

Edgar Filing: GENESOFT PHARMACEUTICALS INC - Form 425

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.

This filing is made for the purpose of filing the transcript of a conference call 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 held on November 18, 2003. The conference call is available for replay on Genome Therapeutics website, [www.genomecorp.com](http://www.genomecorp.com), through November 25, 2003.

#### 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](http://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.

**CORPORATE PARTICIPANTS**

**Chris Taylor**

*Genome Therapeutics Investor Relations*

**Steve Rauscher**

*Genome Therapeutics Chairman, CEO*

**David Singer**

*Genesoft Pharmaceuticals Chairman, CEO*

**Steve Cohen**

*Genome Therapeutics CFO*

**CONFERENCE CALL PARTICIPANTS**

**Tom Shrader**

*Harris Nesbitt Analyst*

**Robert Gilliam**

*Legg Mason Analyst*

**David Wood**

*Rodman & Renshaw Analyst*

**Jean Potvin**

*Sectoral Asset Management Analyst*

**PRESENTATION**

**Operator**

Welcome everyone to the Genome Therapeutics and Genesoft merger agreement conference call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer period. (OPERATOR INSTRUCTIONS) I would now like to turn the call over to the companies. You may begin.

**Chris Taylor - Genome Therapeutics - Investor Relations**

Good morning and thank you for attending the Genome Therapeutics and Genesoft call this morning. We would like to remind investors that statements may be 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 the 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 of 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 our inability to obtain regulatory approval to commercialize Ramoplanin due to negative, inconclusive or insufficient clinical data, and delays in the progress of our clinical trials for Ramoplanin, and increased costs 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 successfully develop products based on our genomics information, obtain the necessary regulatory approval for such products, effectively commercialize any products developed before our competitors are able to commercialize competing products or

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 make with the SEC from time to time.

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 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](http://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, Mass 02453, Attn: Investor Relations, and telephone number 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 interest of such participants by reading the proxy statement prospectus when it is filed with the SEC. The statements made on this call shall not constitute an offer to sell or the solicitation of an offer to buy any securities of Genome Therapeutics. Now I would like to turn the call over to Steve Rauscher, Chairman and CEO of Genome Therapeutics.

**Steve Rauscher - *Genome Therapeutics - Chairman, CEO***

Thank you, Chris. Good morning to everyone joining us on the call today. We welcome our current shareholders, Genesoft stakeholders, members of the media and all other interested parties. Earlier this morning Genome Therapeutics Corp. of Waltham, Massachusetts and Genesoft Pharmaceuticals of South San Francisco, California announced a definitive merger to form a new anti-infective biopharmaceutical company. During this call we will provide an outline of that agreement, the rationale for the merger, and an overview of our new company's anti-infective drug portfolio which includes the FDA approved product, Factive. This will be followed by a question-and-answer session.

Over the last three years we at Genome Therapeutics have been transforming our business to build a product focused biopharmaceutical company. When we licensed Ramoplanin in 2001 we made the first major step in that direction. With this merger today at Genesoft we are taking the next step; creating a new company with a clear focus on the development and commercialization of antibiotics that meet unmet medical needs. We're going to take you through the details of the merger in a few minutes, but first let me highlight why we took this next step, why we're so excited about the opportunity it represents for our shareholders and for our company.

Through this merger we gain immediate access to the FDA approved antibiotic, Factive, that we will launch in 2004. This exciting new product has been studied in 10,000 subjects, nearly 7000 of whom were patients treated at the effective dose. It has been the subject of 200 scientific publications. Factive will enter the US antibiotic market in the growing \$3 billion Quinolone segment of that market. With a very attractive product profile, Factive has a long remaining patent life that will extend at least through 2015, making it the cornerstone around which we will build our company for years to come. This merger creates a biopharmaceutical company with a powerful one-two punch, Factive, an FDA approved product ready to launch, Ramoplanin a late stage product candidate being developed for two indications, and a pipeline of earlier stage opportunities. In other words, this merger completely transforms our company and creates a fully fledged commercial enterprise with an asset base to position ourselves among an entirely different class of more advanced biopharmaceuticals companies.

This new company will be focused on developing innovative treatments for infectious diseases. We will provide more information about Factive and Ramoplanin in a few minutes, and we have posted the label for Factive and other relevant materials on both companies' Websites. But I'd like to briefly summarize some of the key attributes of these two assets.

Factive is FDA approved and poised to enter the largest market in anti-infectives, oral products used for the treatment of community acquired respiratory tract infections. This new product will fill a significant unmet medical need in that market. Initially we will focus intensely on the successful launch of this product in the United States for its two initial indications, mild to moderate community acquired pneumonia and Acute Bacterial Exacerbation of Chronic Bronchitis. Factive has also shown promise in clinical trials for the treatment of other important infections, and we intend to expand this label in the future.

Our plan is to build a highly focused sales force and launch Factive in time for the 2004 respiratory tract infection season. As sales grow we will expand our market presence accordingly. Importantly, this exciting new product currently has the longest patent life, through 2015, of any marketed antibiotic. This is a crucial advantage for building our anti-infective franchise.

Following Factive is our second exciting new product, Ramoplanin, an antibiotic candidate that is a first in class oral therapeutic currently in Phase III clinical development for the

prevention of vancomycin resistant enterococcal bloodstream infections. These are a serious and growing problem in US hospitals. The FDA recognizes the potential for Ramoplanin to address this unmet medical need and therefore has granted it fast-track status. This antibiotic is also being developed for the treatment of Clostridium difficile colitis, another serious hospital acquired infection. We expect to have additional updates on this product candidates advancement over the coming months.

Together Factive and Ramoplanin provide the foundation for our new company. In addition to these key assets we have numerous earlier stage opportunities, and these include an intravenous form of Factive under development, expected to begin clinical trials in the near future; an exciting new class of broad spectrum antibiotics known as Peptide deformylase, or PDF inhibitors, for the potential treatment of respiratory tract infections. We expect to begin clinical trials of an oral PDF inhibitor in the next few years. And seven fully funded preclinical product discovery and development alliances in place with leading pharmaceutical companies, and these include Amgen, AstraZeneca, Schering-Plough and Wyeth which we believe will provide funding and future revenue opportunities for our company.

To capitalize on these significant assets we have a management team with significant experience in anti-infectives, stemming from such companies as Abbott Laboratories, Bayer, GlaxoSmithKline, Lilly, Roche and Wyeth. This same team has participated in the development and marketing of numerous antibiotics including the Quinolones Avelox and Cipro, as well as Biaxin, Ceftin, Erythromycin, Fortaz, Zinacef and Zosyn. The executive team of the new company includes David Singer as Chairman of the Board; myself as President and Chief Executive Officer; Stephen Cohen, Senior Vice President and Chief Financial Officer; and Martin Williams as Senior Vice President of Corporate Development and Marketing.

The new company is slated to be led by a Board of Directors with extensive industry experience that includes Dr. Luke Evnin, Managing Director of MPM Asset Management; Bob Hennessey, former Chairman and CEO of Genome Therapeutics; Vernon Loucks, previous Chairman and CEO of Baxter International; Bill Reardon, former partner in charge of the New England Life Science practice at PricewaterhouseCoopers; Dr. Norbert Riedel, Corporate Vice President and Chief Scientific Officer Baxter International; Dr. William Rutter, Professor Emeritus in Biochemistry at the University of California San Francisco and the founder of Chiron; David Stone, Managing Director Flagship Ventures and former analyst with SG Cowen; David Singer and me.

We are confident that our leadership team has the experience in the anti-infectives industry necessary to deliver on our company vision. And with that I'm going to turn the call over to Genesoft's Chairman and Chief Executive Officer, David Singer. David was the founding President and CEO of three biotechnology companies including Affymetrix, Genesoft and Corcept. David will provide some background on Genesoft's history and his perspective on the new companies.

#### **David Singer - *Genesoft Pharmaceuticals - Chairman, CEO***

Thanks, Steve. As Steve mentioned, Genesoft is an emerging pharmaceutical company with an FDA approved antibiotic and a strong portfolio of preclinical and clinical candidates. Established in 1998, our mission has been the application of proprietary technologies for the discovery of novel anti-infective products. And we believe even more strongly today than we did in 1998 that there is a large commercial opportunity in the antibiotic category; one that too few companies are focused on capturing. And as patents expire big pharmaceutical companies are continuing to exit the field, further reducing the number of companies competing, both in the research and in the marketplace in this important space.

From 1998 to 2002 our commitment to the field grew as we complemented the novel mode of action chemistry upon which we were founded with a second novel mode of action anti-infective program, the PDF inhibitors that Steve described and you'll hear more about in the coming years. In 2002 we seized the unique licensing opportunity and acquired the North American and European rights to Factive, then in late stage clinical development. As our regulatory team began focusing on the FDA approval of Factive, our business priority became the identification of a strategically appropriate partner to take advantage of our antibiotic franchise, and to allow us as shareholders in Genesoft to continue to share

in the financial returns given the value creation subsequent to the close.

Our search for a partner, and Genome Therapeutics' search for an approved product, brought the two companies together in what we anticipate will be a fruitful merger with significant upside potential for all our stakeholders. Specifically we made the decision to merge with another biopharmaceutical company because we want to build a leading anti-infectives company. While we held discussions with a number of companies, few of them shared our vision. Management at Genome Therapeutics saw the same opportunity, which is one reason this merger makes so much sense, and our combined team is focused on building a leading infectious disease company to capture these opportunities.

There is and will be an inexorable unmet medical need in the field of infectious diseases. Our industry needs to be innovative and invest to ensure continued introduction of novel products to combat resistant bacterial strains. This merger creates a new company with critical mass in the field that we believe will enable our shareholders to participate in the significant upside potential of Factive, Ramoplanin and the rest of the pipeline.

The management team at our newly formed company, led by Steve, has deep experience in the field of anti-infectives and, just



as important, a strong passion to capitalize on the significant market opportunity that exists. Initially, our energy will be focused on the successful launch of Factive next summer to establish a solid presence in time for the greatest seasonal demand for this product. Our operating priority is the launch of Factive. This launch will require additional capital resources and, because we are investing to create a leader in the area of infectious disease, we will continually assess our capital needs in order to ensure that we maintain the necessary resources to fuel our future growth. With that I'll turn the call over to Steve Cohen, the Chief Financial Officer at Genome Therapeutics.

**Steve Cohen - *Genome Therapeutics - CFO***

As described in the press release announcing the merger, Genome Therapeutics will issue approximately 28 million shares of common stock to Genesoft's investors. Based on yesterday's closing price of \$2.85, the value of the transaction is roughly \$80 million. In addition to the stock in Genome Therapeutics we'll assume approximately \$24 million of Genesoft's debt, \$22 million of which will be restructured into convertible notes with a five-year term at a 5 percent interest rate. This brings the total enterprise value of the merger to just over \$100 million.

The closing of this merger is contingent on raising additional funds, approximately \$30 million. And during the next several months we will be on the road describing the merged company's potential value for shareholders in both North America and Europe. Pending approval by both company's shareholders, we expect the merger to close in the first quarter of 2004. With this financing and completion of the merger, the combined entity will provide a solid foundation for financial growth as we look to launch Factive, advance the clinical program for Ramoplanin, and progress our early stage product candidates. To further describe the assets of the merged company, I'll turn the call back to Steven Rauscher.

**Steve Rauscher - *Genome Therapeutics - Chairman, CEO***

During the course of my career I've had the opportunity to evaluate countless antibiotic product opportunities. Almost all of my years in this industry have involved launching, selling and marketing antibiotics for respiratory tract infections, and I've never been as excited about launching a product as I am about Factive.

The demand for antibacterials is growing; the global antibacterial drugs market was worth \$25 billion in 2001 and is forecasted to reach close to \$28 billion by 2007. The total sales of fluoroquinolones in the US have grown to \$3 billion as of last year and we expect the growth in that segment to continue. Respiratory tract infections are one of the most common reasons for visits to physicians. Each year there are more than 13 million cases of Acute Bacterial Exacerbations of chronic bronchitis. Patients with chronic bronchitis are prone to one to four exacerbations per year, they are a major cause of morbidity. The two key pathogens causing these infections are *Streptococcus pneumoniae* and *Haemophilus influenzae*. And, emerging resistance is a problem for patients, physicians and payers.

Each year there are 4 million Americans who contract community acquired pneumonia, a condition which is growing increasingly more difficult to treat. Community acquired pneumonia leads to hospitalization in over one million cases annually in this country. Factive, known as Gemifloxacin, is a novel fluoroquinolone, it is a once daily oral antibiotic that is approved for sale in the United States for both of these indications, the treatment of community acquired pneumonia and Acute Bacterial Exacerbations of chronic bronchitis. It is the only fluoroquinolone with approval from the FDA for treating cases of community acquired pneumonia caused by susceptible strains of multidrug resistant *Streptococcus pneumoniae*.

The clinical trials of Factive included approximately 7000 patients at the treatment dose, the data showed that Factive has excellent in vitro and in vivo activity against Gram Positive Bacteria and other serious respiratory pathogens, and these include *streptococcus pneumoniae*, *Haemophilus influenzae*, and the so-called atypical pathogens. Factive has equivalent or better potency relative to other fluoroquinolones against

## Edgar Filing: GENESOF PHARMACEUTICALS INC - Form 425

these respiratory pathogens. Factive at a dose of 320 milligrams is administered once daily for short courses of therapy, five days for acute bacterial exacerbations of chronic bronchitis, and seven days for community acquired pneumonia. We have compelling data from head-to-head trials with other antibiotics for safety, efficacy, and importantly, pharmacoeconomics. Overall, we believe that the promising therapeutic profile of this new antibiotic merits the exploration of additional indications for Factive, and we're planning the regulatory submission for this drug as a five-day treatment for acute bacterial sinusitis for which clinical trials have already been completed.

Some of the most important attributes of Factive include the following: it is active against the key respiratory infection pathogens. It is the only fluoroquinolone with a label claim that includes multidrug resistant Strep pneumo. It has a dual targeting mechanism of action that differentiates it from other fluoroquinolones, and it has a convenient dosing regimen for patients and physicians. For complete prescribing information, we encourage you to see the package insert which you can access on either one of the company's websites. In the coming months as we approach the launch of Factive, we will continue to refine our product positioning, our marketing strategy, and our pricing.

But there is even more to our new company than Factive. We have an exciting lineup of clinical and preclinical candidates in our pipeline. Leading the way is the antibiotic Ramoplanin, and those of you familiar with Genome Therapeutics know Ramoplanin is under development for the treatment, prevention, and control of serious nosocomial or hospital acquired infections. Currently,

Ramoplanin is in a Phase III trial for the prevention of bloodstream infections caused by vancomycin resistant enterococci or VRE. It is in a Phase II trial for the treatment of Clostridium difficile associated diarrhea, and a pilot study is examining its role in infection control for VRE. Clearly as we move forward a main priority of the new company will be to expand our anti-infective franchise through the advancement of Ramoplanin to an NDA submission.

The new company will have two preclinical therapeutics in development, the intravenous form of Factive and the oral PDF inhibitor. The Factive IV program is focused on selecting and developing the appropriate formulation and the dose for intravenous administration of the product. We expect to initiate Phase I clinical trials for the IV formulation of Factive moving forward.

The new company's second therapeutic program will be focused on investigating an oral PDF inhibitor for the potential treatment of respiratory tract infections. The compounds in this program are in the final stages of optimization before selection of a development candidate, and they've already shown promising in vitro and in vivo activity against respiratory pathogens including resistant organisms. We plan to enter human studies in the future with a once daily oral therapeutic from this class. The potential of Factive supported by a strong clinical and preclinical pipeline positions this new company to deliver important new therapies to patients and their physicians. Additionally we believe these assets will build value for all of our stakeholders moving forward. I personally am extremely enthusiastic about the opportunities this merger creates to develop products that will address a need that is all too frequently overlooked by larger pharmaceutical companies.

I'd now like to outline some of the milestones that our investors can expect over the next 18 months following the completion of the merger. The commercialization of Factive will be our top priority. We plan to hire a sales force. The current plan is for a 75 person team to begin with. We will develop supporting sales and marketing materials for the launch of Factive. We will initiate formulary submission activities with managed care organizations. Wholesaler stocking will begin over the summer and we will commence physician detailing activities in the fall of 2004.

While the launch of Factive is our top priority, we will continue to progress the development of Ramoplanin. We will complete the current Phase II Clostridium difficile trial, and we will initiate the Phase III clinical development program for that same indication. We will complete the ongoing infection control pilot study and continue to progress the ongoing Phase III trial for prevention of VRE bloodstream infections. And finally, in our preclinical programs we anticipate forming a development partnership for our oral PDF inhibitors, progressing Factive IV toward the clinic, and continuing to work closely with our existing pharmaceutical company partners to advance our existing programs toward the clinic.

Clearly we have a busy agenda for the next year; we're very excited about the potential for our new company and the launch of our first products. We're looking forward to providing additional information to shareholders in the months ahead. With that I'd now like to open the call up to any questions. Nicole, will you please begin the polling process?

**QUESTION AND ANSWER**

**Operator**

(OPERATOR INSTRUCTIONS) Tom Shrader of Harris Nesbitt.

**Tom Shrader - *Harris Nesbitt - Analyst***

This is obviously quite a change in at least GENE's profile. I'm just curious if you can the fluoroquinolone landscape is obviously quite complicated. Can you tell us what's the low hanging fruit for Factive? What drugs are ripe to be replaced and what indications, things like that? What are people with MDR strep pneumo treated with now?

**Steve Rauscher - *Genome Therapeutics - Chairman, CEO***

You're right, it is a big change for us, we're really excited about it. Let's talk about what is the low hanging fruit. There's a couple things that drive what the market potential is going to be here. First of all just a little background, there are six major promoted brands for community acquired respiratory tract infections, and two of those brands, Biaxin and Zithromax, are going to be going off patent in 2005. And as a result of that we're going to see a decline in promotional effort behind those products. That's going to shift share to the Quinolones. The big Quinolones, Levaquin is obviously the market leader, growing quickly is Avelox.

So those are the key brands in the landscape along with Tequin. We have Biaxin, Zithromax, Levaquin, and Avelox and Tequin. We believe that our product has a very attractive profile, not only against the competitive Quinolones, but also obviously against the macrolides. So we think the shares in this marketplace are going to shift Quinolones, particularly as we see an increase in multi drug resistant Strep pneumo. We're the only drug in the marketplace that has a claim for multidrug resistant Strep pneumo, so we think that's really going to be the low hanging fruit, taking share from those key brands.

**Tom Shrader - *Harris Nesbitt - Analyst***

To shift gears. In terms of the discovery engines of the companies, how much synergy is there? I don't know a lot about Genesoft, it's founded as a chemistry company, is it bringing a lot of chemistry, are you going to have additional chemical abilities now?

**Steve Rauscher - *Genome Therapeutics - Chairman, CEO***

I'll let Dave talk about the capabilities for the Company on a discovery basis, but let me just talk about the first program that we're very excited about, and that's the oral PDF inhibitor program. That is obviously an exciting new class; it's a completely new class of antibiotics against a novel

target. This program came out of a partnership between Genesoft and British Biotech; it has an extensive number of compounds in it that we expect to get it in the clinic in the near future. So that is the key one and I would describe it more as additives than synergies because it really brings a chemistry capability to us that we didn't have previously.

**David Singer - *Genesoft Pharmaceuticals - Chairman, CEO***

To Steve's point, we grew up as a chemistry company. We feel like scientifically in the field of infectious diseases that's really where our core expertise is. We are excited about the PDF program. We feel like it's landscaped, there are a bunch of big competitors in, and our programs are probably more mature than most. On the other hand, this new combined company can't do everything and we're not going to try and do everything. We're going to try and focus on the launch of Factive, completing the clinical development of Ramoplanin, and the additional indications to grow the market for Factive and complete its lifecycle, and selectively invest in novel anti-infectives.

So we do bring that capability, I think we have to be careful as a joint company as we really sort of get out of the biotech mode and really into a mode where we're generating significant revenues and profits at sometime in the future.

**Tom Shrader - *Harris Nesbitt - Analyst***

Do you plan to maintain two sites sort of as is or too early to know?

**Steve Rauscher - *Genome Therapeutics - Chairman, CEO***

I think it's still early in the game, but we obviously are—we have two facilities at this point in time. The facilities in California are primarily focused on discovery activity, and clearly Boston will be the headquarters for clinical development and commercial activity.

**Tom Shrader - *Harris Nesbitt - Analyst***

Great, congratulations.

**Operator**

Robert Gilliam of Legg Mason.

**Robert Gilliam - *Legg Mason - Analyst***

I see that Factive was initially licensed from LG Life Sciences, and I was wondering if you own any royalties through the

company? And also I was wondering what the cash balance was for Genesoft at the end of the last quarter?

**Steve Rauscher - *Genome Therapeutics - Chairman, CEO***

Let me parse both of those. First of all, the product is licensed from LG Life Sciences. We'll be buying our active pharmaceutical ingredient from LG Life Sciences. In addition the company does pay royalties, and those royalties do increase as the sales of the product grows. The gross margin on product sales inclusive of all of our royalty obligations is projected to be about 75 percent or a little higher during the first two years of the life of the product and it will remain in the high 60 percent category thereafter the high 60's thereafter. I will take the second part of your question, which was cash balance, and pass that over to Steve Cohen, our Chief Financial Officer.

**Steve Cohen - *Genome Therapeutics - CFO***

Let me first talk about the Genome Therapeutics balance. At the end of the last quarter, when you consider the financing that we raised just after the end of the quarter, we were roughly \$37 million. Genesoft is a private entity and therefore doesn't report their third-quarter results. We will be filing those in the upcoming S4 shortly, but let's say it's not as significant that will change the overall profile of the cash balance. So it will be additive but it certainly is not a doubling kind of affect. But we'll file those in the S4 in the coming weeks.

**Robert Gilliam - *Legg Mason - Analyst***

Great, thank you.

**Operator**

(OPERATOR INSTRUCTIONS) David Wood of Rodman & Renshaw.

**David Wood - *Rodman & Renshaw - Analyst***

Just a couple of questions. The first one would be for Steve Cohen. Any sense of what the costs will be associated with hiring the salesforce and engaging in sort of marketing and physician education and activities like that?

**Steve Cohen - *Genome Therapeutics - CFO***

## Edgar Filing: GENESOFT PHARMACEUTICALS INC - Form 425

Of course we're looking at our preliminary numbers. But again, I don't want to get ahead of the regulatory filing on this thing, so we will give a little more guidance as we file the S4. But I guess as a just sort of an intro, we did mention a couple of times that we'll need to raise about \$30 million as part of this transaction, and that should put you in sort of the ballpark that you'll be starting to see as we file the S4.

**David Wood - Rodman & Renshaw - Analyst**

Okay, great. And a second question if I may. Can you, Steve or David, can you just run through the markets again, the indications, and can you give us a sense of—especially for the upcoming indication, the acute bronchitis indication, can you just go over the market size again and how you look at those markets?

**David Singer - Genesoft Pharmaceuticals - Chairman, CEO**

Why don't I sort of put this in perspective and then turn it over to Steve to take you to the next level? So the Quinolones for respiratory tract infections really started to grab market share from the other classes of antibiotics with the introduction of Levaquin in the late '90s. And since that time they have continued to grab share both in terms of value and number of scripts in the respiratory tract infection, which we refer to as the RTI market. The big indications in that market are community acquired pneumonia, which we refer to as CAP; acute bacterial exacerbation of chronic bronchitis, which we refer to as ABECB; and acute bacterial sinusitis or ABS. Factive has claimed issued claims for CAP and ABECB, and as Steve said, the clinical trials for a five-day course of therapy for ABS have been completed and we are preparing the submission on that. So that's sort of an overview of where it is and let me turn it over to Steve to sort of talk about his perspective on it.

**Steve Rauscher - Genome Therapeutics - Chairman, CEO**

Let's first talk about respiratory tract infections. And when we talk about respiratory tract infections we're referring to infections of the ears, the nasal passages and the sinuses, the throat and the chest. Within the chest it's sort of two separate categories, the bronchial tree and pneumonia in the alveoli. So you can sort of think about these in two categories of upper and lower, and generally speaking chest infections are referred to as lower respiratory tract infections and upper respiratory includes the sinuses, the throat and the ears.

The marketplace that we will be going after initially is going to be the lower respiratory tract infections for community acquired pneumonia and Acute Bacterial Exacerbations of chronic bronchitis. If you look at the overall Quinolone marketplace in the US, the fastest-growing categories in Quinolones are for use in respiratory tract infections. And really, what leads the way are these lower respiratory tract infections as well as sinusitis. We're going initially after the lower respiratory tract and later on we'll come back with the claim for sinusitis.



Just to give you an idea of how some of the other brands in this category - Levaquin, which was launched in 1997, is the leader in the category, its 2002 sales were close to \$1 billion; Zithromax, which is a macrolide in respiratory tract infections, has sales of \$1.4 billion; and Biaxin, which is also a macrolide, had sales of \$590 million. Those two products are going off patent. Two of the newest Quinolones which are extensively used for respiratory tract infections are Avelox and Levaquin. These products were only launched in the year 2000. So in 2002, which was just their second full year of launch, they've realized combined sales of \$425 million. I think the take-home message there is that because this is a marketplace that turns over every week, every week is a whole new group of infections, good new brands that fill unmet medical needs can gain rapid market share entrance and become big products relatively quickly.

**David Singer - Genesoft Pharmaceuticals - Chairman, CEO**

Maybe I'll add one more perspective on that, stepping back as we've sort of analyzed the antibiotic market there are a few principles that we've gleaned from the data. Which is, one, it's absolutely clear that new antibiotic classes supersede older antibiotic classes over time. That's happened and it will continue to happen, and that's why we're so excited about the PDF program and its trajectory. The second is that within a class newer antibiotics supersede older antibiotics, that the improvements are important. The third is the RTI - in the RTI class the Quinolones are the only growing segment of it, and we believe that they will continue to grow for the foreseeable future both because of the, on the one hand the demands that are placed upon the drugs given resistance in the marketplace; two, the fact that this is a promotion sensitive market and within the next few years most of the other brands will lose their patent exclusivity. Steve, I don't know if you want to mention the guidelines that just came out?

**Steve Rauscher - Genome Therapeutics - Chairman, CEO**

There are new guidelines that have recently been published by the Infectious Diseases Society of America. They are for the treatment of community acquired pneumonia. In those guidelines the ideas they recommend that Quinolone - respiratory Quinolones, and Gemifloxacin, Factive is one of those that is named, are considered to be agents of first choice in patients that have either received antibiotic therapy in the recent past, or patients who have some kind of an underlying comorbidity. And most of the patients in this country who develop pneumonia have some kind of underlying comorbidity that makes them vulnerable and clearly the idea is supporting Quinolones as first-line agents for these patients.

**David Wood - Rodman & Renshaw - Analyst**

That was very helpful, thank you.

**Operator**

Jean Potvin of Sectoral Asset Management.

**Jean Potvin - Sectoral Asset Management - Analyst**

## Edgar Filing: GENESOFT PHARMACEUTICALS INC - Form 425

Could you please go over the deal terms again, and also explain a little bit what are the next steps you need to reach to close this transaction?

**Steve Cohen - *Genome Therapeutics - CFO***

The deal terms are, for those of you that have gone through this process, there's a lot of paperwork and a lot of issues to work through. So when it comes down to the end there are really very few terms. We will issue a little over 28 million shares in this merger to the Genesoft shareholders. We're also going to assist them with some key investments in the Factive product towards building inventory and starting the marketing programs so we don't lose any momentum in that area. To the tune of around \$6 million we will make an investment between now and the time of the closing.

Those are the single biggest terms of the deal itself. Now we are taking, as I mentioned in the transaction, there's about \$24 million in debt that we'll be unassuming, \$22 million of that we have restructured into convertible notes, a five year term, 5 percent interest rate. And we also mentioned we'll be raising the additional monies, approximately \$30 million. Now next step is going to the S4, we will go out to raise we'll be raising money and they go through the process of shareholder approval before moving to final closing. Did I cover that all for you?

**Jean Potvin - *Sectoral Asset Management - Analyst***

Okay, thanks.

**Operator**

(OPERATOR INSTRUCTIONS) Robert Gilliam of Legg Mason.

**Robert Gilliam - *Legg Mason - Analyst***

Just trying to get my hands around the market size for this drug. I was wondering if you could give us what you might think the average length of therapy could be, and also the potential pricing for the drug?

**Steve Rauscher - *Genome Therapeutics - Chairman, CEO***

The length of therapy will be per label. The drug is approved for short courses of therapy, Robert, five days for Acute Bacterial Exacerbations of chronic bronchitis and seven days for the treatment of community acquired pneumonia. And this is clearly the trend in antibiotic therapy is to go for short courses of therapy using highly active antibiotics. In terms of pricing, we're going to make this a competitive product, it will be value priced, but clearly we're not going to look to make price a barrier to adoption of his product. So if you look at the pricing for some of the newer antibiotics in the field you won't be far off in looking at what the pricing is going to be for Factive.

**Robert Gilliam - *Legg Mason - Analyst***

Okay, thank you.

**Operator**

At this time there are no further questions. Are there any closing remarks?

**Steve Rauscher - *Genome Therapeutics - Chairman, CEO***

Yes. First of all, I want to thank everyone for joining us early this morning to hear about the exciting proposed merger between Genesoft Pharmaceuticals and Genome Therapeutics. This combination creates a brand new company, and this company will be focused on the development and commercialization of anti-infective therapeutics. We very much look forward to providing you with further updates as we go through the merger process and on our company's product portfolio. We anticipate your support as we launch this new company. Thank you for joining us this morning.

**Operator**

This concludes today's conference call. You may now disconnect.