OSCIENT PHARMACEUTICALS CORP
Form POS AM
December 20, 2004
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**As filed with the Securities and Exchange Commission on December 20, 2004**

**Registration No. 333-118026**

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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## POST-EFFECTIVE AMENDMENT NO. 1 TO

# FORM S-3

# REGISTRATION STATEMENT

***UNDER***

***THE SECURITIES ACT OF 1933***

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# OSCIENT PHARMACEUTICALS CORPORATION

**(Exact name of registrant as specified in its charter)**

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| **Massachusetts** | **04-2297484** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |

**1000 Winter Street, Suite 2200, Waltham, Massachusetts 02451 (781) 398-2300**

**(Address, including zip code, and telephone number, including area code of principal executive offices)**

**Stephen Cohen**

**Senior Vice President and Chief Financial Officer**

**Genome Therapeutics Corp.**

**1000 Winter Street, Suite 2200, Waltham, Massachusetts 02451 (781) 398-2300**

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

**Please send copies of all communications to:**

**Patrick O Brien**

**Ropes & Gray LLP**

**One International Place**

**Boston, Massachusetts 02110**

**(617) 951-7000**

***Approximate date of commencement of proposed sale to the public:***

*From time to time after the effective date of this Registration Statement.*

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement under the earlier effective registration statement for the same offering. ¨

If this form is a post effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box: ¨

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**PROSPECTUS**

# $152,750,000
# 3 1/2% Senior Convertible Notes due 2011 and the Shares of Common Stock
# Issuable Upon Conversion Thereof

We issued the notes in private placements in May 2004. $143,750,000 aggregate principle amount of notes were issued to two initial purchasers pursuant to one indenture, and the remaining $9,000,000 aggregate principle amount of notes were issued to another purchaser on the same terms and conditions pursuant to a substantially identical indenture. This prospectus will be used by selling securityholders to resell from time to time their notes and the shares of Oscient Pharmaceuticals common stock issuable upon conversion of their notes.

We will pay interest on the notes on April 15 and October 15 of each year, beginning on October 15, 2004.

Holders may convert the notes into shares of our common stock at any time prior to the maturity date of the notes (unless previously repurchased).

The conversion rate will initially be 150.5571 shares of our common stock per $1,000 principal amount of notes, which is equivalent to a conversion price of approximately $6.64 per share of common stock. The conversion rate will be subject to adjustment upon the occurrence of specified events.

We may not redeem the notes before May 10, 2010. On or after that date, we may redeem all or part of the notes for cash at a price equal to 100% of the principal amount of the notes to be redeemed.

Holders may require us to repurchase all or a portion of their notes, subject to specified exceptions, upon the occurrence of a fundamental change specified in this offering memorandum at a price equal to 100% of the principal amount of the notes, plus in certain circumstances, a make-whole premium. Upon a fundamental change, we may pay the repurchase price in cash or, in certain circumstances, we may choose to pay the repurchase price in shares of our common stock or a combination of cash and shares of our common stock.

We used a portion of the net proceeds from the private placements to purchase a portfolio of U.S. government securities that we pledged to secure the first six scheduled interest payments on the notes. Other than this pledge of U.S. government securities, these notes will be unsecured obligations and will rank equally with our other existing and future senior indebtedness. The notes will be structurally subordinated to the indebtedness and other liabilities of our subsidiaries.

The notes have been designated for trading in The Portal[SM] Market, a subsidiary of The Nasdaq Stock Market, Inc. Any notes that are resold by means of this prospectus will no longer be eligible for trading in The Portal[SM] Market. Our common stock is listed on the Nasdaq National Market under the symbol OSCI. On December 17, 2004, the reported last sale price of our common stock on the Nasdaq National Market was $3.77 per share.

**Investing in the securities involves risks. See Risk factors beginning on page 9.**

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

The date of this prospectus is December 20, 2004

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**You should rely only on the information contained in this document or to which we have referred you. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.**

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**Where you can find more information**

This prospectus incorporates by reference information from documents which are not presented in or delivered with this prospectus. You should rely only on the information contained in the prospectus and in the documents that we have incorporated by reference herein. We have not authorized anyone to provide you with information that is different.

We file annual, quarterly and current reports, proxy statements and other information with the SEC under the Securities Exchange Act of 1934, as amended (the Exchange Act ). You may read and copy any reports, statements or other information on file at the SEC s public reference room located at 450 Fifth Street NW, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC filings are also available to the public from commercial document retrieval services. These filings are also available at the Internet website maintained by the SEC at *http://www.sec.gov*. You can also inspect copies of our public filings at the offices of the Nasdaq National Market ( Nasdaq ) located at 1735 K Street NW, Washington, D.C. 20006.

The SEC allows us to incorporate by reference information from other documents that we file with them, which means that we can disclose important information by referring to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. Any statement contained in a document, all or a portion of which is incorporated by reference herein, shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained or incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 prior to the time that all securities covered by this prospectus have been sold; provided, however, that we are not incorporating any information furnished under either Item 9 or Item 12 of any current report on Form 8-K:

| **Oscient Pharmaceuticals SEC Filings (File No. 0-10824)** | **Period** |
|---|---|
| Annual report on Form 10-K | Year ended December 31, 2003, as filed on March 5, 2004 |
| The portions of our Proxy Statement on Schedule 14A for our 2004 Annual Meeting of Shareholders that are deemed filed with the SEC | As filed on March 9, 2004 |
| Current reports on Form 8-K and Form 8-K/A | As filed on January 9, 2004; January 30, 2004; February 2, 2004; February 3, 2004; February 10, 2004; March 8, 2004; April 14, 2004; April 16, 2004; May 3, 2004; May 5, 2004; May 11, 2004; May 14, 2004; May 26, 2004; August 9, 2004; August 10, 2004; August 12, 2004; and November 10, 2004 |
| Quarterly Report on Form 10-Q | Quarters ended March 27, 2004, as filed on May 11, 2004, as amended on December 3, 2004; June 26, 2004, as filed on August 10, 2004; September 25, 2004, as filed on November 9, 2004 |
| The description of our common stock contained in our registration statement on Form 10/A, including any amendment or reports filed for the purpose of updating such description | As filed on January 9, 1996 |

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Documents incorporated by reference are available without charge, excluding all exhibits unless an exhibit has been specifically incorporated by reference into this prospectus, by requesting them in writing or by telephone at:

Oscient Pharmaceuticals Corporation

1000 Winter Street, Suite 2200

Waltham, Massachusetts 02451

Attention: Christopher Taylor, Vice President of Investor Relations

(781) 398-2300

The information contained on our website does not constitute a part of this prospectus.

**Forward-looking statements**

Certain information contained in this prospectus and the documents incorporated by reference herein should be considered forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements represent, among other things, the expectations, beliefs, plans and objectives of management and/or assumptions underlying or judgments concerning the future financial performance and other matters discussed in this document. The words may, will, should, plan, belie estimate, intend, anticipate, project, potential, and

expect and similar expressions are intended to identify forward-looking statements. All forward-looking statements involve certain risks, estimates, assumptions, and uncertainties and we can give no assurance that these expectations will be achieved. You are cautioned that these forward looking statements involve risk and uncertainty and actual results may differ materially from those discussed as a result of various factors described in the Section of this prospectus entitled Risk factors. revenues, cash flows, expenses and the cost of capital, among other things. We undertake no obligation to revise the forward-looking statements included in this prospectus to reflect any future events or circumstances.

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## Summary

*This summary contains basic information about us and the notes and the common stock issuable upon conversion of the notes. Because it is a summary, it does not contain all of the information that you should consider before investing. You should read this entire prospectus carefully, including the section entitled Risk factors, as well as the information incorporated by reference herein before making an investment decision.*

### Oscient Pharmaceuticals Corporation

We are a biopharmaceutical company committed to the clinical development and commercialization of new therapeutics to serve unmet medical needs. On February 6, 2004, we completed our merger with GeneSoft Pharmaceuticals, Inc. (Genesoft), a privately-held pharmaceutical company based in South San Francisco, California. As a result, we gained rights to market the FDA-approved antibiotic FACTIVE® (gemifloxacin mesylate) tablets, indicated for the treatment of community-acquired pneumonia of mild-to-moderate severity and acute bacterial exacerbations of chronic bronchitis. The commercial sale of FACTIVE was launched in September 2004. For the near term, we intend to focus our efforts on the launch of commercial sales of FACTIVE tablets for these indications as well as clinical trials for other indications of FACTIVE.

FACTIVE

Gemifloxacin is a member of the fluoroquinolone class of antibiotics. In April 2003, FACTIVE tablets were approved by the FDA for the treatment of acute bacterial exacerbations of chronic bronchitis (ABECB) and community-acquired pneumonia (CAP) of mild to moderate severity. In July 2003, FACTIVE tablets were also approved to treat CAP caused by multi-drug resistant *Streptococcus pneumoniae*, or *S. pneumoniae*, a growing clinical concern. FACTIVE tablets are the only antimicrobial currently approved for this indication.

Within the antibiotic market, quinolones, a product class with close to $3 billion in annual sales in the U.S. in 2002, have been gaining market share at the expense of older antibiotics, according to IMS Health. This is a trend that is expected to continue as resistance to older antibiotic classes increases. Due to their microbiological activity and clinical efficacy, FACTIVE tablets represent an alternative choice for the treatment of certain respiratory tract infections.

We completed our initial recruitment of over one-hundred sales and marketing professionals in September 2004 to launch the sale of FACTIVE tablets and have begun to recruit and hire an additional one-hundred fifty sales and marketing professionals to support a nationwide sales force for FACTIVE. With the launch of FACTIVE tablets in September of 2004, we do not expect sales of FACTIVE tablets to have a significant impact on our operating results in 2004, with the majority of revenue representing wholesale and pharmacy stocking.

The potential competitive advantages of FACTIVE tablets include the following:

- FACTIVE tablets have been shown in *in vitro* studies to be active against many bacterial isolates resistant to other classes of antibiotics, and are the only fluoroquinolone approved to treat community-acquired pneumonia of mild to moderate severity caused by

multi-drug resistant *S. pneumoniae.*

FACTIVE tablets have a dual mechanism of action in bacteria, which targets two enzymes essential for bacterial growth and survival at therapeutically relevant drug levels, and as a result we believe have low *in vitro* potential for resistance generation.

FACTIVE tablets can be dosed once daily, with short courses of therapy for both ABECB (5 days) and CAP (7 days).

FACTIVE tablets have composition of matter patent protection through 2015, with additional patent protection through 2019.

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FACTIVE tablets have been studied in nearly 7,000 patients and have a favorable safety profile. The incidence of adverse events reported for FACTIVE tablets was low and comparable to comparator drugs, namely beta-lactam antibiotics, macrolides and other fluoroquinolones. Most adverse events were described as mild to

moderate. Although rash was more frequent among FACTIVE-treated patients in the total patient population than among those who received comparator drugs, in the adult population most at risk for CAP of mild to moderate severity and ABECB (patients over 40 years of age) and at the approved dosage (320 mg for 7 days or less), the rate of rash with FACTIVE tablets was low and comparable to that seen with other antibiotics.

As a post-marketing study commitment, the FDA has required that we conduct a prospective, randomized study comparing FACTIVE tablets (5,000 patients) to an active comparator (2,500 patients) in patients with CAP or ABECB. This Phase IV trial commenced during the Fall of 2004 and is scheduled to be completed during the next three years. We also plan to file a New Drug Application for FACTIVE tablets for the treatment of acute bacterial sinusitis in 2005.

We license the rights to gemifloxacin, the active ingredient in FACTIVE tablets, from LG Life Sciences of the Republic of Korea. Under this agreement, we are required to buy bulk drug requirements from LG Life Sciences, and will pay LG Life Sciences a royalty on sales in the U.S. and the territories covered by the license in the rest of North America and Europe. The arrangement also provides for potential additional milestone payments to LG Life Sciences of up to $22 million, upon obtainment of additional regulatory approvals and sales targets.

Ramoplanin

We are also developing a novel investigational antibiotic, Ramoplanin, which is currently in clinical trials for the prevention and treatment of serious hospital-acquired infections. Ramoplanin is in a Phase II trial for the treatment of *Clostridium difficile*-associated diarrhea.

On August 10, 2004, the Company announced preliminary results of its Phase II trial of Ramoplanin for the treatment of CDAD. Pending the outcome of a full analysis of the trial data and discussions with the FDA, including a Special Protocol Assessment, the Company plans to commence a Phase III trial. In July 2004, the Company decided to close enrollment on its Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by VRE prior to completion of the study. The Company intends to analyze the results of the VRE trial and make a determination at a later date as to any future course of action for this indication.

Other Programs

Our preclinical development programs include an oral peptide deformylase inhibitor series for the potential treatment of respiratory tract infections as well as development of a FACTIVE intravenous formulation. As we have done over the past three years, we will also continue to explore ways of expanding our existing product portfolio through the licensing and acquisition of complementary products and product candidates.

We are incorporated as a Massachusetts corporation. The address for our executive offices is 1000 Winter Street, Suite 2200, Waltham, Massachusetts 02451 and our telephone number is (781) 398-2300. Our website is www.oscient.com. The information found on our website and on websites linked from it are not incorporated into or a part of this prospectus. On April 13, 2004, following our annual meeting of

stockholders, we amended our Articles of Organization to change our name from Genome Therapeutics Corp. to Oscient Pharmaceuticals Corporation.

FACTIVE is a trademark of LG Life Sciences, Ltd. Other trademarks and trade names appearing in this prospectus are the property of their holders.

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**The Notes**

*The following summary contains basic information about the notes and is not intended to be complete. It does not contain all the information that is important to you. For a more complete understanding of the notes, please refer to the section of this prospectus entitled Description of Notes. For purposes of the description of the notes included in this prospectus, references to the Company, issuer, us, Oscient Pharmaceuticals we and our refer only to Oscient Pharmaceuticals Corporation and do not include any of its subsidiaries.*

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|---|---|
| Issuer | Oscient Pharmaceuticals Corporation (formerly known as Genome Therapeutics Corp.), a Massachusetts corporation. |
| Securities offered | $152,750,000 principal amount of 3 1/2% Senior Convertible Notes due 2011. |
| Ranking | The notes rank equally in right of payment to our existing and future senior indebtedness, junior to any secured indebtedness to the extent of the assets securing such indebtedness and senior to any subordinated indebtedness. As of September 25, 2004, we had approximately $176 million of indebtedness outstanding. The notes are structurally subordinated to all liabilities of our subsidiaries. The indentures do not limit the amount of debt that we or any of our subsidiaries may incur. |
| Maturity | April 15, 2011, unless earlier redeemed, repurchased or converted. |
| Interest | 3 1/2% per year on the principal amount, payable semi-annually in arrears on April 15 and October 15 of each year, beginning October 15, 2004. |
| Security | We have purchased and pledged to the trustee under the indentures for the exclusive benefit of the holders of the notes an amount of U.S. government securities, which we expect will be sufficient, upon receipt of scheduled principal and interest payments thereon, to provide for the payment in full of the first six scheduled interest payments on the notes when due. We were responsible for determining the sufficiency of the securities to be pledged. A verification agent verified the mathematical accuracy of our computations. The notes will not otherwise be secured. See Description of Notes Security. |
| Redemption at our option | On or after May 10, 2010, we may redeem for cash all or part of the notes, upon not less than 30 nor more than 60 days notice before the redemption date by mail to the trustee, the paying agent and each holder of notes, at 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest, if any. |

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| Conversion rights | Holders may convert their notes into shares of our common stock at an initial conversion rate of 150.5571 shares per $1,000 principal amount of notes (or approximately $6.64 per share of common stock), subject to adjustment, prior to the close of business on the business day prior to the maturity date. |
| Adjustment of conversion rate | We will adjust the conversion rate of the notes if any of the following events occurs:<br>we issue common stock as a dividend or distribution on our common stock or we effect a stock split or stock combination;<br>we issue certain rights or warrants to all or substantially all holders of our common stock;<br>we distribute shares of our capital stock, evidences of indebtedness or assets to all or substantially all holders of our common stock;<br>we make distributions consisting of cash to all or substantially all holders of our common stock; or<br>we or one of our subsidiaries makes purchases of our common stock pursuant to a tender offer or exchange offer for our common stock. |
| Sinking fund | None. |
| Fundamental change | If we undergo a fundamental change (as described in this prospectus), except in certain circumstances, you will have the option to require us to repurchase all or any portion of your notes. The fundamental change repurchase price will be 100% of the principal amount of the notes to be repurchased plus accrued and unpaid interest, if any, plus, in certain circumstances, a make-whole premium. Upon a fundamental change we may pay the repurchase price in cash or, in certain circumstances, we may choose to pay the repurchase price in shares of our common stock or a combination of cash and shares of our common stock. |
| Use of proceeds | We will not receive any proceeds from the sale by any selling security holder of the notes or the common stock issuable upon conversion of the notes. |
| Book-entry form | The notes were issued in book-entry form and are represented by permanent global certificates deposited with, or on behalf of, The Depository Trust Company ( DTC ) and registered in the name of a nominee of DTC. Beneficial interests in any of the notes are shown on, and transfers will be effected only through, records maintained by DTC or its nominee and any such interest may not be exchanged for certificated securities, except in limited circumstances. |

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| Trading | The notes are not listed on any securities exchange or included in any automated quotation system. Any notes that are sold by means of this prospectus will no longer be eligible for trading in The PORTAL[sm] Market. The initial purchasers have advised us that they currently intend to make a market in the notes. However, they are not obligated to do so, and they may discontinue any market making with respect to the notes without notice. We do not intend to apply for a listing of the notes on any securities exchange or any automated dealer quotation system. Our common stock is quoted on the Nasdaq National Market under the symbol OSCI. |
| Further issues | We may from time to time, without notice to or the consent of the registered holders of the notes, create and issue additional debt securities having the same terms as and ranking equally and ratably with the notes in all respects, as described more fully in Description of notes Further issues. |
| Nasdaq symbol for our common stock | OSCI |
| Risk factors | Investment in the notes involves risk. You should carefully consider the information under Risk factors and all other information included in this prospectus and the documents incorporated by reference herein, before investing in the notes. |

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## Risk factors

*Our business faces many risks. The risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our common stock or the notes offered hereby could decline. You should consider the following risks, as well as the other information included or incorporated by reference in this prospectus before deciding to invest in the notes or the common stock issuable upon conversion of the notes.*

### Risks related to our business

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

We have experienced significant operating losses each year since our inception and expect these losses to continue for the foreseeable future. We had a net loss of approximately $29,789,000 for the fiscal year ended December 31, 2003 and as of September 25, 2004, we had an accumulated deficit of approximately $216.6 million. 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.

Prior to the merger, GeneSoft Pharmaceuticals, Inc., referred to as Genesoft, had a net loss of approximately $35,813,000 for the fiscal year ended December 31, 2003 and as of December 31, 2003, Genesoft had an accumulated deficit of approximately $91,381,000. 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 Genesoft s 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 we will incur additional losses in the current year and in future years and cannot predict when, if ever, we will achieve profitability. These losses are expected to increase in the current year as we will significantly increase our expenditures in sales and marketing in connection with the commercial launch of FACTIVE tablets. We also plan to continue to expand our 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.

***Our business will be very dependent on the commercial success of FACTIVE tablets.***

FACTIVE tablets are currently our only commercial product and we expect they will account for substantially all of our revenues for at least the next several years. FACTIVE tablets have 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 tablets will depend upon their 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. The commercial success of FACTIVE tablets will also depend on adequate distribution in wholesalers and pharmacies. If FACTIVE tablets are not commercially successful, we 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 tablets for marketing in April 2003, it required, as a postmarketing study commitment, that we conduct a prospective, randomized study comparing the FACTIVE tablet (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 commenced during the Fall of 2004 and is scheduled to be completed in the next three years. In connection with the approval of FACTIVE tablets, the FDA has also required us to obtain data on the prescribing patterns and use of FACTIVE tablets for the first three years after their 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 tablets.

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

In connection with the merger with Genesoft, we raised approximately $80,907,000, after deducting placement agents fees and estimated offering expenses payable by us. We believe that these funds, along with the proceeds from the offering of convertible notes that closed during the second quarter of this fiscal year, our pre-existing cash and marketable securities, borrowings under equipment financing arrangements and anticipated cash flows from operations will be sufficient to support our current plans for at least 27 months. We will need to raise additional capital in the future to fund our operations and may seek to raise this capital from time to time, depending upon our performance and market factors. In particular, we expect we will raise additional funds to support our sales and marketing activities, and fund clinical trials and other research and development activities. 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, among other factors, 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 to us when needed, or, if available, may not be available on favorable terms. If we cannot obtain adequate financing on acceptable terms when such financing is required, our business will be adversely affected.

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

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

***We will need to develop marketing and sales capabilities to successfully commercialize FACTIVE tablets and our other product candidates.***

FACTIVE tablets are our first FDA approved product. To date, we have very limited marketing and sales experience. We have built a sales and marketing force to launch FACTIVE and market our other product candidates, including Ramoplanin, and are currently in the process of expanding our sales organization from 106 sales representatives to 250 representatives. We will need to continue to expand and retain our sales and marketing staff to successfully commercialize FACTIVE tablets. The development of these marketing and sales capabilities will require significant expenditures, management resources and time. We may be unable to build and maintain such a large enough sales force or the cost of establishing such a sales force may exceed any product revenues, or our marketing and sales efforts may be unsuccessful. In addition, we may be unable to meet our goal of finding a suitable sales and marketing partner for FACTIVE tablets in 2005. Failure to successfully

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establish and maintain sales and marketing capabilities in a timely and regulatory compliant manner or to find suitable sales and marketing partners may prevent us from successfully commercializing FACTIVE tablets which would materially adversely affect our business and results of operations.

***We will depend on third parties to manufacture our product candidates, including FACTIVE tablets and Ramoplanin.***

We will not have the internal capability to manufacture commercial quantities of pharmaceutical products under the FDA s current Good Manufacturing Practices. We are party to an agreement with LG Life Sciences to manufacture bulk quantities of FACTIVE. We have also 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 we expect 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 tablets.

LG Life Sciences is obligated to provide us with finished product until the termination or expiration of its existing agreement with SB Pharmco Puerto Rico, Inc., or SB Pharmco, which provides for the supply of finished FACTIVE product by SB Pharmco. The term of this agreement ended on June 30, 2004, but was extended by LG Life Sciences to complete existing orders and product commitments already in the supply chain pipeline. We have initiated the technology transfer process with a new provider of finished products, which will assume these responsibilities for subsequent periods. We estimate that a new provider of finished FACTIVE tablets will obtain the necessary FDA qualifications by the second half of fiscal 2005. We expect to obtain quantities of FACTIVE tablets from SB Pharmco that will provide us with sufficient inventory until the new provider can be qualified. If we are unable to obtain the FDA approvals necessary to qualify a new provider by the time that our supply of finished FACTIVE tablets to be received from SB Pharmco is exhausted, our supply of FACTIVE product would be interrupted and our business may be materially 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 which could cause our supply of FACTIVE tablets to be interrupted.

We cannot be certain that LG Life Sciences, Vicuron or future manufacturers will be able to deliver commercial quantities of product candidates to us 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, we would incur substantial costs and delay in the commercialization of FACTIVE tablets. If we are 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. We may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. Also, if we change the source or location of supply or modify 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 we 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 we decide to manufacture products, it would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical products. No matter who manufactures the products, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

***We cannot expand the indications for which we will market FACTIVE unless we receive FDA approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for FACTIVE.***

In April 2003, FACTIVE tablets were approved by the FDA for the treatment of community-acquired pneumonia of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis. One of our

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objectives 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 the treatment of acute bacterial sinusitis, or ABS, with FACTIVE tablets have previously been completed, there is no assurance that the FDA or other regulatory agencies will find the results of these trials to be sufficient to approve the sale of FACTIVE for ABS. We may be unable to obtain the necessary regulatory approvals to market FACTIVE for ABS or we may need to conduct additional clinical trials in order to market FACTIVE for this indication. We are also developing an intravenous formulation of FACTIVE, which will be subject to a Phase I bioequivalence study in the coming months. In order to market FACTIVE for other indications, we will need to conduct additional clinical trials, obtain positive results from those trials and obtain FDA approval for such proposed indications. If we are 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 us 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, we or our distribution partners must obtain separate regulatory approvals. Obtaining foreign approvals may require additional trials and expense. We may not be able to obtain approval or may be delayed in obtaining approval from any or all of the jurisdictions in which we seek approval to market FACTIVE.

***Sales of FACTIVE in European countries in which we do not have rights to market the product could adversely affect sales in the European countries in which we have exclusive rights to market the product.***

Our 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. The admission of additional European countries as members of the European Union could negatively impact the profits from our sales of FACTIVE tablets. If, for example, 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 ability to maintain our projected profit margins based on sales in the territories covered by the LG Life Sciences license agreement may be adversely affected because customers in our territory may purchase FACTIVE from neighboring countries in the European Union and our ability to prohibit such purchases may be limited under European Union antitrust restrictions.

***Failure to secure distribution partners in foreign jurisdictions will prevent us from marketing FACTIVE abroad.***

We intend 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. We may not be able to secure distribution partners at all, or those that we do secure may not be successful in marketing and distributing FACTIVE. If we are not able to secure distribution partners or those partners are unsuccessful in their efforts, it would significantly limit the revenues that we expect to obtain from the sales of FACTIVE.

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

Our development and commercialization strategy 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 our clinical trials, manufacture our products and market and sell our products outside of the United States. We will not have the expertise or the resources to conduct such activities on our own and, as a result, we will be particularly dependent on third parties in these areas.

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We may not be able to maintain our 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 we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to FACTIVE, Ramoplanin or any additional products we may acquire on terms which we deem favorable, our results of operations would be materially adversely affected.

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

Our lead product, FACTIVE tablets, 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. On August 10, 2004, the Company announced preliminary results of its Phase II trial of Ramoplanin for the treatment of Clostridium difficile-associated diarrhea (CDAD). We are seeking a Special Protocol Assessment (SPA) from the FDA for a Phase III trial for CDAD in 2005, but there can be no assurance that the FDA will grant the SPA. In July 2004, the Company decided to close enrollment on its Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the trial. The Company intends to analyze the results of the VRE trial and make a determination at a later date as to any future course of action for this 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.

We 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. We may also be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies and we 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 we are able to complete our clinical trials and our 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;
- 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.

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We have limited experience in conducting and managing the preclinical and clinical trials necessary to obtain regulatory marketing approvals. We may not be able to obtain the approvals necessary to conduct clinical studies. Also, the results of our clinical trials 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 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. We 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.

***Our product candidates will face significant competition in the marketplace.***

FACTIVE tablets are 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, but commercialized by Schering - Plough in the United States under a recently announced marketing alliance;

- 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, Ketek®, a new ketolide antibiotic from Aventis Pharmaceuticals, was recently launched in the United States and is being marketed in Europe. Many generic antibiotics are also currently prescribed to treat these infections. Moreover, a number of the antibiotic products that are competitors of FACTIVE tablets will be going off patent at dates ranging from 2003 to 2010. As these competitors lose patent protection, makers of generic drugs will likely begin to produce some of these competing products and this could result in pressure on the price at which we are able to sell FACTIVE tablets and reduce our profit margins.

Ramoplanin is 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 marketed by Viro Pharma, 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. We are aware that Vicuron and Novartis Pharma are jointly developing PDF inhibitor agents that may compete with any PDF products developed by us. In July 2004, in order to devote resources to other development programs, the Company decided to close enrollment on its Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the trial. The Company intends to analyze the results of the VRE trial and make a determination at a later date as to any future course of action for this indication. 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.

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

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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 our competitors will have substantially greater capital resources, facilities and human resources than us. Furthermore, many of those competitors are more experienced than us 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 us. In addition, our competitors 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 we or our collaborators are seeking to develop and commercialize. Moreover, these competitors may obtain patent protection or other intellectual property rights that would limit our rights or the ability of our collaborators to develop or commercialize pharmaceutical products or services.

***We will rely upon alliance partners from our previous Genomics-Based Research and Alliance Business as a means of developing and commercializing our products.***

Our strategy for developing and commercializing therapeutic, vaccine and diagnostic products from our previous Genomics-Based Research and Alliance Business depends, in part, on strategic alliances and licensing arrangements with pharmaceutical and biotechnology partners. We currently have alliances with AstraZeneca, bioMerieux, 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. 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 our control. We 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.

If our partners develop products using our discoveries, we will rely on these partners for product development, regulatory approval, manufacturing and marketing of those products before we can receive some of the milestone payments, royalties and other payments to which we 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. We will not be able to control the amount and timing of resources our partners may devote to our programs or potential products. As a result, there can be no assurance that our partners will perform their obligations as expected.

***Our failure to acquire and develop additional product candidates or approved products will impair our ability to grow.***

As part of our growth strategy, we intend to acquire and develop additional product candidates or approved products. The success of this strategy depends upon our ability to identify, select and acquire biopharmaceutical products that meet our criteria. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

New product candidates acquired or in-licensed by us 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 we develop or acquire will be:

manufactured or produced economically;

successfully commercialized; or

widely accepted in the marketplace.

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***We will depend on key personnel in a highly competitive market for skilled personnel.***

We will be highly dependent on the principal members of our senior management and key scientific and technical personnel. The loss of any of our personnel could have a material adverse effect on our ability to achieve our goals. We currently maintain employment agreements with the following senior officers: Steven M. Rauscher, President and Chief Executive Officer; Stephen Cohen, Senior Vice President and Chief Financial Officer; and Gary Patou, M.D., Executive Vice President, Chief Medical Officer. The term of each employment agreement continues until it is terminated by the officer or us, except for Dr. Patou s agreement which runs through January 1, 2005, after which he becomes a consultant for one year. We do not currently maintain key person life insurance on any of our employees.

Our future success is dependent upon our 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 tablets during the second half of 2004 has required us to significantly increase our hiring of new employees, primarily with expertise in the areas of sales and marketing. We will continue to increase these efforts in the future. Like others in our industry, we may face, and in the past we have faced from time to time, difficulties in attracting and retaining certain employees with the requisite expertise and qualifications. We 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 we will not encounter greater difficulties in the future.

***Our intellectual property protection and other protections may be inadequate to protect our products.***

Our success will depend, in part, on our ability to obtain commercially valuable patent claims and protect our intellectual property. We currently own or license approximately 57 issued U.S. patents, approximately 90 pending U.S. patent applications, 67 issued foreign patents and approximately 154 pending foreign patent applications. These patents and patent applications primarily relate to (1) the field of human and pathogen genetics, (2) the chemical composition, use, and method of manufacturing FACTIVE, (3) metalloenzyme inhibitors, their uses, and their targets, and (4) DNA-Nanobinder(TM) compounds and their use as anti-infective therapeutics. Our material patents are as follows:

U.S. Patent No. 5,633,262 granted May 27, 1997, relating to quinoline carboxylic acid derivatives having 7-(4-amino-methyl-3-oxime) pyrrolidine substituent; licensed from LG Life Sciences; expiring June 15, 2015;

U.S. Patent No. 5,776,944 granted July 7, 1998, relating to 7-(4-aminomethyl-3-methyloxyiminopyrroplidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid ; licensed from LG Life Sciences; expiring June 15, 2015;

U.S. Patent No. 5,869,670 granted February 9, 1999, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015;

U.S. Patent No. 5,962,468 granted October 5, 1999, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3- carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015;

U.S. Patent No. 6,340,689 granted January 22, 2002, relating to methods of using quinolone compounds against atypical upper respiratory pathogenic bacteria; licensed from LG Life Sciences; expiring September 14, 2019;

U.S. Patent No. 6,262,071 granted July 17, 2001, relating to methods of using antimicrobial compounds against pathogenic Mycoplasma bacteria; licensed from LG Life Sciences; expiring September 21, 2019;

U.S. Patent No. 6,331,550 granted December 18, 2001, relating to methods of using of quinolone compounds against anaerobic pathogenic bacteria; licensed from LG Life Sciences; expiring September 21, 2019;

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U.S. Patent No. 6,455,540 granted September 24, 2002, relating to methods of use of quinolone compounds against anaerobic pathogenic bacteria; licensed from LG Life Sciences; expiring September 21, 2019;

U.S. Patent No. 6,723,734 granted April 20, 2004, relating to a crystal form of 7-(3-aminomethyl-4-methoxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid methanesulfonate; licensed from LG Life Science; expiring March 20, 2018.

While it is difficult to assess the value of our 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.

We are not currently involved in any litigation, settlement negotiations, or other legal action regarding patent issues and we are not aware of any patent litigation threatened against us. Our patent position 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 our proprietary rights is uncertain.

Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 14 issued U.S. patents and a broad portfolio of corresponding foreign patents and pending patent applications. These patents include claims that relate to the chemical composition of FACTIVE, methods of manufacturing and their use for the prophylaxis and treatment of bacterial infections. The U.S. patents are currently set to expire at various dates, ranging from 2015, in the case of the principal patents relating to FACTIVE, to 2019. We have filed patent term extension applications, covering the regulatory review process, for the principal patents. If granted, these extensions would extend the exclusivity period through 2017. We also have the exclusive right to use FACTIVE trademarks, trade names, domain names and logos in conjunction with the use or sale of the product in the territories covered by the license.

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 patents that we license to Ramoplanin under our 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, and intend to rely on the five year data exclusivity provisions under the Hatch-Waxman Act.

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

the pending patent applications that we have filed or to which they have exclusive rights may not result in is