GENOME THERAPEUTICS CORP
Form 424B4
February 03, 2004
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**Filed pursuant to Rule 424(b)(4)**

**Registration No. 333-111273**

**Prospectus**

# 16,800,000 Shares

## Common Stock

We are offering up to 16,800,000 shares of common stock.

Our common stock trades on the Nasdaq National Market under the symbol GENE. On February 2, 2004, the reported last sale price of our common stock on the Nasdaq National Market was $5.71 per share.

**Investing in our common stock involves risks. See Risk Factors beginning on page 6 of this prospectus before deciding to invest in our common stock.**

Price $5.25 a share

| | Per Share | Total |
|---|---|---|
| Public price | $ 5.25 | $ 88,200,000 |
| Placement agent fees | $ 0.3642 | $ 6,118,000 |
| Proceeds for the Company, before expenses | $ 4.8858 | $ 82,082,000 |

J.P. Morgan Securities Inc. and Legg Mason Wood Walker, Incorporated will act as our lead placement agent and co-placement agent, respectively, in connection with this offering and will use their best commercially practicable efforts to introduce us to investors. Neither J.P. Morgan Securities Inc. nor Legg Mason Wood Walker, Incorporated has any commitment to buy any of the shares. See Plan of Distribution on page 31 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**

**Legg Mason Wood Walker**

**Incorporated**

February 2, 2004

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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 six product discovery and development alliances with pharmaceutical companies including 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 (which was obtained at the respective shareholder meetings of each company held on February 2, 2004), 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.

At the time of 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**

| | |
|---|---|
| Common stock offered | 16,800,000 shares |
| Common stock to be outstanding after this offering | 73,947,374 shares |
| Use of proceeds | We anticipate using the net proceeds from this offering (i) to fund the commercial launch of FACTIVE, (ii) to fund further clinical development of FACTIVE and our other product candidates, including Ramoplanin, and (iii) to provide working capital and for general corporate purposes. See Use of Proceeds section of this prospectus for additional information. |
| Risk factors | You should read the Risk Factors section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock. |
| NASDAQ National Market symbol | GENE |

The number of shares to be outstanding after the offering is based on the following. As of January 28, 2004, we had 31,671,198 shares of our common stock outstanding. In connection with the merger with Genesoft we expect to issue a total of 28,571,405 shares of our common stock. A portion of these shares will be issued at the time of the closing of the merger and the balance will be reserved for issuance upon the exercise of Genesoft options and warrants to be assumed by us and described below. Assuming the merger closes on February 6, 2004, we will issue approximately 25,476,176 of such shares at the time of the closing of the merger. Accordingly, assuming we sell all of the 16,800,000 shares offered, approximately 73,947,374 shares of our common stock will be outstanding following this offering and the closing of the merger. The number of shares to be outstanding after this offering does not include, as of January 28, 2004:

- 3,917,247 shares of our common stock reserved for issuance pursuant to our outstanding stock options at a weighted average exercise price of $6.06 per share;
- 3,221,250 shares of our common stock reserved for issuance pursuant to our outstanding warrants at a weighted average exercise price of $3.85 per share;
- 3,046,835 shares of our common stock reserved for issuance pursuant to outstanding options issued by Genesoft that will be assumed by us in the merger with a weighted average exercise price of $0.41 per share;
- 48,394 shares of our common stock reserved for issuance pursuant to outstanding warrants issued by Genesoft that will be assumed by us in the merger with a weighted average exercise price of $11.33 per share;

Shares of our common stock issuable upon conversion of $22,309,647 principal amount of our 5% convertible promissory notes to be issued in connection with the merger at a conversion price equal to

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110% of the average closing price of our common stock for the five trading days preceding the closing date of the merger; and

Shares of our common stock issuable upon the conversion of up to $7 million of our convertible promissory notes issuable to Vicuron Pharmaceuticals Inc. upon the achievement of specified milestones under our agreement with Vicuron, which, if issued, will have a conversion price of $15.00 per share, subject to anti-dilution and other adjustments.

Our stockholders, at a meeting held on February 2, 2004, have approved each of the following proposals:

(a) the issuance of a total of 28,571,405 shares of our common stock pursuant to the merger agreement,

(b) 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,

(c) 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

(d) the issuance of up to 20,000,000 shares of our common stock for aggregate consideration of not more than $50,000,000 in order to raise capital to finance the combined company, subject to certain terms and conditions.

The stockholders of Genesoft, at a meeting held on February 2, 2004, have approved each of the following proposals:

(a) the merger agreement, and

(b) the amendment and restatement of Genesoft s certificate of incorporation to eliminate any authorized shares of Genesoft preferred stock if, and only if, the merger is completed.

In order to comply with the possible application of the rules of the Nasdaq Stock Market, we may be limited to selling shares in this offering that result in proceeds to us (before deducting placement agent fees and offering expenses) of not more than $50,000,000. In addition, depending upon market factors, we may not sell all 16,800,000 shares offered by this prospectus. See Plan of Distribution below.

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. and Legg Mason Wood Walker, Incorporated, the placement agents, when funds to pay for the shares have been received. 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 conditions to this offering are not satisfied or waived, then all investor funds that were deposited into escrow will be returned promptly to investors and this offering will terminate.

**NOTE ON TRADEMARKS**

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 in the year following the merger 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

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. We have requested permission from the FDA to commence the Phase IV trial at a later date that is consistent with the planned launch of FACTIVE. The FDA has indicated its willingness to grant this request. If our request is not granted, however, we will commence the Phase IV trial as soon as possible thereafter, which may not be before the end of March 2004. In connection with the approval of FACTIVE, the FDA has also required us to obtain data on the prescribing patterns and use of FACTIVE for the first three years after its initial marketing in the U.S. As part of this requirement, we will furnish periodic reports to the FDA on the number of prescriptions issued, including refills, and the diagnoses for which the prescriptions are dispensed. The results of the Phase IV trial and the periodic reports we are required to provide to the FDA, 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 are seeking to raise in excess of $32 million in this offering. In order to comply with the possible application of the rules of the Nasdaq Stock Market, we may be limited to selling shares in the offering that result in proceeds to us (before deducting placement agent fees and offering expenses) of not more than $50,000,000. In any event, depending upon market factors, we may not sell all 16,800,000 shares offered by this prospectus. If we sell less than all 16,800,000 shares, the amount of proceeds that we receive would be reduced, and we may need to raise additional funds more quickly or pursue our development plans less aggressively.

We may seek 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.

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**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.

**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 further 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

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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 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, in the future, 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, Canada and Mexico. 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.

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**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.

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, a Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat *Clostridium difficile*-associated diarrhea, or CDAD, and a pilot study into the use of Ramoplanin to reduce the transmission of VRE in the hospital setting. 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

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Ramoplanin. We currently expect to complete the Phase II trial of Ramoplanin for CDAD in the first half of 2004 and commence a Phase III CDAD trial before the end of 2004. The pilot study is expected to conclude in the first half of 2004. The Phase III trial of Rampolanin to prevent VRE bloodstream infections continues, but at a slow pace. Many patients are ineligible to participate in this trial because they are participating in other experimental protocols to treat their underlying cancers. We received approval from the FDA to introduce the capsule formulation into the study; however, based on the pace of enrollment, we do not expect to file a New Drug Application, or NDA, based on the results of this trial prior to the end of 2005. We continue to review with the FDA alternative approaches to facilitate filing an NDA for the VRE bloodstream infection prevention indication. We may not be able to complete these trials or make the filings within the timeframes we currently expect. If we are delayed in completing the trials or making the filings, our business may be adversely affected, including as a result of increased costs.

Our combined company may not be able to demonstrate the safety and efficacy of FACTIVE in indications other than those for which it has already been approved or of our other products including Ramoplanin, 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.

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

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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.

In addition, a new drug application for Ketek®, 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 Vancocin® (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.

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**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. In addition, in December 2003 President Bush signed into law new Medicare prescription drug coverage legislation. While we cannot yet predict the impact the new legislation could have on the combined company s ability to commercialize FACTIVE, Ramoplanin and any future products, the new legislation could adversely affect our anticipated revenues and results of operations, possibly materially.

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 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, bioMérieux, Schering-Plough and Wyeth. Over the past several years, we have received a substantial portion of our revenue from these alliances. However, our research obligations under our strategic alliances have been fulfilled or are anticipated to be completed in the near future. As a result, any substantial additional revenues under these alliances will consist of milestone payments based on the achievement by the alliance partner of development milestones or royalties based on the sale of products arising from the alliance. The achievement of any of the development milestones and successful development of any products under these alliances are dependent on the alliance partners activities and are beyond the control of the combined company. The combined company cannot assure you that any milestones will be attained, that any products will be successfully developed by the alliance partners or that we will receive any substantial additional revenues under these alliances.

In order to maintain the collaboration agreement with Wyeth, the combined company must fulfill certain obligations, including providing reasonable technical assistance in using the know-how or other information that it has licensed to them. We believe that we are currently in compliance with our obligations under our collaboration agreement, but there can be no assurance that the combined company will be able to successfully complete its obligations in the future.

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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,

delay in development activities,

legal claims involving significant time,

significant 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.

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**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 or investments in or other relationships and alliances with third parties. Acquisitions may involve significant cash expenditures, debt incurrence, 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 or at all;
- 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, financial condition and results of operations.

**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.

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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, 82 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

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-methyloxyiminopyrroplidin-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.

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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, the patents named above may 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. However, there is no assurance that any of these patents, if challenged, will be found to be enforceable or that any of these patents will provide us with a competitive advantage.

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 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