OSCIENT PHARMACEUTICALS CORP
Form S-3
August 09, 2004
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As filed with the Securities and Exchange Commission on August 6, 2004

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

OSCIENT PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

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

100 Beaver Street Waltham, Massachusetts 02453 (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.

100 Beaver Street Waltham, Massachusetts 02453 (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: ¨

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per Note (1)	Proposed maximum aggregate offering price (1)	Amount of registration fee
3.5% Senior Convertible Notes due 2011	$152,750,000	100%	$152,750,000	$19,353.43
Oscient Common Stock, $.10 Par Value	22,997,597(2)(3)	(3)	(3)	(3)

(1) Estimated solely for the purposes of calculating the registration fee pursuant to Rule 457(a).

(2) This registration statement shall also cover such additional number of shares of Oscient Pharmaceuticals common stock as are required for issuance upon a stock split, stock dividend or other event or transaction that results in an increase in the number shares issuable upon conversion of the notes pursuant to the terms of the indentures.

(3) Pursuant to Rule 457(i), there is no filing fee with respect to the shares of Oscient Pharmaceuticals common stock because these shares would be issued upon conversion of the notes and no additional consideration would be received in connection with the exercise of the conversion privilege.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, August 6, 2004

PROSPECTUS

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

[GRAPHIC APPEARS HERE]

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 August 4, 2004, the reported last sale price of our common stock on the Nasdaq National Market was $4.20 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 , 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; and May 26, 2004
Quarterly Report on Form 10-Q	Quarter ended March 27, 2004, as filed on May 11, 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

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

100 Beaver Street

Waltham, Massachusetts 02453

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

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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 which we expect to launch in September 2004. FACTIVE tablets have been approved by the FDA for the treatment of community-acquired pneumonia of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis.

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 are working towards a commercial launch of FACTIVE tablets for two approved indications in September 2004. We plan to initially market and sell FACTIVE tablets through our own sales and marketing organization in the U.S. We currently plan to have our sales representatives focus on high-prescribing primary care physicians in large markets and on pulmonologists and infectious diseases experts. We intend to seek a co-promotion partner in the U.S. for future periods to broaden our marketing efforts.

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.

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

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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. We expect to commence the Phase IV trial proximate to the product launch in the U.S. Based on the results of several clinical trials, 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, primarily upon achieving 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.

In June 2004, the Company completed enrollment of the Phase II trial of Ramoplanin for the treatment of Clostridium difficile-associated diarrhea (CDAD). Preliminary analysis of the data from this trial is underway, and, pending the outcome of this analysis and discussions with the FDA, the Company plans to commence a Phase III trial for CDAD by the end of this year. In July 2004, in order to devote resources to the CDAD trial, 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). 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 100 Beaver Street, Waltham, Massachusetts 02453 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.

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 June 26, 2004, we had $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.
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: we issue common stock as a dividend or distribution on our common stock or we effect a stock split or stock combination;

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	we issue certain rights or warrants to all or substantially all holders of our common stock; we distribute shares of our capital stock, evidences of indebtedness or assets to all or substantially all holders of our common stock; we make distributions consisting of cash to all or substantially all holders of our common stock; or 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.
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.

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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 June 26, 2004, we had an accumulated deficit of approximately $192,310,000. We had a net loss of approximately $34,017,000 for the fiscal year ended December 31, 2002, and, as of December 31, 2002, we had an accumulated deficit of approximately $125,775,000. For the fiscal year ended December 31, 2001, we had a net loss of approximately $10,090,000, and for the fiscal year ended December 31, 2000, we had a net loss of approximately $5,847,000. The losses have resulted primarily from costs incurred in research and development, including our clinical trials, and from general and administrative costs associated with our operations. These costs have exceeded our revenues which to date have been generated principally from collaborations, government grants and sequencing services.

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 our operations. These costs have exceeded Genesoft s revenues which to date have been generated principally from funding from the U.S. government.

We anticipate that 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 the sales and marketing area to prepare for 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. 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 is in the design stage and the FDA required, as a condition to its approval, that the trial be initiated at or about the time we commence commercial sale of the product. 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.

We expect we will need to raise additional capital in the future to fund our operations. 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 will need to develop a marketing and sales staff to successfully commercialize FACTIVE tablets and our other product candidates, including Ramoplanin. In order to launch FACTIVE tablets in the second half of 2004, we will need to rapidly assemble a sales and marketing force. The development of these marketing and sales capabilities will require significant expenditures, management resources and time. We may be unable to build such a sales force, the cost of establishing such a sales force may exceed any product revenues, or our marketing and sales efforts may be unsuccessful. Failure to successfully establish sales and marketing capabilities in a timely and regulatory compliant manner or to find suitable sales and marketing partners may prevent us from successfully launching FACTIVE tablets in 2004, 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

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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 September 30, 2004. We are currently in discussions with other potential providers of finished products to assume these responsibilities for subsequent periods. We estimate that it will take 9 to 15 months to obtain the FDA approvals necessary for qualification of a new provider of finished FACTIVE tablets. 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 the objectives of ours 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 or ABS or we may need to conduct additional clinical trials in order to market FACTIVE for this indication. 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.

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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. These countries include the current members of the European Union. However, in the future, a number of additional European countries in which we do not have rights to market FACTIVE may be admitted as members of the European Union. If LG Life Sciences were to sell FACTIVE or license a third party to sell FACTIVE in such countries after they are admitted to the European Union, our 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.

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.

Third parties may not perform their obligations as expected.

The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to conduct its activities in a timely and regulatory compliant manner, such breach, termination or failure could:

- delay or otherwise adversely impact the development or commercialization of FACTIVE tablets, Ramoplanin, our other product candidates or any additional product candidates that we may acquire or develop;

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require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of our products; or

result in the termination of the development or commercialization of our products.

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. In June 2004, the Company completed enrollment of the Phase II trial of Ramoplanin for the treatment of Clostridium difficile-associated diarrhea (CDAD). Preliminary analysis of the data from this trial is underway, and, pending the outcome of this analysis and discussions with the FDA, the Company plans to commence a Phase III trial for CDAD by the end of this year. In July 2004, in order to devote resources to the CDAD trial, 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). 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;

fluctuations in the infection rates for patients enrolled in our trials;

compliance of patients and investigators with the protocol and applicable regulations;

prior regulatory agency review and approval of our applications and procedures;

analysis of data obtained from preclinical and clinical activities which are susceptible to varying interpretations, which interpretations could delay, limit or prevent regulatory approval;

changes in the policies of regulatory authorities for drug approval during the period of product development; and

the availability of skilled and experienced staff to conduct and monitor clinical studies, to accurately collect data and to prepare the appropriate regulatory applications.

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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.

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;

- macrolides such as Biaxin® (clarithromycin), a product of Abbott Laboratories and Zithromax® (azithromycin), a product of Pfizer Inc.; and

- penicillins such as Augmentin® (amoxicillin/clavulanate potassium), a product of GlaxoSmithKline.

In addition, a new drug application for Ketek®, a ketolide antibiotic from Aventis Pharmaceuticals, has been approved by the FDA and Ketek is currently 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 Vancomin® (vancomycin), a product of Eli Lilly, and metronidazole, a generic product for treatment of this indication. We are also aware of at least three companies with products in development for the treatment of CDAD Geltex/Genzyme in Phase II; ImmuCell in Phase I/II; and Acambis in Phase I/II. It is also possible that other companies are developing competitive products for this indication. 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 the CDAD trial, 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). 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

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programs at this time. Our industry is very competitive and it therefore is likely that if and when product candidates from our early stage internal programs or our alliance programs reach the clinical development stage or are commercialized for sale, these products will also face competition.

Many of 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 existing and prospective alliance partners, licensees and government grants and contracts as a source of revenue for our operations and as a means of developing and commercializing our products.

Our strategy for developing and commercializing therapeutic, vaccine and diagnostic products depends, in part, on strategic alliances and licensing arrangements with pharmaceutical and biotechnology partners. We currently have alliances with AstraZeneca, 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 strategy will include entering into multiple, concurrent alliances and business partnerships, including, but not limited to in-licensing and co-promotion agreements. There can be no assurance that we will be able to manage multiple alliances and partnerships successfully. The risks we will face in managing multiple alliances and partnerships include maintaining confidentiality among partners, avoiding conflicts between partners and avoiding conflicts between us and our partners. If we fail to manage our alliances and partnerships effectively, or if any of the problems described above arise, one or more of the following could occur which could have a material adverse effect on our business:

- use of significant resources to resolve conflicts,
- delay in, or an adverse effect on, sales and marketing efforts for our products,

delay in development activities,

legal claims involving significant time,

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significant expense,

loss of reputation, and

termination of one or more alliances, or loss of capital and loss of revenues.

We have applied for and received grants from the U.S. government in the past. Our strategy going forward will include the continued pursuit of government grants and contracts. We can not assure you that we will obtain any additional grants or that our existing grants will continue to be funded. If we are unable to obtain additional grants or maintain our existing grants, our revenues would be adversely affected.

Development of therapeutic, diagnostic and vaccine products by our strategic alliance partners based on our discoveries will be subject to the high risks of failure inherent in the development or commercialization of biopharmaceutical products.

There can be no assurance of the successful development or commercialization of any products by our strategic alliance partners. Successful development and commercialization will be subject to numerous risks at each stage. For example, there can be no assurance that the high-throughput screening or lead optimization processes for a given strategic alliance will identify any compounds suitable for clinical development. Even if product candidates based on our discoveries undergo clinical trials, there can be no assurance that those clinical trials will indicate that the product candidates are safe or effective. The pace at which the clinical trials proceed is also uncertain. Furthermore, after the completion of clinical trials, a product could fail to receive necessary regulatory approvals due to negative, inconclusive or insufficient clinical data or other reasons beyond our control. Even if the necessary regulatory approvals for a product are obtained, it may be difficult or impossible to manufacture the product on a large scale, be uneconomical to market, fail to be developed prior to the successful marketing of similar products by competitors or infringe on proprietary rights of third parties.

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