

INCYTE CORP
Form POS AM
August 23, 2004
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As filed with the Securities and Exchange Commission on August 23, 2004

Registration No. 333-114863

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 1

To

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

INCYTE CORPORATION

(Exact Name of registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

94-3136539
(I.R.S. Employer Identification Number)

Incyte Corporation

Experimental Station

Route 141 & Henry Clay Road

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Building E336

Wilmington, DE 19880

(302) 498-6700

(Address, Including Zip Code, and Telephone Number, Including Area Code, of registrant's Principal Executive Offices)

Paul A. Friedman

Chief Executive Officer

Incyte Corporation

Experimental Station

Route 141 & Henry Clay Road

Building E336

Wilmington, DE 19880

(302) 498-6700

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

With copy to:

Stanton D. Wong

Pillsbury Winthrop LLP

P.O. Box 7880

San Francisco, CA 94120

Telephone: (415) 983-1000

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective, as determined by market conditions and other factors.

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

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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.

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.

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.

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

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Explanatory Note

The Registrant is filing this Post-Effective Amendment No. 1 to Form S-3 Registration Statement to update the table under the caption "Selling Securityholders" in the prospectus contained herein to add and delete the names and respective holdings of certain selling securityholders who have requested such changes.

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

Subject to Completion, Dated August , 2004

PROSPECTUS

\$250,000,000

**3 1/2% Convertible Subordinated Notes due 2011
and Shares of Common Stock Issuable upon Conversion of the Notes**

Incyte Corporation issued the notes in a private placement in February and March 2004. This prospectus will be used by selling securityholders to resell their notes and the shares of common stock issuable upon conversion of their notes.

The notes are due on February 15, 2011. We will pay interest on the notes on February 15 and August 15 of each year, beginning August 15, 2004.

Holders may convert the notes at any time prior to maturity into shares of our common stock at a conversion price of \$11.22 per share, which is equivalent to a conversion rate of 89.1385 shares of our common stock per \$1,000 principal amount of notes. This conversion rate is subject to adjustment under the terms of the notes. The notes are general, unsecured obligations that are subordinated to all existing and future senior indebtedness and pari passu in right of payment with our 5.5% convertible subordinated notes due 2007. As of June 30, 2004, we had no senior indebtedness outstanding.

We may redeem any portion of the notes at any time after February 20, 2007 and prior to maturity if specific circumstances are satisfied. You may require us to repurchase your notes upon the occurrence of a designated event, subject to specified exceptions.

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For a more detailed description of the notes, see [Description of Notes](#) beginning on page 22.

Our common stock is traded on the Nasdaq National Market under the symbol [INCY](#). The last reported sale price of our common stock on the Nasdaq National Market on August 20, 2004 was \$6.69 per share.

Investing in the notes or our common stock involves a high degree of risk. You should carefully read and consider the [Risk Factors](#) beginning on page 4.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is August , 2004

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We have not authorized anyone to provide you with information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. The selling securityholders are offering to sell, and seeking offers to buy, only the notes and shares of common stock covered by this prospectus, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or of any sale of the shares.

You should read carefully the entire prospectus, as well as the documents incorporated by reference in the prospectus, before making an investment decision. All references to Incyte, we, us, our, or the Company in this prospectus mean Incyte Corporation and its subsidiaries, except where it is made clear that the term means only the parent company. All references to Incyte in this prospectus mean Incyte Corporation, the parent company.

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SUMMARY

This summary contains basic information about us, the notes and our common stock. Because it is a summary, it does not contain all of the information that you should consider before investing. You should read this entire prospectus carefully, including the section entitled "Risk Factors" and our financial statements and the related notes incorporated in this prospectus by reference, before making an investment decision.

Incyte Corporation is focused on the discovery and development of novel, small molecule drugs to treat major medical conditions, including infection with human immunodeficiency virus, or HIV, inflammatory disorders, cancer and diabetes. We have assembled a team of scientists with core competencies in the areas of medicinal chemistry, and molecular, cellular and in vivo biology.

Our most advanced product candidate, Reverset, is a nucleoside analog reverse transcriptase inhibitor, or NRTI, that is being developed as a once-a-day oral therapy for use in combination with other antiviral drugs for patients with HIV infections. Reverset is currently in Phase IIb clinical trials to treat patients infected with HIV. In a Phase II trial of HIV infected patients who had never undergone previous treatment, Reverset demonstrated potent activity against HIV and was well tolerated during the 10-day trial period. Laboratory data also suggest that Reverset has the potential to treat viruses resistant to other NRTIs.

In addition to our Reverset development program, we have four internally-generated drug discovery programs underway. The most advanced of these programs is focused on developing antagonists to a key receptor involved in inflammation called the CCR2 receptor. A lead candidate from this program has been identified and is currently in Phase I clinical trials. We believe that CCR2 receptor antagonists may represent a new class of compounds to treat various inflammatory diseases, including but not limited to rheumatoid arthritis and multiple sclerosis, and possibly atherosclerosis and neuropathic pain. Our next most-advanced program involves novel sheddase inhibitors that we believe may have application in the treatment of breast cancer and other tumor types. A lead compound has been selected and is expected to enter clinical trials early in 2005. Earlier stage programs have generated other compounds with potential for applications in diabetes and cancer.

For the past several years, Incyte has been a leader in the development and provision of genomic and proteomic information products. However, in response to the decreasing commercial potential of this area of business, Incyte made the decision in February 2004 to close our Palo Alto headquarters and to discontinue further development of the information products produced at that facility. The genomic and proteomic-information related assets remaining within Incyte after this restructuring are our gene-related intellectual property portfolio and our BioKnowledge Library, or BKL product line, produced by our Proteome facility based in Beverly, Massachusetts.

Incyte and BioKnowledge are our registered trademarks. We also refer to trademarks of other corporations and organizations in this prospectus.

Incyte was incorporated in Delaware in 1991. Our executive offices are located at Experimental Station, Route 141 & Henry Clay Road, Building E336, Wilmington, DE 19880 and our telephone number is (302) 498-6700.

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RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of the notes and our common stock could decline due to any of these risks, and you may lose all or part of your investment.

Risks Relating to our Business

We are at the early stage of our drug discovery and development efforts and we may be unsuccessful in our efforts.

We are in the early stage of building our drug discovery and development operations. Our ability to develop and commercialize pharmaceutical products based on proteins, antibodies and other compounds will depend on our ability to:

hire and retain key scientific employees;

identify high quality therapeutic targets;

identify potential drug candidates;

develop products internally or license drug candidates from others;

identify and enroll suitable volunteers, either in the United States or abroad, for our clinical trials;

complete laboratory testing and clinical testing on humans;

obtain and maintain necessary intellectual property rights to our products;

obtain and maintain necessary regulatory approvals for our products, both in the United States and abroad;

enter into arrangements with third parties to provide services or to manufacture our products on our behalf, or develop efficient production facilities meeting all regulatory requirements;

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deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these functions;

lease facilities at reasonable rates to support our growth; and

enter into arrangements with third parties to license and commercialize our products.

Of the compounds that we identify as potential drug products or that we in-license from other companies, only a few, at most, are statistically likely to lead to successful drug development programs. Significant research and development efforts will be necessary. We have limited experience with these activities and may not be successful in developing or commercializing drug products. If we choose to outsource some of these activities, we may be unable to enter into outsourcing or licensing agreements on commercially reasonable terms, if at all. In addition, if we elect to manufacture our products in our own manufacturing facilities, we will require substantial additional capital resources to lease or build and maintain those facilities, including attracting and retaining qualified personnel to lease or build and operate our facilities.

Our efforts to discover and develop potential drug candidates may not lead to the development, commercialization or marketing of drug products.

We are currently engaged in a number of different approaches to discover and develop novel drug candidates. We are internally developing novel small molecule chemokine receptor antagonists to treat

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inflammation and our scientists have produced a number of lead compounds that are in the final stages of preclinical testing and a lead candidate from this program has entered Phase I clinical trials. Our other internal drug discovery programs are focused on sheddase inhibitors to treat cancer and protein phosphatases to treat cancer and metabolic diseases. Discovery and development of potential drug candidates are expensive and time-consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. If our efforts do not lead to the discovery of a drug candidate, we may be unable to grow our clinical pipeline or we may be unable to enter into agreements with collaborators who are willing to develop our drug candidates.

The success of our drug discovery and development efforts may depend on our ability to find suitable collaborators to fully exploit our capabilities. If we are unable to establish collaborations or if these future collaborations are unsuccessful, our research and development efforts may be unsuccessful, which could adversely affect our results of operations and financial condition.

An important element of our business strategy will be to enter into collaborative or license arrangements with third parties under which we license our drugs candidates to those third parties for development and commercialization. We expect that while we may initially seek to conduct initial clinical trials on our drug candidates, we will need to seek collaborators for a number of our drug candidates because of the expense, effort and expertise required to continue additional clinical trials and further develop those drug candidates. Because collaboration arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. Also, we may not have drug compounds that are desirable to other parties, or we may be unwilling to license a drug compound because the party interested in it is a competitor. The terms of any such arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position. If we are not able to establish collaborative agreements, we may not be able to develop and commercialize a drug product, which would adversely affect our business and our revenues.

In order for any of these collaboration efforts to be successful, we must first identify potential collaborators whose capabilities complement and integrate well with ours. We may rely on these arrangements for not only financial resources, but also for expertise or economies of scale that we expect to need in the future relating to clinical trials, manufacturing, sales and marketing, and for licenses to technology rights. However, it is likely that we will not be able to control the amount and timing of resources that our collaborators devote to our programs or potential products. If our collaborators prove difficult to work with, are less skilled than we originally expected or do not devote adequate resources to the program, the relationship will not be successful. If a business combination involving a collaborator and a third party were to occur, the effect could be to diminish, terminate or cause delays in development of a potential product.

We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our drug discovery and development efforts may target diseases and conditions that are already subject to existing therapies or that are being developed by our competitors, many of which have substantially greater resources, larger research and development staffs and facilities, more experience in completing preclinical and clinical trials in order to obtain regulatory approvals and marketing and manufacturing capabilities. As a result of these resources, our competitors may develop drug products that render our products obsolete and noncompetitive by developing more effective drugs or by developing their products more efficiently. Our ability to develop competitive products would be limited if our competitors succeeded in obtaining regulatory approvals for drug candidates more rapidly than we were able to or in obtaining patent protection or other intellectual property rights that limited our drug development efforts. Any drugs resulting from our research and development efforts, or from our joint efforts with collaborators, might not be able to compete successfully with our competitors' existing and future products, or obtain regulatory approval in the United States or elsewhere.

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Our ability to develop and commercialize Reverset may be adversely affected if a dispute arose with Pharmasset.

We are developing Reverset under a collaborative licensing agreement with Pharmasset entered into in September 2003. If a dispute arose with Pharmasset over the terms of the collaborative license agreement, including the alleged breach of any provision, our development, commercialization and marketing of Reverset may be adversely affected.

If conflicts arise between our collaborators or advisors and us, our collaborators or advisors may act in their self-interest, which may adversely affect our business.

If conflicts arise between us and our collaborators, including Pharmasset, or our scientific advisors, the other party may act in its self-interest and not in the interest of our stockholders. Conflicts may arise with our collaborators if they pursue alternative technologies or develop alternative products either on their own or in collaboration with others as a means for developing treatments for the diseases that we have targeted. Competing products, either developed by these future collaborators or to which these future collaborators have rights, may result in their withdrawal of support for our product candidates.

Additionally, conflicts may arise if there is a dispute about the achievement and payment of a milestone amount or the ownership of intellectual property that is developed during the course of the relationship. Similarly, the parties to a collaboration agreement may disagree as to which party owns newly developed products. Should an agreement be terminated as a result of a dispute and before we have realized the benefits of the collaboration, our reputation could be harmed and we may not obtain revenues that we anticipated receiving.

If we fail to enter into additional in-licensing agreements or if these arrangements are unsuccessful, our business and operations might be adversely affected.

In addition to establishing collaborative arrangements under which third parties license our drug candidates for development and commercialization, we intend to continue to explore opportunities to develop our clinical pipeline by in-licensing drug compounds that fit within our expertise and research and development capabilities. We may be unable to enter into any additional in-licensing agreements because suitable product candidates that are within our expertise may not be available to us on terms that are acceptable to us or because competitors with greater resources seek to in-license the same product candidates. Product candidates that we would like to develop may not be available to us because they are controlled by competitors who are unwilling to license the rights to the drug compound or candidate to us. We may also need to license drug delivery or other technology in order to continue to develop our drug candidate pipeline. If we are unable to enter into additional agreements to license drug candidates, drug delivery technology or other technology or if these arrangements are unsuccessful, our research and development efforts could be adversely affected.

We have limited expertise with and capacity to conduct clinical trials, and our resulting dependence on third parties to conduct clinical trials could result in delays in and additional costs for our drug development efforts.

We have only limited experience with clinical trials, manufacturing and commercialization of drug products. We also have limited internal resources and capacity to perform preclinical studies and clinical trials. As a result, we intend to hire contract research organizations, or CROs, to perform most of our clinical trials for drug candidates that we choose to develop without a collaborator. If the CROs that we hire to perform our clinical trials or our collaborators do not meet deadlines or do not follow proper procedures, our clinical trials may take longer than

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expected, may be delayed or may be terminated. If we were forced to find a replacement entity to perform any of our clinical trials, we may not be able to find a suitable entity on favorable terms, or at all. Even if we were able to find another company to perform a trial, the delay in the trial may result in significant expenditures. Events such as these may result in delays in our obtaining regulatory approval for our drug candidates or our ability to commercialize our products and could result in increased expenditures that would adversely affect our operating results.

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In addition, for some of our drug candidates, we plan to contract with collaborators to advance those candidates through later-stage, more expensive clinical trials, rather than invest our own resources to perform these trials. Depending on the terms of our agreements with these collaborators, we may not have any control over the conduct of these clinical trials, and in any event we would be subject to the risks associated with depending on collaborators to develop these drug candidates.

If we are unable to obtain regulatory approval to develop and market products in the United States and foreign jurisdictions, we will not be permitted to manufacture or commercialize products resulting from our research.

In order to manufacture and commercialize drug products in the United States, our drug candidates will have to obtain regulatory approval from the Food and Drug Administration, or the FDA. Satisfaction of regulatory requirements typically takes many years. To obtain regulatory approval, we must first show that our drug products are safe and effective for target indications through preclinical studies (animal testing) and clinical trials (human testing). Preclinical testing and clinical development are long, expensive and uncertain processes, and we do not know whether the FDA will allow us to undertake clinical trials of any potential drug products in addition to Reverset.

Completion of clinical trials may take several years and failure may occur at any stage of testing. The length of time required varies substantially according to the type, complexity, novelty and intended use of the product candidate. Interim results of a preclinical study or clinical trial do not necessarily predict final results, and acceptable results in early trials may not be repeated in later trials. For example, a drug candidate that is successful at the preclinical level may cause harmful or dangerous side effects when tested at the clinical level. Our rate of commencement and completion of clinical trials may be delayed by many factors, including:

- our inability to manufacture sufficient quantities of materials for use in clinical trials;
- variability in the number and types of patients available for each study;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- unforeseen safety issues or side effects;
- poor or unanticipated effectiveness of products during the clinical trials; or
- government or regulatory delays.

Data obtained from the clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. In addition, regulatory authorities may refuse or delay approval as a result of other factors, such as changes in regulatory policy during the period of product development and regulatory agency review.

Due, in part, to the early stage of our drug candidate research and development process, we cannot predict whether regulatory approval will be obtained for any product we develop. At the present time, we have two drug candidates, Reverset and our lead CCR2 antagonist, in Phase II and Phase I clinical trials, respectively, and our other drug candidates are still undergoing preclinical testing. Compounds developed by us, alone or

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with other parties, may not prove to be safe and effective in clinical trials and may not meet all of the applicable regulatory requirements needed to receive marketing approval. If regulatory approval of a product is granted, this approval will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and effective. Failure to obtain regulatory approval would delay or prevent us from commercializing products.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks associated with the FDA approval process described above and may also include additional risks.

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Our reliance on third parties to manufacture and commercialize any of our drug candidates that receives regulatory approval could result in a short supply of the drugs or withdrawal of the FDA's regulatory approval.

The FDA requires that drug products be manufactured according to its current Good Manufacturing Practices, or cGMP, regulations and a limited number of manufacturers comply with these requirements. If the third party that we choose to manufacture our drug products is not compliant with cGMP, the FDA may not approve our application to manufacture our drug products. We may not be able to arrange for our products to be manufactured by one of these companies on reasonable terms, if at all. Failure to comply with cGMP in the manufacture of our products could result in the FDA withdrawing its regulatory approval of our drug product or other enforcement actions. If either of these events occurred, our revenues would be negatively impacted.

If we receive marketing approval from the FDA for any of our drug candidates, we will rely on a third party to manufacture our products. We may not be able to obtain sufficient quantities of our new drug products if the manufacturer does not have the capacity to manufacture our products according to our schedule. Also, raw materials that may be required to manufacture any products we develop may only be available from a limited number of suppliers. If we have promised delivery of a new product and are unable to meet the delivery requirement due to manufacturing difficulties, our reputation would be impaired or our customers may buy our competitors' products. Additionally, we may have to expend additional sums in order to ensure that manufacturing capacity is available when we need it even if we do not use all of the manufacturing capacity. This expense would adversely affect our operating results. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. The third party manufacturer we choose may not perform as agreed or may terminate its agreement with us.

We may incur additional expense in order to market our drug products.

We do not have experience marketing drug products to customers. If the FDA approves one of our drug products to go to market, we would have to employ additional personnel or engage a third party to market our drug products, which would be an additional expense to us.

We might not be able to commercialize our drug candidates successfully, and we may spend significant time and money attempting to do so.

Reverset and our lead CCR2 antagonist are our only two drug candidates in clinical trials. We, or our collaborators, may decide to discontinue development of any or all of our drug candidates at any time for commercial, scientific or other reasons. If a product is developed, but is not marketed, we may have spent significant amounts of time and money on it, which would adversely affect our operating results and financial condition. Even if Reverset, or another drug candidate that we develop, receives regulatory approval, we may decide not to commercialize it if we determine that commercialization of that product would require more money and time than we are willing to invest. For example, drugs that receive approval are subject to post-regulatory surveillance and may have to be withdrawn from the market if previously unknown side effects occur. At this point, the regulatory agencies may require additional clinical studies. Once a drug is marketed, if it causes side effects, the drug product may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. As a result, we may not continue to commercialize a product even though it has obtained regulatory approval. Further, we may decide not to continue to commercialize a product if the market does not accept the product because it is too expensive and third parties such as insurance companies or Medicare have not approved it for substantial reimbursement. Actions of governmental authorities and other groups could result in lower prices for certain drugs, including drugs that address HIV infection. In addition, we may decide not to continue to commercialize a product if another product comes on the market that is as effective but has fewer side effects. There is also a risk that competitors and third parties may develop similar or superior products or have proprietary rights that preclude us from ultimately marketing our products.

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Our ability to generate revenues will be diminished if we are unable to obtain acceptable prices or an adequate level of reimbursement from third-party payors.

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals could reduce the price that we or any of our collaborators receive for any products in the future.

Our ability to commercialize our products successfully will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially and adversely affect our ability to generate revenues.

As our drug discovery and development operations are conducted at our headquarters in Wilmington, Delaware, the loss of access to this facility would negatively impact our business.

Our facility in Wilmington, Delaware is our headquarters and is also where we conduct all of our drug discovery operations and research and development activities. Our lease contains provisions that provide for its early termination upon the occurrence of certain events of default or upon a change of control. Further, our headquarters facility is located in a large research and development complex that may be temporarily or permanently shutdown if certain environmental or other hazardous conditions were to occur within the complex. In addition, actions of activists opposed to aspects of pharmaceutical research may disrupt our experiments or our ability to access or use our facilities. The loss of access to or use of our Wilmington, Delaware, facility, either on a temporary or permanent basis, or early termination of our lease would result in an interruption of our business and, consequently, would adversely affect the advancement of our drug discovery and development programs and our overall business.

We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees would affect our ability to expand our drug discovery and development programs and achieve our objectives.

We are highly dependent on the principal members of our management, operations and scientific staff. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team, key scientific and management personnel and our ability to recruit, train and retain essential scientific personnel for our drug discovery and development programs, including those who will be responsible for our internal preclinical and clinical testing as well as for the establishment of collaborations with other companies. If we lose the services of any of these people, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed. We do not maintain key person insurance on any of our employees.

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We may encounter difficulties in integrating companies we acquire, which may harm our operations and financial results.

As part of our business strategy, we have in the past and may in the future acquire assets, technologies, compounds and businesses. Our past acquisitions, such as the acquisition of Maxia Pharmaceuticals, Inc., have involved, and our future acquisitions may involve, risks such as the following:

we may be exposed to unknown liabilities of acquired companies;

our acquisition and integration costs may be higher than we anticipated and may cause our quarterly and annual operating results to fluctuate;

we may experience difficulty and expense in assimilating the operations and personnel of the acquired businesses, disrupting our business and diverting our management's time and attention;

we may be unable to integrate or complete the development and application of acquired technology, compounds or drug candidates;

we may experience difficulties in establishing and maintaining uniform standards, controls, procedures and policies;

our relationships with key customers of acquired businesses may be impaired, due to changes in management and ownership of the acquired businesses;

we may be unable to retain key employees of the acquired businesses;

we may incur amortization or impairment expenses if an acquisition results in significant goodwill or other intangible assets; or

our stockholders may be diluted if we pay for the acquisition with equity securities.

In addition, if we acquire additional businesses that are not located near our new headquarters, we may experience more difficulty integrating and managing the acquired businesses' operations.

We may encounter difficulties, including higher than anticipated costs and the diversion of management's attention, as a result of the restructuring of our business and the relocation of our headquarters and finance department from California to Delaware.

In April 2004, we had a significant reduction in our workforce and closed our Palo Alto, California research facilities. We may incur higher than anticipated costs or delays associated with closing our California facilities, and this restructuring could result in the diversion of the efforts of our executive management team and other key employees, which could adversely affect our drug discovery and development efforts. As a part of this restructuring, we are discontinuing our information products research and development efforts, with the exception of the activities related to, and products developed by, our Proteome subsidiary. We may encounter difficulties associated with the discontinuation of certain of our information product-related activities that could adversely affect our operating results and financial position. These difficulties could include

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challenges in providing support to our customers, and, in particular, our non-U.S. customers. Some of our database customers could become dissatisfied as a result of our restructuring, and we could incur expenses associated with the amendment, termination or transition of these customer contracts.

As a part of increasing our focus on our drug discovery and development programs, we relocated our headquarters, including our finance and legal staff and systems, to our facility in Wilmington, Delaware. Our operating and financial results could be adversely affected by the risks associated with this relocation, including unanticipated delays, ineffective transition of responsibilities or systems, the retention of certain key employees, the hiring of finance personnel in Delaware, and ineffective transition of responsibilities for our intellectual property portfolio. During this transition process, we expect that we will need to continue to manage multiple locations and our relationships with information products customers, suppliers and other third parties. If we are

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unable to effectively transition our remaining information product line activities, our internal information management activities, our financial reporting, or our management of our intellectual property portfolio to the employees or outside parties who will take over those responsibilities, we may incur higher costs associated with the transition.

Risks Relating to our Financial Results

We expect to incur losses in the future and we may not achieve or maintain profitability in the future.

We had net losses from inception in 1991 through 1996 and in 1999 through 2004. Because of those losses, we had an accumulated deficit of \$672.8 million as of June 30, 2004. We will continue to spend significant amounts on our efforts to discover and develop drugs. As a result, we expect to continue to incur losses in 2004 and in future periods as well.

We expect that any revenues from our information products, intellectual property licensing, and contracts, if any, will be more than offset by expenses for our drug discovery and development efforts. We anticipate that these efforts will increase as we focus on the studies, including preclinical studies and clinical trials prior to seeking regulatory approval, that are required before we can sell, or license to a third party, a drug product. The development of drug products will require us to spend significant funds on research, development, testing, obtaining regulatory approvals, manufacturing and marketing. To date, we do not have any drug products that have generated revenues and we anticipate that we will not generate significant revenues from the drug candidates that we license or develop for several years, if ever. We cannot be certain whether or when we will achieve profitability because of the significant uncertainties relating to our ability to generate commercially successful drug products. Even if we were successful in obtaining regulatory approvals for manufacturing and commercializing Reverset, our leading drug candidate, or another drug, we expect that we will continue to incur losses if our drug products do not generate significant revenues. If we achieve profitability we may not be able to sustain or increase profitability.

We will need additional capital in the future. The capital markets may not permit us to raise additional capital at the time that we require it, which could result in limitations on our research and development or commercialization efforts or the loss of certain of our rights in our technologies or drug candidates.

Our future funding requirements will depend on many factors and we anticipate that we will need to raise additional capital to fund our business plan and research and development efforts on a going-forward basis.

Additional factors that may affect our future funding requirements include:

any changes in the breadth of our research and development programs;

the results of research and development, preclinical studies and clinical trials conducted by us or our future collaborative partners or licensees, if any;

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the acquisition or licensing of businesses, technologies or compounds, if any;

our ability to maintain and establish new corporate relationships and research collaborations;

competing technological and market developments;

the amount of revenues generated from our business activities;

the time and costs involved in filing, prosecuting, defending and enforcing patent and intellectual property claims;

the receipt of contingent licensing or milestone fees from our current or future collaborative and license arrangements, if established;
and

the timing of regulatory approvals.

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If we require additional capital at a time when investment in companies such as ours, or in the marketplace generally, is limited due to the then prevailing market or other conditions, we may have to scale back our operations, eliminate one or more of our development programs, or attempt to obtain funds by entering into an agreement with a collaborative partner that would result in terms that are not favorable to us or relinquishing our rights in certain of our proprietary technologies or drug candidates. If we are unable to raise funds at the time that we desire or at any time thereafter on acceptable terms, we may not be able to continue to develop our potential drug products. The sale of equity or additional convertible debt securities in the future would be dilutive to our stockholders, and debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to incur further indebtedness.

Because our revenues are derived from information products and licensing activities, our revenues may fluctuate substantially due to reductions and delays in research and development expenditures by pharmaceutical and biotechnology companies.

We expect that our revenues from our information products in the foreseeable future will be derived primarily from products and services provided to the pharmaceutical and biotechnology industries as well as to the academic community. Accordingly, these revenues will depend in large part upon the success of the companies within these industries and their demand for our products and services. Our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by companies in these industries or by the academic community. These reductions and delays may result from factors such as:

changes in economic conditions;

consolidation in the pharmaceutical and biotechnology industries;

changes in the regulatory environment, including governmental pricing controls, affecting health care and health care providers;

pricing pressures;

market-driven pressures on companies to consolidate and reduce costs; and

other factors affecting research and development spending.

These factors are not within our control and may cause volatility to the price of our common stock.

Future milestone and royalty payments from our gene-related intellectual property may not contribute significantly to revenues for several years, and may never result in revenues.

Part of our strategy is to license to our database customers and to other pharmaceutical and biotechnology companies our know-how and patent rights associated with the information we have generated in the creation of our proprietary databases, for use in the discovery and development of potential pharmaceutical, diagnostic or other products. Any potential product that is the subject of such a license will require several years of further development, clinical testing and regulatory approval before commercialization, all of which is beyond our control, and possibly beyond the control of our licensee. These licensees may not develop the potential product if they do not devote the necessary resources or decide that they do not want to expend the resources to do the clinical testing necessary to obtain the necessary regulatory approvals. Therefore, milestone

or royalty payments from these licenses may not contribute to our revenues for several years, if at all.

Our long-term investments may decline in value and our losses may increase.

We have made and may in the future make long-term investments in entities that complement our business. These investments may:

often be made in securities lacking a public trading market or subject to trading restrictions, either of which increases our risk and reduces the liquidity of our investment;

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require us to record losses and expenses related to our ownership interest;

require us to record acquisition-related charges, such as in-process research and development;

require us to record charges related to the impairment in the value of the securities underlying our investment; and

require us to invest greater amounts than anticipated or to devote substantial management time to the management of research and development relationships or other relationships.

The market values of many of these investments can fluctuate significantly. We evaluate our long-term investments for impairment of their value on a quarterly basis. The volatility of the equity markets and the uncertainty of the biotechnology industry may result in fluctuations in the value of our investments in public companies. The value of our investments in private companies can fluctuate significantly. In past periods, market conditions have caused us to write-down the value of our private company investments, sometimes substantially, and market conditions may cause us to write down additional amounts. In addition, we have in the past written down the value of our debt investments in companies experiencing financial difficulties. Impairment could result in future charges to our earnings. Decreases in the value of our strategic investments may cause our losses to increase. As of June 30, 2004, the total aggregate value of our long-term investments was \$13.2 million. We incurred charges related to write-downs in the valuation of long-term investments of \$2.7 million during the six months ended June 30, 2004.

We have a large amount of debt and our debt service obligations may prevent us from taking actions that we would otherwise consider to be in our best interests.

As of June 30, 2004, we had total consolidated debt of \$417.6 million and stockholders' equity of \$52.6 million. In February 2004 and March 2004, we issued the \$250 million of notes offered by this prospectus. The indentures pursuant to which our outstanding convertible subordinated notes were issued do not limit the issuance of additional indebtedness, and the indenture under which the notes offered by this prospectus were issued specifically permits us to issue additional notes that will be treated as a single class with these notes. Our substantial leverage could have significant negative consequences for our future operations, including:

increasing our vulnerability to general adverse economic and industry conditions;

limiting our ability to obtain additional financing for working capital, capital and research and development expenditures, and general corporate purposes;

requiring the dedication of a substantial portion of our expected cash flow or our existing cash to service our indebtedness, thereby reducing the amount of our cash available for other purposes, including working capital and capital expenditures;

limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; or

placing us at a possible competitive disadvantage compared to less leveraged competitors and competitors that have better access to capital resources.

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In the past five years, we have had negative cash flow from operations. We likely will not generate sufficient cash flow from our operations in the future to enable us to meet our anticipated fixed charges, including our debt service requirements with respect to our outstanding convertible subordinated notes. As of June 30, 2004, \$166.5 million aggregate principal amount of our 5.5% convertible subordinated notes due 2007 were outstanding. Our annual interest payments for the 5.5% notes through 2006, assuming none of these notes are converted, redeemed, repurchased or exchanged, are \$9.2 million, and an additional \$4.6 million in interest is payable in 2007. Our annual interest payments for the 3 1/2% notes through 2010, assuming none of these notes are converted, redeemed, repurchased or exchanged, are \$8.8 million, and an additional \$4.4 million in interest will be payable in 2011. We intend to fulfill our debt service obligations from our existing cash and marketable securities. If we are unable to generate cash from our operations or raise additional cash through financings

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sufficient to meet these obligations, we will need to use existing cash or liquidate marketable securities in order to fund these obligations, which may delay or curtail our research, development and commercialization programs.

Risks Relating to Intellectual Property and Legal Matters

We are involved in patent litigation, which, if not resolved favorably, could require us to pay damages.

In October 2001, Invitrogen Corporation, or Invitrogen, filed an action against us in federal court, alleging infringement of three patents. The complaint seeks unspecified money damages and injunctive relief. In November 2001, we filed our answer to Invitrogen's patent infringement claims, and asserted seven counterclaims against Invitrogen, seeking declaratory relief with respect to the patents at issue, implied license, estoppel, laches and patent misuse. We are also seeking our fees, costs and expenses. Invitrogen filed its answer to our counterclaims in January 2002. In February 2003, we added a counterclaim for unfair business practices. On February 9, 2004, the Court ordered a stay of all proceedings pending disposition of the appeal in a related case of a judgment invalidating the same patents that are asserted in this case.

Our defenses against the suit brought by Invitrogen may be unsuccessful. At this time, we cannot reasonably estimate the possible range of any loss or damages resulting from this suit due to uncertainty regarding the ultimate outcome. If the case goes forward, we expect that the Invitrogen litigation will result in future legal and other costs to us, regardless of the outcome, which could be substantial.

We are involved in contractual arbitration, which could be costly to us.

We are in an arbitration with Iconix Pharmaceuticals, Inc., or Iconix, with respect to payments that Iconix alleges we owe it pursuant to a contract. Iconix initiated the arbitration process under the contract seeking final and binding arbitration. An arbitration panel has been selected and hearings have been scheduled for the fourth quarter of 2004 and the first quarter of 2005. Based upon our pre-arbitration correspondence with Iconix, we believe Iconix is alleging that we are obligated to make payments to it in the aggregate amount of \$28.25 million. Based on Iconix's amended demand for arbitration, we understand Iconix is also seeking return of a \$4.5 million license fee paid to us and recovery of amounts paid to a third-party supplier. There can be no assurance as to the ultimate outcome of the arbitration and, at this time, we cannot predict the financial impact to us of the results of the arbitration. Regardless of the outcome, we could incur substantial costs and diversion of management time as a result of the arbitration.

If we are subject to additional litigation and infringement claims, they could be costly and disrupt our drug discovery and development efforts.

The technology that we use to develop our drug products, the technology that we incorporate in our products, and the products we are developing may be subject to claims that they infringe the patents or proprietary rights of others. The success of our drug discovery and development efforts will also depend on our ability to develop new compounds, drugs and technologies without infringing or misappropriating the proprietary rights of others.

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From time to time we may receive notices from third parties alleging patent or copyright infringement, claims regarding trade secrets or other contract claims. Receipt of these letters could result in significant costs as a result of the diversion of the attention of management from our drug discovery and development efforts. Except for Invitrogen and Iconix, no third party has a current filed patent lawsuit or arbitration against us. If a successful claim were brought against us, we would have to attempt to license the technology from the claimant or to spend time and money to design around the technology. Any such license of the technology may not be available at reasonable terms, or at all.

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We may, however, be involved in future lawsuits or other legal proceedings alleging patent infringement or other intellectual property rights violations. In addition, litigation or other legal proceedings may be necessary to:

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

We may be unsuccessful in defending or pursuing these lawsuits or claims. Regardless of the outcome, litigation can be very costly and can divert management's efforts. An adverse determination may subject us to significant liabilities or require us or our collaborators to seek licenses to other parties' patents or proprietary rights. We or our collaborators may also be restricted or prevented from manufacturing or selling a drug product that we develop. Further, we or our future collaborators may not be able to obtain any necessary licenses on acceptable terms, if at all.

We may be unable to adequately protect or enforce our proprietary information, which may result in its unauthorized use, a loss of revenue under a collaboration agreement or loss of sales to generic versions of our products or otherwise reduce our ability to compete.

Our business and competitive position depend upon our ability to protect our proprietary technology, including any drug products that we create. Despite our efforts to protect this information, unauthorized parties may attempt to obtain and use information that we regard as proprietary. For example, one of our collaborators may disclose proprietary information pertaining to our drug discovery efforts. Any patents issued in connection with our drug discovery efforts may not be broad enough to protect all of the potential uses of the product.

Additionally, when we do not control the prosecution, maintenance and enforcement of certain important intellectual property, such as a drug compound in-licensed to us, the protection of the intellectual property rights may not be in our hands. In the case of Reverset, we do not control the intellectual property rights with respect to the compound and therefore may be unable to protect those rights. If the entity that controls the intellectual property rights related to Reverset does not adequately protect those rights, our rights may be impaired, which may impact our ability to develop, market and commercialize Reverset.

Our means of protecting our proprietary rights may not be adequate, and our competitors may:

independently develop substantially equivalent proprietary information and techniques;

otherwise gain access to our proprietary information; or

design around patents issued to us or our other intellectual property.

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We pursue a policy of having our employees, consultants and advisors execute proprietary information and invention agreements when they begin working for us. However, these agreements may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. If we fail to maintain trade secret and patent protection, our potential, future revenues may be decreased.

If the effective term of our patents is decreased due to changes in the United States patent laws or if we need to refile some of our patent applications, the value of our patent portfolio and the revenues we derive from it may be decreased.

The value of our patents depends in part on their duration. A shorter period of patent protection could lessen the value of our rights under any patents that we obtain and may decrease the revenues we derive from our patents. The United States patent laws were amended in 1995 to change the term of patent protection from 17 years from patent issuance to 20 years from the earliest effective filing date of the application. Because the

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average time from filing to issuance of biotechnology applications is at least one year and may be more than three years depending on the subject matter, a 20-year patent term from the filing date may result in substantially shorter patent protection. Also, we may need to refile some of our applications claiming large numbers of genes or other additional subject matter and, in these situations, the patent term will be measured from the date of the earliest priority application. This would shorten our period of patent exclusivity and may decrease the revenues that we might obtain from the patents.

If patent application filing fees are significantly increased, our expenses related to intellectual property or our intellectual property strategy may be adversely affected.

Our ability to license proprietary genes may be dependent on our ability to obtain patents. We have a large portfolio of issued United States patents covering human full-length genes, the proteins they encode and the antibodies directed against them and a significant number of pending applications. If the United States Patent and Trademark Office and other patent offices where we file our patent applications increase the fees associated with filing and prosecuting patent applications we would incur higher expenses and our intellectual property strategy could be adversely affected.

International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.

Biotechnology patent law outside the United States is even more uncertain than in the United States and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as United States laws. For example, certain countries do not grant patent claims that are directed to the treatment of humans. We may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts.

If product liability lawsuits are successfully brought against us, we could face substantial liabilities and may be required to limit commercialization of our products and our results of operations could be harmed.

The clinical testing and marketing of medical products that are intended for human use entails an inherent risk of product liability. If any product that we or any of our collaborators develops causes injury or is found to be unsuitable during clinical trials, manufacturing or sale, we may be held liable. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities, including substantial damages to be paid to the victims and legal costs, or we may be required to limit commercialization of our products. Although we currently carry a product liability insurance policy that provides coverage for liabilities arising from our clinical trials, it may not fully cover our potential liabilities. In addition, we may determine that we should increase our coverage upon the addition of new clinical trials, and this insurance may be prohibitively expensive to us or our collaborators and may not fully cover our potential liabilities. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with our collaborators. Additionally, any product liability lawsuit could cause injury to our reputation, recall of products, participants to withdraw from clinical trials, and potential collaborators to seek other partners, any of which could impact our results of operations.

Because our activities involve the use of hazardous materials, we may be subject to claims relating to improper handling, storage or disposal of these materials that could be time consuming and costly.

