

OSCIENT PHARMACEUTICALS CORP

Form POS AM

September 02, 2005

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As filed with the Securities and Exchange Commission on September 2, 2005

Registration No. 333-118026

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**POST-EFFECTIVE AMENDMENT NO. 5 TO**  
**FORM S-3**  
**REGISTRATION STATEMENT**

*UNDER*

*THE SECURITIES ACT OF 1933*

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**OSCIENT PHARMACEUTICALS CORPORATION**

(Exact name of registrant as specified in its charter)

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Massachusetts  
(State or other jurisdiction of  
incorporation or organization)

04-2297484  
(I.R.S. Employer  
Identification Number)

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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)

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**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)

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

**Patrick O Brien**

**Ropes & Gray LLP**

**One International Place**

**Boston, Massachusetts 02110**

**(617) 951-7000**

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***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. "

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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.

Holder 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.

Holder 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.

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The notes have been designated for trading in The Portal<sup>SM</sup> 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<sup>SM</sup> Market. Our common stock is listed on the Nasdaq National Market under the symbol OSCI. On August 30, 2005, the reported last sale price of our common stock on the Nasdaq National Market was \$2.30 per share.

Investing in the securities involves risks. See **Risk factors** beginning on page 6.

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 September 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.**

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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 100 F Street, NE, 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:

<b><u>Oscient Pharmaceuticals SEC Filings (File No. 0-10824)</u></b>	<b><u>Period</u></b>
Quarterly Report on Form 10-Q	Fiscal Quarter Ended March 31, 2005, as filed on May 10, 2005, and Fiscal Quarter Ended June 30, 2005, as filed on August 9, 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; May 3, 2005; June 6, 2005; June 7, 2005; July 20, 2005 and August 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

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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.

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**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, plans to expand our sales force, the success of our co-promotion efforts with Auxilium, 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 timing of the filing of an sNDA for FACTIVE for the treatment of ABS and a 5-day course of treatment of CAP, the potential competitive advantages of FACTIVE tablets 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, 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. Our lead product is the fluoroquinolone 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 and is currently promoted nationally by our 250-person sales team. We also co-promote Auxilium Pharmaceuticals, Inc.'s marketed product, TESTIM, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. For the near term, we intend to focus our efforts on commercial sales of FACTIVE tablets for the indications set forth above, clinical trials for additional indications of FACTIVE and commercial sales of TESTIM.

On February 6, 2004, we completed our merger with GeneSoft Pharmaceuticals, Inc., a privately-held pharmaceutical company based in South San Francisco, California. The merger was accounted for as a purchase by us under accounting principles generally accepted in the United States.

**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. In 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 began selling FACTIVE tablets in September 2004 with an initial sales force of 100 representatives. In order to support national sales of FACTIVE, during the second half of 2004 and first quarter of 2005, we focused our efforts on building a 250-person sales force which was contracted through Publicis Selling Solutions. In June 2005, we completed the planned conversion of our sales force to full-time Oscient employee status. We are also planning to add approximately 50 contract sales representatives in our highest volume territories to grow the FACTIVE physician prescribing base. We plan to have such new contract sales representatives in place and trained in the fourth quarter of 2005.

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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

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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 study commitment, the FDA has required a prospective, randomized study comparing FACTIVE tablets (5,000 patients) to an active comparator (2,500 patients) in patients with CAP or AECB. This study includes 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 are evaluated for clinical and laboratory measures of safety. This Phase IV trial commenced during the fall of 2004 and is scheduled to be completed within three to four years. In connection with the approval of FACTIVE tablets, the FDA has also required us to perform a utilization study 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 furnish annual reports to the FDA on the number of prescriptions issued, including refills and the diagnoses for which the prescriptions are dispensed.

We are also seeking to expand the commercial opportunities for FACTIVE through additional development and clinical study plans for the product. As part of the FACTIVE development program, several studies relating to acute bacterial sinusitis, or ABS, were completed. We are in the process of discussing with the FDA activities related to an anticipated filing of an sNDA for this indication during 2005. Additionally, we have completed 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. Based on our preliminary data analysis, this study achieved its primary endpoint (non-inferior clinical response rate at the follow-up visit). Our goal is to file an sNDA for the 5-day CAP indication by the end of 2005. Our ability to achieve this goal, however, is subject to a number of risks, including the possibility that the FDA may find that our clinical data fail to establish a favorable risk/benefit assessment for the ABS indication. As a result of these many risks and uncertainties, we cannot predict when material cash inflows from our ABS program will commence, if ever.

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 ended 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.

In May 2005, we completed the technology transfer process for the manufacture of finished products by Patheon Inc. and filed a supplemental application with the FDA to approve Patheon, replacing the previous fill and finish provider, SB Pharmco. More than 30 days have passed following FDA's receipt of our supplemental application without questions or comments from the FDA, and we now use Patheon as our fill and finish provider of FACTIVE tablets pending final action by the FDA on the supplemental filing. We commenced shipping product from Patheon to our distribution center in the second quarter 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

On April 11, 2005, we entered into a co-promotion agreement with Auxilium 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 male hypogonadism. Pursuant to the agreement, we have the exclusive right to promote TESTIM jointly with Auxilium to primary care physicians using our 250-person sales force. The initial term of the agreement 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 related to physician detailing, market share and gross sales. 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.

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Both organizations continue to 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 physician market 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, including approval and sale of a generic form of TESTIM in the United States, in which case Auxilium is obligated to pay to us a specified percentage of the profits for the following two years. Also, we have been granted the exclusive option to co-promote any future Auxilium product candidate that treats male 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 developing a novel investigational antibiotic candidate, Ramoplanin. 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 acceptance of the SPA and successful contractual timetable discussions with our partner, Vicuron, the program would be ready to begin planning Phase III testing.

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 treatment of bacterial 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](http://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

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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.

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*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 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 July 31, 2005, we had approximately \$178 million of indebtedness outstanding (including accrued interest and excluding trade payables and accrued liabilities). 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: <ul style="list-style-type: none"> <li>we issue common stock as a dividend or distribution on our common stock or we effect a stock split or stock combination;</li> <li>we issue certain rights or warrants to all or substantially all holders of our common stock;</li> <li>we distribute shares of our capital stock, evidences of indebtedness or assets to all or substantially all holders of our common stock;</li> <li>we make distributions consisting of cash to all or substantially all holders of our common stock; or</li> <li>we or one of our subsidiaries makes purchases of our common stock pursuant to a tender offer or exchange offer for our common stock.</li> </ul>
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



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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.

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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 <sup>SM</sup> Market. The initial purchasers have advised us that they currently intend to make a market in the notes. However, they are not obligated to do so, and they may discontinue any market making with respect to the notes without notice. We do not intend to apply for a listing of the notes on any securities exchange or any automated dealer quotation system. Our common stock is quoted on the Nasdaq National Market under the symbol OSCI.
Further issues	We may from time to time, without notice to or the consent of the registered holders of the notes, create and issue additional debt securities having the same terms as and ranking equally and ratably with the notes in all respects, as described more fully in Description of notes Further issues.
Nasdaq symbol for our common stock	OSCI
Risk factors	Investment in the notes involves risk. You should carefully consider the information under Risk factors and all other information included in this prospectus and the documents incorporated by reference herein, before investing in the notes.

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### **Risk factors**

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

#### **Risks related to our business**

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

We have experienced significant operating losses each year since our inception and expect these losses to continue for the foreseeable future. We had a net loss of approximately \$93,271,000 for the fiscal year ended December 31, 2004 and as of June 30, 2005, we had an accumulated deficit of approximately \$298,416,000. 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 and product sales of FACTIVE tablets. These costs have exceeded our revenues which to date have been generated principally from sales of FACTIVE, 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 continue the co-promotion of TESTIM<sup>®</sup> 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 that 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 male 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 male hypogonadism, in the case of TESTIM. The commercial success of TESTIM is also dependent, 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.

***We will need to continue 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 the co-promotion of TESTIM began in May 2005. The continued development of these marketing and sales capabilities, including the expansion of our sales force, will require significant expenditures, management resources and time. Further, as part of this development, we are seeking to establish a co-promotion partnership to expand FACTIVE commercialization in the U.S. and/or acquire additional products for our expanded sales force. However, there is no assurance that we will be able to enter into a co-promotion agreement or acquire new products on favorable terms or at all. 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.

***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

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potential commercial or development opportunities. We may seek funding through additional public or private equity offerings, debt or other strategic financings or agreements with customers or vendors. 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. 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.

### ***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<sup>®</sup> (levofloxacin), a product of Ortho-McNeil Pharmaceutical, Inc., Tequin<sup>®</sup> (gatifloxacin), a product of Bristol-Myers Squibb Company, and Cipro<sup>®</sup> (ciprofloxacin) and Avelox<sup>®</sup> (moxifloxacin), both products of Bayer Corporation;

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

Ketek<sup>®</sup> (telithromycin), a ketolide from Aventis Pharmaceuticals; and

penicillins such as Augmentin<sup>®</sup> (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 have gone or 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 male hypogonadism is ANDROGEL<sup>®</sup>, marketed by Solvay Pharmaceuticals. ANDROGEL was launched approximately three years before TESTIM and, according to NDC, has a much larger share of the testosterone gel market than TESTIM and also accounted for approximately 57% of total testosterone prescriptions for the five months ended May 31, 2005. TESTIM also competes with other forms of testosterone replacement therapies, or TRT, such as oral treatments, patches, injectables and a

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buccal tablet. Generally, TESTIM is more expensive than patches and injectables. ANDRODERM<sup>®</sup> is a transdermal testosterone patch marketed by Watson Pharmaceuticals. ANDRODERM is the leading patch product and accounted for approximately 11% of total testosterone prescriptions for the five months ended May 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 Pharmaceuticals and Par Pharmaceutical, that have filed abbreviated new drug applications, or ANDAs, with the FDA to be approved as generics of ANDROGEL. 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 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<sup>®</sup> pulvules (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.

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Additionally, we are aware that Vicuron and Novartis AG 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 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 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 indications for which FACTIVE is approved for marketing by the FDA, including for the indication of acute bacterial sinusitis, or ABS, as well as a five day course of treatment for CAP. While we believe the necessary clinical trials for ABS have been completed, we plan to gather additional data based on the use of FACTIVE following commercial launch to supplement an sNDA filing for ABS. We also recently completed a Phase III trial for a five-day course of therapy for the treatment of CAP and are in the process of preparing an sNDA for this indication. We hope to file for both of these indications in the second half of 2005, but we cannot guarantee the timing of such submissions. We cannot be certain whether additional data will be required, if we will be required to conduct additional clinical trials or if either sNDA, once submitted, will ultimately be approved. 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.

***Seasonal fluctuations in demand for FACTIVE may cause our operating results to vary significantly from quarter to quarter.***

We expect demand for FACTIVE to be higher between November 1 and March 31 as incidents of respiratory tract infection, including CAP and AECB, tend to increase during the winter months. As a result, we expect our sales of FACTIVE to be higher during this season. In addition, fluctuations in the severity of the annual respiratory tract infection season may cause our product sales to vary from year to year. Due to these seasonal fluctuations in demand, our results in any particular quarter may not be indicative of the results for any other quarter or for the entire year.

***We as well as our partners are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.***

The testing, development and manufacturing and distribution of our products are subject to regulation by numerous governmental authorities in the U.S., Europe and elsewhere. These regulations govern or affect the testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, advertising and promotion of FACTIVE, TESTIM, Ramoplanin and our other product candidates, as well as safe working conditions and the experimental use of animals. Noncompliance with any applicable regulatory requirements can result in refusal of the government to approve products for marketing, criminal prosecution and fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts. The U.S. government agencies include, but are not limited to, the FDA, the Office of Inspector General and the Department of Justice. Our corporate compliance program cannot ensure that we are in compliance with all applicable laws and regulations, and a failure to comply with such regulations or a failure to prevail in litigation related to noncompliance could harm our business.



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The FDA and comparable governmental authorities have the authority to withdraw product approvals that have been previously granted. Currently, there is a substantial amount of congressional and administrative review of the FDA and the regulatory approval process for drug candidates in the U.S. As a result, there may be significant changes made to the regulatory approval process in the U.S. In addition, the regulatory requirements relating to the manufacturing, testing, and promotion, marketing and distribution of our products may change in the U.S. or the other jurisdictions in which we may have obtained or be seeking regulatory approval for our products or product candidates. Such changes may increase our costs and adversely effect our operations.

In addition, pharmaceutical companies have faced lawsuits and investigations pertaining to violations of health care fraud and abuse laws, such as the federal false claims act, the federal anti-kickback statute, and other state and federal laws and regulations. While we have developed and implemented a corporate compliance program based upon what we believe are current best practices, we cannot guarantee that this program will protect us from future lawsuits or investigations.

Failure to comply with or changes to the regulatory requirements that are applicable to FACTIVE, TESTIM or our other product candidates may result in a variety of consequences, including the following:

restrictions on our products or manufacturing processes;

warning letters regarding promotional and marketing materials and activities;

withdrawal of FACTIVE, TESTIM or a product candidate from the market;

voluntary or mandatory recall of FACTIVE, TESTIM or a product candidate;

finances against us or our partners;

suspension or withdrawal of regulatory approvals for FACTIVE, TESTIM or a product candidate;

suspension or termination of any of our ongoing clinical trials of a product candidate;

refusal to permit import or export of our products;

refusal to approve pending applications or supplements to approved applications that we or our partners submit;

denial of permission to file an application or supplement in a jurisdiction;

product seizure; and

injunctions or the imposition of civil or criminal penalties against us or our partners.

*Testosterone is classified by the U.S. Drug Enforcement Agency as a controlled substance and our failure or Auxilium's failure to comply with these heightened regulations could harm our business.*

TESTIM contains testosterone which is listed by the U.S. Drug Enforcement Agency, or DEA, as a Schedule III substance under the Controlled Substances Act of 1970. The DEA classifies substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Scheduled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures. For example, all regular Schedule III drug prescriptions must be signed by a physician and may not be refilled. Auxilium must register annually with the DEA to manufacture, distribute, dispense, import, export, and conduct research using controlled substances. State controlled substance laws also require registration for similar activities. In addition, the DEA requires entities handling controlled substances to maintain records and file reports, follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration.

In addition, products containing controlled substances may generate public controversy. As a result, these products may have their marketing rights or regulatory approvals withdrawn. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the marketing of TESTIM. Such delays, restrictions or expenses could harm our business.

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*If testosterone replacement therapies are perceived to create or do 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, or 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.

*Sales of TESTIM will be highly dependent upon physician acceptance of testosterone replacement therapy for the treatment of hypogonadism.*

TESTIM is a testosterone replacement therapy, or TRT, approved for the treatment of hypogonadism, a disorder that affects approximately 20% of the U.S. male population over age 50. However, only about 5% of hypogonadal men currently receive TRT to treat their condition. Significant effort may be necessary to educate physicians, particularly primary care physicians, regarding the benefits of TRT for hypogonadal men. If TRT does not gain wider acceptance among physicians for the treatment of hypogonadism, the growth of TESTIM sales could be adversely affected.

*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 it manufactures bulk quantities of the active pharmaceutical ingredient of FACTIVE. The Co-Promotion Agreement for TESTIM provides that Auxilium is responsible for 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. Further, our license agreement with respect to Ramoplanin provides that Vicuron is responsible for the manufacture of the bulk drug substance of Ramoplanin.

In May 2005, we completed the technology transfer process for the manufacture of finished products by Patheon Inc. and filed a supplemental application with the FDA to approve Patheon, replacing the previous fill and finish provider, SB Pharmco. Although more than thirty days have passed following the FDA's receipt of the supplemental application without questions or comments from the FDA, and we now use Patheon as our fill and finish provider of FACTIVE tablets pending final action by the FDA, if the FDA ultimately rejects our application to qualify Patheon, we could be unable to maintain sufficient inventory of FACTIVE tablets to meet demand which could adversely affect our business and results of operations.

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

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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 substance is LG Life Sciences' facility in South Korea, and Patheon is currently our only source of

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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.

***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 support the development and commercialization of our products do not fulfill their obligations.***

In addition to using third parties to fulfill our manufacturing, distribution and supply chain services, our development and commercialization strategy entails entering into arrangements with corporate collaborators, contract research organizations, licensors, licensees and others to conduct development work, manage our clinical trials 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 existing products, FACTIVE and TESTIM, 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.

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Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing and commercializing our products are not within our control. Furthermore, our interests may differ from those of third parties that 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 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.

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*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.*

We are currently conducting a Phase IV post-approval clinical trial relating to FACTIVE tablets in compliance with FDA requirements pursuant to the product's approval and we recently have completed 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 product candidate, Ramoplanin, to assess the safety and efficacy to treat *Clostridium difficile*-associated diarrhea, or CDAD, was completed in 2004. Pursuant to the terms of the license agreement for Ramoplanin, we are in discussion with Vicuron to develop a timetable for the development and approval of Ramoplanin, including initiation of a Phase III trial for CDAD. The Phase III program will be ready for initiation subject to,

completion of discussions with the FDA regarding a Special Proto