

GENOME THERAPEUTICS CORP

Form S-3

December 17, 2003

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As filed with the Securities and Exchange Commission on December 17, 2003

Registration No. 333-

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM S-3**

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

**GENOME THERAPEUTICS CORP.**

(Exact name of registrant as specified in its charter)

Massachusetts  
(State or other jurisdiction)

04-2297484  
(I.R.S. Employer

of incorporation or organization)

Identification Number)

100 Beaver Street

Waltham, Massachusetts 02453

(781) 398-2300

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

Stephen Cohen

Senior Vice President and Chief Financial Officer

Genome Therapeutics Corp.

100 Beaver Street

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Waltham, Massachusetts 02453

(781) 398-2300

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

*with copies to:*

**Patrick O Brien  
Ropes & Gray LLP  
One International Place  
Boston, Massachusetts 02110-2624  
(617) 951-7000**

**James A. Lebovitz  
Dechert LLP  
4000 Bell Atlantic Tower  
1717 Arch Street  
Philadelphia, Pennsylvania 19103-2793  
(215) 994-4000**

**Approximate date of commencement of proposed sale to the 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, as amended (the Securities Act ) 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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**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 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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**CALCULATION OF REGISTRATION FEE**

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| <b>Title of Shares to be Registered</b>  | <b>Amount to be Registered</b> | <b>Proposed Maximum Offering Price Per Share(1)</b> | <b>Proposed Maximum Aggregate Offering Price(1)</b> | <b>Amount of Registration Fee</b> |
|--|--------------------------------|---|---|-----------------------------------|
| Common Stock, \$0.10 par value per share | 11,000,000                     | \$3.175   | \$34,925,000  | \$2,825.43                        |

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- (1) Estimated solely for purposes of calculating the amount of registration fee pursuant to Rule 457(c) under the Securities Act of 1933 and based upon the average of the high and low sale prices reported on the Nasdaq National Market on December 11, 2003.
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The information in the prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where an offer is not permitted.

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**Prospectus (Subject to Completion)**

Issued December 17, 2003

**11,000,000 Shares**

**GENOME THERAPEUTICS CORP.**

**Common Stock**

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We are offering up to 11,000,000 shares of common stock.

Our common stock trades on the Nasdaq National Market under the symbol GENE. On December 12, 2003, the reported last sale price of our common stock on the Nasdaq National Market was \$3.30 per share.

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Investing in our common stock involves risks. See **Risk Factors** beginning on page 5 of this prospectus before deciding to invest in our common stock.

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Price \$                      a share

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**Per Share**

**Total**

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|   |    |    |
|---|----|----|
| Public price                              | \$ | \$ |
| Placement agent fees                      | \$ | \$ |
| Proceeds for the Company, before expenses | \$ | \$ |

J.P. Morgan Securities Inc. will act as our placement agent in connection with this offering and will use its best commercially practicable efforts to introduce us to investors. J.P. Morgan Securities Inc. has no commitment to buy any of the shares. See "Plan of Distribution" on page 26 of this prospectus for more information about these arrangements.

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

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**JPMorgan**

, 2003

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### **GENOME THERAPEUTICS CORP.**

We are a biopharmaceutical company focused on the discovery, development and commercialization of pharmaceutical products.

We have nine established product development programs. We are managing the development and commercialization of our lead product candidate, Ramoplanin, in the United States and Canada. This product is in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) and a Phase II trial for the treatment of patients with *Clostridium difficile*-associated diarrhea (CDAD). We have seven product discovery and development alliances with pharmaceutical companies including Amgen, AstraZeneca, bioMérieux, Schering-Plough and Wyeth. Our biopharmaceutical product candidates are all currently in discovery or development phases and are neither approved by the U.S. Food and Drug Administration nor available for commercial sale.

Over the past two years, our primary business focus has evolved from providing basic research and genomic services for pharmaceutical companies to more downstream efforts emphasizing clinical development and commercialization of our own product candidates. We continue to reduce our expenditures in the early-stage product discovery and development research areas, including genomics research, and to focus our resources on later stage drug discovery and development. This evolution in our strategic focus reflects our goals of getting products to market more rapidly and generating more substantial revenues and, ultimately, profits for our shareholders.

On November 17, 2003, we entered into an Agreement and Plan of Merger and Reorganization, or merger agreement, pursuant to which we will combine with GeneSoft Pharmaceuticals, Inc. ( " Genesoft " ). In connection with the merger we will issue a total of 28,571,405 shares of our common stock (i) in exchange for all shares of capital stock of Genesoft, (ii) as payment of certain interest and related amounts due to Genesoft's note holders and (iii) upon the exercise of Genesoft options and warrants, which will be assumed by us. We will also assume the approximately \$24 million of debt of Genesoft by means of exchanging \$22,309,647 of promissory notes of Genesoft for convertible promissory notes of ours, which will bear interest at 5% per annum and have a maturity date of five years from the closing date, and assuming approximately \$1.7 million of equipment financing debt, which will be paid at closing. These convertible notes will be convertible into shares of our common stock at the holder's election at any time after the closing of the merger at a price per share equal to one hundred and ten percent of the average closing price of our common stock for the five trading days preceding the closing date of the merger, subject to subsequent adjustment.

The merger has been unanimously approved by our board of directors and the board of directors of Genesoft. The transaction is subject to several conditions, including approval by the stockholders of both companies, effectiveness of our registration statement on Form S-4 filed with the Securities and Exchange Commission and other customary closing conditions. It is also a condition of the merger that on or prior to closing we raise a minimum of \$32 million of additional capital to fund the merged company pursuant to this offering. Completion of this offering is expected to occur immediately prior to the closing of the merger.

Coincident with the signing of the merger agreement, we made a bridge loan of \$6.2 million to Genesoft pursuant to a promissory note issued by Genesoft, which is repayable within 60 days of an event of default (as defined in the note) or termination of the merger agreement.

Genesoft is a specialty pharmaceutical company based in South San Francisco focused on the discovery and development of novel anti-infective agents. FACTIVE® (gemifloxacin mesylate) is the company's lead product, an orally administered, broad-spectrum fluoroquinolone antibiotic approved in April 2003 by the FDA for the treatment of acute bacterial exacerbations of chronic bronchitis, or ABECB, and community-acquired pneumonia, or CAP, of mild to moderate severity. Under an agreement with LG Life Sciences, Genesoft exclusively licensed the rights to develop and commercialize FACTIVE in North America, France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco,

San Marino and Vatican City.



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Genesoft is also developing two classes of novel mode of action antibiotics. Peptide deformylase, or PDF, inhibitors represent a new class of molecules that target an essential bacterial enzyme and have antibacterial activities suitable for the potential treatment of respiratory tract infections. DNA-Nanobinder compounds target certain DNA sequences and have the potential to serve as biological warfare countermeasures.

The address for our executive offices is 100 Beaver Street, Waltham, Massachusetts 02453 and our telephone number is (781) 398-2300.

## THE OFFERING

We are offering up to 11,000,000 shares of our common stock in this offering. The offering is subject to:

1. our stockholders, at a meeting to be held on or before \_\_\_\_\_, 2004:
  - (a) approving the issuance of a total of 28,571,405 shares of our common stock pursuant to the merger agreement,
  - (b) approving the issuance of shares of our common stock upon the potential conversion of our convertible notes in an aggregate principal amount of \$22,309,647 to be exchanged for Genesoft promissory notes in connection with the merger, and
  - (c) approving an amendment to our articles of organization to increase the number of shares of common stock that we are authorized to issue from 50,000,000 to 175,000,000 shares of common stock; and
  
2. the stockholders of Genesoft, at a meeting to be held on or before \_\_\_\_\_, 2004:
  - (a) adopting and approving the merger agreement, and
  - (b) approving the amendment and restatement of Genesoft's certificate of incorporation to eliminate any authorized shares of Genesoft preferred stock if the merger is completed.

To facilitate the closing of the offering, certain investor funds will be deposited into an escrow account with an escrow agent. The escrow agent will not accept any investor funds until the date of this prospectus. Before the closing date, the escrow agent will notify J.P. Morgan Securities Inc., the placement agent, when funds to pay for the shares have been received. If all of the required shareholder approvals described above are received, then we will deposit the shares to be sold in this offering with the Depository Trust Company. At the closing, Depository Trust Company will credit the shares to the respective accounts of the investors.

If the stockholder approvals described above are not obtained, then all investor funds that were deposited into escrow will be returned promptly to investors and this offering will terminate.

## NOTE ON TRADEMARKS

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The following trademarks are the property of the specified holders: FACTIVE® is the property of LG Life Sciences, Ltd., Nanobinder® is the property of Genesoft, Levaquin® is the property of Ortho-McNeil Pharmaceutical, Inc., Tequin® is the property of Bristol-Myers Squibb Company, Cipro® and Avelox® are both the property of Bayer Corporation, Biaxin® is the property of Abbott Laboratories, Zithromax® is the property of Pfizer Inc., Augmentin® is the property of GlaxoSmithKline, Ketek® is the property of Aventis Pharmaceuticals and Vanconin® is the property of Eli Lilly and Company. Unless otherwise indicated, trademarks or service marks appearing in this prospectus are the property of their respective holders.

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**RISK FACTORS**

*This offering involves a high degree of risk. You should consider carefully the risks and uncertainties described below and the other information in this prospectus, including the financial statements and related notes, before deciding to invest in shares of our common stock. If any of the following risks or uncertainties actually occurs, our business, prospects, financial condition and operating results would likely suffer. In that event, the market price of our common stock could decline and you could lose all or part of your investment.*

**Risks Relating to Our Business**

**Both we and Genesoft have a history of significant operating losses and expect these losses to continue in the future.**

We had a net loss of approximately \$28,455,000 for the nine months ended September 27, 2003 and as of September 27, 2003, we had an accumulated deficit of approximately \$154,231,000. We had a net loss of approximately \$34,017,000 for the fiscal year ended December 31, 2002, and, as of December 31, 2002, we had an accumulated deficit of approximately \$125,775,000. For the fiscal year ended December 31, 2001, we had a net loss of approximately \$10,090,000, and for the fiscal year ended December 31, 2000, we had a net loss of approximately \$5,847,000. The losses have resulted primarily from costs incurred in research and development, including our clinical trials, and from general and administrative costs associated with our operations. These costs have exceeded our revenues which to date have been generated principally from collaborations, government grants and sequencing services.

Genesoft had a net loss of approximately \$19,796,000 for the nine months ended September 30, 2003 and as of September 30, 2003, Genesoft had an accumulated deficit of approximately \$75,364,000. Genesoft had a net loss of approximately \$25,569,000 for the fiscal year ended December 31, 2002, and, as of December 31, 2002, Genesoft had an accumulated deficit of approximately \$55,568,000. For the fiscal year ended December 31, 2001, Genesoft had a net loss of approximately \$18,321,000, and for the fiscal year ended December 31, 2000, Genesoft had a net loss of approximately \$7,921,000. The losses have resulted primarily from costs incurred in research and development, including Genesoft's clinical trials, and from general and administrative costs associated with our operations. These costs have exceeded Genesoft's revenues which to date have been generated principally from funding from the U.S. government.

We anticipate that our combined company will incur additional losses this year and in future years and cannot predict when, if ever, our combined company will achieve profitability. These losses are expected to increase following the consummation of the merger as our combined company significantly increases its expenditures in the sales and marketing area to prepare for the commercial launch of FACTIVE. Our combined company also plans to continue to expand its research and development and clinical trial activities. In addition, our partners' product development efforts which utilize our genomic discoveries are at an early stage and, accordingly, we do not expect our losses to be substantially mitigated by revenues from milestone payments or royalties under those agreements for a number of years, if ever.

**The business of our combined company will be very dependent on the commercial success of FACTIVE.**

FACTIVE will be the only commercial product of our combined company upon the closing of the merger and we expect it will account for substantially all of the revenues of our combined company for at least the next several years. FACTIVE has FDA marketing approval for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or ABECB. The commercial success of FACTIVE will depend upon its acceptance by regulators, physicians, patients and other key

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decision-makers as a safe, therapeutic and cost-effective alternative to other anti-infectives and other products used, or currently being developed, to treat CAP and ABECB. If FACTIVE is not commercially successful, our combined company will have to find additional sources of funding or curtail or cease operations.

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In December 2000, the FDA issued a non-approvable letter to the prior owner of rights to FACTIVE due, in part, to safety concerns arising out of an increased rate of rash relative to comparator drugs, especially in young women. While the FDA did approve FACTIVE for marketing in April 2003, it required, as a postmarketing study commitment, that Genesoft conduct a prospective, randomized study comparing FACTIVE (5,000 patients) to an active comparator (2,500 patients) in patients with CAP or ABECB. This study will include patients of different ethnicities, to gain safety information in populations not substantially represented in the existing clinical trial program, specifically as it relates to rash. Patients will be evaluated for clinical and laboratory safety. This Phase IV trial is in the design stage and the FDA required, as a condition to its approval, that the trial be initiated by March 2004. The results of this trial, as well as other safety information arising out of the marketing of the product, could restrict our ability to commercialize FACTIVE.

### **We will need to raise additional funds in the future.**

As described above, we need to raise a minimum of \$32 million as a condition to the closing of the merger, unless this condition is waived by both parties. If we raise that money, we believe that those new funds along with our existing cash and marketable securities together with borrowings under equipment financing arrangements and anticipated cash flows from operations would be sufficient to support our current plans for the combined company for approximately 12 months following the closing of the merger. We expect to raise additional capital over the course of the twelve months following the closing of the merger for our combined company. In particular, we will need additional funds to support our sales and marketing activities, and fund clinical trials and other research and development activities of our combined company. We may seek funding through additional public or private equity offerings, debt financings or agreements with customers. Our ability to raise additional capital, however, will be heavily influenced by the investment market for biotechnology companies and the progress of the FACTIVE and Ramoplanin commercial and clinical development programs over that period. Additional financing may not be available when needed, or, if available, may not be available on favorable terms. If our combined company cannot obtain adequate financing on acceptable terms when such financing is required, its business will be adversely affected.

### **Future fund raising could dilute the ownership interests of our stockholders.**

In order to raise additional funds, our combined company may issue equity or convertible debt securities in the future. Depending upon the market price of the shares of our combined company at the time of any transaction, we may be required to sell a significant percentage of the outstanding shares of common stock of our combined company in order to fund its operating plans, potentially requiring a stockholder vote. In addition, our combined company may have to sell securities at a discount to the prevailing market price, resulting in further dilution to our stockholders.

### **Our combined company will need to develop marketing and sales capabilities to successfully commercialize FACTIVE and our other product candidates.**

FACTIVE will be the first FDA approved product of our combined company. Accordingly, following the closing of the merger, our combined company will have very limited marketing and sales experience. Our combined company will need to develop a marketing and sales staff to successfully commercialize FACTIVE and our other product candidates, including Ramoplanin. In order to launch FACTIVE in the second half of 2004, our combined company will need to rapidly assemble a sales and marketing force. The development of these marketing and sales capabilities will require significant expenditures, management resources and time. Our combined company may be unable to build such a sales force, the cost of establishing such a sales force may exceed any product revenues, or the marketing and sales efforts of our combined company may be unsuccessful. Failure to successfully establish sales and marketing capabilities in a timely and regulatory compliant manner or to find suitable sales and marketing partners may prevent our combined company from successfully launching FACTIVE in 2004, which would materially adversely affect the business and results of operations of our combined company.



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### **Our combined company will depend on third parties to manufacture our product candidates, including FACTIVE and Ramoplanin.**

Our combined company will not have the internal capability to manufacture commercial quantities of pharmaceutical products under the FDA's current Good Manufacturing Practices. Genesoft has entered into an agreement with LG Life Sciences to manufacture bulk quantities of FACTIVE. We have entered into an agreement with Biosearch (which merged with Versicor Inc. in March 2003 and subsequently changed its name to Vicuron Pharmaceuticals Inc.) to manufacture bulk quantities of Ramoplanin, and our combined company expects to enter into similar agreements with third parties for the manufacture of future product candidates. Although the LG Life Sciences facilities have previously been inspected by the FDA, they had not been actively manufacturing product for 32 months until their re-start of activity in October 2003. Future inspections may find deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of FACTIVE.

Genesoft expects to purchase its requirements for the final drug product from LG Life Sciences for 2004, which final drug product will be tableted and packaged for LG Life Sciences by SB Pharmco at its manufacturing facility in Puerto Rico. This arrangement with SB Pharmco is expected to conclude by the end of 2004. Genesoft is in discussions with a new secondary manufacturer to assume these responsibilities for subsequent periods. Genesoft may be unable, however, to successfully complete these arrangements. If our combined company is unable to obtain an agreement with a qualified finish and fill contractor to provide services by the end of 2004, the commercialization of FACTIVE could be delayed and our business may be adversely affected. In addition, we cannot assure you that SB Pharmco or any new secondary manufacturer will be able to avoid batch failures or other production delays.

We cannot be certain that LG Life Sciences, Vicuron or future manufacturers will be able to deliver commercial quantities of product candidates to our combined company or that such deliveries will be made on a timely basis. Currently, the only source of supply for FACTIVE bulk drug product is LG Life Sciences' facility in South Korea, and if such facility were damaged or otherwise unavailable, our combined company would incur substantial costs and delay in the commercialization of FACTIVE. If our combined company is forced to find an alternative source for Ramoplanin or other product candidates, we could also incur substantial costs and delays in the commercialization of such products. Our combined company may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. Also, if our combined company changes the source or location of supply or modifies the manufacturing process, regulatory authorities will require us to demonstrate that the product produced by the new source or from the modified process is equivalent to the product used in any clinical trials that we had conducted.

Moreover, while our combined company may choose to manufacture products in the future, we have no experience in the manufacture of pharmaceutical products for clinical trials or commercial purposes. If our combined company decides to manufacture products, it would be subject to the regulatory requirements described above. In addition, our combined company would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical products. No matter who manufactures the products, our combined company will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

### **Our combined company cannot expand the indications for which it will market FACTIVE unless it receives FDA approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for FACTIVE.**

In April 2003, Genesoft received approval from the FDA for the use of FACTIVE to treat community-acquired pneumonia of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis. One of the objectives of our combined company is to expand the indications for which FACTIVE is approved for marketing by the FDA, including for the indication of acute bacterial sinusitis. While clinical trials for acute bacterial sinusitis have previously been completed, our combined company may need to conduct additional





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clinical trials in order to market FACTIVE for this indication. In order to market FACTIVE for other indications, our combined company will need to conduct additional clinical trials, obtain positive results from those trials and obtain FDA approval for such proposed indications. If our combined company is unsuccessful in expanding the approved indications for the use of FACTIVE, the size of the commercial market for FACTIVE will be limited.

### **Failure to obtain regulatory approval in foreign jurisdictions will prevent our combined company from marketing FACTIVE abroad.**

In order to market FACTIVE in the European Union and other foreign jurisdictions for which we have rights to market the product, our combined company or its distribution partners must obtain separate regulatory approvals. Obtaining foreign approvals may require additional trials and expense. Our combined company may not be able to obtain approval or may be delayed in obtaining approval from any or all of the jurisdictions in which it seeks approval to market FACTIVE.

### **Sales of FACTIVE in European countries in which Genesoft does not have rights to market the product could adversely affect sales in the European countries in which Genesoft has exclusive rights to market the product.**

Genesoft's exclusive rights to market FACTIVE in Europe are limited to France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino and Vatican City. These countries include the current members of the European Union. However, over the next several years, a number of additional European countries in which Genesoft does not have rights to market FACTIVE may be admitted as members of the European Union. If LG Life Sciences were to sell FACTIVE or license a third party to sell FACTIVE in such countries after they are admitted to the European Union, our combined company's ability to maintain its projected profit margins based on sales in the territories covered by the LG Life Sciences license agreement may be adversely affected because customers in Genesoft's territory may purchase FACTIVE from neighboring countries in the European Union and our combined company's ability to prohibit such purchases may be limited under European Union antitrust restrictions.

### **Failure to secure distribution partners in foreign jurisdictions will prevent our combined company from marketing FACTIVE abroad.**

Our combined company intends to market FACTIVE through distribution partners in most, if not all, of the international markets for which we have a license to market the product. This will include the European Union. Our combined company may not be able to secure distribution partners at all, or those that we do secure may not be successful in marketing and distributing FACTIVE. If we are not able to secure distribution partners or those partners are unsuccessful in their efforts, it would significantly limit the revenues that we expect to obtain from the sales of FACTIVE.

### **The development and commercialization of the products of our combined company may be terminated or delayed, and the costs of development and commercialization may increase, if third parties who our combined company relies on to manufacture and support the development and commercialization of its products do not fulfill their obligations.**

The development and commercialization strategy of our combined company entails entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage its clinical trials, manufacture its products and market and sell its products outside of the United States. Our combined company

will not have the expertise or the resources to conduct such activities on its own and, as a result, will be particularly dependent on third parties in these areas.

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Our combined company may not be able to maintain its existing arrangements with respect to the commercialization of FACTIVE or establish and maintain arrangements to develop and commercialize Ramoplanin or any additional product candidates or products it may acquire on terms that are acceptable to it. Any current or future arrangements for development and commercialization may not be successful. If our combined company is not able to establish or maintain agreements relating to FACTIVE, Ramoplanin or any additional products it may acquire on terms which it deems favorable, its results of operations would be materially adversely affected.

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

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

delay or otherwise adversely impact the development or commercialization of FACTIVE, Ramoplanin, our other product candidates or any additional product candidates that our combined company may acquire or develop;

require our combined company to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of its products; or

result in the termination of the development or commercialization of the products of our combined company.

**Clinical trials are costly, time consuming and unpredictable, and our combined company will have limited experience conducting and managing necessary preclinical and clinical trials for our product candidates.**

Genesoft's lead product, FACTIVE, will need to complete a Phase IV post-approval clinical trial in compliance with FDA requirements pursuant to the product's approval. Additionally, clinical trials may be necessary to gain approval to market the product for the treatment of acute bacterial sinusitis. Additional clinical trials will be required to gain approval to market FACTIVE for other indications. Our lead product candidate, Ramoplanin, is in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci, also known as VRE, and a Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat *Clostridium difficile*-associated diarrhea (CDAD). Prior clinical and preclinical trials for Ramoplanin were conducted by Biosearch Italia S.p.A. and its licensees, from whom we acquired our license to develop Ramoplanin.

Our combined company may not be able to demonstrate the safety and efficacy of Ramoplanin or of FACTIVE in indications other than those for which it has already been approved or our other products, in each case, to the satisfaction of the FDA, or other regulatory authorities. Our combined company may also be required to demonstrate that its proposed products represent an improved form of treatment over existing therapies and it may be unable to do so without conducting further clinical studies. Negative, inconclusive or inconsistent clinical trial results could prevent regulatory approval, increase the cost and timing of regulatory approval or require additional studies or a filing for a narrower indication.



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The speed with which our combined company is able to complete its clinical trials and its applications for marketing approval will depend on several factors, including the following:

the rate of patient enrollment, which is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the nature of the protocol;

fluctuations in the infection rates for patients enrolled in our trials;

compliance of patients and investigators with the protocol and applicable regulations;

prior regulatory agency review and approval of our applications and procedures;

analysis of data obtained from preclinical and clinical activities which are susceptible to varying interpretations, which interpretations could delay, limit or prevent regulatory approval;

changes in the policies of regulatory authorities for drug approval during the period of product development; and

the availability of skilled and experienced staff to conduct and monitor clinical studies, to accurately collect data and to prepare the appropriate regulatory applications.

In addition, the cost of human clinical trials varies dramatically based on a number of factors, including the order and timing of clinical indications pursued, the extent of development and financial support from alliance partners, the number of patients required for enrollment, the difficulty of obtaining clinical supplies of the product candidate, and the difficulty in obtaining sufficient patient populations and clinicians.

Our combined company will have limited experience in conducting and managing the preclinical and clinical trials necessary to obtain regulatory marketing approvals. Our combined company may not be able to obtain the approvals necessary to conduct clinical studies. Also, the results of the clinical trials of our combined company may not be consistent with the results obtained in preclinical studies or the results obtained in later phases of clinical trials may not be consistent with those obtained in earlier phases. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing. If regulatory approval of a drug is granted, such approval is likely to limit the indicated uses for which it may be marketed. Furthermore, even if a product of our combined company gains regulatory approval, the product and the manufacturer of the product will be subject to continuing regulatory review, including the requirement to conduct post-approval clinical studies. Our combined company may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered.

**The product candidates of our combined company will face significant competition in the marketplace.**

FACTIVE is approved for the treatment of community-acquired pneumonia of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis. There are several classes of antibiotics that are primary competitors for the treatment of these indications, including:

other fluoroquinolones such as Levaquin® (levofloxacin), a product of Ortho-McNeil Pharmaceutical, Inc., Tequin® (gatifloxacin), a product of Bristol-Myers Squibb Company, and Cipro® (ciprofloxacin) and Avelox® (moxifloxacin), both products of Bayer Corporation;

macrolides such as Biaxin® (clarithromycin), a product of Abbott Laboratories and Zithromax® (azithromycin), a product of Pfizer Inc.; and

penicillins such as Augmentin® (amoxicillin/clavulanate potassium), a product of GlaxoSmithKline.

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In addition, a new drug application for Ketek<sup>®</sup>, a ketolide antibiotic from Aventis Pharmaceuticals, has been submitted to the FDA and Ketek is currently marketed in Europe. Many generic antibiotics are also currently prescribed to treat these infections.

Ramoplanin, is currently in development for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE). We have no knowledge of any product currently approved by the FDA for this indication, nor are we aware of any product candidate currently in clinical trials for this indication. It is possible that competition exists without our knowledge and that current discovery and preclinical efforts are ongoing for this indication. Ramoplanin is also in clinical development for the treatment of *Clostridium difficile*-associated diarrhea (CDAD). We are aware of two products currently utilized in the marketplace Vancomin<sup>®</sup> (vancomycin), a product of Eli Lilly, and metronidazole, a generic product for treatment of this indication. We are also aware of at least three companies with products in development for the treatment of CDAD Geltex/Genzyme in Phase II; ImmuCell in Phase I/II; and Acambis in Phase I/II. It is also possible that other companies are developing competitive products for this indication. Genesoft is aware that Vicuron and Novartis Pharma are jointly developing PDF inhibitor agents that may compete with any PDF products developed by our combined company.

All of our other internal product programs are in earlier stages and have not yet reached clinical development and are not yet indication specific. Our alliance-related product development programs are also all in preclinical stages, and it is therefore not possible to identify any product profiles or competitors for these product development programs at this time. Our industry is very competitive and it therefore is likely that if and when product candidates from our early stage internal programs or our alliance programs reach the clinical development stage or are commercialized for sale, these products will also face competition.

Many of the competitors of our combined company will have substantially greater capital resources, facilities and human resources than our combined company. Furthermore, many of those competitors are more experienced than our combined company in drug discovery, development and commercialization, and in obtaining regulatory approvals. As a result, those competitors may discover, develop and commercialize pharmaceutical products or services before our combined company. In addition, the competitors of our combined company may discover, develop and commercialize products or services that are more effective than, or otherwise render non-competitive or obsolete, the products or services that our combined company or its collaborators are seeking to develop and commercialize. Moreover, these competitors may obtain patent protection or other intellectual property rights that would limit the rights of our combined company or the ability of our collaborators to develop or commercialize pharmaceutical products or services.

### **Health care insurers and other payers may not pay for our combined company's products or may impose limits on reimbursement.**

The ability of our combined company to commercialize FACTIVE, Ramoplanin and its future products will depend, in part, on the extent to which reimbursement for such products will be available from third-party payers, such as Medicare, Medicaid, health maintenance organizations, health insurers and other public and private payers. If our combined company succeeds in bringing FACTIVE, Ramoplanin or other products in the future to market, we cannot assure you that third-party payers will pay for such products or will establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development. If adequate coverage and reimbursement levels are not provided by government and private payers for use of the products of our combined company, our products may fail to achieve market acceptance and the results of operations of our combined company may be materially adversely affected.

Many health maintenance organizations and other third-party payers use formularies, or lists of drugs for which coverage is provided under a health care benefit plan, to control the costs of prescription drugs. Each payer that maintains a drug formulary makes its own determination as to whether a new drug will be added to the formulary and whether particular drugs in a therapeutic class will have preferred status over other drugs in the





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same class. This determination often involves an assessment of the clinical appropriateness of the drug and sometimes the cost of the drug in comparison to alternative products. We cannot assure you that FACTIVE, Ramoplanin or any of the future products of our combined company will be added to payers' formularies, whether the products of our combined company will have preferred status to alternative therapies, nor whether the formulary decisions will be conducted in a timely manner. Our combined company may also decide to enter into discount or formulary fee arrangements with payers, which could result in our receiving lower or discounted prices for FACTIVE, Ramoplanin or future products.

**Our combined company will rely upon existing and prospective alliance partners, licensees and government grants and contracts as a source of revenue for its operations and as a means of developing and commercializing its products.**

The strategy of our combined company for developing and commercializing therapeutic, vaccine and diagnostic products depends, in part, on strategic alliances and licensing arrangements with pharmaceutical and biotechnology partners. We currently have alliances with AstraZeneca, Amgen, bioMérieux, Schering-Plough and Wyeth. We have received a substantial portion of our revenue from these alliances, and the combined company expects to continue to earn revenues from them. Under these arrangements, the combined company will be entitled to receive payments and royalties based on the achievement by it and its partners of certain development milestones and the successful development of products arising from the collaborations. Although we have achieved many of the scientific milestones under our agreements, the combined company cannot assure you that it will continue these achievements in the future or that milestones dependent on its partners' development and commercialization activities will be attained.

In order to maintain the collaboration agreements with each of Amgen and Wyeth, the combined company must fulfill certain obligations, including carrying out research programs agreed to by the parties, keeping records of its research activities, providing periodic reports on the status of each research program, devoting qualified personnel to each research program, and providing its collaborators with reasonable technical assistance in using the know-how or other information that it has licensed to them. Under our other collaboration agreements, we have fulfilled all of our research and development obligations and the combined company will have no material obligations going forward. We believe that we are currently in compliance with our obligations under our collaboration agreements, but there can be no assurance that the combined company will be able to successfully complete its obligations in the future due to, among other things, an inability to achieve scientific goals or a lack of qualified personnel.

If the partners of our combined company develop products using our discoveries, it will rely on these partners for product development, regulatory approval, manufacturing and marketing of those products before it can receive some of the milestone payments, royalties and other payments to which it may be entitled under the terms of some of its alliance agreements. Our agreements with our partners typically allow the partners significant discretion in electing whether to pursue any of these activities. Our combined company will not be able to control the amount and timing of resources its partners may devote to its programs or potential products. As a result, there can be no assurance that the partners of our combined company will perform their obligations as expected.

The strategy of our combined company will include entering into multiple, concurrent alliances and business partnerships, including, but not limited to in-licensing and co-promotion agreements. There can be no assurance that our combined company will be able to manage multiple alliances and partnerships successfully. The risks our combined company will face in managing multiple alliances and partnerships include maintaining confidentiality among partners, avoiding conflicts between partners and avoiding conflicts between our combined company and its partners. If our combined company fails to manage its alliances and partnerships effectively, or if any of the problems described above arise, one or more of the following could occur which could have a material adverse effect on the business of our combined company:

use of significant resources to resolve conflicts,

delay in, or an adverse effect on, sales and marketing efforts for the combined company's products,

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delay in development activities,

legal claims involving significant time,

expense,

loss of reputation, and

termination of one or more alliances, or loss of capital and loss of revenues.

Both we and Genesoft have applied for and received grants from the U.S. government in the past. The strategy of our combined company going forward will include the continued pursuit of government grants and contracts. We can not assure you that our combined company will obtain any additional grants or that our existing grants will continue to be funded. If our combined company is unable to obtain additional grants or maintain its existing grants, its revenues would be adversely affected.

**Development of therapeutic, diagnostic and vaccine products by the strategic alliance partners of our combined company based on its discoveries will be subject to the high risks of failure inherent in the development or commercialization of biopharmaceutical products.**

There can be no assurance of the successful development or commercialization of any products by the strategic alliance partners of our combined company. Successful development and commercialization will be subject to numerous risks at each stage. For example, there can be no assurance that the high-throughput screening or lead optimization processes for a given strategic alliance will identify any compounds suitable for clinical development. Even if product candidates based on discoveries of our combined company undergo clinical trials, there can be no assurance that those clinical trials will indicate that the product candidates are safe or effective. The pace at which the clinical trials proceed is also uncertain. Furthermore, after the completion of clinical trials, a product could fail to receive necessary regulatory approvals due to negative, inconclusive or insufficient clinical data or other reasons beyond the control of our combined company. Even if the necessary regulatory approvals for a product are obtained, it may be difficult or impossible to manufacture the product on a large scale, be uneconomical to market, fail to be developed prior to the successful marketing of similar products by competitors or infringe on proprietary rights of third parties.

**The failure of our combined company to acquire and develop additional product candidates or approved products will impair its ability to grow.**

As part of its growth strategy, our combined company intends to acquire and develop additional product candidates or approved products. The success of this strategy depends upon its ability to identify, select and acquire biopharmaceutical products that meet its criteria. Our combined company may not be able to acquire the rights to additional product candidates and approved products on terms that it finds acceptable, or at all.

New product candidates acquired or in-licensed by our combined company may require additional research and development efforts prior to commercial sale, including extensive preclinical and/or clinical testing and approval by the FDA and corresponding foreign regulatory authorities. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe, non-toxic and effective or approved by regulatory authorities. In addition, it is uncertain whether any approved products that our combined company develops or acquires will be:

manufactured or produced economically;

successfully commercialized; or

widely accepted in the marketplace.

**Future acquisitions may absorb significant resources and may be unsuccessful.**

As part of its strategy, our combined company may pursue acquisitions of businesses or assets, investments and other relationships and alliances. Acquisitions may involve significant cash expenditures, debt incurrence,

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additional operating losses, dilutive issuances of equity securities, and expenses that could have a material adverse effect on the financial condition and results of operations of our combined company. For example, to the extent that our combined company elects to pay the purchase price for such acquisitions in shares of its stock, the issuance of additional shares of its stock will be dilutive to our stockholders. Acquisitions involve numerous other risks, including:

difficulties integrating acquired technologies and personnel into the business of our combined company;

diversion of management from daily operations;

inability to obtain required financing on favorable terms;

entering new markets in which our combined company has little or no previous experience;

potential loss of key employees or customers of acquired companies;

assumption of the liabilities and exposure to unforeseen liabilities of acquired companies; and

amortization of the intangible assets of acquired companies.

It may be difficult for our combined company to complete these types of transactions quickly and to integrate the businesses efficiently into its business. Any acquisitions or investments by our combined company may ultimately have a negative impact on its business and financial condition.

### **Our combined company will depend on key personnel in a highly competitive market for skilled personnel.**

Our combined company will be highly dependent on the principal members of our senior management and key scientific and technical personnel. The loss of any of its personnel could have a material adverse effect on its ability to achieve its goals. Our combined company will maintain employment agreements with our existing senior officers: Steven M. Rauscher, President and Chief Executive Officer; Stephen Cohen, Senior Vice President and Chief Financial Officer; and Martin D. Williams, Senior Vice President, Corporate Development & Marketing. The term of each employment agreement continues until it is terminated by the officer or the combined company. We do not currently maintain key person life insurance on any of our employees.

The future success of our combined company is dependent upon its ability to attract and retain additional qualified sales and marketing, clinical development, scientific and managerial personnel. The plan to launch the commercial sale of FACTIVE during the second half of 2004 will require the combined company to hire approximately 90 to 100 new employees, primarily with expertise in the areas of sales and marketing. Like others in our industry, our combined company may face, and in the past we and Genesoft have faced from time to time, difficulties in attracting and retaining certain employees with the requisite expertise and qualifications. We and Genesoft believe that our historical recruiting periods and employee turnover rates are similar to those of others in our industry, however, we cannot be certain that our combined company will not encounter greater difficulties in the future.

**The intellectual property protection and other protections of our combined company may be inadequate to protect its products.**

The success of our combined company will depend, in part, on its ability to obtain commercially valuable patent claims and protect its intellectual property. We currently have 15 issued U.S. patents, 86 pending U.S. patent applications, 10 issued foreign patents and 39 pending foreign patent applications. These patents and patent applications primarily relate to the field of human and pathogen genetics. Our material patents are as follows:

U.S. Patent No. 6,380,370 granted April 30, 2002, relating to *Staphylococcus epidermidis*; expiring August 13, 2018

U.S. Patent No. 6,551,795 granted April 22, 2003, relating to *Pseudomonas aeruginosa*; expiring February 18, 2019

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U.S. Patent No. 6,562,958 granted May 13, 2003, relating to *Acinetobacter baumannii*; expiring June 4, 2019

U.S. Patent No. 6,583,275 granted June 24, 2003, relating to *Enterococcus faecium*; expiring June 30, 2018

U.S. Patent No. 6,583,266 granted June 24, 2003, relating to *Mycobacterium tuberculosis* and *leprae*; expiring June 24, 2020

U.S. Patent No. 6,605,709 granted August 12, 2003, relating to *Proteus mirabilis*; expiring April 5, 2020

U.S. Patent No. 6,6105,836 granted August 26, 2003, relating to *Klebsiella pneumoniae*; expiring January 27, 2020

U.S. Patent No. 6,617,156 granted September 9, 2003, relating to *Enterococcus faecalis*; expiring August 13, 2018

Genesoft currently owns or licenses 34 issued U.S. patents, approximately 42 pending U.S. patent applications, approximately 40 issued foreign patents and approximately 104 pending foreign patent applications. These patents and patent applications primarily relate to the chemical composition, use, and method of manufacturing FACTIVE, to metalloenzyme inhibitors, their uses, and their targets, and to DNA-Nanobinder compounds and their use as anti-infective therapeutics. The following list of U.S. patents (along with their foreign counterparts) constitutes Genesoft's material patents:

U.S. Patent No. 5,633,262 filed June 15, 1995, entitled Quinoline carboxylic acid derivatives having 7-(4-amino-methyl-3-oxime) pyrrolidine substituent and processes for preparing thereof, licensed from LG Life Sciences; expiring June 15, 2015.

U.S. Patent No. 5,776,944 filed April 4, 1997, entitled 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid and the process for the preparation thereof, licensed from LG Life Sciences; expiring June 15, 2015.

U.S. Patent No. 5,869,670 filed March 27, 1998, entitled 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid and the process for the preparation thereof, licensed from LG Life Sciences; expiring June 15, 2015.

U.S. Patent No. 5,962,468 filed November 9, 1998, entitled 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid and the process for the preparation thereof, licensed from LG Life Sciences; expiring June 15, 2015.

U.S. Patent No. 6,423,690, entitled Antibacterial agents, licensed from Vernalis; expiring February 5, 2019.

U.S. Patent No. 6,441,042, entitled Hydroxamic acid derivatives as antibacterials, licensed from Vernalis; expiring May 14, 2019.

While it is difficult to assess the value of our combined company's intellectual property portfolio, we anticipate that the patents named above will provide a competitive advantage in certain instances in the pathogen and anti-infective field by requiring others to obtain a license from us if they wish to produce competing products.

Neither we nor Genesoft is currently involved in any litigation, settlement negotiations, or other legal action regarding patent issues and neither we nor Genesoft is aware of any patent litigation threatened against them. The patent position of both us and Genesoft involves complex legal and factual questions, and legal standards relating to the validity and scope of claims in the applicable technology fields are still evolving. Therefore, the degree of future protection for the proprietary rights of our combined company is uncertain.

The patents that we license to Ramoplanin under the License and Supply Agreement with Vicuron include claims relating to methods of manufacturing Ramoplanin as well as methods increasing the yield of the active



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compound. We also have applications pending relating to various novel uses of Ramoplanin. The patent covering the chemical composition of Ramoplanin has expired. To provide additional protection for Ramoplanin, we rely on proprietary know-how relating to maximizing yields in the manufacture of Ramoplanin, as well as the five year data exclusivity provisions under the Hatch-Waxman Act.

LG Life Sciences, as owner of U.S. Patent Nos. 5,776,944 and 5,962,468, submitted requests for reexamination to the U.S. Patent & Trademark Office, or PTO, in order to place additional references into the record of each patent. Both requests were granted by the PTO. Patent 468 has been reexamined with relatively minor modifications to the claims and confirmed patentable over the submitted references. The reexamination of Patent 944 is currently pending. If the PTO does not confirm the claims in this patent as patentable, our patent protection with respect to FACTIVE in the U.S. may be weakened.

The risks and uncertainties that our combined company will face with respect to its patents and other proprietary rights include the following:

the pending patent applications that we and Genesoft have filed or to which they have exclusive rights may not result in issued patents or may take longer than expected to result in issued patents;

the claims of any patents which are issued may be limited from those in the patent applications and may not provide meaningful protection;

our combined company may not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to our combined company or our partners may not provide a competitive advantage;

other companies may challenge patents licensed or issued to our combined company or our partners;

patents issued to other companies may harm the ability of our combined company to do business;

other companies may independently develop similar or alternative technologies or duplicate the technologies of our combined company; and

other companies may design around technologies our combined company has licensed or developed.

In addition, we are aware that some companies have published patent applications relating to nucleic acids and proteins from various pathogenic organisms. If these companies receive issued patents, their patents may limit the ability of our combined company and the ability of its collaborators to practice under any patents that may be issued to our combined company or its collaborators. Because of this, our combined company or its collaborators may not be able to obtain patents with respect to the genes of infectious agents or the value of certain other patents issued to our combined company or its collaborators may be limited. Also, even if a patent were issued to our combined company, the scope of coverage or protection afforded to such patent may be limited.

**Our combined company will bear substantial responsibilities under its license agreements for FACTIVE and Ramoplanin, and there can be no assurance that our combined company will successfully fulfill its responsibilities.**

Under our agreement with Vicuron, we have obtained an exclusive license to develop and market oral Ramoplanin in the United States and Canada. Under this agreement, we are responsible, at our expense, for the clinical and non-clinical development of Ramoplanin in our field, the prevention and treatment of human disease, in the United States and Canada, including the conduct of clinical trials and the filing of drug approval applications with the FDA and other applicable regulatory authorities. Vicuron is responsible for providing us with all information in its possession relating to Ramoplanin in our licensed field, for cooperating with us in

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obtaining regulatory approvals of Ramoplanin and for using diligent efforts to provide us with bulk Ramoplanin sufficient to carry out our clinical development activities. We believe that we are currently in compliance with our obligations under the License and Supply Agreement, but there can be no assurance that our combined company will be able to remain in compliance due to the limitations on its resources and the many risks of conducting clinical trials, as described above in Clinical trials are costly, time consuming and unpredictable, and our combined company has limited experience conducting and managing necessary preclinical and clinical trials for its product candidates .

Under our agreement with Vicuron, Vicuron has the obligation to prosecute patents relating to Ramoplanin that are made by Vicuron personnel or conceived jointly by our personnel and Vicuron s personnel. We have the obligation to prosecute patents relating to Ramoplanin that are made solely by our personnel. We have the right to control any suits brought by a third party alleging that the manufacture, use or sale of Ramoplanin in our licensed field in the United States or Canada infringes upon our rights. Our combined company will bear the costs of any such actions, which could be substantial; provided that if our combined company is obligated to pay any royalties or other payments to a third party to sell Ramoplanin as a result of this litigation, including any settlement reached with Vicuron s consent, Vicuron is obligated to pay that expense.

We also have the primary right to pursue actions for infringement of any patent licensed from Vicuron under the License and Supply Agreement within the United States and Canada within our licensed field. Vicuron has the primary right to pursue actions for infringement of any patents that it licenses to us under the License and Supply Agreement outside of our licensed field within the United States and Canada and for all purposes outside of the United States and Canada. If the party with the primary right to pursue the infringement actions elects not to pursue it, the other party generally has the right to pursue it. The costs of any infringement actions are first paid out of any damages recovered and are then allocated to the parties depending upon their interest in the suit. The costs of pursuing any such action could substantially diminish the resources of our combined company.

Under Genesoft s License and Option Agreement with LG Life Sciences, its has obtained an exclusive license to develop and market FACTIVE in North America and France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino and Vatican City. Under this agreement, Genesoft is responsible, at its expense and through consultation with LG Life Sciences, for the clinical and commercial development of FACTIVE in the countries covered by the license, including the conduct of clinical trials, the filing of drug approval applications with the FDA and other applicable regulatory authorities and the marketing, distribution and sale of FACTIVE in its territory. The agreement also requires a minimum sales commitment over a period of time, which if not met, would result in the technology being returned to LG Life Sciences. Genesoft believes that it is currently in compliance with its obligations under its agreement with LG Life Sciences, but there can be no assurance that our combined company will be able to remain in compliance due to the limitations on its resources and the many risks of conducting clinical trials, as described above in Clinical trials are costly, time consuming and unpredictable, and our combined company has limited experience conducting and managing necessary preclinical and clinical trials for its product candidates and the challenges inherent in the commercialization of new products as described above in The product candidates of our combined company will face significant competition in the marketplace .

Under Genesoft s License and Option Agreement with LG Life Sciences, LG Life Sciences has the obligation to diligently maintain its patents and the patents of third parties to which it has rights that, in each case, relate to FACTIVE. Genesoft has the right to control any litigation relating to suits brought by a third party alleging that the manufacture, use or sale of FACTIVE in its licensed field in the territories covered by the license infringes upon their rights. Our combined company will bear the costs of any such actions, which could be substantial.

Genesoft also has the primary right to pursue actions for infringement of any patent licensed from LG Life Sciences under the License and Option Agreement within the territories covered by the license. If Genesoft elects not to pursue any infringement action, LG Life Sciences has the right to pursue it. The costs of any infringement actions are first paid out of any damages recovered. If Genesoft is the plaintiff, the remainder of the damages are



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retained by Genesoft, subject to its royalty obligations to LG Life Sciences. If LG Life Sciences is the plaintiff, the remainder of the damages are divided evenly between the parties, subject to Genesoft's royalty obligations to LG Life Sciences. The costs of pursuing any such action could substantially diminish the resources of our combined company.

### **The proprietary position of our combined company may depend on its ability to protect trade secrets.**

Our combined company will rely on trade secret protection for its confidential and proprietary information and procedures. We and Genesoft currently protect such information and procedures as trade secrets. Our combined company will continue to protect our trade secrets through recognized practices, including access control, confidentiality agreements with employees, consultants, collaborators, and customers, and other security measures. These confidentiality agreements may be breached, however, and our combined company may not have adequate remedies for any such breach. In addition, the trade secrets of our combined company may otherwise become known or be independently developed by competition.

### **Our combined company may infringe the intellectual property rights of third parties and may become involved in expensive intellectual property litigation.**

The intellectual property rights of biotechnology companies, including our combined company, are generally uncertain and involve complex legal, scientific and factual questions. The success of our combined company in developing and commercializing biopharmaceutical products may depend, in part, on its ability to operate without infringing on the intellectual property rights of others and to prevent others from infringing on its intellectual property rights.

There has been substantial litigation regarding patents and other intellectual property rights in the biopharmaceutical industry. Our combined company may become party to patent litigation or proceedings at the U.S. Patent and Trademark Office or a foreign patent office to determine its patent rights with respect to third parties which may include competitors in the biopharmaceutical industry. Interference proceedings in the U.S. Patent and Trademark Office or opposition proceedings in a foreign patent office may be necessary to establish which party was the first to discover such intellectual property. Our combined company may become involved in patent litigation against third parties to enforce its patent rights, to invalidate patents held by such third parties, or to defend against such claims. The cost to our combined company of any patent litigation or similar proceeding could be substantial, and it may absorb significant management time. Our combined company does not expect to maintain separate insurance to cover intellectual property infringement. The general liability insurance policy of our combined company may not cover infringement by it of the intellectual property rights of others, depending upon the circumstances. The aggregate coverage provided under our existing general liability insurance policy is \$10,000,000. We do not currently intend to increase the amount of this insurance following completion of the merger, though our combined company will continue to evaluate the sufficiency of its coverage levels periodically. If an infringement litigation against our combined company is resolved unfavorably, our combined company may be enjoined from manufacturing or selling certain of its products or services without a license from a third party. Our combined company may not be able to obtain such a license on commercially acceptable terms, or at all.

### **Our combined company may not be able to obtain meaningful patent protection for discoveries under its government contracts.**

Under the government grants and contracts of our combined company, the government will have a statutory right to practice or have practiced any inventions developed under the government research contracts. In addition, under certain circumstances, such as inaction on the part of our combined company or its licensees to achieve practical application of the invention or a need to alleviate public health or safety concerns not reasonably satisfied by our combined company or its licensees, the government will have the right to grant to other parties licenses to any

inventions first reduced to practice under the government grants and contracts. If the

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government grants such a license to a third party, the patent position of our combined company may be jeopardized. In addition, the government will have ownership rights in the data and discoveries derived from any materials furnished to our combined company by the government.

### **International patent protection is uncertain.**

Patent law outside the United States is uncertain and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect the intellectual property rights of our combined company to the same extent as U.S. laws. Our combined company may participate in opposition proceedings to determine the validity of its or its competitors' foreign patents, which could result in substantial costs and diversion of its efforts.

### **The activities of our combined company will involve hazardous materials and may subject it to environmental liability.**

The research and development activities of our combined company will involve the controlled use of hazardous and radioactive materials and biological waste. Our combined company will be subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. Although we and Genesoft believe that their existing safety procedures for handling and disposing of these materials comply with legally prescribed standards, our combined company will not be able to completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, our combined company could be held liable for damages or penalized with fines, and this liability could exceed its resources. We do not expect our combined company to maintain separate insurance to cover contamination or injuries relating to hazardous materials. Such liabilities may not be covered by our existing general liability insurance coverage, depending upon the circumstances. The aggregate coverage provided under our general liability insurance policy is \$10,000,000. We do not currently intend to increase the amount of this insurance following completion of the merger, though our combined company will continue to evaluate the sufficiency of its coverage levels periodically.

### **If a successful product liability claim or series of claims is brought against our combined company for uninsured liabilities or in excess of insured liabilities, our combined company could be forced to pay substantial damage awards.**

The use of any of our combined company's product candidates in clinical trials, and the sale of any approved products, might expose our combined company to product liability claims. We currently maintain, and we expect that our combined company will continue to maintain, product liability insurance coverage in the amount of \$10 million per occurrence and \$10 million in the aggregate. Such insurance coverage might not protect our combined company against all of the claims to which our combined company might become subject. Our combined company might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, our combined company might be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, our combined company might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our combined company's business.

### **Risks Related to the Merger**

**The issuance of 28,571,405 shares of our common stock to Genesoft security holders in the merger will substantially reduce the percentage interests of our security holders.**

If the merger is completed, 28,571,405 shares of our common stock will be issued to current Genesoft security holders, including shares of our common stock to be issued upon the exercise of Genesoft options and warrants that we will assume. As of November 30, 2003, we had 31,451,099 shares of our common stock outstanding, outstanding options exercisable into 4,086,634 shares of our common stock, outstanding warrants



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exercisable into 3,221,250 shares of common stock or a total of 38,758,983 shares of common stock on a fully diluted basis. The issuance of the 28,571,405 shares of our common stock to current Genesoft stockholders will cause a significant reduction in the relative percentage interests of our current stockholders in earnings, voting, liquidation value and book and market value.

### **We may suffer negative consequences if the merger is not completed.**

If the merger is not completed for any reason, we may suffer negative consequences and be subject to material risks, including:

we will be unable to market FACTIVE, and since all of our products are at a significantly earlier stage of development than FACTIVE and none of these products has yet been approved by the FDA, it will take us longer to achieve the commercial launch of a product, if we are able to do so at all, and as a result we will need to find additional sources of funding or curtail or cease operations;

the market price of our common stock may decline to the extent that the current market price of such shares reflects a market assumption that the merger will be completed, or for other reasons;

costs related to the merger, such as legal and accounting fees, must be paid even if the merger is not completed;

the provision in the merger agreement which provides that under specified circumstances we could be required to pay Genome a termination fee of approximately \$3 million, plus up to \$1 million of expenses incurred in connection with the merger;

the diversion of management attention from the day-to-day business of our company and the unavoidable disruption to our employees during the period before completion of the merger may make it difficult for us to regain our financial position and strategic focus if the merger does not occur;

employees important to our success as a stand-alone company may have left in anticipation of the merger; and

business opportunities important to us as a stand-alone company may have been terminated or not pursued by either us or third parties in anticipation of the merger.

**The assumption by us of approximately \$24 million of debt of Genesoft at the closing will substantially increase our leverage and, to the extent that a portion of this debt is subsequently converted into our common stock, will substantially reduce the percentage interests of the stockholders of the combined company.**

Upon the closing of the merger, we will assume approximately \$24 million of debt of Genesoft. We will pay approximately \$1.7 million of this debt at closing. The remainder of the debt consists of promissory notes of Genesoft that we will exchange for our convertible promissory notes, which will bear interest at 5% per annum and have a maturity date of five years from the closing date. If these notes are not converted into shares of our common stock during the five-year period, the subsequent payment of these notes at maturity may require us to expend a significant portion of its capital resources. Depending upon the combined company's capital resources at the maturity date, the payment of these notes could impair the combined company's working capital and prevent it from pursuing important clinical development and commercialization programs.

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The \$22,309,647 in aggregate original principal amount of our convertible notes to be issued at the closing of the merger will be convertible into shares of our common stock at the holder's election at any time after the closing of the merger at a price per share equal to one hundred and ten percent of the average closing price of our common stock for the five trading days preceding the closing date of the merger, subject to subsequent adjustment. In addition, following the one year anniversary of the closing of the merger, the combined company will have the right to force conversion if the price of our common stock closes above 150% of the then effective conversion price for 15 consecutive days. The conversion of all or a substantial portion of these convertible notes would cause a

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significant reduction in the relative percentage interests of our stockholders and Genesoft stockholders in the earnings, voting power, liquidation value and book and market value of the combined company.

**Upon the consummation of the merger, we will be required to pay \$8 million to LG Life Sciences, Ltd. under Genesoft's License and Option Agreement with LG Life Sciences for FACTIVE, which will diminish the combined company's financial resources.**

Upon the closing of the merger, we will be required to pay \$8 million to LG Life Sciences as a milestone payment under Genesoft's License and Option Agreement with LG for FACTIVE. This payment will consume a substantial portion of the combined company's available cash at closing and, depending upon how much capital has been raised at that point, may limit the combined company's ability to pursue additional development or commercialization programs.

**The combined company may not realize all of the anticipated benefits of the merger.**

The success of the merger will depend, in part, on the ability of the combined company to realize the anticipated synergies, cost savings and growth opportunities from integrating our business with the business of Genesoft. The combined company's success in realizing these benefits and the timing of this realization depends upon the successful integration of the operations of Genesoft. The integration of two independent companies, especially when one company is located on the West Coast and the other on the East Coast, is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies and realizing the expected benefits of the merger include, among others:

coordinating commercial and clinical development initiatives and staffs for FACTIVE and Ramoplanin;

raising sufficient capital to fund the significant expenditures that are needed to launch and successfully commercialize FACTIVE and the further clinical development of Ramoplanin;

retaining key employees;

consolidating research and development operations;

consolidating corporate and administrative infrastructures and physical plant;

integrating and managing the technology of two companies; and

minimizing the diversion of management's attention from ongoing business concerns.

We cannot assure you that the integration of Genesoft with us will result in the realization of the full benefits anticipated by them to result from the merger.

**If the merger does not close, we may not be able to obtain repayment of the \$6.2 million bridge loan made to Genesoft.**

Coincident with the signing of the merger agreement, we made a bridge loan of \$6.2 million to Genesoft pursuant to a promissory note issued by Genesoft, which is repayable within 60 days of an event of default (as defined in the note) or termination of the merger agreement, unless the merger agreement is terminated by Genesoft due to our failure to obtain the stockholder vote necessary to approve the merger, in which case it is repayable within 180 days of termination. However, if the note becomes repayable, it is uncertain whether we will be able to obtain repayment due to Genesoft's lack of liquid assets, and even if we are able to obtain repayment, we may be required to expend additional resources and time to foreclose on assets of Genesoft.

**The cash resources of the combined company could be materially depleted if a substantial number of Genesoft stockholders exercise their dissenters' rights under California law or appraisal rights under Delaware law.**

Holders of Genesoft capital stock who dissent and do not consent to the approval and adoption of the merger agreement may be entitled to certain dissenters' rights under the California Corporations Code and to appraisal

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rights under Delaware General Corporation Law, or DGCL, in connection with the merger. If the merger is consummated, a holder of record of Genesoft stock who complies with the statutory procedures will be entitled to have those shares appraised by the Delaware Court of Chancery under Section 262 of the DGCL and to receive payment for the fair value of those shares instead of the consideration provided for in the merger agreement. Similarly, under Chapter 13 of the California Corporations Code, a holder of Genesoft common stock who complies with the statutory procedures will be entitled to have its shares converted into the right to receive from Genesoft such consideration as may be determined to be due under the statute. If a substantial number of Genesoft stockholders exercise their dissenters' rights under California law or appraisal rights under Delaware law, as the case may be, the combined company may be required to make substantial payments in cash to these stockholders, thereby materially depleting the cash resources of the combined company.

## **Risks Related to The Securities Market and This Offering**

### **Our stock price is highly volatile.**

The market price of our stock has been and is likely to continue to be highly volatile due to the risks and uncertainties described in this section of the prospectus, as well as other factors, including:

our ability to successfully launch and commercialize FACTIVE;

the revenues that we may derive from the sale of FACTIVE, as compared to analyst estimates;

the results of our clinical trials for Ramoplanin and additional indications for FACTIVE and the pace of our progress in those clinical trials;

our ability to license or develop other compounds for clinical development;

the timing of achievement of our development milestones and other payments under our strategic alliance agreements;

termination of, or an adverse development in, our strategic alliances;

conditions and publicity regarding the biopharmaceutical industry generally;

price and volume fluctuations in the stock market at large which do not relate to our operating performance; and

comments by securities analysts, or our failure to meet market expectations.

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Over the two-year period ending December 12, 2003 the closing price of our common stock as reported on the Nasdaq National Market ranged from a high of \$7.18 to a low of \$1.03. The stock market has from time to time experienced extreme price and volume fluctuations that are unrelated to the operating performance of particular companies. In the past, companies that have experienced volatility have sometimes been the subject of securities class action litigation. If litigation were instituted on this basis, it could result in substantial costs and a diversion of management's attention and resources.

**We have issued warrants to purchase 3,221,250 shares of common stock and the re-sale of the shares underlying these warrants could cause a dilution of our existing shareholders.**

On June 4, 2003, as part of the Amendment, Redemption and Exchange Agreement pertaining to our convertible notes held by two institutional investors, we issued warrants that are exercisable to purchase 511,250 shares of common stock at an exercise price of \$3.53 per share (subject to anti-dilution and other adjustments), which are exercisable and expire on June 4, 2008. In connection with the issuance of these convertible notes, we are also obligated to issue to the placement agent warrants that are exercisable to purchase up to 100,000 shares of common stock at an exercise price of \$15.00 per share, which warrants expire on March 5, 2005. On September 29, 2003 and October 15, 2003, we had closings of a private placement transaction in which we issued warrants to purchase 1,910,000 and 700,000 shares of common stock, respectively, at an exercise price of \$3.48. The September 2003 warrants become exercisable on March 29, 2004 and remain exercisable until September 29, 2008. The October 2003 warrants become exercisable on April 15, 2004 and remain exercisable until October 15, 2008. The shares underlying the June 2003, September 2003 and October 2003 warrants are registered for

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re-sale. If any of the warrants are exercised, these shares could be sold into the market creating dilution of the ownership of our shareholders at that time.

### **Multiple factors beyond our control may cause fluctuations in our operating results and may cause our business to suffer.**

Our revenues and results of operations may fluctuate significantly, depending on a variety of factors, including the following:

the pace of our commercial launch of FACTIVE;

the level of acceptance by physicians and third party payors of FACTIVE;

the progress of our clinical trials for FACTIVE, Ramoplanin and our other product candidates;

our success in concluding deals to acquire additional approved products and product candidates;

the introduction of new products and services by our competitors;

regulatory actions; and

expenses related to, and the results of, litigation and other proceedings relating to intellectual property rights.

We will not be able to control many of these factors. In addition, if our revenues in a particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our business to suffer. We believe that period-to-period comparisons of our financial results will not necessarily be meaningful. You should not rely on these comparisons as an indication of our future performance. If our operating results in any future period fall below the expectations of securities analysts and investors, our stock price may fall, possibly by a significant amount.

**Because the total price you will pay for your shares in the offering will be much greater than the value of our assets after subtracting our liabilities, the value of your investment in our common stock will be diluted.**

If you purchase our common stock in this offering, the price you will pay for our common stock will be much greater than the book value per share of our outstanding common stock after the offering. In addition, the total amount of our capital will be less than it would have been had you and all of the existing stockholders, optionees, and warrant holders paid the same amount per share of our common stock. Accordingly, you will suffer immediate and substantial dilution of your investment. In the past, we have issued options and warrants to buy our common stock at prices below the offering price. You will experience further dilution to the extent that additional shares of our common stock are issued upon the exercise of outstanding stock options and warrants. See [Dilution](#) for a detailed calculation of the dilution that will result from this offering.

**Certain of our financial statements have been audited by Arthur Andersen LLP, and the ability to recover damages from Arthur Andersen may be limited.**

Prior to June 24, 2002, Arthur Andersen LLP served as our independent public accountants. Our inability to obtain the consent of Arthur Andersen to include its report on certain financial statements audited by Arthur Andersen and incorporated by reference in this prospectus may limit your recovery against Arthur Andersen. SEC rules require us to include or incorporate by reference in this prospectus certain historical financial statements for the years ended December 31, 2001 and 2000 that were audited by Arthur Andersen. As a result of the well-publicized events concerning Arthur Andersen, we have not been able to obtain the consent of Arthur Andersen to the inclusion of its audit report in this prospectus and will not be able to obtain Arthur Andersen's consent in the future. The absence of this consent may limit any recovery to which you might be entitled against Arthur Andersen. It is also likely that these events concerning Arthur Andersen would adversely affect its ability to satisfy any claims we might have arising from its provision of auditing and other services to us.



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**CAUTIONARY STATEMENTS REGARDING  
FORWARD-LOOKING STATEMENTS IN THIS PROSPECTUS**

This prospectus and the documents we incorporate by reference into this prospectus contain forward-looking statements about the merger, us and Genesoft within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements represent the judgment of our management regarding future events. Forward-looking statements typically are identified by use of terms such as may, will, should, plan, expect, intend, anticipate, estimate, and similar words, although forward-looking statements are expressed differently. We do not plan to update these forward-looking statements. You should be aware that actual results could differ materially from those contained in the forward-looking statements due to a number of risks affecting our business and the businesses of Genesoft and the combined company.

Although we believe that our plans, intentions and expectations as reflected in or suggested by these forward-looking statements are reasonable, we can give no assurance that these plans, intentions or expectations will be achieved. You are cautioned that all forward-looking statements involve risks and uncertainties and actual results may differ materially from those discussed as a result of various risk factors described in the section entitled **Risk Factors**. Discussed in the **Risk Factors** section and elsewhere in this prospectus are some important risks, uncertainties and contingencies which could cause our, Genesoft's or the combined company's actual results, performances or achievements to be materially different from the forward-looking statements made in this prospectus, particularly if the merger is not completed.

**USE OF PROCEEDS**

We estimate that our net proceeds from the sale of 11,000,000 shares of common stock offered by us, assuming a public offering price of \$3.30 per share, will be approximately \$33.2 million after deducting placement agent fees and all estimated offering expenses that are payable by us.

We anticipate using the net proceeds from this offering as follows:

to fund the commercial launch of FACTIVE;

to fund further clinical development of FACTIVE and our other product candidates, including Ramoplanin; and

to provide working capital and for general corporate purposes.

We cannot estimate precisely the allocation of the net proceeds from the offering among these uses, and we will retain broad discretion over the use of the net proceeds. The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of our commercial launch of FACTIVE. We also may use a portion of the net proceeds to acquire additional products consistent with our strategy, although we have not allocated any portion of the net proceeds for any specific acquisition.

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Pending the use of the net proceeds, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities or guaranteed obligations of the United States or its agencies.

**Table of Contents****CAPITALIZATION**

The following table sets forth our capitalization as of September 27, 2003:

on an actual basis;

on a pro forma basis to reflect the receipt of net proceeds of \$11.6 million from the issuance in October 2003 of 5.2 million shares of our common stock, as well as to give effect to the proposed combination with Genesoft Pharmaceuticals and the amendment to our Articles of Organization to increase the number of shares of common stock we are authorized to issue to 175,000,000; and

on a pro forma as adjusted basis to reflect, in addition to the pro forma adjustments discussed above, the sale of 11,000,000 shares of common stock by us in this offering at an assumed sale price of \$3.30 per share, after deducting placement agent fees and estimated offering expenses payable by us.

This table should be read in conjunction with Genesoft Management's Discussion and Analysis of Financial Condition and Results of Operations, Unaudited Pro Forma Condensed Combined Financial Information, Genesoft's financial statements and related notes, our management discussion and analysis of financial condition and results of operations and our consolidated financial statements and related notes, each of which is incorporated by reference into this prospectus.

|  | <b>As of September 27, 2003</b>          |                  |                                  |
|--|--|------------------|----------------------------------|
|  | <b>Actual</b>                            | <b>Pro Forma</b> | <b>Pro Forma<br/>As Adjusted</b> |
|  | <b>(In thousands, except share data)</b> |                  |                                  |
| Cash and cash equivalents, restricted cash, and long and short-term marketable securities  | \$ 25,786                                | \$ 35,515        | \$ 68,693                        |
| Long-term debt, including current portion  | 1,750                                    | 26,362           | 26,362                           |
| Shareholders' equity:  |  |                  |                                  |
| Common stock, par value \$0.10 per share 50,000,000 shares authorized, actual and 175,000,000 shares authorized, pro forma and as adjusted, 26,172,776 shares issued actual, 56,872,293 shares issued pro forma and 67,872,293 shares issued as adjusted | 2,617                                    | 5,687            | 6,787                            |
| Additional paid-in capital   | 170,797                                  | 270,241          | 302,319                          |
| Accumulated deficit  | (154,231)                                | (166,008)        | (166,008)                        |
| Other shareholders' equity   | 163                                      | (4,496)          | (4,496)                          |
| Total shareholders' equity   | 19,346                                   | 105,424          | 138,602                          |
| Total capitalization   | \$ 21,096                                | \$ 131,786       | \$ 164,964                       |

This table excludes the following shares as of November 14, 2003:

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4,102,046 shares of our common stock reserved for issuance pursuant to outstanding stock options at a weighted average exercise price of \$5.89 per share;

3,221,250 shares of our common stock reserved for issuance pursuant to outstanding warrants at a weighted average exercise price of \$3.85 per share.

This table also excludes:

3,043,547 shares of our common stock reserved for issuance pursuant to outstanding options issued by Genesoft that will be assumed by us in the merger, these options have a weighted average exercise price of \$0.41 per share; and

48,341 shares of our common stock reserved for issuance pursuant to outstanding warrants issued by Genesoft that will be assumed by us in the merger, these warrants have a weighted average exercise price of \$11.34 per share.

**Table of Contents****DILUTION**

Our pro forma net tangible book value as of September 27, 2003 is \$5.2 million, or \$0.09 per share of common stock. Pro forma net tangible book value per share represents the amount of total tangible assets less total liabilities, divided by the number of outstanding shares of common stock after giving effect to our issuance of 5.2 million shares of our common stock in October 2003 and assuming the combination with Genesoft Pharmaceuticals occurred on September 27, 2003.

After giving effect to the sale of 11,000,000 shares of common stock offered by us in this prospectus at an assumed public offering price of \$3.30 per share, less placement agent fees and estimated offering expenses payable by us, our pro forma net tangible book value as of September 27, 2003 would have been \$38.4 million, or \$0.57 per share. This represents an immediate increase in the pro forma net tangible book value to existing stockholders of \$0.48 per share and an immediate dilution to new investors of \$2.73 per share. The following table illustrates this dilution on a per share basis:

|  |         |         |
|--|---------|---------|
| Assumed public offering price per share                              |         | \$ 3.30 |
| Pro forma net tangible book value per share as of September 27, 2003 | \$ 0.09 |         |
| Increase per share attributable to new investors                     | 0.48    |         |
|  | <hr/>   |         |
| Pro forma net tangible book value per share after this offering      |         | 0.57    |
|  |         | <hr/>   |
| Dilution per share to new investors                                  |         | \$ 2.73 |
|  |         | <hr/>   |

This table excludes the following shares as of November 14, 2003:

4,102,046 shares of our common stock reserved for issuance pursuant to outstanding stock options at a weighted average exercise price of \$5.89 per share;

3,221,250 shares of our common stock reserved for issuance pursuant to outstanding warrants at a weighted average exercise price of \$3.85 per share.

This table also excludes:

3,043,547 shares of our common stock reserved for issuance pursuant to outstanding options issued by Genesoft that will be assumed by us in the merger, these options have a weighted average exercise price of \$0.41 per share; and

48,341 shares of our common stock reserved for issuance pursuant to outstanding warrants issued by Genesoft that will be assumed by us in the merger, these warrants have a weighted average exercise price of \$11.34 per share.

If any shares are issued in connection with outstanding options or warrants, you may experience further dilution.

**PLAN OF DISTRIBUTION**

J.P. Morgan Securities Inc. has entered into a placement agent agreement with us. Pursuant to the placement agent agreement, J.P. Morgan Securities Inc. has agreed to act as placement agent in connection with this offering. J.P. Morgan Securities Inc. is using its best commercially practicable efforts to introduce us to investors who will purchase the shares. J.P. Morgan Securities Inc. has no obligation to buy any of the shares from us, nor is it required to arrange the purchase or sale of any specific number or dollar amount of the shares.

The placement agent agreement provides that the obligations of the placement agent are subject to certain conditions precedent, including the absence of any material adverse change in our business and the receipt of certain opinions, letters and certificates from our counsel, our independent auditors and us.

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Certain investor funds will be deposited into an escrow account set up at \_\_\_\_\_ . \_\_\_\_\_ will not accept any investor funds until the date of this prospectus. Before the closing date, \_\_\_\_\_ will notify J.P. Morgan Securities Inc. when funds to pay for the shares have been received. If, at a meeting of our stockholders to be held on or before \_\_\_\_\_, 2004, our stockholders approve:

the issuance of 28,571,405 shares of our common stock pursuant to the Agreement and Plan of Merger and Reorganization, dated as of November 17, 2003, among us, Guardian Acquisition, Inc., our wholly-owned subsidiary, GeneSoft and Luke Evnin, as the representative of the GeneSoft stockholders,

the issuance of shares of our common stock upon the potential future conversion of the \$22,309,647 of our convertible notes to be issued to holders of GeneSoft promissory notes; and

the amendment to our Articles of Organization to increase the number of shares of our common stock that we are authorized to issue from 50,000,000 to 175,000,000 shares of common stock,

and, at a meeting of Genesoft's stockholders to be held on or before \_\_\_\_\_, 2004, the Genesoft stockholders approve:

the adoption of the merger agreement, and

the amendment and restatement of Genesoft's Seventh Amended and Restated Certificate of Incorporation to eliminate all authorized shares of Genesoft preferred stock if the merger is completed,

then we will file the amendment to our Articles of Organization with the Secretary of State of the State of Delaware and then deposit the shares to be sold in this offering with the Depository Trust Company. At the closing, Depository Trust Company will credit the shares to the respective accounts of the investors.

If our stockholders do not approve each of the three proposals described above at a meeting of our stockholders to be held on or before \_\_\_\_\_, 2004, then all investor funds that were deposited into escrow will be returned promptly to investors and this offering will terminate.

Confirmations and definitive prospectuses will be distributed to all investors who agree to purchase shares of the common stock, informing investors of the closing date as to such shares. We currently anticipate that closing of the sale of the shares of common stock will take place on or about \_\_\_\_\_, 2004. Investors will also be informed of the date on which they must transmit the purchase price into the designated accounts.

We have agreed to indemnify J.P. Morgan Securities Inc. and certain other persons against certain liabilities under the Securities Act. We have also agreed to contribute to payments J.P. Morgan Securities Inc. may be required to make in respect of such liabilities. J.P. Morgan Securities Inc. has informed us that it will not engage in over-allotment, stabilizing transactions or syndicate covering transactions in connection with this offering.

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We, along with our executive officers and certain directors, have agreed to certain lock-up provisions with regard to future sales of our common stock for a period of 90 days after this offering as set forth in the placement agent agreement.

We have agreed to pay J.P. Morgan Securities Inc. a fee equal to \_\_\_\_\_ % of the proceeds of this offering and to reimburse J.P. Morgan Securities Inc. for reasonable expenses that it incurs in connection with this offering. The following table shows the per share and total commissions we will pay to J.P. Morgan Securities Inc. in connection with the sale of the shares offered pursuant to this prospectus.

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|           |    |
|-----------|----|
| Per share | \$ |
| Total     | \$ |

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This is a brief summary of the material provisions of the placement agent agreement and does not purport to be a complete statement of its terms and conditions. The placement agent agreement is included as an exhibit to the registration statement.

The transfer agent for our common stock is EquiServe Trust Company N.A.



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**LEGAL MATTERS**

Ropes & Gray LLP, Boston, Massachusetts, will pass on the validity of the shares of common stock offered by this prospectus. Certain legal matters in connection with this offering will be passed upon for the placement agent by Dechert LLP, Philadelphia, Pennsylvania.

**EXPERTS**

The consolidated financial statements of Genome at December 31, 2002, and for the year ended December 31, 2002, incorporated by reference in this prospectus and elsewhere in this registration statement have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon incorporated by reference herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The financial statements of Genesoft (a development stage company) at December 31, 2001 and 2002, and for each of the three years in the period ended December 31, 2002, incorporated by reference in this prospectus and elsewhere in this registration statement have been audited by Ernst & Young LLP, independent auditors, as set forth in their reports thereon (which contain an explanatory paragraph describing conditions that raise substantial doubt about the ability of Genesoft to continue as a going concern as described in Note 1 to the financial statements), and are incorporated by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The consolidated financial statements for the years ended December 31, 2001 and 2000 and as of December 31, 2001, and included in our 2002 Annual Report had been audited by Arthur Andersen LLP, independent accountants, as indicated in their report thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given the authority of such firm as experts in auditing and accounting. Arthur Andersen has not consented to the inclusion of their report in this prospectus, and in reliance on Rule 437a under the Securities Act, we have not obtained their consent to do so. We refer you to Risk Factors Risks Related to the Securities Market Certain of our financial statements have been audited by Arthur Andersen LLP, and the ability to recover damages from Arthur Andersen may be limited. contained in the Risk Factors.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC allows us to incorporate by reference information from other documents that we file with them, which means that we can disclose important information by referring to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. Any statement contained in a document, all or a portion of which is incorporated by reference herein, shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained or incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. 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 filing of a post-effective amendment that indicates that all securities covered by this prospectus have been sold or which deregisters all securities remaining unsold:

- (a) Our Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

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- (b) Our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2002.
- (c) Our Quarterly Report on Form 10-Q for the fiscal quarter ended March 29, 2003.

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- (d) Our Quarterly Report on Form 10-Q for the fiscal quarter ended June 28, 2003.
- (e) Our Quarterly Report on Form 10-Q for the fiscal quarter ended September 27, 2003.
- (f) Our Current Report on Form 8-K as filed on January 2, 2003.
- (g) Our Current Report on Form 8-K as filed on June 5, 2003.
- (h) Our Current Report on Form 8-K as filed on June 13, 2003.
- (i) Our Current Report on Form 8-K as filed on October 1, 2003.
- (j) Our Current Report on Form 8-K as filed on October 16, 2003.
- (k) Our Current Report on Form 8-K as filed on November 18, 2003.
- (l) Our Current Report on Form 8-K as filed on December 17, 2003.
- (m) The description of our common stock contained in our registration statement on Form 10/A filed with the Commission on January 9, 1996 under the Exchange Act, including any amendment or reports filed for the purpose of updating such description.

We will provide to you, without charge, upon your written or oral request, a copy of any or all of the documents that we incorporate by reference, (other than exhibits to such documents unless such exhibits are specifically incorporated by reference into the documents that this prospectus incorporates). Written or oral requests for copies should be directed to Christopher Taylor, Senior Director of Investor Relations, 100 Beaver Street, Waltham, Massachusetts 02453, telephone number (781) 398-2300.

**WHERE YOU CAN FIND MORE INFORMATION**

You should rely only on the information contained in this prospectus. We have not authorized any person to provide you different information. You should not assume that the information in this prospectus is accurate as of any date other than the date on the cover. We are subject to the informational requirements of the Exchange Act, and, accordingly, file reports, proxy statements and other information with the Commission. You can read our Commission filings over the Internet at the Commission's website at <http://www.sec.gov>. You may also read and copy any document we file with the Commission at its public reference facilities at 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549; and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the operation of public reference facilities.

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

The expenses in connection with the securities being registered are as follows:

|                                 | <b>Amount To<br/>Be Paid</b> |
|---------------------------------|------------------------------|
| Registration fee                | \$ 2,825.43                  |
| Printing and Engraving Expenses | 30,000.00                    |
| Legal fees and expenses         | 240,000.00                   |
| Accounting fees and expenses    | 20,000.00                    |
| Miscellaneous                   | 107,174.57                   |
| <b>Total</b>                    | <b>\$ 400,000.00</b>         |

All of the above figures, except the SEC registration fee, are estimated, and we will pay all of the above expenses.

**ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS**

The Company is organized under the laws of The Commonwealth of Massachusetts. The Massachusetts Business Corporation Law provides that indemnification of directors, officers, employees, and other agents of another organization, or who serve at its request in any capacity with respect to any employee benefit plan, may be provided by the corporation to whatever extent specified in its charter documents or votes adopted by its shareholders, except that no indemnification may be provided for any person with respect to any matter as to which the person shall have been adjudicated in any proceeding not to have acted in good faith in the reasonable belief that his action was in the best interest of the corporation. Under Massachusetts law, a corporation can purchase and maintain insurance on behalf of any person against any liability incurred as a director, officer, employee, agent, or person serving at the request of the corporation as a director, officer, employee, or other agent of another organization or with respect to any employee benefit plan, in his capacity as such, whether or not the corporation would have power to itself indemnify him against such liability.

The Company's Restated Articles of Organization, as amended to date, provide that its directors shall not be liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent that the exculpation from liabilities is not permitted under the Massachusetts Business Corporation Law as in effect at the time such liability is determined. The By-Laws provide that the Company shall indemnify its directors and officers to the full extent permitted by the laws of The Commonwealth of Massachusetts. In addition, the Company holds a Directors and Officer Liability and Corporate Indemnification Policy.



**Table of Contents****ITEM 16. EXHIBITS**

| <b>Exhibit<br/>Number</b> | <b>Description of Document</b>  |
|---------------------------|---|
| 3.1                       | Restated Articles of Organization and Bylaws. (1)                                   |
| 3.2                       | Amendment dated January 5, 1982 to Restated Articles of Organization. (2)           |
| 3.3                       | Amendment dated January 24, 1983 to Restated Articles of Organization. (3)          |
| 3.4                       | Amendment dated January 17, 1984 to Restated Articles of Organization. (4)          |
| 3.5                       | Amendment dated October 20, 1987 to the Bylaws. (5)                                 |
| 3.6                       | Amendment dated December 9, 1987 to Restated Articles of Organization. (6)          |
| 3.7                       | Amendment dated October 16, 1989 to the Bylaws. (7)                                 |
| 3.8                       | Amendment dated January 24, 1994 to Articles Restated Articles of Organization. (8) |
| 3.9                       | Amendment dated August 31, 1994 to Restated Articles of Organization. (8)           |
| 3.10                      | Amendment dated March 15, 2001 to Restated Articles of Organization. (9)            |
| 3.11                      | Bylaws of Genome Therapeutics Corp (as amended through July 24, 2001). (10)         |
| 4.1                       | Specimen Common Stock Certificate. (11)   |
| 5.1                       | Opinion of Ropes & Gray LLP. (12)   |
| 23.1                      | Consent of Ernst & Young LLP, on Genome Therapeutics Corp.                          |
| 23.2                      | Consent of Ernst & Young LLP, on GeneSoft Pharmaceuticals, Inc.                     |
| 23.3                      | Consent of Ropes & Gray LLP.  |
| 24.1                      | Power of Attorney. Included on signature page.                                      |
| 99.1                      | Placement Agent Agreement. (12)   |

(1) Filed as exhibits to the Company's Registration Statement on Form S-1 (No. 2-75230) and incorporated herein by reference.

(2) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended February 27, 1982 and incorporated herein by reference.

(3) Filed as exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ended February 26, 1983 and incorporated herein by reference.

(4) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended February 25, 1984 and incorporated herein by reference.

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(5) Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended August 31, 1987 and incorporated herein by reference.

(6) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended November 28, 1987 and incorporated herein by reference.

(7) Filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 1989 and incorporated herein by reference.

(8) Filed as exhibits of the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 1994 and incorporated herein by reference.

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- (9) Filed as an exhibit to the Company's 10-Q for the quarter ended February 24, 2001 and incorporated herein by reference.
- (10) Filed as an exhibit to the Company's 10-Q for the quarter ended September 29, 2001 and incorporated herein by reference.
- (11) Incorporated by reference to our Registration Statement on Form S-3 (File No. 333-00127).
- (12) To be filed by amendment.

**ITEM 17. UNDERTAKINGS**

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

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against 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 Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial *bona fide* offering thereof.





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|   |          |                   |
|---|----------|-------------------|
| <hr/> <i>/s/</i> LAWRENCE LEVY            | Director | December 16, 2003 |
| <b>Lawrence Levy</b>                      |          |                   |
| <hr/> <i>/s/</i> NORBERT G. RIEDEL, PH.D. | Director | December 16, 2003 |
| <b>Norbert G. Riedel, Ph.D.</b>           |          |                   |
| <hr/> <i>/s/</i> DAVID K. STONE           | Director | December 16, 2003 |
| <b>David K. Stone</b>                     |          |                   |
| <hr/> <i>/s/</i> WILLIAM S. REARDON       | Director | December 16, 2003 |
| <b>William S. Reardon</b>                 |          |                   |

**Table of Contents****ITEM 16. EXHIBITS**

| <b>Exhibit<br/>Number</b> | <b>Description of Document</b>  |
|---------------------------|---|
| 3.1                       | Restated Articles of Organization and Bylaws. (1)                                   |
| 3.2                       | Amendment dated January 5, 1982 to Restated Articles of Organization. (2)           |
| 3.3                       | Amendment dated January 24, 1983 to Restated Articles of Organization. (3)          |
| 3.4                       | Amendment dated January 17, 1984 to Restated Articles of Organization. (4)          |
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(11) Incorporated by reference to our Registration Statement on Form S-3 (File No. 333-00127).

(12) To be filed by amendment.