OSCIENT PHARMACEUTICALS CORP
Form POS AM
June 02, 2005
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As filed with the Securities and Exchange Commission on June 2, 2005

Registration No. 333-118026

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 3 TO

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)**

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

Oscient Pharmaceuticals 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 May 25, 2005, the reported last sale price of our common stock on the Nasdaq National Market was $1.74 per share.

Investing in the securities involves risks. See Risk factors beginning on page 5.

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 June 2, 2005

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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.

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.

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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**
Quarterly Report on Form 10-Q	Fiscal Quarter Ended March 31, 2005, as filed on May 10, 2005
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 April 20, 2005
Annual report on Form 10-K and 10-K/A	Year ended December 31, 2004, as filed on March 16, 2005, as amended on May 4, 2005
Current reports on Form 8-K and Form 8-K/A	As filed on January 6, 2005; January 7, 2005; January 10, 2005; January 10, 2005; February 8, 2005; March 22, 2005; March 29, 2005; April 6, 2005, April 13, 2005; and May 3, 2005
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

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 statements and information contained in this prospectus and the documents incorporated by reference herein related to our intent to focus in the near term on the commercial and clinical development of FACTIVE and the sale of Testim, the outcome of our discussions with Vicuron regarding the filing of an NDA for Ramoplanin, the trend relating to the increase market share of quinolones, the qualification of alternative manufacturers for our products, the timing of the filing of an NDA for FACTIVE for the treatment of ABS, as well as other statements related to the progress and timing of product development, present or future licensing, collaborative or financing arrangements or that otherwise relate to future periods, are forward-looking statements as defined by 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, believe, estimate, intend, anticipate, project, and expect and similar expressions are intended to identify forward-looking statements. All forward-looking statements involve certain risks, estimates, assumptions, and we can give no assurance that these expectations will be achieved. You are cautioned that these forward looking statements involve 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. We encourage you to read those descriptions carefully. We caution investors not to place significant reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated) and we undertake no obligation to update or revise the statements.

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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 began in September 2004. Additionally, on April 11, 2005, we entered into a co-promotion agreement with Auximlium Pharmaceuticals, Inc. under which we and Auxilium will co-promote in the U.S. Auxilium s marketed product, Testim a topical 1% testosterone gel indicated for the treatment of hypogonadism. For the near term, we intend to focus our efforts on commercial sales of FACTIVE tablets for the indications set forth above, the commercial sales of Testim 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 (AECB) and community-acquired pneumonia (CAP) of mild to moderate severity. n July 2003, FACTIVE tablets were also approved to treat CAP caused by multi-drug resistant *Streptococcus pneumoniae*, or MDRSP, a growing clinical concern. FACTIVE was the first antimicrobial approved by the FDA for this indication.

Within the antibiotic market, quinolones, a product class with close to $3 billion in annual sales in the U.S. in 2004, have been gaining market share at the expense of older antibiotics, according to NDC 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 recently completed the hiring of an additional one-hundred fifty sales and marketing professionals to support a nationwide sales force for FACTIVE.

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 MDRSP.

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 AECB (5 days) and CAP (7 days).

FACTIVE tablets have composition of matter patent protection through 2018, with additional patent protection through 2019.

FACTIVE tablets have been studied in nearly 7,000 patients and have an acceptable profile. The incidence of adverse events reported for FACTIVE tablets was comparable to comparator drugs, namely beta-lactam antibiotics, macrolides and other fluoroquinolones. Most adverse events were described as mild to moderate. Although rash was reported more frequently among FACTIVE-treated patients than among those who received comparator drugs, the rate of rash with FACTIVE tablets is similar to other approved antibiotics.

As a post-marketing 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 mild to moderate CAP or AECB. This Phase IV trial commenced during the Fall of 2004 and is scheduled to be completed during the next three years.

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We are in the process of discussing with the FDA activities related to an anticipated filing of a NDA for acute bacterial sinusitis, or ABS, indication during 2005. We have also completed enrollment in a clinical trial to demonstrate that a five-day course of FACTIVE for the treatment of mild to moderate CAP is as effective as the currently approved seven-day course of treatment. Due to the risks and uncertainties inherent in clinical trials, we cannot predict if these efforts will be successful or when material cash flows from these programs will commence.

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 royalty is fixed at a nominal rate during the first two years of commercial sales and increases thereafter. These royalty obligations expire with respect to each country covered by the agreement on the later of the expiration of the patents covering FACTIVE in such country or ten years following the first commercial sale of FACTIVE in such country. On March 31, 2005, we amended our license and option agreement with LG Life Sciences which included a reduction of future royalties payable to LG Life Sciences at certain FACTIVE revenue levels in territories covered by the agreement. As part of the modified agreement, we made a one time payment of $2 million to LG Life Sciences which was recorded to general and administrative expense in the three month period end March 31, 2005. In addition, the modified agreement requires additional milestone payments of up to $30 million upon obtainment of additional regulatory approvals and certain sales thresholds.

We have initiated a technology transfer process with Patheon Inc. including a CBE30 submission in April 2005, for the manufacture of finished FACTIVE products, to replace the previous fill and finish provider, SB Pharmco. We estimate that Patheon will obtain the necessary FDA qualifications to be the fill and finish provider of FACTIVE tablets during the first half of 2005.

Our ability to successfully commercialize FACTIVE tablets is subject to a number of risks, including the ability of our manufacturing partners to timely produce the needed quantities of the drug in compliance with regulations and competition in the marketplace from competing anti-infective products. If we are unable to successfully commercialize FACTIVE tablets, our operations, financial position and liquidity would be negatively affected to a significant degree.

Co-Promotion of Testim

Pursuant to the co-promotion agreement with Auxilium Pharmaceuticals, Inc under which we and Auxilium have begun to co-promote Testim in the U.S, we have the exclusive right to promote Testim jointly with Auxilium to primary care physicians by using our 250-person sales force. The initial term of the co-promotion agreement with Auxilium ends on April 30, 2007. We may extend the agreement for two consecutive two-year periods provided that we have met certain milestones for each extension. If these milestones are met and we do not elect to terminate the co-promotion agreement, the first extension period will commence on January 1, 2007 and end on December 31, 2008 and the second extension period will commence January 1, 2009 and end on April 30, 2011.

Both organizations will jointly develop a promotion plan which sets forth the responsibilities of both parties with respect to the marketing and promotion of Testim in the U.S. primary care physician market. We are obligated to share Testim promotional expenses to this audience equally with Auxilium. Each party will be responsible for the costs associated with its own sales force. In addition, Auxilium is obligated to pay us a co-promotion fee based on a specified percentage of the gross profit from Testim sales attributable to primary care physicians in the U.S. that exceeds a specified sales threshold. The specific percentage is based upon Testim sales levels attributable to primary care physicians and the marketing expenses incurred by us in connection with the promotion of Testim under the co-promotion agreement. The co-promotion agreement can be terminated by either party upon the occurrence of certain termination events. Auxilium may be obligated to make termination payments in certain instances. Also, we have been granted the exclusive option to co-promote any future product candidate of Auxilium s that treats hypogonadism and contains testosterone as the active ingredient. Our failure to successfully co-promote Testim in the U.S. would have a significant negative impact on our operations, financial position and liquidity.

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. In July of 2004 we completed our Phase II trial of Ramoplanin for the treatment of *Clostridium difficile*-associated diarrhea (CDAD). We have submitted a special protocol assessment (SPA) to the FDA for the Phase III program of Ramoplanin for CDAD. These Phase II results are being discussed with the FDA as part of our SPA submission. Pending a successful outcome of these discussions and successful timetable

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discussions with our partner, Vicuron, the program would be ready to initiate the Phase III trial. The clinical development program of Ramoplanin for the potential treatment of CDAD received Fast Track status from the FDA in February 2004.

In July 2004, we 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 due to slow enrollment. We expect to use the data from the study as part of a safety database for Ramoplanin.

The successful commercialization of Ramoplanin is subject to many risks and uncertainties, including delays in the progress of our clinical trials, and increased cost, due to the pace of enrollment of patients in the trials, our inability to obtain product approval due to negative, inconclusive or insufficient clinical data and our inability to successfully market our product due to competition from other competing drugs. On November 8, 2004, we received a letter from Vicuron indicating that it intends to seek to terminate the License and Supply Agreement between Vicuron and Oscient and reacquire rights to Ramoplanin. In the letter, Vicuron claims that it will have a right to terminate the agreement based on the fact that an NDA with respect to Ramoplanin is not expected to be filed with the FDA prior to the date originally specified in the agreement. We believe the letter contradicts an amendment to the agreement entered into in October of 2002 (filed as exhibit 10.64 to our Annual Report on Form 10-K filed with the SEC on March 31, 2003), and we have addressed this issue with Vicuron. Pursuant to the terms of the amended agreement, we are in discussions with Vicuron to develop a timetable for the completion of development and outside date for the NDA submission. There is no assurance we will be able to agree upon such a date, that Vicuron will not renew its attempt to terminate the agreement again in the future or that we will prevail in any potential dispute with Vicuron. As a result of these many risks and uncertainties, we can not predict when material cash inflows from our Ramoplanin project will commence, if ever. A failure to obtain a marketing approval for Ramoplanin and to successfully commercialize the drug would have a significant negative impact on our operations, financial position and liquidity.

Other Programs

Our preclinical development programs include an oral peptide deformylase inhibitor (PDF) 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. Testim is a trademark of Auxilium Pharmaceuticals, Inc. Other trademarks and trade names appearing in this prospectus are the property of their holders.

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 issuer, us, Oscient Pharmaceuticals, we and ou 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 March 31, 2005, we had approximately $175 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.

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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; 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.

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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.

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 $93,271,000 for the fiscal year ended December 31, 2004 and as of March 31, 2005, we had an accumulated deficit of approximately $276,672,000. We had a net loss of approximately $29,789,000 for the fiscal year ended December 31, 2003, and, as of December 31, 2003, we had an accumulated deficit of approximately $155,564,000. For the fiscal year ended December 31, 2002, we had a net loss of approximately $34,017,000, and for the fiscal year ended December 31, 2001, we had a net loss of approximately $10,090,000. 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, prior to 2004, and product sales of FACTIVE tablets. These costs have exceeded our revenues which to date have been generated principally from collaborations, government grants and sequencing services.

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 continue and potentially increase as we continue significant levels of expenditures, principally in the sales and marketing area as we seek to grow sales of FACTIVE tablets and begin co-promotion of Testim and in research and development in connection with clinical trials and formulation activities to support the existing labeling of FACTIVE tablets and potentially the expanded FACTIVE labeling claims. 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 and Testim.

FACTIVE tablets and Testim are currently our only commercial products and we expect they will likely account for substantially all of our product 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 AECB. Testim has been approved by the FDA for the treatment of hypogonadism. The commercial success of FACTIVE and Testim will depend upon their continued acceptance by regulators, physicians, patients and other key decision-makers as a safe, therapeutic and cost-effective alternative to other products used, or currently being developed, to treat CAP and AECB, in the case of FACTIVE tablets, or hypogonadism, in the case of Testim. The commercial success of Testim is also dependant, in part, on the marketing and detailing efforts of Auxilium, which efforts are beyond our control. If FACTIVE and Testim are not commercially successful, we will have to find additional sources of funding or curtail or cease operations.

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

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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 AECB. 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, with the approval from the FDA, was initiated in the second half of 2004. 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 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 may need to raise additional funds in the future.

We believe our existing funds and anticipated cash flows from operations would be sufficient to support our current plans through the end of 2006. We may need to raise additional capital in the future to fund our operations, in particular, to support our sales and marketing activities, fund clinical trials and other research and development activities, and other potential commercial or development opportunities 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 biopharmaceutical companies and the progress of the FACTIVE, Testim 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, Testim and our other product candidates.

FACTIVE tablets are our first FDA approved product. To date, we still have limited marketing and sales experience considering the launch of FACTIVE occurred in September of 2004 and co-promotion of Testim began in May of 2005. The continued development of these marketing and sales capabilities will require significant expenditures, management resources and time. Failure to successfully establish sufficient sales and marketing capability in a timely and regulatory compliant manner or to find suitable sales and marketing partners may adversely affect our business and results of operations.

If testosterone replacement therapies are perceived to create or create health risks, sales of Testim may be adversely affected.

Recent studies of female hormone replacement therapy products have reported an increase in health risks. As a result of such studies, some companies that sell or develop female hormone replacement products have experienced decreased sales of these products, and in some cases, a decline in the value of their stock. Publications have, from time to time, suggested potential health risks associated with testosterone replacement therapy (TRT). Potential health risks were described in various articles, including a 2002 article published in *Endocrine Practice* and a 1999 article published in the *International Journal of Andrology*. The potential health risks detailed were fluid retention, sleep apnea, breast tenderness or enlargement, increased red blood cells, development of clinical prostate disease, increased cardiovascular disease risk and the suppression of sperm production. It is possible that studies on the effects of TRT could demonstrate these or other health risks. This, as well as negative publicity about the risks of hormone replacement therapy, including TRT, could adversely affect patient or prescriber attitudes and impact Testim sales.

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

We do not have the internal capability to manufacture pharmaceutical products under the FDA s current Good Manufacturing Practices. Under our agreement with LG Life Sciences they manufacture bulk quantities of the active pharmaceutical ingredient of FACTIVE. The Co-Promotion Agreement for Testim provides that Auxilium is responsible for

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the manufacture and distribution of Testim. Testim is currently manufactured for Auxilium by DPT Laboratories. Although the LG Life Sciences and DPT Laboratories facilities have previously been inspected by the FDA, future inspections may find deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of our products.

We are seeking to qualify Patheon, Inc. as a manufacturer to provide finished FACTIVE tablets, replacing SB Pharmco. We estimate that Patheon will obtain the necessary FDA qualifications to be the fill and finish provider during the first half of 2005. We expect that the quantities of FACTIVE tablets currently on hand, in combination with the quantities to be delivered from SB Pharmco (under its current obligations), will provide sufficient inventory until Patheon can be qualified. However, if there is significant delay in the qualification of Patheon, we could have insufficient inventory of FACTIVE tablets to meet demand which could adversely affect our business and results of operations. In addition, we cannot assure you that SB Pharmco will be able to avoid batch failures or production delays for its outstanding commitments.

Auxilium s contract with DPT Laboratories to manufacture Testim expires on December 31, 2005. Although Auxilium is currently in the process of qualifying a back-up supplier to manufacture Testim, there is currently no alternative manufacturer of Testim. If there is significant delay in qualifying this back-up supplier, there could be future supply shortages of Testim. Auxilium also relies on third party suppliers for their supply of testosterone and pentadecalactone, or CPD, two key ingredients of Testim. Testosterone is available to Auxilium from only two sources. Auxilium relies exclusively on one outside source for their supply of CPD. Auxilium does not have any agreements with these suppliers regarding these key ingredients. If either of the two sources that produce testosterone stops manufacturing it, or if Auxilium is unable to procure testosterone on commercially favorable terms, Auxilium may be unable to continue to produce Testim on commercially viable terms, if at all. In addition, if Auxilium s third-party source of CPD stops manufacturing pharmaceutical grade CPD, or does not make CPD available to Auxilium on commercially favorable terms, Auxilium may be unable to continue to produce Testim on commercially viable terms, if at all. Furthermore, the limited number of suppliers of testosterone and CPD may provide such companies with greater opportunity to raise their prices. Any increase in price for testosterone or CPD may reduce the gross margins on sales of Testim.

We cannot be certain that LG Life Sciences, DPT Laboratories, Patheon, Vicuron or future manufacturers will be able to deliver commercial quantities of product or that such deliveries will be made on a timely basis. The only source of supply for FACTIVE bulk drug product is LG Life Sciences facility in South Korea, and upon FDA qualification, Patheon will be our only source of finished FACTIVE tablets. DPT Laboratories is currently the only qualified manufacturer of Testim. If these facilities are damaged or otherwise unavailable, we would incur substantial costs and delay in the commercialization of our products. 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 will depend on third parties to manage our product supply chain for FACTIVE tablets and Testim.

We do not have the internal capability to perform product supply chain services including warehousing, inventory management and distribution of commercial and sample quantities of FACTIVE tablets. In June, we entered into an exclusive agreement with Integrated Commercial Solutions, Inc. (ICS), to perform such supply chain manufacturing services for a three-year period. Under our agreement with Auxilium,

Auxilium provides all supply chain services for Testim.

We cannot be certain that ICS and Auxilium will be able to perform uninterrupted supply chain services. If ICS or Auxilium were unable to perform their services for any period, we may incur substantial loss of sales to wholesalers and other purchasers of our products. If we are forced to find an alternative supply chain service provider for FACTIVE tablets, in addition to loss of sales, we may also incur costs in establishing a new arrangement.

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 objectives is to expand the

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indications for which FACTIVE is approved for marketing by the FDA, including for the indication of acute bacterial sinusitis. While we believe the necessary clinical trials for acute bacterial sinusitis have been completed, we are gathering additional data based on the use of FACTIVE following commercial launch to supplement an NDA filing for acute bacterial sinusitis (ABS). We cannot be certain how many additional data will be required or whether we will be required 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.

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 included all of the members of the European Union on the date of the original agreement to license FACTIVE. However, in 2004, a number of additional European countries in which we do not have rights to market FACTIVE were 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, 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 our products 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 our current products, 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.

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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, Testim, Ramoplanin, our other product candidates or any additional product candidates that we may acquire or develop;
- 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, is currently conducting a Phase IV post-approval clinical trial in compliance with FDA requirements pursuant to the product s approval and a Phase III clinical trial for a five-day course of therapy for the treatment of community-acquired pneumonia of mild to moderate severity. 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/formulations.

The Phase II trial for our lead product candidate, Ramoplanin, to assess the safety and efficacy to treat *Clostridium difficile*-associated diarrhea, or CDAD, was completed in 2004. Pending completion of discussions with the FDA regarding a Special Protocol Assessment submitted in late 2004 and completion of discussions with our partner, Vicuron, concerning timelines required to complete the Phase III program and submission to the FDA, the Phase III program will be ready for initiation. Prior clinical and preclinical trials for Ramoplanin were conducted by Vicuron and its licensees, from whom we acquired our license to develop Ramoplanin. 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.

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;
- macrolides such as Biaxin® (clarithromycin), a product of Abbott Laboratories and Zithromax® (azithromycin), a product of Pfizer Inc.;
- Ketek, a ketolide from Aventis Pharmaceuticals; and
- penicillins such as Augmentin® (amoxicillin/clavulanate potassium), a product of GlaxoSmithKline.

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 2015. 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.

The primary competition for Testim for the treatment of hypogonadism is AndroGel(R), marketed by Solvay Pharmaceuticals. AndroGel(R) was launched approximately three years before Testim and, according to IMS, has a much larger share of the testosterone gel market than Testim and also accounted for approximately 58% of total testosterone prescriptions for the quarter ended March 31, 2005. Testim also competes with other forms of testosterone replacement therapies such as oral treatments, patches, injectables and a buccal tablet. Generally, Testim is more expensive than patches and injectables. AndroDerm(R) is a transdermal testosterone patch marketed by Watson Pharmaceuticals. AndroDerm(R) is the leading patch product and accounted for approximately 12% of total testosterone prescriptions for the quarter ended March 31, 2005. Other new treatments are being sought for TRT which may compete with Testim, including a new class of drugs called Selective Androgen Receptor Modulators.

We are also aware of at least two companies, Watson and Par Pharmaceutical, that have filed abbreviated new drug applications, or ANDAs, with the FDA to be approved as generics of AndroGel(R). Solvay has filed patent infringement lawsuits against these two companies to block the approval and marketing of the generic products. On November 1, 2004, Par Pharmaceutical s partner, Paddock Laboratories, received tentative approval of its ANDA from the FDA, but cannot market its generic of AndroGel(R) until the Solvay action is resolved and until final approval is received from the FDA. The final approval of either or both of these ANDAs would result in increased competition for Testim at lower prices.

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 marketed by ViroPharma, and metronidazole, a generic product for treatment of this indication. We are also aware of at least four companies with products in development for the treatment of CDAD Genzyme in Phase III; Par Pharmaceuticals/Optimer Pharmaceuticals in Phase IIa; 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.

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

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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 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 & 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 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.

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; Nick Colangelo, Esq., Senior Vice President, Corporate Development and Operations; and Ton Bunt, M.D., Ph.D., Senior Vice President, Clinical Development

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and Medical Affairs. The term of each employment agreement continues until it is terminated by the officer or us. 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.