramius Capital Group, LLC is C4S & Co., the Managing Members of which are Peter Cohen, Morgan Stark and Thomas Strauss. As such, Messrs. Cohen, Stark and Strauss may be deemed beneficial owners of such shares. Messrs. Cohen, Stark and Strauss disclaim beneficial ownership of such shares.
- (4) At August 14, 2003, we had 39,916,881 shares of common stock, \$0.01 par value per share, outstanding.

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**PLAN OF DISTRIBUTION**

The selling stockholders may, from time to time, sell any or all of their shares of common stock covered by this prospectus on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sales. The selling stockholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

The selling stockholders may also engage in short sales against the box, puts and calls and other transactions in our securities or derivatives of our securities and may sell or deliver shares in connection with these trades.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders, or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser, in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or



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broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

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The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares of common stock. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling stockholder. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling stockholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholders.

In order to comply with the securities laws of certain states, if applicable, the shares must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We have agreed with the selling stockholders to keep the Registration Statement of which this prospectus constitutes a part effective until the earlier of (i) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the Registration Statement or (ii) such shares may be resold without registration by reason of Rule 144(k) under the Securities Act or any other rule of similar effect.

## **LEGAL MATTERS**

The validity of the shares offered by this prospectus has been passed upon by Hale and Dorr LLP.

## **EXPERTS**

Our audited financial statements as of December 31, 2000 and 2001 and for the years ended December 31, 2000 and December 31, 2001 incorporated by reference in this prospectus, have been audited by Arthur Andersen LLP, independent public accountants, as indicated in their reports with respect thereto, and are included herein in reliance upon Arthur Andersen LLP as experts on auditing and accounting in giving such reports. Arthur Andersen LLP has not consented to the inclusion of their report in this prospectus, and we have not obtained their consent to do

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so in reliance upon Rule 437a of the Securities Act of 1933. Because Arthur Andersen LLP has not consented to the inclusion of their report in this prospectus, you will not be able to recover against Arthur Andersen LLP under Section 11(a) of the Securities act for any untrue statements of a material fact contained in the financial statements audited by Arthur Andersen LLP or any omissions to state a material fact required to be stated therein.

The financial statements as of December 31, 2002 and for the year ended December 31, 2002 incorporated by reference in this Prospectus have been so incorporated by reference in reliance on the report of

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PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND MORE INFORMATION**

We file reports, proxy statements and other documents with the SEC. You may read and copy any document we file at the SEC's public reference room at Judiciary Plaza Building, 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549. You should call 1-800-SEC-0330 for more information on the public reference room. Our SEC filings are also available to you on the SEC's Internet site at <http://www.sec.gov>.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and our common stock, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC's Internet site.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC requires us to incorporate into this prospectus information that we file with the SEC in other documents. This means that we can disclose important information to you by referring to other documents that contain that information. The information incorporated by reference is considered to be part of this prospectus. Information contained in this prospectus and information that we file with the SEC in the future and incorporate by reference in this prospectus automatically updates and supersedes previously filed information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, prior to the sale of all the shares covered by this prospectus.

- (1) Our Annual Report on Form 10-K for the year ended December 31, 2002 as amended by an Amendment No. 1 on Form 10-K/A;
- (2) Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2003 and June 30, 2003;
- (3) Our Current Reports on Form 8-K filed with the SEC on June 3, 2003, July 10, 2003, and August 11, 2003;
- (4) All of our filings pursuant to the Exchange Act after the date of filing the initial registration statement and prior to effectiveness of the registration statement; and
- (5) The description of our common stock contained in our registration statement on Form 8-A dated April 14, 2000, and including any other amendments or reports filed for the purpose of updating that description.

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Information contained in this prospectus supplements, modifies or supersedes, as applicable, the information contained in earlier-dated documents incorporated by reference. Information contained in later-dated documents incorporated by reference supplements, modifies or supersedes, as applicable, the information contained in this prospectus or in earlier-dated documents incorporated by reference.

You may request a copy of these documents, which will be provided to you at no cost, by writing or telephoning us using the following contact information:

Curis, Inc.

61 Moulton Street

Cambridge, MA 02138

Attention: Investor Relations

Telephone: (617) 503-6500

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You should rely only on the information contained in this prospectus, including information incorporated by reference as described above, or any prospectus supplement that we have specifically referred you to. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front of those documents or that any document incorporated by reference is accurate as of any date other than its filing date. You should not consider this prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****1. Item 14. *Other Expenses of Issuance and Distribution.***

The following table sets forth the various expenses to be incurred in connection with the sale and distribution of the securities being registered hereby, all of which will be borne by Curis, Inc. (except any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares). All amounts shown are estimates except the Securities and Exchange Commission registration fee.

|   |            |
|---|------------|
| Filing Fee Securities and Exchange Commission . | \$ 2,373   |
| Legal fees and expenses                         | \$ 150,000 |
| Accounting fees and expenses                    | \$ 8,000   |
|   | <hr/>      |
| Total Expenses                                  | \$ 160,373 |
|   | <hr/>      |

**2. Item 15. *Indemnification of Directors and Officers.***

Article Sixth of the registrant's Certificate of Incorporation provides that no director shall be personally liable the registrant or any of its stockholders for any monetary damages for any breach of fiduciary duty as a director of the registrant, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breach of fiduciary duty.

Article Eighth of the registrant's Certificate of Incorporation provides, in general, that registrant shall indemnify each person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the registrant), by reason of the fact that such person is or was, or has agreed to become, a director or officer of the registrant, or is or was serving or has agreed to serve, at the request of the registrant, as a director, officer or trustee of, or in a similar capacity with, another corporation (including any partially or wholly owned subsidiary of the registrant), partnership, joint venture, trust or other enterprise (including any employee benefit plan), against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any such action, suit or proceeding to the maximum extent permitted by the General Corporation Law of Delaware. The foregoing right of indemnification is in no way be exclusive of any other rights of indemnification to which any such director or officer may be entitled, under any by-law, agreement, vote of directors or stockholders or otherwise.

Section 102 of the Delaware General Corporation Law allows a corporation to eliminate or limit the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase or redemption in violation of Delaware corporate law or obtained an improper personal benefit. Curis has included such a provision in its Certificate of Incorporation.

Section 145 of the Delaware General Corporation Law provides, in general, that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against amounts paid and expenses incurred in connection with an action or proceeding (other than an action by or in the right of the corporation) to which he is or is threatened to be made a party by reason of such position, if such person shall have acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal proceeding, if such person had no reasonable cause to believe his conduct was unlawful; provided that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any

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matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the adjudicating court determines that such indemnification is proper under the circumstances.

The Company maintains a general liability insurance policy which covers certain liabilities of directors and officers of the Company arising out of claims based on acts or omissions in their capacities as directors or officers.

**3. Item 16. Exhibits**

| <b>Exhibit<br/>Number</b> | <b>Description</b>  |
|---------------------------|---|
| 4.1(*)                    | Restated Certificate of Incorporation of the Registrant, as amended to date.                      |
| 4.2(**)                   | Amended and Restated By-Laws of the Registrant.   |
| 4.3(*)                    | Specimen common stock certificate for shares of Common Stock, \$.01 par value, of the Registrant. |
| 5.1                       | Opinion of Hale and Dorr LLP.   |
| 23.1                      | Notice Regarding Consent of Arthur Andersen LLP.  |
| 23.2                      | Consent of PricewaterhouseCoopers LLP.  |
| 23.3                      | Consent of Hale and Dorr LLP (included in Exhibit 5.1).   |
| 24.1                      | Power of Attorney (see page II-4 of this Registration Statement).                                 |

(\*) Incorporated by reference to the Registrant's Joint Proxy Statement-Prospectus on Form S-4 filed June 19, 2000 (File No. 333-32446).

(\*\*) Incorporated by reference to the Registrant's Registration Statement on Form S-1 filed November 29, 2000 (File No. 333-50906).

**4. Item 17. Undertakings.**

*Item 512(a) of Regulation S-K.* 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, as amended (the Securities Act );

(ii) To reflect in the prospectus any facts or events arising after the effective date of this Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this Registration Statement. Notwithstanding the foregoing, any increase or decrease in the 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) if, in the aggregate, the changes in volume

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and price represent no more than 20 percent 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 this Registration Statement or any material change to such information in this Registration Statement;

*provided, however*, that paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to

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the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act ), that are incorporated by reference in this Registration Statement.

(2) That, for the purposes of determining any liability under the Securities Act, each 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 the 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.

*Item 512(b) of Regulation S-K.* The Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this 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.

*Item 512(h) of Regulation S-K.* Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the indemnification provisions described herein, 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 Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such 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 Securities Act and will be governed by the final adjudication of such issue.



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/s/ SUSAN B. BAYH

Director

September 5, 2003

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**Susan B. Bayh**

/s/ JOSEPH M. DAVIE

Director

September 5, 2003

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**Joseph M. Davie**

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| <u>Signature</u>   | <u>Title</u> | <u>Date</u>       |
|--|--------------|-------------------|
| <u>/s/ MARTYN D. GREENACRE</u><br><b>Martyn D. Greenacre</b> | Director     | September 5, 2003 |
| <u>/s/ RUTH B. KUNATH</u><br><b>Ruth B. Kunath</b>           | Director     | September 5, 2003 |
| <u>/s/ DOUGLAS A. MELTON</u><br><b>Douglas A. Melton</b>     | Director     | September 5, 2003 |
| <u>/s/ JAMES R. TOBIN</u><br><b>James R. Tobin</b>           | Director     | September 5, 2003 |

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**EXHIBIT INDEX**

| <b><u>Exhibit<br/>Number</u></b> | <b><u>Description</u></b>   |
|----------------------------------|---|
| 4.1(*)                           | Restated Certificate of Incorporation of the Registrant, as amended to date.                      |
| 4.2(**)                          | Amended and Restated By-Laws of the Registrant.   |
| 4.3(*)                           | Specimen common stock certificate for shares of Common Stock, \$.01 par value, of the Registrant. |
| 5.1                              | Opinion of Hale and Dorr LLP.   |
| 23.1                             | Notice Regarding Consent of Arthur Andersen LLP.  |
| 23.2                             | Consent of PricewaterhouseCoopers LLP.  |
| 23.3                             | Consent of Hale and Dorr LLP (included in Exhibit 5.1).   |
| 24.1                             | Power of Attorney (see page II-4 of this Registration Statement).                                 |

(\*) Incorporated by reference to the Registrant's Joint Proxy Statement-Prospectus on Form S-4 filed June 19, 2000 (File No. 333-32446).

(\*\*) Incorporated by reference to the Registrant's Registration Statement on Form S-1 filed November 29, 2000 (File No. 333-50906).