GENESOFT PHARMACEUTICALS INC
Form 425
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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.

This filing is made for the purpose of filing a fact sheet on FACTIVE®. The materials are 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.

Fact Sheet* **FACTIVE® - *Fast and Active*** **[FACTIVE logo here]**

Introduction

FACTIVE® (gemifloxacin mesylate tablets), a novel and unique member of the quinolone class of antibiotics, was recently approved by the FDA for the treatment of acute bacterial exacerbation of chronic bronchitis (ABECB) and community acquired pneumonia (CAP) (of mild to moderate severity) due to susceptible strains of indicated pathogens. FACTIVE® is the only antimicrobial approved to treat community acquired pneumonia caused by multi-drug resistant *Streptococcus pneumoniae* a growing clinical concern. FACTIVE® is active against susceptible strains of indicated Gram-positive, Gram-negative and atypical pathogens including the key respiratory pathogens and is bactericidal at clinically achievable concentrations. FACTIVE® targets multiple enzyme sites in bacteria and has very low minimum inhibitory concentrations (MICs), as low as 0.03 µg/ml for *Streptococcus pneumoniae*. FACTIVE® has been studied in nearly 7,000 patients and has an excellent overall safety and tolerability profile (please see important safety information on page 5).

Indications and Usage

FACTIVE® is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in: **Acute bacterial exacerbations of chronic bronchitis** caused by *Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae,* or *Moraxella catarrhalis.* **Community acquired pneumonia** (of mild to moderate severity) caused by *Streptococcus pneumoniae* (including multi-drug resistant strains (MDRSP), *Haemophilus influenzae, Moraxella catarrhalis, Mycoplasma pneumoniae, Chlamydia pneumoniae,* or *Klebsiella pneumoniae.*

Microbiology

FACTIVE® has potent *in vitro* activity against a wide range of Gram-positive, Gram-negative and atypical pathogens and is bactericidal at low concentrations. FACTIVE® acts by inhibiting bacterial DNA synthesis through the inhibition of both DNA gyrase and topoisomerase IV, two enzymes which are essential for bacterial growth and survival. *Streptococcus pneumoniae* showing mutations in both DNA gyrase and topoisomerase IV (double mutants) are resistant to most fluoroquinolones. Since FACTIVE® has the ability to inhibit both target enzymes at therapeutically relevant drug levels (a dual targeting mechanism), some of these *S. pneumoniae* double mutants remain susceptible to FACTIVE®.

There is no known bacterial cross-resistance between FACTIVE® and any other class of antimicrobials.

(*in vitro* activity does not necessarily imply clinical effectiveness)

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Microbiology

(cont d) *In vitro* studies have shown a low potential for the development of bacterial resistance to FACTIVE®. Resistance to FACTIVE® develops slowly via multistep mutations and efflux in a manner similar to other fluoroquinolones. The frequency of spontaneous mutation yielding resistance to FACTIVE® is low (10^{-7} $<10^{-10}$).

(*in vitro* activity does not necessarily imply clinical effectiveness)

Dosing FACTIVE® is dosed orally once daily with a single 320 mg tablet. For the treatment of community acquired pneumonia (of mild to moderate severity) the duration is 7 days. For the treatment of acute bacterial exacerbations of chronic bronchitis the duration is 5 days.

No dosage adjustment is recommended in patients with mild, moderate or severe hepatic impairment.

No dosage adjustment is recommended in the elderly.

No dosage adjustment is recommended in patients with creatine clearance >40 mL/min. Modification of the dose is recommended in patients with creatine clearance < 40 mL/min.

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Fact Sheet* **FACTIVE® - *Fast and Active*** **[FACTIVE logo here]**

Clinical Efficacy:

Acute Bacterial Exacerbations of

Chronic Bronchitis

FACTIVE® was studied for the treatment of acute bacterial exacerbation of chronic bronchitis in three large, double-blind, randomized, active controlled studies using 320 mg once daily for 5 days. These studies showed that FACTIVE® 5-day treatment was highly effective and was comparable to 7-day treatment of comparator agents; levofloxacin, clarithromycin, or amoxicillin/clavulanate. The clinical success rates in these studies were:

- FACTIVE® 5 days (320 mg): 88.2%

Levofloxacin 7 days (500 mg): 85.1%

- FACTIVE® 5 days (320 mg): 86.0%

Clarithromycin 7 days (500 mg bid): 84.8%

- FACTIVE® 5 days (320 mg): 93.6%

Amoxicillin/clavulanate 7 days (500mg/125mg tid): 93.2%

Clinical Efficacy:

Community Acquired Pneumonia

(of mild to moderate severity)

FACTIVE® was studied for the treatment of community acquired pneumonia in 6 large clinical studies, 3 with a fixed duration of 7 days. The results of these studies showed FACTIVE® was highly effective in the treatment of CAP. The clinical success rates for FACTIVE® ranged from 88.7% to 91.7%. FACTIVE® 7-day treatment was shown to be comparable to amoxicillin/clavulanate 10-day treatment:

- FACTIVE® 7 days (320 mg): 88.7%

Amoxicillin/clavulanate 10 days (500mg/125mg tid): 87.6%

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Clinical Efficacy:

Community Acquired Pneumonia

(of mild to moderate severity)

(cont d)

- In CAP clinical studies, FACTIVE® achieved high rates of bacterial eradication for all of the key pathogens in CAP; 84.6% to 100% eradication.

- FACTIVE® was also highly effective in the treatment of CAP due to multi-drug resistant *Streptococcus pneumoniae* (MDRSP). MDRSP includes isolates previously known as PRSP (pencillin-resistant *Streptococcus pneumoniae*), and are strains resistant to two or more of the following antibiotics: penicillin, 2nd generation cephalosporins, Macrolides, tetracyclines and trimethoprim/sulfamethoxazole. The clinical and bacteriological success rates with FACTIVE® 7-day treatment with MDRSP are shown in the following table. FACTIVE® is the only antimicrobial with an approved claim against MDRSP.

Screening Susceptibility	**Clinical Success**	**Bacteriological Success**
Penicillin-resistant	100%	100%
2nd Generation cephalosporin-resistant	100%	100%
Macrolide-resistant	84.2%	84.2%
Trimethoprim/sulfamethoxazole-resistant	100%	100%
Tetracycline-resistant	81.3%	81.3%

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Safety and Adverse Reactions

FACTIVE® (320 mg) has been studied extensively in nearly 7,000 patients and has been demonstrated an excellent safety and tolerability profile. The incidence of adverse events was low and comparable to comparator drugs (beta-lactam antibiotics, macrolides or other fluoroquinolones). Adverse events with a frequency of >1% were as follows:

	FACTIVE®	Comparators
Diarrhea	3.6%	4.6%
Rash	2.8%	0.6%
Headache	1.2%	1.5%
Abdominal pain	0.9%	1.1%
Vomiting	0.9%	1.1%
Dizziness	0.8%	1.5%
Taste perversion	0.3%	1.9%

The percent of patients that discontinued therapy because of adverse events was similar in FACTIVE® treated patients (2.2%) and comparator antibiotic treated patients (2.1%).

Laboratory abnormalities were noted infrequently in FACTIVE® treated patients. Those abnormalities with an incidence of 0.5% or greater included; ALT (1.5%), AST (1.1%), increased platelets (0.9%), CPK elevations (0.8%), increased creatine phosphokinase (0.6%), decreased neutrophils (0.5%), increased neutrophils (0.5%), increased potassium (0.5%), increased gammaglutamyl transferase (0.5%).

Important Safety Considerations

FACTIVE® is contraindicated in patients with a history of hypersensitivity to gemifloxacin, fluoroquinolone antibiotic agents, or any of the product components.

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. Gemifloxacin 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.

Prescribing FACTIVE® in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and may increase the risk of the development of drug-resistant bacteria.

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Manufacturing

The active pharmaceutical ingredient in FACTIVE® (gemifloxacin mesylate) will be manufactured by LG Life Science at its quinolone plant in Iksan, South Korea. Launch quantities of FACTIVE® are currently being tableted and finished and launch supplies will be packaged and available in Q1 2004. FACTIVE® will be available commercially in convenient fixed dose packs of 5 tablets and 7 tablets.

Intellectual Property

The FACTIVE® composition of matter and method of use patents have been issued in the U.S., with most expiring in 2015. Patent term extension applications, covering the regulatory review process, have been filed. If granted, these extensions would extend the exclusivity period to 2017. Additional process and specific use patents may further extend the exclusivity period. FACTIVE® has patent protection for longer than any currently marketed fluoroquinolone or other antibiotic widely used to treat respiratory tract infections.

Lifecycle Management

Additional life cycle management opportunities include:

- Acute bacterial sinusitis (ABS): Clinical studies demonstrating the effectiveness of a 5-day course of FACTIVE® for the treatment of ABS, due to susceptible pathogens, have already been completed. FACTIVE® will offer the shortest treatment duration of any quinolone, if approved. Preparation of the supplemental NDA is planned to begin shortly.

- I.V. formulation: The development plan for the I.V. formulation is currently being prepared.

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