GENESOFT PHARMACEUTICALS INC
Form 425
November 18, 2003

Filed by Genome Therapeutics Corp.

Pursuant to Rule 425 under the Securities Act of 1933

and deemed filed pursuant to Rule 14a-12

of the Securities Exchange Act of 1934

Subject Company: GeneSoft Pharmaceuticals, Inc.

Commission File No. 0-10824

This filing relates to the proposed merger transaction pursuant to the terms of that certain Agreement and Plan of Merger and Reorganization, dated as of November 17, 2003 (the Merger Agreement), by and among Genome Therapeutics Corp. (Genome Therapeutics), Guardian Acquisition, Inc., a wholly owned subsidiary of Genome Therapeutics, GeneSoft Pharmaceuticals, Inc. (Genesoft) and the Stockholders Representative named therein. The Merger Agreement is on file with the Securities and Exchange Commission as an exhibit to the Current Report on Form 8-K filed by Genome Therapeutics on November 18, 2003, and is incorporated by reference into this filing.

This filing is made for the purpose of filing the joint press release of Genome Therapeutics and Genesoft dated November 18, 2003. The press release is also available on Genome Therapeutics website, www.genomecorp.com.

Forward-Looking Statements

This document may contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements represent our management s judgment 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 some forward-looking statements are expressed differently. We do not plan to update these forward-looking statements. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of risks affecting our business. These factors include the risk that the proposed merger may not be approved by stockholders of Genome Therapeutics or Genesoft, Genome Therapeutics or Genesoft s inability to satisfy the closing conditions of the merger, including the condition of raising additional capital to finance the combined company, the risk that the two companies businesses will not be integrated successfully and the significant costs related to the proposed merger . Upon completion of the merger, our business will be significantly dependent upon the combined company s ability to launch the commercial sale of FACTIVE®, and, due to the limitations on our resources and experience in commercializing products, there can be no assurance that we will be able to successfully launch FACTIVE®. We continue to be subject to the risks related to our lead product candidate, Ramoplanin, such as (i) our inability to obtain regulatory approval to commercialize Ramoplanin due to negative, inconclusive or insufficient clinical data and (ii) delays in the progress of our clinical trials for Ramoplanin, and increased cost, due to the pace of enrollment of patients in the trials or fluctuations in the infection rate of enrolled patients. We are also subject to risks related to our inability or the inability of our alliance partners to (i) successfully develop products based on our genomics information, (ii) obtain the necessary

regulatory approval for such products, (iii) effectively commercialize any products developed before our competitors are able to commercialize competing products or (iv) obtain and enforce intellectual property rights. In addition, we are subject to the risk factors set forth in Exhibit 99.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended September 27, 2003 and those set forth in other filings that we may make with the Securities and Exchange Commission from time to time.

Additional Information About the Transaction and Where You Can Find It

Genome Therapeutics will file a proxy statement/prospectus and other documents concerning the proposed merger transaction with the SEC. **Investors are urged to read the proxy statement/prospectus when it becomes available and the other relevant documents filed with the SEC because they will contain important information.**

You will be able to obtain the proxy statement/prospectus and other related documents free of charge at the website maintained by the SEC at www.sec.gov. In addition, you may obtain documents filed with the SEC by Genome Therapeutics free of charge by requesting them in writing from Genome Therapeutics Corp., 100 Beaver Street, Waltham, MA 02453 Attention: Investor Relations, telephone: (781) 398-2300.

Genome Therapeutics and Genesoft and their respective directors, executive officers and other members of their management and employees, may be deemed to be participants in the solicitation of proxies from their respective shareholders in connection with the merger. Information about the directors and executive officers of Genome Therapeutics and their ownership of Genome Therapeutics shares is set forth in the proxy statement for Genome Therapeutics 2003 annual meeting of shareholders, filed with the SEC on April 2, 2003. Investors may obtain additional information regarding the interests of such participants by reading the proxy statement/prospectus when it is filed with the SEC.

This document shall not constitute an offer to sell or the solicitation of an offer to buy any securities of Genome Therapeutics.

[Genesoft Pharmaceuticals logo appears here]

[Genome Therapeutics Corporation logo appears here]

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For Immediate Release

Genome Therapeutics and Genesoft Pharmaceuticals Announce

Definitive Merger Agreement

Merged Companies Combine Expertise to Create Leading

Anti-Infectives Biopharmaceutical Company

Launch of FDA-Approved FACTIVE® (gemifloxacin mesylate tablets)

Planned for Summer 2004

Conference Call with Management Today at 8:30 AM ET

Waltham, Mass. and South San Francisco, CA, November 18, 2003 Genome Therapeutics (Nasdaq: GENE) and Genesoft Pharmaceuticals Inc., a privately-held pharmaceutical company, have entered into a definitive agreement to merge in an all-stock transaction. Pending successful completion of the merger, Genome Therapeutics and Genesoft will become a leading, integrated biopharmaceutical company focused on the commercialization and development of new anti-infective therapeutics.

The merged company will focus on the 2004 launch of FACTIVE® (gemifloxacin mesylate tablets), which received FDA approval for two indications this year, the Ramoplanin clinical development program and the maturation of the companies earlier stage assets. The combined company will keep the name Genome Therapeutics, and continue to trade on the Nasdaq National Market under the ticker GENE until a new name for the company is selected. A conference call with senior management from both companies is scheduled for today at 8:30 AM ET (details below).

Revenues from the launch of FACTIVE®, an orally administered, broad-spectrum fluoroquinolone antibiotic, will drive the merged company s near-term growth as a biopharmaceutical company. FACTIVE® currently has FDA marketing approval for the treatment of community-acquired pneumonia of mild to moderate severity (CAP)* and acute bacterial exacerbations of chronic bronchitis (ABECB)**. FACTIVE® expected to be launched during the summer of 2004. Strengthened by a robust pipeline led by Ramoplanin, which is in development for the prevention, treatment and control of serious hospital-based infections, the merged companies product development and managerial synergies position the new company as a leader in the anti-infectives market.

Merging with Genesoft is a transforming event for our company, as we will immediately realize our goal of becoming a biopharmaceutical company with a high-profile product and a complementary near-term product candidate in late-stage clinical trials, stated Steven M. Rauscher, Chairman and CEO of Genome Therapeutics, who will serve as President and CEO of the new company. Initially, we will be focusing

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our efforts on ensuring the successful launch of FACTIVE® to coincide with next year s respiratory tract infections season, thus positioning the company as a key participant in the commercialization of anti-infective therapeutics.

The increase in bacterial resistance to numerous antibiotic classes is quickly becoming a serious concern for physicians, who are recognizing the need to use the most potent antibiotic as first-line treatment in order to stem this growing problem, said Gary Patou, M.D., President of Genesoft. Increasingly, physicians are realizing that their prescribing decisions can not only affect the individual patient receiving a drug, but also can have a larger societal impact. FACTIVE®, a unique fluoroquinolone, and Ramoplanin, a first-in-class antibiotic, could help address this challenge.

Product Portfolio

FACTIVE® has FDA approval for two indications: community-acquired pneumonia of mild to moderate severity* (including cases caused by multi-drug resistant *Streptococcus pneumoniae*) and acute bacterial exacerbations of chronic bronchitis**. A regulatory filing for a third indication of FACTIVE® for acute bacterial sinusitis is planned. In addition, an intravenous form of the antibiotic is currently under development. Supplementing the FACTIVE® development pipeline are two novel anti-infectives: Ramoplanin, currently in Phase III and Phase II trials for the prevention and treatment of serious hospital-based infections, and a series of oral PDF (peptide deformylase) inhibitors, expected to enter Phase I testing in the future for treating respiratory tract infections. Genome Therapeutics also brings seven partnered programs to the merger through strategic alliances with pharmaceutical companies including Wyeth, Schering-Plough, Amgen and AstraZeneca.

We are committed to building a premiere anti-infectives company, which will introduce products that satisfy the medical community s intensifying need for new therapeutic options, stated David B. Singer, Founder, Chairman and CEO of Genesoft Pharmaceuticals, who will assume the role of Chairman of the new company. This merger supports our efforts to successfully launch FACTIVE®, as the management team at Genome Therapeutics possesses proven expertise in marketing antibiotics into the community and hospital settings. Our shareholders will also participate in the success of the integrated company s extensive portfolio of anti-infective opportunities.

Details of the Transaction

This merger agreement has been unanimously approved by the Board of Directors at both Genome Therapeutics and Genesoft Pharmaceuticals. Genome Therapeutics will issue approximately 28 million shares of Genome Therapeutics common stock to the existing security holders of Genesoft, and assume debt of $24 million. The transaction is expected to qualify as a tax-free reorganization for federal income tax purposes. Consummation of this transaction is subject to the receipt of certain third-party approvals and consents, as well as approval by both parties shareholders and raising additional capital, approximately $30 million, to fund the merged company. Selected stockholders of Genome Therapeutics and Genesoft have agreed to vote in favor of the merger. Both parties will strive to complete this merger by the end of the first quarter of 2004. Genesoft was advised by Merrill Lynch with respect to this merger. Genome Therapeutics Board of Directors received a fairness opinion from Harris Nesbitt Gerard on this transaction.

Board of Directors

The new company will be led by a Board of Directors with extensive industry experience. The new board is slated to consist of: Luke Evnin, Ph.D., Managing Director of MPM Asset Management, Robert J. Hennessey, former Chairman and CEO of Genome Therapeutics, Vernon R. Loucks, Jr., former Chairman and CEO of Baxter International, Steve Rauscher, President and CEO of the new company, William S. Reardon, former partner at PricewaterhouseCoopers, Norbert G. Riedel, Ph.D., Corporate Vice President and Chief Scientific Officer at Baxter International, William Rutter, Ph.D., Professor Emeritus

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of Biochemistry at the University of California, San Francisco and Founder of Chiron, David B. Singer, Chairman of the Board and David K. Stone, Managing Director of Flagship Ventures.

Conference Call

A conference call will be held today at **8:30 AM ET** with Steven Rauscher, Chairman and CEO of Genome Therapeutics, David Singer, Chairman and CEO of Genesoft and Stephen Cohen, Sr. Vice President and Chief Financial Officer of Genome Therapeutics. **Domestic participants can access the call by dialing 1-888-634-4009. International participants are asked to dial 1-706-634-2285.** The call will also be available via webcast on Genome Therapeutics website at www.genomecorp.com. A replay will be available two hours after the conclusion of the call until November 25, 2003. **Domestic participants can access the replay by dialing 1-800-642-1687, while international participants are asked to dial 1-706-645-9291. The conference ID number for the replay is 4110022.** A replay of the webcast will also be available at www.genomecorp.com.

About FACTIVE®

FACTIVE® (gemifloxacin mesylate tablets) is an orally administered, broad-spectrum fluoroquinolone antibiotic to which Genesoft has licensed, from LG Life Sciences, all North American and European rights for commercialization. FACTIVE® was approved by the FDA for sale in the United States in April 2003. FACTIVE® is approved for the treatment of community-acquired pneumonia of mild to moderate severity* and for treating acute bacterial exacerbations of chronic bronchitis**.

FACTIVE® should only be used to treat infections that are proven or strongly suspected to be caused by bacteria. It does not treat viral infections. The most common side effects include diarrhea, rash, nausea and headache. Rash is generally mild to moderate in nature, and more likely to occur if taken for longer than the recommended course. In addition, the safety and effectiveness of FACTIVE® in children, adolescents, pregnant women, and lactating women have not been established. Gemifloxacin may prolong the QT interval in some patients and should be avoided in patients with a history of prolongation of the QTc interval, patients with uncorrected electrolyte disorders, and patients receiving class 1A or class III antiarrhythmic agents. For complete prescribing information, please see package insert.

* Caused by *Streptococcus pneumoniae* (including multi-drug resistant strains), *Haemophilus influenzae, Moraxella catarrhalis, Mycoplasma pneumoniae, Chlamydia pneumoniae or Klebsiella pneumoniae*.

** Caused by *Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae or Moraxella catarrhalis*.

About Ramoplanin

Genome Therapeutics lead product candidate, Ramoplanin, is an investigational new drug in clinical development for the prevention, treatment and control of certain serious hospital-based infections. The company licensed the North American rights to Ramoplanin from Vicuron Pharmaceuticals. Ramoplanin has Fast Track status from the FDA and is currently in a Phase III clinical trial for the prevention of VRE bloodstream infections and in a Phase II study for treating *Clostridium difficile*-associated diarrhea (CDAD). Existing preclinical data suggest Ramoplanin has activity against several antibiotic-resistant, Gram-positive bacteria such as vancomycin-resistant enterococci (VRE), methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant *Staphylococcus aureus*. The antibiotic has also been shown to be bactericidal *in vitro* against *Clostridium difficile*. In a Phase II study, Ramoplanin was shown to be highly effective at decolonizing patients carrying VRE in their gastrointestinal (GI) tracts. A pilot study is also underway examining Ramoplanin s potential role in controlling the spread of nosocomial bacteria.

For more information on Genome Therapeutics and on Genesoft Pharmaceuticals, please visit their respective websites at www.genomecorp.com and www.genesoft.com.

Forward-Looking Statement for Genome Therapeutics

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