(OSI)™ pharmaceuticals

ANNUAL REPORT 2007

"We hold ourselves to the highest ethical standards and work hard every day to change the face of cancer and diabetes treatment to best serve our patients and the medical community."

Dr. Colin Goddard,
Chief Executive Officer

To Our Shareholders

2007 was a pivotal year for our company as we successfully followed through on a commitment to you, our shareholders, to take the company profitable – recording earnings from continuing operations of $1.70 per share on income of $97 million. Revenues were $340 million (up 41% on the prior year) and expenses – at $243 million – reflected a concerted effort on our part to establish an effective balance between financial performance and disciplined re-investment in the business for sustained long-term growth. We consider this financial transformation of the business to be a necessary pre-requisite to our emergence as an elite biotechnology organization.

Robert A. Ingram, Chairman of the Board (left)
Colin Goddard, Ph.D., Chief Executive Officer

The business continues to be anchored around our flagship anti-cancer therapy Tarceva® which, just three years after the November 2004 approval in non-small cell lung cancer (NSCLC), exited the year with fourth quarter global sales of $250 million – an annualized run-rate of $1 billion, the recognized industry-wide metric of a blockbuster. Global sales of Tarceva increased 36% in 2007 to $886 million, fueled primarily by growth in sales outside of the U.S. However, of more importance to cancer patients and their families, their caregivers, and our dedicated employees, is our estimate that Tarceva has now been used in the treatment of approximately 250,000 lung and pancreatic cancer patients around the world and has added in the region of 40,000 years of cumulative life extension to these patients.

Today, thanks largely to the success of Tarceva, we are a profitable mid-cap biotechnology company that remains committed to discovering, developing and commercializing innovative and differentiated molecular targeted therapies that can make a meaningful healthcare impact on the treatment of oncology, diabetes and obesity patients around the world.

Cancer patient Mike Corcoran, who has been on Tarceva since October 2005, visited the OSI Boulder office to share his inspirational story in his fight against lung cancer with employees.

Even in today's challenging healthcare environment, we firmly believe that focusing our investments on pioneering, breakthrough therapies that really "move the needle" on patient care can still produce a significant return on investment for committed healthcare investors who share our belief in the fundamental value of innovation.

In our primary oncology business, we are well en route to building a leading franchise around Tarceva by "following the science" - in our case, by aggressively exploiting our growing understanding of the biology of Epithelial-to-Mesenchymal Transition (EMT) to develop new combination regimens of molecular targeted therapies. These regimens are being designed to drive substantial benefit to patients who will be selected on the basis of their likelihood to benefit from these EMT guided targeted therapy cocktails. Our scientists have shown that diagnostic markers of a tumor's EMT status may be equally as important in patient selection as markers that identify genetic aberrations such as gene mutations and over-expression. This breakthrough observation first arose out of our translational research efforts directed toward better understanding those patients who most benefit from Tarceva therapy.

We believe this kind of highly focused, scientifically driven and *differentiation* oriented strategy is not only the *right* approach for cancer patients but makes sound ***business sense*** for OSI. We are convinced that disciplined investments in differentiated strategies like these are essential to our ability to compete in an increasingly crowded oncology marketplace and to separate ourselves from competitor oncology pipelines collectively comprised of hundreds of candidates.

We are following the same basic blueprint in our UK-based diabetes and obesity subsidiary Prosidion. Once again the approach centers on highly

We are aggressively exploiting our growing understanding of the biology of Epithelial-to-Mesenchymal Transition (EMT) to develop new combination regimens of molecular targeted therapies.

focused R&D investments with differentiation as a key driver to candidate selection. In this case the identification of "best-in-class" follow-on strategies that will allow us to rapidly test our differentiation hypotheses in the clinic has given Prosidion a running start. For example, PSN602 – our anti-obesity agent which will soon begin clinical trials – is specifically designed to deliver superior weight loss to Meridia® (the market leader in its class) without the associated cardiovascular side-effects seen at higher doses of Meridia. Validating our differentiation hypothesis for PSN602 – avoiding acute increases in heart rate and blood pressure – can be accomplished early in our clinical program and provides a cost-effective means for us to establish the kind of competitive differentiation that could represent a meaningful step forward in patient care and warrant aggressive pursuit of the program.

Building around these core principles, 2007 saw us continue to make strides on a business plan that:

- invests (together with our partners at Genentech and Roche) significantly in furthering the Tarceva franchise;
- focuses our R&D investments in areas where we have exploitable differentiation and seeks to actively partner and monetize non-core assets; and
- maintains control over expenses, enabling an appropriate balance of delivering current financial performance and reinvesting for future growth.

Tarceva®
erlotinib

Tarceva has now been used in the treatment of approximately 250,000 lung and pancreatic cancer patients around the world and has added in the region of 40,000 years of cumulative life extension to these patients.

We have continued to execute well on the key elements of the Tarceva development plan and enter 2008 with two key potentially label expanding Phase III trials – SATURN and BeTa Lung – due to deliver top-line results in the second half of 2008. SATURN assesses the value of monotherapy Tarceva as a first-line maintenance therapy in NSCLC. Our goal is to extend the period of time patients, who have achieved either tumor shrinkage or stabilization of their disease following front-line chemotherapy regimens, are able to survive without progression of their cancer. BeTa Lung assesses the ability of a combination of two leading targeted therapies – Avastin® as an anti-VEGF targeted anti-angiogenesis agent and Tarceva as an anti-EGFR therapy – to extend the survival of second-line NSCLC patients compared to Tarceva alone. The BeTa study is based on a prior Phase II program and, if successful, we believe it will herald the dawn of "all targeted therapy combination regimens" - an important next step in the treatment of cancer patients. The success of these studies could both expand the number of NSCLC patients who receive Tarceva and increase the duration of their therapy with Tarceva.

At OSI, we completed a pharmacokinetic study demonstrating that NSCLC patients who continue to smoke may need twice the normal dose of Tarceva to achieve equivalent systemic blood levels of the drug. This important observation was submitted to the FDA at the end of 2007. The PDUFA date for our proposed sNDA label change is in September of 2008.

The success of the SATURN and BeTa Lung studies could both expand the number of NSCLC patients who receive Tarceva and increase the duration of their therapy with Tarceva.

We also saw good progress in additional Phase III programs assessing Tarceva in NSCLC patients who are "never smokers"; in a maintenance setting in ovarian cancer; with Avastin as a maintenance combination regimen in NSCLC; and the RADIANT adjuvant trial in NSCLC, despite the need to restart this study following identification of an operational issue at our CRO. This last study is important to the long-term life cycle management of the Tarceva brand. Further, in addition to a series of studies that will initiate in 2008, the Tarceva program is supported by over 340 completed, ongoing or planned studies with investigators and key opinion leaders around the world.

Tarceva faces, and will continue to face, competition both from approved agents (like Erbitux® and Alimta® – both of which will have important data on their programs presented at ASCO 2008) and developmental agents (like AstraZeneca's Zactima™, which has a Phase III trial against Tarceva due to read out this year). None-the-less, considering our own development programs and the extent of the established role of Tarceva in the treatment of lung and pancreatic cancer patients, we believe it would take an unlikely confluence of events to diminish prospects for the continued growth of the brand.

Tarceva's success also means that it has – and will - attract the interest of a global generics industry that is employing increasingly aggressive tactics toward innovator intellectual property rights around the world. We believe that a trend toward the erosion of innovator IP protection will ultimately undermine our industry's willingness and ability to invest in the next generation

(OSI)™ oncology

We believe that our emerging pipeline of differentiated, wholly owned development candidates – all products of OSI research – is laying a strong foundation for longer-term success.

of breakthrough therapies like Tarceva. As a result we, together with our partners, are taking proactive steps to defend and optimally position our global intellectual property rights surrounding Tarceva. These include taking legal action against companies producing a generic version of Tarceva in India (in the face of our issued Indian patent) and seeking a reissue of one of two Orange Book listed patents for Tarceva in the U.S. We remain confident in our ability to protect the unique inventiveness of Tarceva through its patent expiry in 2018 (in the U.S.) and 2020 (in the E.U.).

Beyond Tarceva, we believe that our emerging pipeline of differentiated, wholly owned development candidates – all products of OSI research – is laying a strong foundation for longer-term success.

In oncology, OSI-906 is potentially a "first-in-class" small molecule IGF-1R inhibitor that we advanced to Phase I trials in 2007. IGF-1R is widely regarded as an attractive target in most major tumor types and OSI-906 has been shown to synergize with Tarceva in pre-clinical models. OSI-027 is a next generation mTOR inhibitor designed to truncate mTOR signaling by blocking both signaling complexes (TORC-1 and TORC-2), whereas first generation molecules such as Wyeth's Torisel® (recently approved for kidney cancer) only block one of these signaling complexes. We anticipate beginning the clinical program for OSI-027 in 2008.

(OSI)™ prosidion

In diabetes and obesity we expect to advance two candidates to clinical trials in 2008.

In diabetes and obesity we expect to advance two candidates to clinical trials in 2008, our anti-obesity agent PSN602 and our dual anti-diabetic/weight loss agent, PSN821 – a high quality candidate which acts as a GPR119 agonist. PSN821 acts by causing GLP-1 release and by delaying gastric emptying. As a result, GPR119 agonists offer the tantalizing prospect of simultaneously providing an oral anti-diabetic function analogous to DP-IV inhibitors (like Merck's Januvia™) while also eliciting weight-loss. PSN821 has been shown pre-clinically to be highly effective over a sustained period and we look forward to advancing this promising agent to the clinic.

We completed two important deals to bolster our research efforts during 2007. A collaborative arrangement with AVEO Pharmaceuticals has provided us with animal models, diagnostic tools and potential targets in support of our EMT focused research efforts in oncology, and a small asset acquisition from AdipoGenix gave us access to a unique fat cell technology platform in support of our diabetes and obesity research efforts.

We ceased development of our own DP-IV inhibitor (PSN9301) in 2007 because we were unable to substantiate sufficient selectivity against related enzymes DP8 and 9 leading to inadequate safety margins. However, the success of Januvia and Janumet™ – together with new licenses and milestones – led to approximately $35MM in license revenues from our DP-IV patent estate. In addition, we focused on realizing value from our R&D assets that were not in our core focus areas in 2007 and garnered revenues of approximately $34 million from this ongoing exercise.

OSI is a founding member of the CEO Gold Standard program. The Company is proud to be part of this national commitment to raise cancer awareness and prevention in the workplace.

We believe that we exited 2007 with an effective balance between an appropriate level of fiscal discipline married to an exciting portfolio of emerging R&D assets that warrant continued investment. We enter 2008 with the potential for appreciable "step-ups" in value of the business, with major Phase III trial results for Tarceva anticipated in the second half of 2008 and important clinical validation of our pipeline assets on the horizon.

We believe this will set the stage for an exciting future for our company. Even adjusting for all the nuances and volatility of the biotech sector, we have moved the value of our business from $30-40 million ten years ago to $2-3 billion today, and we believe that there is no reason not to aspire to another major increase in value over the next ten years. In fact, when you take into account Tarceva, an enhanced financial base, our greater experience, and our stronger asset base – this appears even more achievable than the challenges we faced a decade ago.

We face the future with confidence in our ability to execute, a commitment to make a real difference in the treatment of the patients we serve and a determination to realize a successful return for our shareholders.

We thank you for your continued support of OSIP.

Colin Goddard, Ph.D.
Chief Executive Officer

Robert A. Ingram
Chairman of the Board

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2007 or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 0-15190

OSI PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**13-3159796**
(State or other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
41 Pinelawn Road, Melville, N.Y.	**11747**
(Address of Principal Executive Offices)	*(Zip Code)*

Registrant's Telephone Number, including area code
(631) 962-2000

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $.01 per share	**The NASDAQ Stock Market LLC**
Series SRPA Junior Participating Preferred Stock Purchase Rights	

Securities Registered Pursuant to Section 12(g) of the Act: None
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

As of June 30, 2007, the aggregate market value of the Registrant's voting stock held by non-affiliates was $1,092,947,540. For purposes of this calculation, shares of common stock held by directors, officers and stockholders whose ownership exceeds five percent of the common stock outstanding at June 30, 2007 were excluded. Exclusion of shares held by any person should not be construed to indicate that the person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant, or that the person is controlled by or under common control with the Registrant.

As of February 21, 2008, there were 57,120,496 shares of the Registrant's common stock, par value $.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2008 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K.

On the following pages, we have reproduced the first nine items of our annual report on the Form 10-K filed with the Securities and Exchange Commission on February 28, 2008, and amended on April 1, 2008. The Form 10-K has not been approved by the Securities and Exchange Commission, nor has the Commission passed upon the accuracy or adequacy of the data included therein. A copy of the complete Form 10-K, with exhibits, as filed with the Securities and Exchange Commission may be obtained without charge by writing to: Kathy Galante, Corporate Communications, OSI Pharmaceuticals, Inc., 41 Pinelawn Road, Melville, New York 11747.

In this Form 10-K, "OSI," "the Company," "we," "us," and "our" refer to OSI Pharmaceuticals, Inc. and subsidiaries.

We own or have rights to various copyrights, trademarks and trade names used in our business including the following: Tarceva® (erlotinib); Macugen® (pegaptanib sodium injection); and Novantrone® (mitoxantrone for injection concentrate). This Form 10-K also includes other trademarks, service marks and trade names of other companies.

PART I

ITEM 1. BUSINESS

We are a mid-cap biotechnology company committed to building a scientifically strong and financially successful top tier biopharmaceutical organization that discovers, develops and commercializes innovative molecular targeted therapies addressing major unmet medical needs in oncology, diabetes and obesity.

Our largest area of focus is oncology where our business is anchored by our flagship product, Tarceva (erlotinib), a small molecule inhibitor of the epidermal growth factor receptor, or EGFR, which is our primary source of revenues. In November 2004, Tarceva was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of advanced non-small cell lung cancer, or NSCLC, in patients who have failed at least one prior chemotherapy regimen and, subsequently, in November 2005, for the treatment of patients with locally advanced and metastatic pancreatic cancer in combination with the chemotherapy agent, gemcitabine. Tarceva was also approved for sale in the European Union, or EU, for the treatment of advanced NSCLC in September 2005 and, in January 2007, as a first-line therapy for metastatic pancreatic cancer in combination with gemcitabine. In October 2007, Tarceva was approved in Japan for the treatment of patients with nonresectable, recurrent and advanced NSCLC which is aggravated following therapy, and launched in Japan at the end of 2007. Tarceva, which as of January 31, 2008, was approved for sale in 88 countries for advanced NSCLC after failure of chemotherapy and 60 countries for pancreatic cancer, achieved global sales of approximately $886 million for 2007. We co-promote Tarceva in the United States with Genentech, Inc. and receive royalties on sales outside of the United States from our international collaborator, Roche.

We have a highly disciplined approach to research and development, prioritizing investment in a portfolio of differentiated and competitive drug candidates and technologies. We have an emerging oncology pipeline of molecular targeted therapies, or MTTs, in clinical and late-stage pre-clinical development which we intend to develop and commercialize independently. These include OSI-906 (an insulin-like growth factor 1 receptor, or IGF-1R, inhibitor implicated in all major tumor types) and OSI-027 (a next generation mammalian target of rapamycin, or mTOR, kinase inhibitor). In addition, we are developing two anti-angiogenesis agents, OSI-930 and OSI-632, for which we are considering seeking a development partner. OSI-906, OSI-027, OSI-930 and OSI-632, as well as Tarceva, are all small molecules designed to be administered orally as a tablet rather than by the less convenient intravenous infusion methods characteristic of many anti-cancer drugs. The focus of our proprietary oncology research efforts is the discovery and development of novel therapeutic agents that target the biological process of epithelial-to-mesenchymal transition, or EMT, a process of emerging significance in tumor development and disease progression. This research has grown out of our translational research efforts to understand which patients may optimally benefit from Tarceva. We believe that our EMT research investment will allow us to better design combinations of MTTs for specific sub-sets of cancer patients, thereby enabling us to demonstrate significant improvements in patient outcomes and to enhance our competitive position in the oncology marketplace.

We also have research and early development programs in diabetes and obesity which are conducted through our U.K. subsidiary, Prosidion Limited. Two compounds from our diabetes and obesity research efforts, PSN821 and PSN602, are in late stage pre-clinical development and are anticipated to enter into clinical trials in 2008. PSN821 is an orally administered G protein-coupled receptor 119, or GPR119, agonist with potential anti-diabetic and appetite suppressing features, and PSN602 is an oral dual serotonin and noradrenaline reuptake inhibitor and 5-HT_{1A} agonist for the treatment of obesity. In January 2007, we exclusively licensed our glucokinase activator, or GKA, program, including our clinical candidate PSN010, to Eli Lilly and Company for an upfront fee of $25.0 million and up to $360.0 million in potential development and sales milestones and other payments, plus royalties on any compounds successfully commercialized from this program. Prosidion also contributes an important second source of revenues from the licensing of our patent estate relating to the use of dipeptidyl peptidase IV, or DPIV, inhibitors for the treatment of type II diabetes and related indications. Twelve pharmaceutical companies have taken non-exclusive

licenses to these patents, which provide us with upfront payments as well as potential milestones and royalties. As of December 31, 2007, this patent estate has generated approximately $70 million in upfront license fees, milestones and royalties.

Strategy

Our strategy, which is anchored around the continued growth of and reinvestment in Tarceva, seeks to appropriately balance our financial performance with disciplined, focused and selective investments in research and development designed to realize long term growth for our company. 2007 was a key transition year for us financially as we achieved our first full year of profitability on the strength of global sales of Tarceva, a growing revenue stream from our DPIV patent estate and disciplined expense management. Throughout 2007, we endeavored to balance financial performance with reinvestment in our oncology and diabetes/obesity businesses by: (a) re-aligning our cost base and infrastructure with our projected revenues through headcount reductions and facilities rationalization; (b) engaging in highly disciplined research and development, or R&D, investments focused on an internal pipeline that has the potential to produce differentiated drug candidates and innovative technology platforms; and (c) divesting and monetizing those assets deemed not to be core, as evidenced by the outlicense of our GKA program to Eli Lilly and the divestiture of our anti-platelet derived growth factor, or PDGF, aptamer program to Ophthotech Corporation.

We believe that our efforts in 2007 to aggressively manage our business have laid the foundation for sustained growth in 2008. We anticipate that continued growth of global Tarceva sales coupled with robust growth in the market for DPIV inhibitors, which fuels a royalty stream to us from our DPIV patent estate, will provide us with solid revenue growth for 2008. We plan to continue our highly disciplined approach to our R&D programs by directing our investment to those programs which we believe can produce novel, differentiated, "first-in-class" or "best-in-class" drug candidates. We refer to these programs as our core assets. We believe that successfully advancing innovative and differentiated drug candidates through clinical development will result in the creation of additional value for our company. A cornerstone of our longer term growth strategy is to maintain significant ownership and control over these core assets. We also believe that a key element to disciplined management of our R&D investment is the pursuit of an out-licensing or partnering strategy for any program or candidate that we determine no longer meets our criteria as a core asset.

Over the past decade or more, we have demonstrated our ability to discover MTTs in both oncology and diabetes/obesity, and this remains at the core of our efforts to build a differentiated pipeline. Moreover, we have learned from our translational research efforts for Tarceva that developing and exploiting a comprehensive understanding of the biology of EMT may be the key to determining the optimal targeting, patient selection and combination of MTTs in the treatment of cancer. We have, therefore, invested internally and externally through collaborations, such as our alliance with AVEO Pharmaceuticals, Inc., in order to establish a leadership position in the understanding of this process and its implications in oncology drug discovery and development. We believe that our EMT-driven approach to oncology research will provide us with a pathway to obtaining the efficacy improvements that will be needed in order to compete in a growing and increasingly competitive market for oncology therapeutics. We also have had a long-term commitment to the discovery and development of differentiated MTTs in diabetes and obesity, two inter-related areas of growing and unmet medical need, and we continue to believe that our programs in these areas are of significant, long-term strategic value to our company.

Our Primary Marketed Product — Tarceva

Overview

Tarceva is an oral, once-a-day, small molecule therapeutic designed to inhibit the receptor tyrosine kinase activity of the protein product of the HER1/EGFR gene. HER1/EGFR is a key component of the HER signaling pathway, which

plays a role in the abnormal growth of many cancer cells. EGFR inhibitors were designed to arrest the growth of tumors, referred to as cytostasis; however, under certain circumstances, EGFR inhibition can lead to apoptosis, or programmed cell death, which in turn results in tumor shrinkage. The HER1/EGFR gene is over-expressed, mutated or amplified in approximately 40% to 60% of all cancers and contributes to the abnormal growth signaling in these cancer cells. There is a strong scientific rationale and a substantial potential market for EGFR inhibitors. The initial focus of our development program has been on NSCLC and pancreatic cancer. We, either on our own or together with our collaborators or other third parties, continue to explore the use of Tarceva in other tumor types, including hepatocellular carcinoma, or HCC, and ovarian and colorectal cancers.

The American Cancer Society estimates that approximately 182,767 cancer patients in the United States will be diagnosed with NSCLC in 2008. Based on data from the Tandem Oncology Monitor, a national audit in 2007 by Synovate, Inc. of cancer patients receiving therapy, approximately 60,000 subsequent courses of therapy were provided to NSCLC Stage IIIB/IV patients in the United States following a course of front-line chemotherapy. The American Cancer Society estimates that approximately 34,290 cancer patients in the United States will die from pancreatic cancer in 2008, which makes it the fourth leading cause of cancer death in the United States. In Europe, based on information collected by the International Agency for Research on Cancer in Lyon, France, the third most common incident form of cancer in 2006 was lung cancer, with approximately 380,000 cases. The International Agency for Research on Cancer also reported that lung cancer was the most common cause of cancer death in Europe, with approximately 340,000 deaths in 2006.

On November 18, 2004, we received full approval from the FDA for monotherapy Tarceva use in the treatment of NSCLC patients after the failure of at least one prior chemotherapy regimen, and we launched Tarceva on November 22, 2004. Tarceva was approved for NSCLC by the European Medicines Agency in September 2005. On November 2, 2005, the FDA approved Tarceva in combination with gemcitabine for the treatment of advanced pancreatic cancer in patients who have not received previous chemotherapy. In January 2007, Tarceva was approved in the EU as first-line therapy for metastatic pancreatic cancer in combination with gemcitabine. In October 2007, Tarceva was approved in Japan for the treatment of patients with nonresectable, recurrent and advanced NSCLC which is aggravated following therapy, and launched in Japan at the end of 2007. As of January 31, 2008, Tarceva has received regulatory approval in a total of 88 countries for NSCLC and 60 countries for pancreatic cancer.

We have an ongoing collaboration with Genentech and Roche for the continued development and commercialization of Tarceva. We co-promote Tarceva in the United States with Genentech and receive a 50% share of net profits after the deduction of costs of goods and certain sales and marketing expenses. We are also responsible for manufacturing and supply of Tarceva in the United States and receive reimbursement of manufacturing costs from Genentech. Roche is responsible for sales outside of the United States and we receive a royalty on net sales of approximately 20%. Tarceva R&D expenses that are part of the alliance's global development program generally are shared equally among the three parties.

Global sales of Tarceva for 2007 were approximately $886 million, a 36% increase over 2006 global sales. Robust growth outside of the United States was the principal component of the increase in 2007 sales over 2006. We believe there will be sales growth in the United States during 2008 driven largely by price, and continued sales growth in the rest of the world driven largely by volume growth and sales from new markets.

Lifecycle Plan

SATURN and Beta-Lung Studies. We, together with Genentech and Roche, continue to invest in Tarceva through a broad development program. We expect results from two key label-expanding studies for Tarceva, the SATURN study and the Beta-Lung study, in the second half of 2008. The SATURN study is a double-blind randomized 850-patient Phase III study to evaluate the efficacy of Tarceva as a maintenance therapy versus placebo following four cycles of chemotherapy in patients with advanced, recurrent or metastatic NSCLC who have not experienced disease

progression or unacceptable toxicity during the four cycles of front-line chemotherapy. The primary end-point of the study is an improvement in progression-free survival, and the secondary endpoint is an improvement in overall survival. There is also a co-primary endpoint of progression-free survival in EGFR positive patients as measured by immunohistochemistry, or IHC. If the data from this study are positive, it could provide the basis for an expanded label for Tarceva as front-line maintenance therapy. The SATURN study is being conducted by our ex-U.S. collaborator, Roche, and has been through the FDA's special protocol assessment, or SPA, process. The Beta-Lung study, which is being conducted by our U.S. collaborator, Genentech, is a Phase III, placebo-controlled, double-blind, randomized trial to evaluate the efficacy of Tarceva in combination with Avastin® (bevacizumab) as compared with Tarceva alone for the treatment of advanced NSCLC in the second line setting. The primary endpoint of the study is an improvement in overall survival. If the data from this study are positive, it could result in an expanded label for Tarceva to be used in combination with Avastin in second-line NSCLC. The SATURN and Beta-Lung studies, if positive, have the potential to expand Tarceva sales by increasing the number of NSCLC patients eligible to receive Tarceva, the duration of Tarceva therapy, and market share.

In addition to the SATURN and Beta-Lung studies, several randomized trials are underway or in the planning stage, including trials which: (i) study Tarceva as adjuvant therapy for NSCLC; (ii) may help further elucidate optimal ways to use Tarceva in NSCLC; (iii) combine Tarceva with other targeted therapies, such as Avastin and Sutent® (sunitinib malate); and (iv) target other tumor types such as ovarian, colorectal and HCC. In addition, over 250 studies investigating other Tarceva uses and regimens are ongoing or planned, including both investigator-sponsored studies and studies sponsored by the National Cancer Institute.

Key studies for our Tarceva lifecycle plan are summarized below.

RADIANT Study (Adjuvant Tarceva after Surgery and Chemotherapy in Patients with Stage IB-IIIA NSCLC). Due to its demonstrated efficacy, safety profile and convenience, we believe that Tarceva is well suited for testing in the adjuvant treatment of patients with fully resected stage IB through IIIA NSCLC. Over the last few years, it has been demonstrated that certain patients with resectable NSCLC may benefit from platinum-containing adjuvant chemotherapy. This treatment paradigm is becoming the standard of care in the United States. In the 950-patient RADIANT study, patients with fully resected NSCLC who are EGFR-positive by IHC and/or fluorescent *in situ* hybridization, or FISH, and do or do not receive platinum-containing adjuvant chemotherapy, are randomized to Tarceva or placebo for up to two years. This study has the potential to change the standard of care for patients with early stage NSCLC. We began opening sites and enrolling patients in this study in late 2006. In early November 2007, we were informed by our clinical research organization, or CRO, for the study that errors had been made in the randomization of the initial 278 patients, resulting in the data from these patients being deemed ineligible for analysis. Following remediation, enrollment in the study was recommenced in late November 2007. As of February 14, 2008, 199 patients had been screened for entry into the study and 103 patients randomized. We hope to complete enrollment by the end of 2009, and assuming we meet this enrollment target and intermediate enrollment goals, expect data from this trial in 2014 or 2015. This study is an important component of our later stage lifecycle plan for Tarceva.

Smoker Maximum Tolerated Dose Study. Pharmacokinetic analyses from our BR.21 study for Tarceva, which was the basis upon which Tarceva was approved by the FDA for NSCLC in November 2004, suggested that patients that are current smokers have lower drug exposure. In addition, as judged by the lower incidence of rash and diarrhea, these patients appear to have a less marked biological effect from Tarceva. Retrospective analyses for the BR.21 study showed that the treatment effect of Tarceva on survival was less pronounced in this population. A Phase I study in healthy volunteers demonstrated that the plasma levels of Tarceva achieved in active smokers were approximately half of those observed in non-smokers. In 2006, we initiated a two-stage Phase I dose escalation study with Tarceva in NSCLC patients who continue to smoke. The first part of the study established the maximum tolerated dose, or MTD, of Tarceva in this population as 300 mg/day. The second stage of the study compared the steady state pharmacokinetics of Tarceva at 300 mg/day versus 150 mg/day. We filed a supplemental new drug application, or sNDA, with the

FDA in the fourth quarter of 2007 seeking a change in the prescribing information for Tarceva to reflect the new MTD in patients who smoke while on therapy. We expect the FDA to act upon this sNDA by September 2008.

TITAN Study. The TITAN study is a randomized 650-patient Phase III study to evaluate the efficacy of Tarceva compared to either of two chemotherapy agents, Alimta® (pemetrexed) or Taxotere® (docetaxel), following front-line chemotherapy in advanced, recurrent metastatic NSCLC patients who have experienced rapid disease progression or unacceptable toxicity. Like the SATURN study, the TITAN study is part of our post-marketing commitments agreed to with the FDA upon the approval of Tarceva. Patients who do not progress on chemotherapy are enrolled in SATURN and randomized to Tarceva or placebo. Patients with progressive disease as best response to platinum-containing chemotherapy are eligible for enrollment in TITAN and are randomized to Tarceva or chemotherapy (Alimta or Taxotere at the discretion of the investigator). This study will provide comparative data for Tarceva versus chemotherapy in the sub-set of patients who rapidly progress on front-line chemotherapy. The TITAN study is currently enrolling. It is difficult to predict when enrollment will be complete for this study, as the rate of enrollment has been slower then anticipated.

Atlas Study. In addition to the Beta-Lung trial, Genentech is also conducting the Atlas study in NSCLC. The Atlas study is a randomized, double-blind, placebo-controlled, Phase IIIb study that compares Avastin therapy with Avastin plus Tarceva, as a front-line maintenance therapy after completion of chemotherapy plus Avastin for the first-line treatment of locally advanced, recurrent, or metastatic NSCLC. This trial is being conducted in the United States and is currently enrolling. Results of the trial are anticipated in the first half of 2010.

Phase II Study in Never-smokers. The Cancer and Leukemia Group B, or CALGB, is conducting a randomized Phase II study in previously untreated NSCLC patients with adenocarcinoma who have never smoked or were previous light smokers. A target of 180 patients with Stage IIIB or IV disease will receive either Tarceva alone or in combination with the drugs carboplatin and paclitaxel. This study will add further insight to the results seen in retrospective analyses of the never-smoker patients in the prior TRIBUTE and BR.21 randomized Phase III studies. In TRIBUTE, a first-line NSCLC study, the never-smoker group receiving Tarceva in combination with chemotherapy had a median survival of 22.5 months, compared to 10.1 months for those receiving chemotherapy alone, and in BR.21, the hazard ratio for benefit in never-smokers was 0.42 with a single agent response rate of 24.7%. A hazard ratio is a statistical measure of the difference in overall survival between the study drug and the control group. A hazard ratio of less then one indicates a reduction in the risk of death. The CALGB study is currently open in more than 60 study centers which are part of the CALGB cooperative group network and, as of January 31, 2008, has enrolled more than 100 patients.

Phase II Study in Enriched Population. The use of molecular markers to select patients with NSCLC for treatment with Tarceva may be useful in identifying patients who could particularly benefit from Tarceva therapy. We are conducting a 140-patient Phase II study in which we are prospectively selecting patients with untreated NSCLC based on EGFR positivity using IHC and/or FISH. After enrollment, patients are randomized to either single agent Tarceva or Tarceva intercalated with chemotherapy. The treatment regimen for the patients in the Tarceva plus chemotherapy arm differs from the concurrent regimen utilized in the two front-line Phase III Tarceva studies. We hypothesize that the administration of Tarceva in combination with chemotherapy in a unique schedule to patients with EGFR-positive tumors may have the potential for an increased effect on survival when compared with historical controls. Enrollment was completed in this study in the fourth quarter of 2007 and data is expected in the second half of 2008.

TASK Study. The TASK study is being conducted by our collaborator, Roche. While the Beta-Lung study focuses on understanding the potential benefit of Tarceva combined with Avastin in the second-line NSCLC setting, it is also important to better understand the potential benefits of this combination in the first-line NSCLC setting. Toward that end, our collaborator, Roche, has initiated TASK, a 200-patient randomized, open label, Phase II study of Tarceva in

combination with Avastin compared to standard chemotherapy regimens (gemcitabine plus cisplatin or paclitaxel plus carboplatin) plus Avastin in first-line NSCLC patients. This study is currently enrolling.

RACHEL Study. Sub-set analysis from the PA.3 study in pancreatic cancer suggest that those patients who have a grade 2 Tarceva-related rash have an approximately two-fold increase in their rate of survival. The RACHEL study seeks to explore this observation in a prospective, randomized fashion. This study is part of our post-marketing commitments agreed to with the EU regulatory authorities. Approximately 400 patients will be entered into the study and will receive four weeks of the standard gemcitabine plus 100 mg/day Tarceva regimen. Those patients who have not either progressed or demonstrated a grade ⅔ rash will be randomized to either continue the standard regimen or undergo a dose escalation protocol for the Tarceva component of the regimen. This study is in the planning stage.

MARK Study. The MARK study is a randomized Phase II study in pancreatic cancer which is primarily designed to provide extensive biomarker follow-up. This study is part of our post-marketing commitments agreed to with the EU regulatory authorities. Approximately 200 patients whose cancer has progressed on prior chemotherapy or who were considered unsuitable for chemotherapy will be randomized to Tarceva monotherapy or placebo.

Treatment Beyond Progression. From an exploratory study conducted at Memorial Sloan Kettering Cancer Center, it has been reported that, in patients who progressed on EGFR tyrosine kinase inhibitors, or EGFR TKI, therapy, there appeared to be acceleration of disease progression when EGFR TKI therapy was discontinued. Upon reintroduction of EGFR TKI therapy, disease progression deaccelerated. Based upon this observation, we believe that continuing Tarceva therapy beyond disease progression should be studied to determine if such Tarceva use provides a treatment benefit. Three investigator-sponsored studies are planned to explore this hypothesis.

Studies in Other Tumor Types. Additional collaborative group Phase III trials are under way in both ovarian cancer and colorectal cancer. The ovarian cancer study is an 830-patient Phase III trial being conducted by the European Organization for Research into the Treatment of Cancer, or EORTC, and follows a similar maintenance design to the SATURN study, in which Tarceva is used as a monotherapy following initial chemotherapy. The colorectal cancer study is a 640-patient study being conducted through a study group in the EU and also employs Tarceva in a maintenance setting. This study tests Tarceva in combination with Avastin as maintenance therapy compared to Avastin alone in patients who have had a partial response or stable disease after treatment in the first-line setting with modified FOLFOX 7 (folinic acid, fluorouracil and oxaliplatin) plus Avastin or modified XELOX (capecitabine plus oxaliplatin) plus Avastin, two widely employed treatment regimens for colorectal cancer. Both of these studies are currently enrolling patients. We are currently exploring various options to study the combination of Tarceva with other MTTs, and are currently in the planning stage for a Phase III trial comparing Tarceva plus Nexavar® (sorafenib) with placebo plus Nexavar, for the treatment of hepatocellular carcinoma.

Investigator Sponsored Studies. In addition to the studies listed above, over 250 studies investigating other Tarceva uses and regimens are ongoing or planned, including both investigator-sponsored studies and studies sponsored by the National Cancer Institute. These studies are exploring monotherapy and combination uses of Tarceva, including with other novel agents, in various tumor types and with a variety of treatment modalities, such as radiation and surgery. Some studies are also examining the use of Tarceva earlier in the treatment paradigm in both the adjuvant and chemoprevention settings. In general, many of these studies are carried out at minimal cost to us or our collaborators beyond the supply of Tarceva.

Sales and Marketing

In order to maximize the Tarceva brand and to ensure the optimal competitive positioning of Tarceva, we entered into a co-development and commercialization alliance with Genentech and Roche in January 2001. Under the alliance, Genentech leads the marketing efforts in the United States and Roche sells and markets the drug in the rest of the world. In April 2007, we amended our agreement with Genentech to adjust the size and composition of the combined

U.S. sales force for calendar years 2007 and 2008, and are in discussions to further extend this relationship beyond 2008. We agreed to increase the total number of OSI full time employees, comprising the sales force to 50% of the combined sales force. Our oncology sales specialists currently perform sales calls to certain high-volume physician call targets and associated medical staff, in addition to attending our promotional exhibit booths at medical meetings and tradeshows.

OSI/Genentech/Roche Alliance

We manage the ongoing development program for Tarceva with Genentech and Roche through a global development committee under our co-development and commercialization alliance with Genentech and Roche, the Tripartite Agreement. OSI and Genentech are parties to a collaboration agreement which was amended in 2004 to provide us with the right to co-promote Tarceva. The OSI/Genentech collaboration agreement continues until the date on which neither we nor Genentech are entitled to receive a share of the operating profits or losses on any products resulting from the collaboration, that is, until the date that we and Genentech mutually agree to terminate the collaboration or until either party exercises its early termination rights as described as follows. The OSI/Genentech collaboration agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. Genentech also has the right to terminate the OSI/Genentech collaboration agreement with six months' prior written notice. Upon such termination, the sole right to commercialize Tarceva in the United States would revert to us. The provisions of the amendment allowing us to co-promote are also subject to termination by Genentech upon a material breach of the amendment by us, which remains uncured, or upon a pattern of non-material breaches which remain uncured. In 2004, we signed a Manufacturing and Supply Agreement with Genentech that clarified our role in supplying Tarceva for the U.S. market.

We are also parties to an agreement with Roche whereby we have provided Roche with the right to sell Tarceva worldwide except for the United States, its territories, possessions and Puerto Rico, in exchange for a royalty and milestones. The OSI/Roche agreement continues until the date on which we are no longer entitled to receive a royalty on products resulting from the development of Tarceva, that is, until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva or, in countries where there is no valid patent covering Tarceva, on the tenth anniversary of the first commercial sale of Tarceva in that country. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, Roche has the right to terminate the agreement on a country-by-country basis with six months' prior written notice. We also currently have the right to terminate the agreement on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances. Upon a termination, the sole right to commercialize Tarceva in any terminated country would revert to us.

Manufacturing and Supply

We currently manage the supply of Tarceva in the United States through third-party manufacturers. Under our collaboration agreement with Genentech, we are responsible for the manufacture and supply of erlotinib, the active pharmaceutical ingredient, or API, and Tarceva tablets for pre-clinical and clinical trials and for the supply of commercial quantities of Tarceva tablets for sales within the United States. Under our collaboration agreement with Roche, Roche has elected to take responsibility for the manufacture and supply of Tarceva tablets for sales outside of the United States.

Erlotinib is manufactured in a three-step process with high yield. Sumitomo Chemical Co., Ltd. and Dipharma S.p.A are our manufacturers of the API used for commercial supplies. Both of these manufacturers also manufacture API for Tarceva clinical trials. Schwarz Pharma Manufacturing, Inc. is our manufacturer of Tarceva tablets for clinical and commercial supplies as well as placebo for blinded clinical studies. We have entered into long term supply agreements with our API and tablet manufacturers. We have recently identified a second manufacturer to serve as an

alternate provider of Tarceva tablets, and the process of qualifying this manufacturer is ongoing. Clinical supplies of Tarceva tablets are currently stored, labeled, packaged and distributed by Catalent Pharma Solutions LLC and AccuLogix Inc., a subsidiary of Fisher Clinical Services, Inc. Catalent Pharma Solutions also labels and provides secondary packaging services for commercial supplies of Tarceva tablets before their subsequent distribution to Genentech or a storage facility designated by Genentech. All manufacturers of the API and Tarceva tablets are required to comply with current good manufacturing practices, or cGMPs. We have produced sufficient quantities of Tarceva tablets to conduct our ongoing clinical trials, and we have a supply chain organization in place, with approximately six months or more of inventory on hand, to support the commercial sales of Tarceva.

Our Clinical Development Programs

Core Programs

We have four core assets in either late stage pre-clinical development or clinical development in 2008 in oncology and diabetes/obesity, all of which are the result of our internal research efforts. Our immediate goal is to move these programs through to clinical proof-of-concept over the next 15 to 18 months. Longer term, we intend to maintain significant control over these assets and to commercialize them, in whole or in part, particularly in the United States.

OSI-906. OSI-906 is an oral small molecule IGF-1 receptor inhibitor which we believe is among the first small molecule inhibitors against the IGF-1R target to enter clinical trials. In preclinical studies, OSI-906 has demonstrated synergy with Tarceva and potential utility in a number of different cancers, including NSCLC, breast, pancreas, prostate and colorectal. We believe that OSI-906 is potentially more effective than antibodies, given its inhibition of the pAKT survival pathway and that its oral administration will provide more scheduling flexibility and convenience than antibodies. It is currently in Phase I studies exploring both continuous and intermittent dose schedules, and an additional Phase I study of OSI-906 in combination with Tarceva is planned to be initiated in the second half of 2008.

PSN821. PSN821, a novel GPR119 agonist, is an oral small molecule drug with potential anti-diabetic and appetite suppressing effects. In pre-clinical models, PSN821 has been shown to release endogenous GLP-1 and increase beta-cell cAMP leading to improved glucose control, delayed gastric emptying and appetite suppression. We believe that PSN821 has the potential to be "best-in-class" and "first-in-class" due to delays in a competitor program which, while successfully validating the target, was unable to progress its lead candidate. PSN821 is currently undergoing chemistry, manufacturing and control, or CMC, development as well as drug metabolism and pharmacokinetics, or DMPK, and preclinical safety testing to support Phase I and Phase IIa clinical studies. We anticipate that the first-in-man Phase I clinical study will commence in the third quarter of 2008.

OSI-027. OSI-027 is a small molecule TORC1/TORC2 inhibitor which has the potential to supersede first generation mTOR inhibitors. Unlike existing agents targeting the mTOR pathway, OSI-027 inhibits both the TORC1 and TORC2 signaling complexes, allowing for the potential for complete truncation of aberrant cell signaling through this pathway. Inhibition of TORC1 and TORC2 has been shown in pre-clinical studies to elicit robust anti-tumor activity but to carry an appreciable toxicity burden. Pending regulatory approval, initiation of Phase I studies is planned for the second quarter of 2008.

PSN602. PSN602 is a novel dual serotonin and noradrenaline reuptake inhibitor which also elicits $5HT_{1A}$ receptor agonism. It is being developed for the long-term treatment of obesity. This molecule has been shown preclinically to counterbalance the undesirable cardiovascular effects of increased noradrenaline activity seen with other anti-obesity agents which inhibit the reuptake of noradrenaline and serotonin. Because of this potential to demonstrate a favorable side-effect profile, and/or greater efficacy, relative to current therapies, we believe that PSN602 has the potential to be "best-in-class." PSN602 is currently undergoing CMC development, as well as DMPK and preclinical safety testing to support Phase I and Phase IIa clinical studies. We plan to initiate the first-in-man Phase I clinical study of PSN602 in the third quarter of 2008.

Other Development Programs

OSI-930. OSI-930 is a multi-targeted tyrosine kinase inhibitor that principally acts as a potent co-inhibitor of the receptor tyrosine kinases c-kit and the vascular endothelial growth factor receptor-2, or VEGFR-2. It is designed to target the suppression of both cancer cell proliferation and blood vessel growth, or angiogenesis, in selected tumors. We have completed Phase I dose escalation studies of OSI-930 in healthy volunteer patients and a Phase I dose escalation study in cancer patients, which has determined the MTD to be 500mg/day. We are currently enrolling the expanded cohort at the MTD, which is expected to be completed by the end of 2008. We have also initiated a combination trial in cancer patients to study the effects of OSI-930 and Tarceva. Because of the large number of VEGFR-2 inhibitors already on the market and currently in development, differentiation of this program is critical and potentially challenging. As a result, we are considering various strategic alternatives for this program, including partnering, which would enable us to support a more comprehensive development program.

OSI-632. From 1986 to 2001, our oncology drug discovery efforts in targeted therapies were conducted in collaboration with Pfizer. During the course of the alliance, five novel molecular targeted therapies, including Tarceva, were advanced to clinical development. OSI-632, an inhibitor of VEGFR-2, is another clinical development candidate from the Pfizer collaboration. Pfizer elected to discontinue development of OSI-632 (formerly CP-547,632) and, pursuant to our agreement with Pfizer, it reverted to us and we have the right to pursue its development. We are examining our options with respect to this candidate.

CP-868,596. Pfizer is continuing to develop one clinical stage targeted therapy from our prior alliance, CP-868,596, a PDGFR inhibitor in Phase I trials. Pursuant to our agreement with Pfizer for this collaboration, if Pfizer is successful in commercializing this drug candidate, we will receive a royalty from Pfizer on sales of this drug. If Pfizer chooses to discontinue development of this drug candidate, it will revert to us and we will have the right to pursue development of it.

PSN9301. PSN9301, a short acting DPIV inhibitor that Prosidion acquired from Probiodrug AG in July 2004, was scheduled to enter Phase IIb clinical studies in mid-2008. However, following a 13-week toxicology study in primates, mandated by the FDA for all DPIV inhibitor programs, the decision was taken at the end of 2007 to discontinue the PSN9301 program due to an inadequate safety margin for this compound.

Outlicensing Activities

We outlicensed and/or divested three preclinical/clinical programs in 2007. In January 2007, we outlicensed our GKA program, including the small molecule Phase I clinical candidate PSN010, to Eli Lilly. Glucokinase activators have a dual effect in the pancreas and the liver resulting in increased hepatic glucose uptake in the liver and stimulated insulin secretion by the pancreas. Under the terms of our license with Eli Lilly, Eli Lilly is responsible for all aspects of clinical development, manufacturing and commercialization of PSN010 or any back-up compound included within the licensed GKA program. In return for such rights, we received an upfront payment of $25.0 million and will potentially receive milestones and other payments of up to $360.0 million and a competitive royalty structure based on net sales of any product arising from the licensed GKA program. In August 2007, we divested our pre-clinical PDGF aptamer program to Ophthotech for an upfront cash payment, shares of Ophthotech preferred stock and potential future milestones and royalties. In December 2007, we outlicensed our clinical compound OSI-7904L, a liposomal formulation of an inhibitor of the enzyme thymidylate synthase, to OncoVista Innovative Therapies, Inc., or OncoVista, for an upfront payment, equity in OncoVista and potential future milestones and royalties. We had previously ceased development of OSI-7904L.

Our Oncology and Diabetes/Obesity Discovery Efforts

Oncology Research

Our oncology research efforts are broadly centered around both translational research and drug discovery, each of which is anchored by our continued focus on understanding the biological process known as EMT and its reverse, mesenchymal-to-epithelial transition, or MET, both of which are important phenomena in developmental biology that are becoming increasingly associated with tumor biology. EMT is characterized by the combined loss of epithelial cell junction proteins, such as E-cadherin, and the gain of mesenchymal markers, such as vimentin, fibronectin or MMP-2. An increase in the proportion of cancer cells in a tumor that exhibit the loss of E-cadherin and the acquisition of a more mesenchymal phenotype has been shown to correlate with poor prognosis in multiple epithelial derived solid tumors. We believe that EMT may be a marker of tumor progression, with tumors that express mesenchymal markers having a greater tendency to be invasive and to metastasize than those tumors only expressing epithelial markers. Because mesenchymal tumor cells co-opt different sets of oncogenic signaling pathways, we believe that EMT targets represent a novel therapeutic opportunity.

Our early understanding of EMT emanated from work done by our translational research group on Tarceva's effects on different types of cancer cells relative to the EMT-status of these cancer cells in order to better understand which patients might more optimally benefit from Tarceva treatment. Retrospective analysis of tumor samples from the TRIBUTE Phase III study of Tarceva in combination with chemotherapy for the treatment of front-line NSCLC patients suggested that those patients whose tumors abundantly expressed E-cadherin responded better to Tarceva. By acquiring or co-opting a mesenchymal phenotype, we believe that epithelial derived tumor cells utilize different growth and survival pathways and become less dependent on EGFR signaling and ultimately acquire or gain the ability to migrate, invade and metastasize. These properties suggest the need to target distinctly different signaling pathways in order to effectively treat these tumors. This new insight is leading our development project teams to plan and conduct studies of markers of EMT and EGFR signaling in retrospective and prospective clinical trials for Tarceva. These studies may enhance the likelihood of success of Tarceva in additional indications by selecting those patients most likely to better respond to therapy.

Given the importance and relevance of EMT to the therapeutic activity of Tarceva, we have focused our oncology discovery efforts on exploiting our understanding of the signaling pathways that drive EMT and on identifying drug targets that could lead to novel molecular targeted therapies. We have focused our oncology discovery research on: (i) discovering and validating EMT-related targets; (ii) developing novel therapies and combinations of therapies against EMT-related targets; (iii) developing specialized animal models that recapitulate EMT processes; and (iv) identifying and validating biomarkers to support these programs.

On September 28, 2007, we entered into a three-year oncology drug discovery and translational research collaboration with AVEO which we believe will help us to better understand the underlying mechanisms of the process of EMT in cancer. A main focus of the collaboration is the development of proprietary target-driven tumor models which we will use in drug screening, translational research and biomarker validation. As part of the collaboration, AVEO will provide us with access to its databases of tumor targets identified from AVEO genetic screens, focusing on tumor maintenance genes that drive EMT. AVEO will use its proprietary technology platform of genetically-defined mouse models of human cancer to develop for us *in vivo* tumor models driven by EMT target genes of interest to us, validating key EMT targets and creating tools for our oncology discovery and translational research. Under the terms of the collaboration, we will be responsible for the development and commercialization of all clinical candidates that arise from the collaboration. Rights to antibodies and antibody-related biologics against those targets are retained by AVEO. In addition to an upfront payment, we pay AVEO for ongoing research funding, and milestones and royalties upon successful development and commercialization of products from the collaboration.

Diabetes/Obesity Discovery

Prosidion's discovery efforts currently focus on innovative, small molecule and orally bioavailable MTTs for the treatment of diabetes and obesity. The International Diabetes Foundation, or IDF, estimates that up to 246 million people worldwide have diabetes, and estimates that this number will reach 385 million by 2025. The IDF also estimates that up to 3.8 million deaths worldwide each year are a result of diabetes, representing the fourth leading cause of death by disease globally. Diabetes is a chronic disease with multiple complications, including cardiovascular and renal disease, neuropathy, blindness and premature mortality. Type 2 diabetes accounted for approximately 90% of diabetics worldwide as of 2005 and, while historically considered a disease found in adults, it is increasingly occurring in obese children. As for obesity, The World Heath Organization, or WHO, estimated in 2005 that over 1.6 billion adults worldwide were overweight, and over 400 million adults were obese. The WHO estimates that these figures will rise to 2.3 billion and 700 million, respectively, by 2015. Obesity is a major risk factor for diabetes, cardiovascular disease, musculo-skeletal disorders and certain cancers.

In the near term, we are focusing our diabetes/obesity discovery research efforts on identifying back-up investigational new drug, or IND, candidates for the GPR119 and oral dual serotonin and nonadrenaline reuptake inhibitor and 5-HT_{1A} agonist programs, together with a number of novel, early stage exploratory programs. In addition, at the end of the fourth quarter of 2007, we acquired substantially all of the assets of AdipoGenix, Inc., a Boston-based company having a proprietary human fat cell technology platform. The assets acquired under the AdipoGenix transaction provide us with access to potentially novel early stage diabetes and obesity targets, together with potential starting chemical matter, a human fat cell screening and assay technology platform and expertise that is not widely available.

Our Eye Disease Business

On November 6, 2006, we announced our intention to divest our eye disease business, which consists principally of Macugen, our marketed product for the treatment of neovascular age-related macular degeneration, or wet AMD, as well as research assets in the eye disease area. We made the decision to exit the eye disease business based on our determination that a key strategic goal of the acquisition of the business in November 2005 — the generation of significant cash flow from the business in the 2006 through 2008 fiscal years — would not be realized. We finalized our exit plan during the first quarter of 2007 and began to actively market our eye disease business. We explored several potential transactions to divest our entire eye disease business, but were unable to identify a transaction that would provide us with satisfactory terms for the sale of the business as a whole. Therefore, we switched to a strategy of separately divesting the assets and, in July 2007, we entered into an agreement with Ophthotech to divest our anti-platelet derived growth factor, or PDGF, aptamer program for an upfront cash payment, shares of Ophthotech preferred stock and potential future milestones and royalties. We continue to pursue the divestiture of the remaining eye disease assets, including Macugen, and we are planning to complete this process in 2008.

Our Intellectual Property

Patents and other proprietary rights are vital to our business. Our policy is to protect our intellectual property rights through a variety of means, including applying for patents in the United States and other major industrialized countries, to operate without infringing on the valid proprietary rights of others and to prevent others from infringing our proprietary rights. We also rely upon trade secrets and improvements, unpatented proprietary know-how and continuing technological innovations to develop and maintain our competitive position. In this regard, we seek restrictions in our agreements with third-parties, including research institutions, with respect to the use and disclosure of our proprietary technology. We also enter into confidentiality agreements with our employees, consultants and scientific advisors.

Tarceva-Related Intellectual Property

We have obtained patents for erlotinib, the API for Tarceva, in the United States, Europe, Japan, and a number of other countries. We are pursuing extensions of the patent term and/or of the data exclusivity term in the countries where such extensions are available. We have been granted patent term extensions that extend our U.S. patent for erlotinib to November 2018 and corresponding patents in Europe to March 2020. We are pursuing a patent term extension in Japan that, if granted, would extend our Japanese patent protection for Tarceva through 2020. We are also currently pursuing U.S. and international patents for new inventions concerning various other formulations of erlotinib and related intermediate chemicals and processes in an effort to enhance our intellectual property rights in this compound. We have obtained a patent covering a key polymorphic form of Tarceva in the United States, which expires in 2020. We are also currently seeking patent protection for additional methods of use for Tarceva, including the use of Tarceva in combination with other compounds.

Separate and apart from this patent protection, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, entitles Tarceva to various periods of non-patent statutory protection, known as marketing exclusivity. The patent system and marketing exclusivity work in tandem to protect our products. For Tarceva, under Hatch-Waxman, we have a five-year period of new chemical entity exclusivity. This period of exclusivity expires on November 18, 2009. On its own, this exclusivity means that another manufacturer cannot submit an ANDA (i.e., an application for approval of a generic version of our product) or a 505(b)(2) NDA (i.e., an application for a modified version of Tarceva that relies to some degree on the FDA's previous approval of our product) until the five-year marketing exclusivity period ends. There is an exception, however, for a competitor that seeks to challenge our patents. Four years into the exclusivity period (i.e., as of November 18, 2008), a manufacturer who alleges that one or more of the patents listed in the FDA's Orange Book are invalid, unenforceable and/or not infringed may submit an ANDA or 505(b)(2) NDA for a generic or modified version of Tarceva. This patent challenge is commonly known as a Paragraph IV certification.

If a Paragraph IV certification is filed against Tarceva, the applicant will be required to notify us, and we will have an opportunity to bring a patent infringement suit against the applicant. If we do so within 45 days of receiving the Paragraph IV certification, the FDA cannot approve the ANDA or 505(b)(2) NDA for 30 months from the date of our receipt of the Paragraph IV certification. In addition, if such patent infringement action is so commenced within such 45-day period and occurs during the one-year period beginning on the fourth anniversary of the commencement of Tarceva's marketing exclusivity period, the 30-month period is extended by an amount of time such that the FDA cannot approve the ANDA until seven and one-half years have elapsed from the date of Tarceva's initial approval (i.e., May 18, 2012). This period of protection, referred to as the statutory litigation stay period, may end early, however, if we lose the patent infringement case (i.e., the court finds the patent invalid, unenforceable, or not infringed) before the statutory litigation stay period expires or if we fail to reasonably cooperate in expediting the litigation. On the other hand, if we win the patent suit, the ANDA or 505(b)(2) NDA cannot be approved until the patent expires.

In the current environment, generic companies are becoming increasingly aggressive in asserting challenges to innovator intellectual property. In light of this, we, together with our collaborators, Genentech and Roche, are continually assessing the intellectual property estate for Tarceva around the world. On February 27, 2008, we filed with the U.S. Patent and Trademark Office, or USPTO, an application to reissue our composition of matter patent for Tarceva, U.S. Patent No. 5,747,498, or the '498 patent, in order to correct certain errors relating to the claiming of compounds, other than Tarceva, which fall outside of the scope of the main claim in the patent. The reissue application seeks to correct these errors by deleting surplus compounds from the claims. Like most composition of matter patents, the '498 patent claims many compounds in addition to Tarceva. Tarceva itself is accurately described in the '498 patent. We believe that eliminating these errors as an arguable basis for challenging the '498 patent is a prudent course of action given the aggressive strategy of generic companies in seeking to bring generic versions of innovator drugs to market at the earliest possible time, notwithstanding the patent protection of the innovator product. While we

seek to correct these errors, the '498 patent remains listed with the FDA and subject to Paragraph IV certification by potential ANDA filers and may be asserted by us in an infringement action. In the reissue application, we are also seeking to add narrower claims to the '498 patent. In addition, we also filed with the USPTO a request for a certificate of correction with respect to the '498 patent seeking to correct errors of a clerical or typographical nature.

In the reissue proceeding, the USPTO will once again review our patent on the merits and an initial rejection is not unusual. However, we will have the opportunity to respond to any such rejection before it becomes final, and thereafter pursue appeals with the USPTO and in the U.S. federal courts, if necessary. We believe that the patent was properly granted and will be reissued particularly since the reissue, in addition to correcting the errors, seeks to narrow the patent claims. This process may take up to five years.

A patent corresponding to the U.S. composition of matter patent for Tarceva was granted in February 2007 in India and we, along with our collaborator Roche, successfully opposed a pre-grant opposition by Natco Pharma, Ltd. of Mumbai, India in July 2007. We are also opposing Natco Pharma's request for a compulsory license to manufacture Tarceva in India for export to Nepal. A hearing on this matter is scheduled at the Indian Patent Office in New Delhi on February 28, 2008. We and Roche are also currently seeking to enforce this patent against CIPLA, Ltd. of Mumbai, India, with respect to a generic form of Tarceva launched by CIPLA in India in January 2008. A lawsuit was filed in India on January 15, 2008 and we are awaiting the decision of a preliminary injunction hearing which concluded on January 31, 2008.

In addition, Teva Pharmaceutical Industries filed an opposition to the grant of a patent in Israel corresponding to our U.S. patent directed to a particular polymorph of Tarceva (U.S. Patent No. 6,900,221) in August 2007. This Israeli proceeding will be delayed until prosecution of a co-pending patent application in Israel is completed.

Other Intellectual Property

The DPIV assets we acquired from Probiodrug include a portfolio of medical use patents. This portfolio contains a number of patent families comprising issued and pending patents and patent applications with claims relating to the use of DPIV inhibitors for the treatment of diabetes and related indications. We also have licensed sub-licensable rights to patents and patent applications claiming combinations of DPIV inhibitors with other oral anti-diabetic drugs such as metformin. Our rights to this patent estate provide us with a source of upfront payments, and milestone and royalty revenue through the issuance of non-exclusive licenses to the patent estate. Twelve pharmaceutical companies, including Merck & Co., Inc., Novartis AG and Bristol-Myers Squibb Company have taken licenses to this patent estate. These licenses provide us with upfront payments, milestones and royalties which vary according to the individual license agreements. As of December 31, 2007, we have generated approximately $70 million in upfront license fees, milestones and royalties from the patent estate. In October 2006, Merck announced that it had received FDA approval for its DPIV inhibitor, Januvia™, which resulted in our receipt of a milestone payment. In March 2007, Merck received EU approval for Januvia and FDA approval for Janumet™, its combination product of Januvia and metformin. We receive royalty payments from sales of Januvia and Janumet. Novartis, in September 2007, received EU approval for its DPIV inhibitor, Galvus® (vildagliptin), and in November 2007, received EU approval for its combination product with metformin, Eucreas®. We are entitled to royalties from sales of Galvus and Eucreas.

The patents which are the subject of these DPIV licenses will expire between 2017 and 2027. The earliest of these patents, which relates to the use of DPIV inhibitors for lowering blood glucose levels, was revoked by the European Patent Office in opposition proceedings in May 2004. We have appealed this revocation and a hearing date for the appeal has been set for March 2008. If we are unsuccessful in our appeal and the patent is revoked without the further possibility of appeal, this will reduce the potential royalty revenue we derive from the non-exclusive licenses we have granted in those territories where the patent is revoked.

We have filed a number of U.S. and international patent applications relating to the OSI-906, OSI-027 and OSI-930 compounds, each of which we are developing as potential treatments for cancer. We have been granted a U.S. patent which protects the OSI-930 compound and method of use until 2024.

We have also sought patent protection for PSN602, our oral dual serotonin and noradrenaline reuptake $5HT_{1A}$ agonist candidate, and potential back-up candidates for this compound, as well as for compounds arising from the GPR119 agonist program.

We have assembled a strong gene transcription patent portfolio which we have non-exclusively out-licensed to a number of pharmaceutical companies. We also have non-exclusive licenses from Cadus Pharmaceutical Corporation and Wyeth to a portfolio of patents and applications covering yeast cells engineered to express heterologous G-Protein coupled receptors, or GPCRs, and G-protein polypeptides, methods of use thereof in screening assays, and DNAs encoding biologically active yeast-mammalian hybrid GPCRs.

Our Competition

The pharmaceutical and biotechnology industries are very competitive. We face, and will continue to face, intense competition from large pharmaceutical companies, as well as from numerous smaller biotechnology companies and academic and research institutions. Our competitors are pursuing technologies that are similar to those that comprise our technology platforms and are pursuing pharmaceutical products or therapies that are directly competitive with ours. Many of these competitors have greater capital resources than we do, which provide them with potentially greater flexibility in the development and marketing of their products. In the case of Tarceva, we chose to seek partnerships with leading biotechnology and pharmaceutical industry companies, Genentech and Roche, in order to ensure our competitiveness on a global basis.

The market for oncology products is very competitive, with many products currently in Phase III development. Most major pharmaceutical companies and many biotechnology companies, including our collaborators for Tarceva, Genentech and Roche, currently devote a portion or all of their operating resources to the research and development of new oncology drugs or additional indications for oncology drugs which are already marketed.

The current competition to Tarceva for the NSCLC indication includes existing chemotherapy options such as Alimta, Taxotere and Gemzar® (gemcitabine), as well as Genentech's Avastin, which is approved in combination with chemotherapy for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC. Tarceva also competes with AstraZeneca plc's Iressa® (gefitinib) in the limited markets where it is available, such as Japan and Canada. AstraZeneca announced positive results in September 2007 from its international non-inferiority study comparing the use of Iressa versus Taxotere for the treatment of NSCLC after the failure of a first-line treatment. AstraZeneca indicated, in January 2008, that it plans to file for EU regulatory approval in the second quarter of 2008, which, if successful, would result in additional competition for Tarceva in the EU. It is also possible that AstraZeneca may seek to amend its label in the United States.

Tarceva may compete in the future with Erbitux® (cetuximab). ImClone Systems Incorporated, BMS and Merck KGaA announced that Erbitux met its primary endpoint of increased overall survival in a Phase III study, referred to as FLEX, of the combination of Erbitux and chemotherapy in the treatment of first-line advanced NSCLC. Results for this study will be presented at the June 2008 American Society of Clinical Oncology, or ASCO, conference. In addition, Eli Lilly recently announced a positive outcome for a Phase III NSCLC maintenance therapy trial for Alimta. Since Alimta has not yet been approved in this setting, its potential impact on treatment is not yet known. Eli Lilly has indicated, however, that it expects to provide a report on this data at the June 2008 ASCO conference, which would result in the release of the Alimta data prior to our expected announcement of the outcome of our SATURN maintenance study in the second half of 2008. Eli Lilly also announced recently that Alimta, with cisplatin, has been submitted for approval to regulatory authorities in the United States and Europe for the first-line treatment of NSCLC. Tarceva may also face

competition in the future from AstraZeneca's Zactima™ (vandetanib). We are aware of four current Phase III trials investigating Zactima use in NSCLC, including ZEST, a head-to-head superiority trial versus Tarceva in the second line setting. AstraZeneca has indicated that it expects to report data from its ZEST trial in 2008, which, if positive, could allow Zactima to compete with Tarceva in NSCLC. Other oncology drugs currently in clinical trials for treatment of NSCLC either as a single agent or as a combination therapy, such as Vectibix™ (panitumumab), Velcade® (bortezomib), Sutent and Nexavar, could compete for market share in NSCLC in the future.

In the pancreatic setting, Tarceva primarily competes with Gemzar monotherapy in the first line. In addition, Tarceva's use in pancreatic cancer may be affected by experimental use of other products, such as Xeloda® (capecitabine).

Our four core development programs could face competition in the future if successful. OSI-906, which is in Phase I clinical trials, could face competition from a number of other pre-clinical and clinical candidates which target the IGF-1R gene, including more advanced antibody clinical candidates from Pfizer, ImClone Systems and Roche. Our pre-clinical candidate, OSI-027, a small molecule inhibitor of both mTOR complexes, TORC1 and TORC2, could compete with rapamycin analogs, such as Wyeth's Torisel™ (temsirolimus) and Novartis' RAD001, which are known to inhibit the TORC1 complex. OSI-906 and OSI-027 may also compete in the future with therapeutic agents which target other molecular pathways or cellular functions, but potentially have similar clinical applications. The market for PSN821, our GPR119 agonist for the treatment of type 2 diabetes, is highly competitive, and PSN821 would potentially compete against a number of similar agents in this class currently in development, including a GPR119 agonist in preclinical development by Arena Pharmaceuticals, Inc. and Johnson & Johnson. PSN602, our dual serotonin and noradrenaline reuptake inhibitor which also elicits $5HT_{1A}$ receptor agonism, could compete in the future with current and future obesity treatments, including Neurosearch A/S's tesofensine, a triple reuptake inhibitor currently in Phase III trials, and other targeted therapies using different methods of action for the treatment of obesity, such as Abbott Laboratories' Meridia® (sibutramine) and Sanofi-Aventis' Acomplia® (rimonabant).

OSI-930 is in Phase I clinical trials. As it is a dual c-Kit/VEGFR-2 inhibitor, it would potentially compete against Avastin, Gleevec® (imatinib mesylate), Sutent, and Nexavar, each of which is already in the market. In addition, at least six other VEGF or VEGFR targeted agents are in advanced stages of development, some of which are, like OSI-930, multi-targeted small molecule tyrosine kinase inhibitors, and many other anti-angiogenesis agents are in earlier stages of development.

Government Regulation

As developers and sellers of pharmaceutical products, we and our collaborators are subject to, and any potential products discovered and developed by us must comply with, comprehensive regulation by the FDA, the Centers for Medicare and Medicaid Services, or CMS, and other regulatory agencies in the United States and by comparable authorities in other countries. These national agencies and other, state, and local entities regulate, among other things, the pre-clinical and clinical testing, safety, effectiveness, approval, manufacture, quality, labeling, distribution, marketing, export, storage, record keeping, advertising, promotion and reimbursement of pharmaceutical and diagnostic products.

FDA Approval Process

FDA approval of our products is required before the products may be commercialized in the United States. The process of obtaining NDA approvals from the FDA can be costly and time consuming and may be affected by unanticipated delays.

The process required by the FDA before a new drug (pharmaceutical product) or a new route of administration of a pharmaceutical product may be approved for marketing in the United States generally involves:

- pre-clinical laboratory and animal tests;

- submission to the FDA of an IND, which must be in effect before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for its intended indication(s);
- FDA compliance inspection and/or clearance of all manufacturers;
- submission to the FDA of an NDA; and
- FDA review of the NDA or product license application in order to determine, among other things, whether the drug is safe, effective and of appropriate quality for its intended uses.

Pre-clinical and clinical testing should conform with all applicable regulations and guidances regarding good laboratory practices and good clinical practices, respectively, including requirements for institutional review board, or IRB, ethics approvals and informed consent. Failure to comply may result in an agency rejection of the data and a corresponding delay in approving the drug.

Clinical trials are time-consuming and costly and typically are conducted in three sequential Phases, which may overlap. During Phase I, when the drug is initially given to human subjects, the product is tested for safety, dosage tolerance, absorption, distribution, metabolism, excretion and, increasingly for targeted therapies, for effects on potential biomarkers of activity. Phase I studies are often conducted with a limited number of healthy volunteers depending on the drug being tested; however, in oncology or other areas where the product may be too inherently toxic to ethically administer to healthy volunteers, Phase I trials are more often conducted in patients.

Phase II involves studies in a limited patient population, typically patients with the conditions needing treatment, to:

- evaluate preliminarily the efficacy of the product for specific, targeted indications;
- determine dosage tolerance and optimal dosage; and
- identify possible adverse effects and safety risks.

Pivotal or Phase III adequate and well-controlled trials are undertaken in order to evaluate efficacy and safety in a comprehensive fashion within an expanded patient population for the purpose of registering the new drug.

Meeting clinical endpoints in early stage clinical trials does not assure success in later stage clinical trials. The FDA monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate clinical trials at any point in this process for various reasons, including a finding that patients are being exposed to an unacceptable health risk or if they decide it is unethical to continue the study. The FDA can also request additional clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of products under development. Furthermore, IRBs have the authority to suspend clinical trials at any time for a variety of reasons, including safety issues.

New indications or other changes to an already approved product also must be approved by the FDA. An sNDA is a supplement to an existing NDA that provides for changes to the NDA and therefore requires FDA approval. There are two types of sNDAs depending on the content and extent of the change. These two types are (i) supplements requiring FDA approval before the change is made and (ii) supplements for changes that may be made pending FDA approval. Supplements to the labeling that change the indication section require prior FDA approval before the change can be made to the labeling. Clinical trials are necessary to support sNDAs for new indications.

Under the Pediatric Research Equity Act of 2007, an application for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration is required to contain an assessment, generally based on clinical study data of the safety, efficacy, and dosing of the drug for all relevant pediatric populations. The statute provides for full or partial waivers or deferrals of this requirement in certain situations.

The FDA reviews all NDAs submitted before it accepts them for filing. It may refuse to file the application and request additional information rather than accept an NDA for filing, in which case the application must be resubmitted with the supplemental information. Once an NDA is accepted for filing, the FDA begins an in-depth review of the application to determine, among other things, whether a product is safe and effective for its intended use. Drugs that successfully complete NDA review may be marketed in the United States, subject to all conditions imposed by the FDA. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA. The FDA also may issue an "approvable" letter which indicates that the FDA is prepared to approve an NDA, but only upon the satisfaction of the conditions described in the letter, such as submitting additional information or conducting additional studies. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the marketing application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a "not approvable" letter.

Even if a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Both before and after marketing approval is obtained, a product, its manufacturer and the holder of the NDA for the product are subject to comprehensive regulatory oversight. Any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements, submitting periodic reports to the FDA, maintaining and providing updated safety and efficacy information to the FDA, reporting of adverse experiences with the drug, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, and complying with the FDA's promotion and advertising requirements. The FDA may also impose certain post-marketing commitments as a condition of product approval, or Phase IV commitments, which are required at the time of approval. This commitment may involve continued testing of a product and development of data, including clinical data about the product's effects in various populations and any side effects associated with long-term use.

Manufacturing procedures must conform to cGMPs, which must be followed at all times. In complying with this requirement, manufacturers, including a drug sponsor's third-party contract manufacturers, must continue to expend time, money and effort in the area of production, quality assurance and quality control to ensure compliance. Manufacturing establishments are subject to periodic inspections by the FDA in order to assess, among other things, compliance with cGMP. To supply products for use in the United States, foreign manufacturing establishments also must comply with current good manufacturing practices and are subject to periodic inspection by the FDA or by regulatory authorities in certain countries under reciprocal agreements with the FDA.

We are required to comply with requirements concerning advertising and promotional labeling. Our advertising and promotional labeling must be truthful, not misleading and contain fair balance between claims of efficacy and safety. We are prohibited from promoting any claim relating to safety and efficacy that is not approved by the FDA, otherwise known as "off-label" use of products. Physicians may prescribe drugs for uses that are not described in the product's labeling and that differ from those approved by the FDA. Such off-label uses are common across medical specialties, including in the area of oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. Although the FDA does not regulate the behavior of physicians in their choice of treatments, the FDA does restrict our communications to physicians and patients on the subject of off-label use. Failure to comply with this requirement could result in adverse publicity, significant enforcement action by the FDA, including warning letters, corrective advertising, orders to pull all promotional materials, and substantial civil and criminal penalties. The Department of Justice may also pursue enforcement actions against off-label promotion which could result in criminal and/or civil fines, as well as other restrictions on the future sales of our products.

We are also required to comply with post-approval safety and adverse event reporting requirements. Adverse events related to our products must be reported to the FDA according to regulatory timelines based on their severity and expectedness. Failure to make required safety reports and to establish and maintain related records could result in withdrawal of a marketing application.

Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's delay in approving or refusal to approve a product, withdrawal or recall of an approved product from the market, other voluntary or FDA-initiated action that could delay further marketing, and the imposition of criminal penalties against the manufacturer and NDA holder. In addition, later discovery of previously unknown problems may result in restrictions being placed on the product, manufacturer or NDA holder, including withdrawal of the product from the market.

The Hatch-Waxman Act

As discussed above, the Hatch-Waxman Act entitles our products to various periods of non-patent statutory protection, known as marketing exclusivity, which works in tandem with the patent system to protect our products. Thus, even if our patents are successfully challenged by our competitors, another manufacturer cannot submit an application for generic or modified versions of our products until the respective marketing exclusivity periods end.

Four years into this marketing exclusivity period, the Hatch-Waxman Act permits another manufacturer to submit an application for approval of generic or modified versions of our products by alleging that one or more of the patents listed in the FDA's Orange Book are invalid, unenforceable and/or not infringed. This allegation is commonly known as a Paragraph IV certification. If a Paragraph IV certification is filed, the NDA and patent holders may bring a patent infringement suit against the applicant. If this action is brought within 45 days of receipt of the Paragraph IV certification, the FDA cannot approve the ANDA or 505(b)(2) application for 30 months (or longer in certain circumstances), referred to as the statutory litigation stay period, from the date of our receipt of the Paragraph IV certification. This 30-month stay may end early, however, if we lose the patent infringement case (i.e., a court finds the patent invalid, unenforceable or not infringed) before the statutory litigation stay period expires or if we fail to reasonably cooperate in expediting the litigation. On the other hand, if we win the patent suit, the ANDA or 505(b)(2) application cannot be approved until the expiration of the patent.

Under the Hatch-Waxman Act, the life of our patents may be extended to compensate for marketing time lost while developing our products and awaiting FDA approval of our applications. The extension cannot exceed five years, and the total life of the patent with the extension cannot exceed 14 years from a product's approval date. The period of extension is generally one-half of the time between the effective date of the IND and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. Only one patent claiming each approved product is eligible for the extension. We have been granted patent term extensions that extend our U.S. patent for erlotinib through November 2018, and corresponding patents in Europe have been extended through March 2020 under European legislation for supplementary protection certificates.

Pricing and Reimbursement

Insurance companies, health maintenance organizations, other third-party payors and federal and state governments seek to limit the amount they reimburse for our drugs. Although there are currently no government price controls over private sector purchases in the United States, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under certain public health care programs. Various states have adopted mechanisms under Medicaid that seek to control drug reimbursement, including by disfavoring certain higher priced drugs and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products.

Effective January 1, 2006, an expanded prescription drug benefit for all Medicare beneficiaries, known as Medicare Part D, commenced. This is a voluntary benefit that is being implemented through private plans under contractual arrangements with the federal government. Like pharmaceutical coverage through private health insurance, Medicare Part D plans establish formularies and other utilization management tools that govern access to the drugs and biologicals that are offered by each plan. These formularies can change on an annual basis, subject to federal governmental review. These plans may also require beneficiaries to provide out-of-pocket payments for such products. As a prescription medication, Tarceva is frequently administered through Medicare Part D plans. As a result, changes in the formularies or utilization management tools employed by these plans could restrict patient access to Tarceva or increase the out-of-pocket cost for our drug, which in turn could negatively impact Tarceva sales.

Regulatory approval of prices is required in most foreign countries. Certain countries will condition their approval of a product on the agreement of the seller not to sell that product for more than a certain price in that country and in the past have required price reductions after or in connection with product approval. Certain foreign countries also require that the price of an approved product be reduced after that product has been marketed for a period of time. A number of European countries, including Germany, Italy, Spain and the United Kingdom, have implemented, or are considering, legislation that would require pharmaceutical companies to sell their products subject to reimbursement at a mandatory discount. Such mandatory discounts would reduce the revenue we receive from our drug sales in these countries.

Other Regulation

In addition to regulations enforced by the FDA, we must also comply with regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. For example, sales, marketing and scientific/educational grant programs must comply with the Federal Health Care Programs' Anti-Fraud and Abuse provisions in the federal Social Security Act, as amended, the Federal False Claims Act, also as amended, the privacy rules issued pursuant to the Health Insurance Portability and Accountability Act of 1996, and similar state laws. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements may apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. In addition, our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds, the handling and disposal of which are governed by various state and federal laws and regulations.

We are subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws generally make it illegal for a prescription drug manufacturer to knowingly and willfully solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the recommendation, purchase or prescription of a particular drug. Due to the breadth of the statutory provisions, the limited regulatory guidance for some of these laws, and few court decisions addressing the application of some of these laws to industry practices, it is possible that our practices might be challenged under some anti-kickback or similar laws. False claims laws prohibit, among other things, anyone from knowingly and willfully presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including imprisonment, fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to allege or convict us of violating these laws, our business could be harmed. In addition, under some of these laws, there is an ability for private individuals to bring similar actions. Our activities could be subject to challenge for the reasons discussed above and

due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in these laws and their implementation, our reporting actions could be subject to the enforcement and penalty provisions of the pertinent state authorities.

In addition, federal and state laws protect the confidentiality of certain health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These rules protect health information by regulating its use and disclosure, including for research purposes. In addition, many state laws apply to the use and disclosure of health information. Such state laws are not necessarily preempted by HIPAA, and typically have their own penalty provisions that could be applied in the event of an unlawful action affecting health information.

Our Employees

We believe that our success is largely dependent upon our ability to attract and retain qualified employees. As of December 31, 2007, we had a total of 488 full time employees worldwide, which included 26 employees associated with our eye disease business. In addition, we employed 29 part time employees as of December 31, 2007.

Available Information

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 electronically with the Securities and Exchange Commission, or SEC. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is *http://www.sec.gov*.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website on the World Wide Web at *http://www.osip.com* or by contacting the Investor Relations Department at our corporate offices by calling (631) 962-2000 or sending an e-mail message to investorinfo@osip.com.

ITEM 1A. RISK FACTORS

This report contains forward-looking statements that do not convey historical information, but relate to predicted or potential future events, such as statements of our plans, strategies and intentions, or our future performance or goals for our product development programs. These statements can often be identified by the use of forward-looking terminology such as "believe," "expect," "intend," "may," "will," "should," or "anticipate" or similar terminology. The statements involve risks and uncertainties and are based on various assumptions. Stockholders and prospective stockholders are cautioned that these statements are only projections. In addition, any forward-looking statement that we make is intended to speak only as of the date on which we made the statement. Except for our ongoing obligations to disclose material information under the federal securities laws, we will not update any forward-looking statement to reflect events or circumstances that occur after the date on which the statement is made. The following risks and uncertainties, among others, may cause our actual results to differ materially from those described in forward-looking statements made in this report or presented elsewhere by management from time to time.

Risks Related to Our Business

We depend heavily on our principal marketed product, Tarceva, to generate revenues in order to fund our operations.

We currently derive most of our revenues from our principal marketed product, Tarceva, which represented approximately 79% of our total revenues from continuing operations for the year ended December 31, 2007. For the next several years, we will continue to rely on Tarceva to generate the majority of our revenues. Our ability to maintain or increase our revenues for Tarceva will depend on, and may be limited by, a number of factors, including the following:

- Our ability to maintain and expand the market share, both in the United States and in the rest of the world, and revenues for Tarceva in the treatment of second-line and third-line NSCLC and for first-line pancreatic cancer in the midst of numerous competing products which are currently in late stage clinical development;
- Whether data from the SATURN and Beta-Lung studies and other clinical trials for additional indications are positive and whether such data, if positive, will be sufficient to achieve approval from the FDA and its foreign counterparts to market and sell Tarceva in such additional indications;
- The reluctance of physicians to switch from existing treatment methods, including traditional chemotherapy agents (where certain reimbursement practices in the United States favor the use of intravenously administered drugs), to Tarceva; and
- Adequate coverage or reimbursement for Tarceva by third-party payors, including private health coverage insurers and health maintenance organizations.

If Tarceva were to become the subject of problems related to its efficacy, safety, or otherwise, or if new, more effective treatments were introduced into the market, our revenues from Tarceva could decrease.

If Tarceva becomes the subject of problems, including those related to, among others:

- efficacy or safety concerns with the product, even if not justified;
- unexpected side-effects;
- regulatory proceedings subjecting the product to potential recall;
- publicity affecting doctor prescription or patient use of the product;
- pressure from competitive products;
- introduction of more effective treatments; or

- manufacturing or quality problems that would reduce or disrupt product availability;

our revenues from Tarceva could decrease. For example, efficacy or safety concerns from time to time arise, whether or not justified, that could lead to additional safety warnings on the label or to the recall or withdrawal of Tarceva. In the event of a recall or withdrawal of Tarceva, our revenues would decline significantly.

We cannot be certain of the outcomes of the SATURN and Beta-Lung studies and, even if positive, the data may not support the necessary regulatory approvals needed for new indications for Tarceva.

We expect results from two key Phase III studies for Tarceva, the SATURN study and the Beta-Lung study, in the second half of 2008. These studies have the potential to support the expansion of Tarceva use in NSCLC to the maintenance setting following first line treatment and to solidify its use in the second line setting. However, clinical trial results are difficult to predict; positive results from pilot studies or other similar studies, including subset analyses from prior studies, are not a guarantee of success in subsequent studies. Until we receive the final data from the SATURN and Beta-Lung studies, we cannot be certain of the outcomes of those studies. If one or both of these studies is negative, our existing market share for Tarceva may decrease and it will be more difficult for us to grow our market share for Tarceva in the future. Furthermore, there can be no assurance that positive data will result in an approval from the FDA for new indications for Tarceva, or that any such approvals will be received in a timely manner. The primary endpoint of the SATURN study is progression-free-survival, or PFS. Although the SATURN trial has been through the FDA's SPA process, there can be no guarantee that the PFS endpoint will not be subject to further scrutiny by the FDA. In studies of other oncology drugs with a PFS endpoint, the FDA has required additional information, such as overall survival data, before determining whether to grant approval. Such requests for additional information can delay the time to approval and there can be no assurance that any such additional information will be sufficient to support approval.

We depend heavily on our co-development and marketing alliance with Genentech and Roche for Tarceva. If Genentech or Roche terminate these alliances, or are unable to meet their contractual obligations, it could negatively impact our revenues and harm our business until appropriate corrective measures have been taken.

Tarceva is being developed and commercialized in an alliance under co-development and marketing agreements with Genentech and Roche. Genentech leads the marketing efforts in the United States, and Roche markets the drug in the rest of the world. The OSI/Genentech collaboration agreement continues until the date on which neither we nor Genentech are entitled to receive a share of the operating profits or losses on any products resulting from the collaboration, that is, until the date that we and Genentech mutually agree to terminate the collaboration or until either party exercises its early termination rights as described as follows. The OSI/Genentech collaboration agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, Genentech has the right to terminate the OSI/Genentech collaboration agreement with six months' prior written notice. The provisions of the amendment to the agreement allowing us to co-promote are also subject to termination by Genentech upon a material breach of the amendment by us, which remains uncured, or upon a pattern of nonmaterial breaches which remain uncured.

The OSI/Roche agreement continues until the date on which we are no longer entitled to receive a royalty on products resulting from the development of Tarceva, that is, until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva or, in countries where there is no valid patent covering Tarceva, on the tenth anniversary of the first commercial sale of Tarceva in that country. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, Roche has the right to terminate the agreement on a country-by-country basis with six months' prior

written notice. We also currently have the right to terminate the agreement with respect to a particular country under certain circumstances if Roche has not launched or marketed a product in such country.

If we do not maintain a successful collaborative alliance with Genentech and/or Roche for the co-development and commercialization of Tarceva, or if Genentech or Roche are unable to meet their contractual obligations, we may be forced to focus our efforts internally to further commercialize and develop Tarceva without the assistance of a marketing and promotion partner. This would require greater financial resources and would result in us incurring greater expenses and may cause a delay in market penetration while we expand our commercial operations or seek alternative collaborative partners. Such costs may exceed the increased revenues we would receive from direct Tarceva sales, at least in the near term.

We are responsible for the manufacture and supply of Tarceva in the United States. Because we have no commercial manufacturing facilities, we are dependent on two suppliers for the API for Tarceva and a single supplier for the tableting of Tarceva in the United States. If any of these third parties fails to meet its obligations, our revenues from Tarceva could be negatively affected.

We are responsible for manufacturing and supplying Tarceva in the United States under the terms of a Manufacturing and Supply Agreement entered into with Genentech in 2004. We rely on two third-party suppliers to manufacture erlotinib, the API for Tarceva. We also currently rely on a single manufacturer to formulate the Tarceva tablets.

If our relationships with any of these manufacturers with respect to Tarceva terminate or if these manufacturers are unable to meet their obligations, we would need to find other sources of supply. Such alternative sources of supply may be difficult to find on terms acceptable to us or in a timely manner, and, if found, would require FDA approval which could cause delays in the availability of erlotinib and ultimately Tarceva tablets, which, in turn, would negatively impact our revenues derived from Tarceva.

We may not be able to successfully obtain the grant of the Tarceva patent reissue application which could limit our ability to assert the '498 patent to prevent or stop competitors from marketing or selling products similar to Tarceva.

On February 27, 2008, we filed a reissue application and a request for a certificate of correction with the USPTO to correct certain errors with respect to the '498 patent. In the reissue proceeding, the USPTO may determine that one or more of the claims in the '498 patent are unpatentable. We are unable to predict the outcome of the reissue proceeding. If we are unsuccessful in obtaining a grant of a reissued '498 patent with at least one claim covering Tarceva, we would be limited in our ability to assert the '498 patent to prevent or stop competitors from marketing or selling products that are similar to Tarceva which would adversely impact our revenues from Tarceva in the United States.

If our competitors succeed in developing products and technologies that are more effective than our own, or if scientific developments change our understanding of the potential scope and utility of our products, then our products and technologies may be rendered less competitive.

We face significant competition from industry participants that are pursuing products and technologies that are similar to those we are pursuing and who are developing pharmaceutical products that are competitive with our products and potential products. Some of our industry competitors have greater capital resources, larger overall research and development staffs and facilities, and a longer history in drug discovery and development, obtaining regulatory approval and pharmaceutical product manufacturing and marketing than we do. With these additional resources, our competitors may be able to respond to the rapid and significant technological changes in the biotechnology and pharmaceutical industries faster than we can. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Rapid technological development, as

well as new scientific developments, may result in our compounds, products or processes becoming obsolete before we can recover any of the expenses incurred to develop them.

The current competition to Tarceva for the NSCLC indication includes existing chemotherapy options such as Alimta, Taxotere and Gemzar, as well as Genentech's Avastin, which is approved in combination with chemotherapy for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC. Tarceva also competes with AstraZeneca's Iressa in the limited markets where it is available, such as Japan and Canada. AstraZeneca announced positive results in September 2007 from its international non-inferiority study comparing the use of Iressa versus Taxotere for the treatment of NSCLC after the failure of a first-line treatment. AstraZeneca indicated in January 2008 that it plans to file for EU regulatory approval in the second quarter of 2008, which, if successful, would result in additional competition for Tarceva in the EU. It is also possible that AstraZeneca may seek to amend its label in the United States.

Tarceva may compete in the future with Erbitux. Imclone Systems, BMS and Merck KGaA announced that Erbitux met its primary endpoint of increased overall survival in a Phase III study, referred to as FLEX, of the combination of Erbitux and chemotherapy in the treatment of first-line advanced NSCLC. Results from this study will be presented at the June 2008 ASCO conference. In addition, Eli Lilly recently announced a positive outcome for a Phase III NSCLC maintenance therapy trial for Alimta. Since Alimta has not yet been approved in this setting, its potential impact on treatment is not yet known. Eli Lilly has indicated however that it expects to provide a report on this data at the June 2008 ASCO conference, which would result in the release of the Alimta data prior to our expected announcement of the outcome of our SATURN maintenance study in the second half of 2008. Eli Lilly also announced recently that Alimta, with cisplatin, has been submitted for approval to regulatory authorities in the United States and Europe for the first-line treatment of NSCLC. Tarceva could also face competition in the future from AstraZeneca's Zactima. We are aware of four current Phase III trials investigating Zactima use in NSCLC, including ZEST, a head-to-head superiority trial versus Tarceva in the second line setting. AstraZeneca has indicated that it expects to report data from its ZEST trial in 2008, which, if positive, could allow Zactima to compete with Tarceva in NSCLC. Other oncology drugs currently in clinical trials for treatment of NSCLC either as a single agent or as a combination therapy, such as Vectibix, Velcade, Sutent and Nexavar, could compete for market share in NSCLC in the future.

In the pancreatic cancer setting, Tarceva primarily competes with Gemzar monotherapy in the first line. In addition, Tarceva use in pancreatic cancer may be affected by experimental use of other products, such as Xeloda.

Our four core development programs could face competition in the future if successful. OSI-906, which is in Phase I clinical trials, could face competition from a number of other pre-clinical and clinical candidates which target the IGF-1R gene, including more advanced antibody clinical candidates from Pfizer, ImClone Systems and Roche. Our pre-clinical candidate OSI-027, a small molecule inhibitor of both mTOR complexes, TORC1 and TORC2, could compete with rapamycin analogs, such as Wyeth's Torisel and Novartis' RAD001, which are known to inhibit the TORC1 complex. OSI-906 and OSI-027 may also compete in the future with therapeutic agents which target other molecular pathways or cellular functions, but potentially have similar clinical applications. PSN821, our GPR119 receptor agonist for the treatment of type 2 diabetes, would potentially compete against a number of similar agents in this class currently in development, including a GPR119 agonist in preclinical development by Arena Pharmaceuticals and Johnson & Johnson. PSN602, our dual serotonin and noradrenaline reuptake inhibitor which also elicits $5HT_{1A}$ receptor agonism, could compete in the future with current and future obesity treatments, including Neurosearch's tesofensine, a triple reuptake inhibitor currently in Phase III trials, and other targeted therapies using different methods of action for the treatment of obesity, such as Abbott Laboratories' Meridia and Sanofi-Aventis' Acomplia.

OSI-930 is in Phase I clinical trials. As it is a dual c-Kit/VEGFR-2 inhibitor, it would potentially compete against Avastin, Gleevec, Sutent, and Nexavar, each of which is already in the market. In addition, at least six other VEGF or

VEGFR targeted agents are in advanced stages of development, some of which are, like OSI-930, multi-targeted small molecule tyrosine kinase inhibitors and many other anti-angiogenesis agents are in earlier stages of development.

Our revenues from our DPIV patent portfolio licenses are contingent upon the ability of our licensees to successfully develop and commercialize their products which are the subject of these licenses and our ability to protect our intellectual property rights in our DPIV patent estate.

We have licensed our DPIV medical use patent portfolio to pharmaceutical companies developing DPIV inhibitor products. We currently derive or have the potential to derive in the future revenues from the milestone and royalty obligations under these license agreements. Licensees include Merck, whose product Januvia was approved by the FDA in late 2006 and in the EU in March 2007. Merck's combination product with metformin, Janumet, was approved by the FDA in March 2007. Novartis is also a licensee and it received EU regulatory approval for its product, Galvus, in September 2007. Additionally, in November 2007, Novartis received EU regulatory approval for its combination product with metformin, Eucreas. There can be no assurance that Galvus, Eucreas or any other DPIV inhibitors covered by license agreements with us will be approved by the FDA or other regulatory authorities. The amount of royalties and other payments that we derive from our DPIV patent estate is not only dependent on the extent to which products covered by the license agreements receive regulatory approval but is also dependent on how successful Merck, Novartis and other licensees are in expanding the global market for DPIV inhibitors, as well as other factors that could affect their market share, such as safety issues. The extent to which we receive revenue under such licenses also depends on our ability to enforce our patent rights in our DPIV portfolio. In addition, our patent which relates to the use of DPIV inhibitors for lowering blood glucose levels was revoked by the European Patent Office in opposition proceedings in May 2004. We have appealed this revocation, and a hearing date for the appeal has been set for March 2008. If we are unsuccessful in our appeal and the patent is revoked without possibility of appeal, this will reduce the potential royalty revenue we derive from the non-exclusive licenses we have granted under the patent in those territories where it is revoked.

Although we have clinical and pre-clinical candidates in the pipeline for oncology and diabetes and obesity that appear to be promising at early stages of development, none of these potential products may reach the commercial market for a number of reasons.

Successful research and development of pharmaceutical products is high risk. Most products and development candidates fail to reach the market. Our success depends on the discovery and development of new drugs that we can commercialize. Our pipeline for our oncology and diabetes and obesity clinical programs, including those that we deem to be core assets, is at an early stage. Other than the development of Tarceva for additional indications, the two oncology candidates that we consider to be core assets, OSI-906 and OSI-027, either are or will be in Phase I studies in 2008. The two candidates in our diabetes and obesity portfolio which we consider to be core assets, PSN821 and PSN602, are currently undergoing pre-clinical testing prior to entry into Phase I trials in 2008. Given the early stage of each of these clinical candidates, there can be no assurance at this time that any of them will become a marketed drug. In November 2007, we elected to discontinue development of our DPIV inhibitor, PSN9301, which had completed Phase IIa studies, after it failed to show an adequate safety margin in a three-month primate toxicology study.

The clinical candidates in our pipeline may never reach the market for a number of reasons. They may be found ineffective or may cause harmful side-effects during pre-clinical testing or clinical trials or fail to receive necessary regulatory approvals. Interim results of pre-clinical or clinical studies are not necessarily predictive of their final results, and acceptable results in early studies might not be seen in later studies, in large part because earlier phases of studies are often conducted on smaller groups of patients than later studies, and without the same trial design features, such as randomized controls and long-term patient follow-up and analysis. We may find that certain products cannot be manufactured on a commercial scale and, therefore, they may not be economical to produce. Our products could also fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties.

We must provide the FDA and similar foreign regulatory authorities with pre-clinical and clinical data that demonstrate that our product candidates are safe and effective for each target indication before they can be approved for commercial distribution. The pre-clinical testing and clinical trials of any product candidates that we develop must comply with regulations by numerous federal, state and local government authorities in the United States, principally the FDA, and by similar agencies in other countries. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections based on our inability to enroll or keep enrolled enough patients to complete our clinical trials, especially as new competitors are approved to enter into the market. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial. Delays in patient enrollment may result in increased costs and a longer than anticipated period of time until data become available, which could have a harmful effect on our ability to develop products.

A significant portion of the research that we are conducting involves new and unproven technologies. Research programs to identify disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield candidates for clinical development for a number of reasons, including difficulties in formulation which cannot be overcome, inadequate intellectual property protection and timing and competitive concerns.

Our business strategy with respect to development candidates or programs which we do not consider to be part of our core business is to enter into collaborations with third parties to research, develop and commercialize such non-core assets or to outlicense them. We may not be successful in establishing such collaborations or entering into such license agreements, which may adversely affect the prospects for these candidates or programs to become commercialized.

A component of our business strategy is to enter into collaborations or licensing, co-promotion or other agreements with third parties for the research, development and commercialization of certain of our programs and product candidates which we do not consider to be core assets. We may face significant competition in seeking appropriate collaborators and licensees. Moreover, these collaboration arrangements and license agreements can be complex to negotiate and time consuming to document. We may not be successful in our efforts to establish these collaborations or outlicensing arrangements. If we are unable to reach such agreements, we may fail to meet our business objectives with respect to our non-core assets. Moreover, these collaborations or license agreements may not be successful and the termination of these arrangements might adversely affect our ability to develop, commercialize and market our non-core assets.

The success of any of these potential collaboration arrangements will depend heavily on the efforts and activities of our future collaborators and licensees. Our collaborators and licensees will have significant discretion in determining the efforts and resources that they will apply to the programs or product candidates subject to these arrangements.

Our reliance on third parties, such as CROs, may result in delays in completing, or a failure to complete, clinical trials if they fail to perform under our agreements with them.

In the course of product development, we engage CROs to conduct and manage clinical studies. Because we have engaged and intend to continue to engage CROs to help us conduct our clinical studies and obtain market approval for our drug candidates, many important aspects of this process have been and will be out of our direct control. If the CROs fail to perform their obligations under our agreements with them or fail to perform their responsibilities with respect to clinical trials in compliance with good clinical practices, regulations and guidelines enforced by the FDA and similar foreign regulatory authorities, such trials may be materially delayed or terminated, adversely impacting our ability to commercialize our drug candidates. For example, in early November 2007, we were

informed by our CRO for our RADIANT study for Tarceva that errors had been made in the randomization of the initial cohort of patients for the study, which compromised the scientific integrity of data from the first 278 randomized patients, resulting in the data from these patients being deemed ineligible for analysis. This error is likely to result in data from this study becoming available later than we had originally projected. Furthermore, any loss or delay in obtaining contracts with such CROs may also delay the completion of our clinical trials and the market approval of drug candidates.

We may not be able to make our required payments of interest and principal under our outstanding indebtedness when due, and may not be able to repurchase for cash our 2% convertible senior subordinated notes due 2025, or our 2025 Notes, or our 3% convertible senior subordinated notes due 2038, or our 2038 Notes, if required to do so in 2010 and 2013, respectively. If we elect to repurchase our 31/4% convertible senior subordinated notes due 2023, or our 2023 Notes, with our common shares, our shareholders will experience dilution and our stock price may decline.

Our aggregate debt under our 2023 Notes, 2025 Notes and 2038 Notes was $465 million as of January 9, 2008, the closing date of the offering of our 2038 Notes. While we are currently generating sufficient net cash flow to satisfy our anticipated annual interest payments on our outstanding convertible debt, there can be no assurances that we will be able to do so in the future. In addition, the holders of the 2023 Notes, the 2025 Notes or the 2038 Notes have the right to first require us to repurchase their notes in September 2008, December 2010, and January 2013, respectively. We believe that we will have sufficient capital resources to repurchase the 2023 Notes for cash, and we also will have the option of delivering our common stock in lieu of cash in the event that the holders of the 2023 Notes require us to repurchase all or a portion of their 2023 Notes. However, the 2025 Notes and the 2038 Notes must be repurchased with cash. If we do not have sufficient resources at the time these obligations are due, we may be required to borrow additional funds or sell additional equity to meet these obligations, but there can be no guarantee that we will be able to raise such capital at the appropriate time on favorable terms or at all. If we are unable to make our annual interest payments or repay any of our convertible notes when due, we will default on our 2023 Notes, the 2025 Notes and the 2038 Notes, permitting the note holders to declare the notes immediately due and payable. There can be no assurance that we will have sufficient capital resources to repay our convertible notes in the event that such a default right is triggered. In addition, if we elect to repurchase our 2023 Notes with our common stock in September 2008, our stockholders will experience dilution and our stock price may decline.

Risks Relating to Regulatory Matters

Starting in November 2008, generic competitors can challenge our patents by filing an ANDA or a 505(b)(2) NDA for a generic or a modified version of Tarceva and adversely affect our competitive position.

Separate and apart from the protection provided under the U.S. patent laws for Tarceva, it is also subject to the provisions of the Hatch-Waxman Act which provides Tarceva with a five-year period of marketing exclusivity following FDA approval on November 18, 2004. The Hatch-Waxman Act prohibits the FDA from receiving an ANDA (for a generic product) or a 505(b)(2) NDA (for a modified version of the product) for such five-year period. A manufacturer who alleges that one or more of the patents listed in the FDA's Orange Book are invalid, unenforceable or not infringed need not wait five years, however, and may submit an ANDA or 505(b)(2) NDA for a generic or modified version of Tarceva four years into the exclusivity period (*i.e.,* beginning on November 18, 2008). This patent challenge is commonly known as a Paragraph IV certification. Within the past several years, the generic industry has aggressively pursued approvals of generic versions of innovator drugs at the earliest possible point in time. Accordingly, it is likely that an ANDA or 505(b)(2) NDA filing and Paragraph IV certification for a generic version of Tarceva will be made on or soon after November 18, 2008.

In response to a Paragraph IV certification, we will need to initiate a patent infringement action against the generic filer within 45 days following receipt of notice of the Paragraph IV certification in order to enforce our rights in the Tarceva patents. Patent litigation is complex, time-consuming and expensive and, as the outcome of any litigation proceeding is difficult to predict, there is no assurance that we will prevail in such an action. If we initiate an infringement suit within 45 days of receiving the Paragraph IV certification, the FDA cannot approve the ANDA or 505(b)(2) NDA for 30 months from the date of our receipt of the Paragraph IV certification. In addition, if such patent infringement action is so commenced within such 45-day period and occurs during the one-year period beginning on the fourth anniversary of the commencement of Tarceva's marketing exclusivity period, the 30-month period is extended by an amount of time such that the FDA cannot approve the ANDA until seven and one-half years have elapsed from the date of Tarceva's initial approval (i.e., May 18, 2012). This period of protection, referred to as the statutory litigation stay period, may end early, however, if we lose the patent infringement case (*i.e.,* the court finds the patent invalid, unenforceable or not infringed), or if we fail to reasonably cooperate in expediting the litigation, and a generic or modified version of Tarceva could come to market soon after expiration of the five-year exclusivity period. Moreover, if we fail to sue within 45 days, we will not enjoy the protection of the statutory litigation stay and the FDA may approve the ANDA or 505(b)(2) NDA whenever the requirements for approval are met after the expiration of the five-year exclusivity period. Additionally, following the conclusion of the statutory litigation stay period or earlier date due to a loss of the statutory litigation stay protection, if the ANDA or 505(b)(2) NDA filing has been approved, a generic company may choose to launch a generic version of Tarceva notwithstanding the pendency of our infringement action or any appeal. This is referred to as an at-risk launch and, in another example of the aggressive strategy pursued by generic companies, has occurred more frequently in the last few years. Any launch of a generic version of Tarceva prior to the expiration of patent protection, whether as a result of the loss of the patent infringement litigation or due to an at-risk launch, will have a material adverse effect on our revenues for Tarceva and our results of operations.

The manufacture and packaging of pharmaceutical products, such as Tarceva, are subject to the requirements of the FDA and similar foreign regulatory bodies. If we or our third party manufacturers fail to satisfy these requirements, our or their product development and commercialization efforts may be materially harmed.

The manufacture and packaging of pharmaceutical products, such as Tarceva and our future product candidates, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's cGMPs and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these current good manufacturing practices regulations who are both capable of manufacturing our products, and willing to do so. Our failure or the failure of our third party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us or them, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. We cannot be certain that we or our present or future suppliers will be able to comply with the pharmaceutical cGMP regulations or other FDA regulatory requirements. If we fail to meet our manufacturing obligations for Tarceva, our collaborator, Genentech, has the contractual right to take over the supply of Tarceva in the United States.

Changes in the manufacturing process or procedure, including a change in the location where a product is manufactured or a change of a third party manufacturer, require prior FDA review and/or approval of the manufacturing process and procedures in accordance with the FDA's cGMPs. This review may be costly and time consuming and could delay or prevent the launch of a product or the use of a facility to manufacture a product. In addition, if we elect to manufacture products at the facility of another third party, we will need to ensure that the new facility and the manufacturing process are in substantial compliance with cGMPs. Any such change in facility would be subject to a

pre-approval inspection by the FDA and the FDA would require us to demonstrate product comparability. Foreign regulatory agencies have similar requirements.

Any prolonged interruption in the operations of our contractor's manufacturing facilities could result in cancellations of shipments, loss of product in the process of being manufactured, or a shortfall or stock-out of available product inventory, any of which could have a material adverse impact on our business. A number of factors could cause prolonged interruptions in manufacturing.

In addition, the U.S. federal government and several states impose drug pedigree law requirements designed to record the chain of custody of prescription drugs. Compliance with these pedigree laws may require implementation of tracking systems as well as increased documentation and coordination with our customers. For example, effective January 1, 2009, California will require that we implement costly electronic track and trace technology to record the chain of custody of Tarceva while in our control. Although there may be changes in these requirements and government enforcement may vary, failure to comply could result in fines or penalties, as well as supply disruptions that could have a material adverse effect on our business.

The FDA and similar foreign regulatory bodies may also implement new standards, or change their interpretation and enforcement of existing standards and requirements, for manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory, civil actions or penalties which could significantly and adversely affect our business.

If government agencies do not grant us or our collaborative partners required approvals for any of our potential products in a timely manner or at all, we or our collaborative partners will not be able to distribute or sell our products currently under development.

All of our potential products must undergo extensive regulatory approval processes in the United States and other countries. These regulatory processes, which include pre-clinical testing and clinical trials of each compound to establish safety and efficacy, can take many years and require the expenditure of substantial resources. The FDA and the other regulatory agencies in additional markets which are material to us and our collaborative partners, including the European Agency for the Evaluation of Medicinal Products and the Japanese Ministry of Health, may delay or deny the approval of our potential products. Although we have been successful in gaining regulatory approval for Tarceva in the United States and our collaboration partners have gained approval for Tarceva in Canada, Japan, the EU and a number of other territories, there can be no guarantee of subsequent approvals for Tarceva in other territories or for other indications in the United States or for other products in the United States and other territories.

Delays or rejections may be encountered during any stage of the regulatory process based upon the failure of the clinical data to demonstrate compliance with, or upon the failure of the product to meet, a regulatory agency's requirements for safety, efficacy and quality. Any such delay could have a negative effect on our business. A drug candidate cannot be marketed in the United States until it has been approved by the FDA. Once approved, drugs, as well as their manufacturers, are subject to continuing and ongoing review, and discovery of previously unknown problems with these products or the failure to adhere to manufacturing or quality control requirements may result in restrictions on their distribution, sale or use, or their withdrawal from the market. The FDA also has the authority, when approving a product, to impose significant limitations on the product in the nature of warnings, precautions and contraindications, or restrictions on the indicated use, conditions for use, labeling, advertising, promotion, marketing, distribution, and/or production of the product that could negatively affect the profitability of a drug. Failure to comply with a Phase IV commitment can lead to FDA action either to withdraw approval of a drug or to limit the scope of approval.

Furthermore, once a drug is approved, it remains subject to ongoing FDA regulation. For example, the recently enacted Food and Drug Administration Amendments Act of 2007 provides the FDA with expanded authority over drug

products after approval. This legislation enhances the FDA's authority with respect to post-marketing safety surveillance, including, among other things, the authority to require: (i) additional post-approval studies or clinical trials; (ii) the submission of a proposed risk evaluation and mitigation strategy; and (iii) label changes as a result of safety findings. These requirements may affect our ability to maintain marketing approval of our products or require us to make significant expenditures to obtain or maintain such approvals. This new law also enhances FDA's enforcement authority, as well as civil and criminal penalties for violations.

Approved drugs may be marketed only for the indications and claims approved by the FDA. If we fail to comply with the FDA regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained, the FDA, the Office of the Inspector General of the U.S. Department of Health and Human Services, the Department of Justice, or state Attorney Generals could bring an enforcement action against us that would inhibit our marketing capabilities as well as result in significant penalties. Additional post-approval regulation by the FDA includes changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians or a product recall.

The current regulatory framework could change or additional regulations could arise at any stage during our product development or marketing, which may affect our ability to obtain or maintain approval of our products or require us to make significant expenditures to obtain or maintain such approvals. The ability to market and sell a drug product outside of the United States is also subject to stringent and, in some cases, equally complex regulatory processes that vary depending on the jurisdiction.

Some of our activities may subject us to risks under federal and state laws prohibiting "kickbacks" and false or fraudulent claims, which could subject us to potential civil and criminal penalties and exclusion from federal healthcare programs.

We are subject to the provisions of a federal law commonly known as the Federal Health Care Programs' anti-kickback law, and several similar state laws, which prohibit, among other things, payments intended to induce physicians or others either to purchase or arrange for, or recommend the purchase of, healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws may apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of drugs such as us, by limiting the kinds of financial arrangements, including sales programs, manufacturers have with hospitals, physicians, and other potential purchasers or prescribers of drugs. Other federal and state laws generally prohibit individuals or entities from knowingly and willfully presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial, including the possibility of imprisonment, fines, and exclusion from federal healthcare programs (including Medicare and Medicaid).

Pharmaceutical companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting violations of the federal False Claims Act, the federal health care programs' anti-kickback statute, and other violations in connection with off-label promotion of products and Medicare and/or Medicaid reimbursement, or related to claims under state laws, including state anti-kickback and false claims laws. While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices is ever evolving and even an unsuccessful challenge could cause adverse publicity and be costly to respond to.

If we do not receive adequate third-party reimbursement for the sales of our marketed products, we may not be able to sell such products on a profitable basis.

Sales of our marketed products depend, in part, upon the extent to which the costs of our products are paid by health maintenance organizations, managed care, pharmacy benefit and similar reimbursement sources, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Such third-party payors continue to aggressively challenge the prices charged for healthcare products and services. Additionally, federal and state governments have prioritized the containment of healthcare costs, and drug prices have been targeted in this effort. If these organizations and third-party payors do not consider our products to be cost-effective, they may not reimburse providers of our products, or the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

Beginning January 1, 2006, Medicare beneficiaries could obtain expanded prescription drug coverage through a new Medicare drug benefit that is administered by private, Medicare-approved drug plans. This voluntary benefit allows beneficiaries to choose among various Medicare prescription drug plans based on cost and scope of coverage. Generally, such plans include Tarceva within the scope of the plan, with beneficiaries having to pay various amounts of copayments when obtaining Tarceva. Since plans adjust their formularies on an annual basis, we cannot provide assurance that Tarceva will continue to be included in the same number of plans, and this could adversely affect our revenues. In addition, new legislation may be proposed that could change the Medicare prescription drug benefit and affect the payments for Tarceva under the program.

Government involvement and/or control over pricing of pharmaceutical products outside of the United States can have an effect on the revenues that we receive from Tarceva.

In some foreign countries, particularly Canada and the EU countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies. In most countries within Europe, individual governments determine the pricing of medicines, which can result in wide variations for the same product, and member states of the EU may impose new or additional cost-containment measures for drug products. Indeed, in recent years, price reductions and rebates have been mandated in several European countries, including Germany, Italy, Spain and the United Kingdom. Future mandatory price reductions in the EU or Japan could adversely impact our royalty revenues for Tarceva.

Future legislative or regulatory reform of the healthcare system may affect our ability to sell certain of our products profitably.

In both the United States and some non-U.S. jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell certain of our products profitably. In the United States, new legislation may be enacted at the federal and state levels that would result in significant changes to the healthcare system, either nationally or at the state level. For example, federal Medicare proposals, along with state Medicaid drug payment changes and healthcare reforms, could lower payments for our products or create financial disincentives for plans to provide access to Tarceva. Further, some states have proposed health care reform legislation requiring greater price reductions and narrowing coverage for drugs, which could impact our products. Additionally, these proposals or separate state and federal proposals could increase the costs of doing business in their respective jurisdictions. If future legislative or regulatory changes were to reduce reimbursement or make reimbursement unavailable, it would adversely affect our business.

If Tarceva is imported into the United States, the EU or Japan from countries where the cost of the drug is lower, it will affect our sales and profitability and harm our business.

Our revenues for Tarceva will be adversely impacted if we face competition in the United States, the EU or Japan from lower priced imports from countries where government price controls or other market dynamics have resulted in lower price for Tarceva. The ability of patients and other customers to obtain these lower priced imports has grown significantly as a result of the Internet, an expansion of pharmacies which specifically target purchasers in countries where drug costs are higher and other factors. Many of these foreign imports are illegal under current law. However, the volume of imports continues to rise due to the limited enforcement resources of U.S. and foreign regulatory and customs authorities, and political pressure in the United States, the EU and Japan to permit the imports as a mechanism for expanding access to lower priced medicines.

In the United States, in December 2003, federal legislation was enacted to modify U.S. import laws and expand the ability for lower priced pharmaceutical products to be imported from Canada, where government price controls have been enacted. These changes to the import laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The current Secretary of Health and Human Services has indicated that there is not a basis to make such a certification at this time. However, it is possible that this Secretary, or a subsequent Secretary, could make such a certification in the future. In addition, legislation has been proposed to implement the changes to the import laws without any requirement for certification from the Secretary of Health and Human Services, and to broaden permissible imports in other ways. Even if these changes to the import laws do not take effect, and other changes are not enacted, lower priced imports of products from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the U.S. Customs Service and other government agencies. For example, state and local governments have suggested that they may import drugs from Canada for employees covered by state health plans or others, and some have already enacted such plans.

In Europe, the importation of pharmaceutical products from countries where prices are low to those where prices for those products are higher, known as parallel trade, may increase. Parallel trade occurs because third parties can exploit the price differential by purchasing drug products in markets where low prices apply and selling them to state authorities and other purchasers in those markets where drugs can be sold at higher prices. There are indications that parallel trade is affecting markets in the EU, and the recent addition of countries from central and eastern Europe to the EU could result in significant increases in the parallel trading of drug products in that region.

Lower priced imports will adversely affect our sales and profitability. This impact could become more significant in the future, and the impact could be even greater if there is a further change in the law or if state or local governments take further steps to permit lower priced imports from abroad.

Risks Related to Intellectual Property and Legal Matters

If we cannot successfully protect, exploit or enforce our intellectual property rights, our ability to develop and commercialize our products, and receive revenues from licenses under our intellectual property, will be adversely affected.

We hold numerous U.S. and foreign patents as well as trademarks and trade secrets; we also have many pending applications for additional patents. We intend to continue to seek patent protection for, or maintain as trade secrets, the potentially valuable intellectual property arising from our research and development activities, including commercially promising product candidates that we have discovered, developed or acquired. Our success depends, in part, on our ability and our collaborative partners' ability to obtain and maintain patent protection for new product candidates, maintain trade secret protection and operate without infringing the valid and enforceable proprietary rights of third parties. As with most biotechnology and pharmaceutical companies, our patent position is highly uncertain and

involves complex legal and factual questions. Without patent and other similar protection, other companies could offer the same or substantially identical products for sale without incurring the sizeable discovery and development costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished. The process of obtaining patents can be time-consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent may not issue or it may insufficiently protect the technology it was intended to protect. Even if issued, such issuance is not conclusive as to a patent's validity or its enforceability.

Our patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to prevent or stop competitors from marketing similar products or may limit the length of term of patent protection we may have for our products. Specifically, a patent corresponding to the U.S. composition of matter patent for Tarceva was granted in February 2007 in India and survived a pre-grant opposition by Natco Pharma, Ltd. of Mumbai, India in July 2007. We, with our collaborator Roche, are currently seeking to enforce this patent against CIPLA of Mumbai, India, with respect to a generic form of Tarceva launched by CIPLA in India. A lawsuit was filed in India on January 15, 2008, a hearing for preliminary injunction concluded January 31, 2008 and we are awaiting the outcome of the hearing. In addition, Teva Pharmaceuticals filed an opposition to the grant of a patent in Israel corresponding to our U.S. patent directed to a particular polymorph of Tarceva (U.S. Patent No. 6,900,221) in August 2007. This Israeli proceeding will be delayed until prosecution of a co-pending patent application in Israel is completed. If we are unsuccessful in enforcing or defending our patents in either of these proceedings and the patents are revoked without possibility of appeal in India and/or Israel, this could reduce our future potential royalty revenue from sales of Tarceva in these countries and increase the possibility that generic Tarceva will be unlawfully distributed and/or sold into countries where we have patent exclusivity.

In addition, our patent which relates to the use of DPIV inhibitors for lowering blood glucose levels was revoked by the European Patent Office in opposition proceedings in May 2004. We have appealed the revocation of our patent by the European Patent Office, and a hearing date for the appeal has been set for March 2008. If we are unsuccessful in our appeal and the patent is revoked without possibility of appeal, this will reduce the potential royalty revenue we derive from the non-exclusive licenses we have granted under the patent in those territories where it is revoked.

We can never be certain that we were first to develop the technology or that we were first to file a patent application for the particular technology because most U.S. patent applications are confidential until a patent publishes or issues, and publications in the scientific or patent literature lag behind actual discoveries. If our pending patent applications are not approved for any reason or if we are unable to receive patent protection for additional proprietary technologies that we develop, the degree of future protection for our proprietary rights will remain uncertain. Third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our pending or issued patents. Furthermore, the laws of foreign countries may not protect our intellectual property rights effectively or to the same extent as the laws of the United States. In addition, some countries do not offer patent protection for certain biotechnology-related inventions. If our intellectual property rights are not adequately protected, we may not be able to commercialize our technologies, products or services and our competitors could commercialize our technologies, which could result in a decrease in our sales and market share that would harm our business and operating results.

We are also party to licenses that give us rights to third-party intellectual property that may be necessary or useful to our business. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce our licensed intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we have licenses. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially

identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

If we or our collaborative partners are required to obtain licenses from third parties, our revenues and royalties on any commercialized products could be reduced.

The development of some of our products may require the use of technology developed by third parties. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which we or our collaborative partners will be forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our collaborative partners must obtain licenses from third parties, fees must be paid for such licenses, which would reduce the revenues and royalties we may receive on commercialized products.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be negatively impacted.

In addition to patented technology, we rely upon unpatented proprietary technology, trade secrets, processes, and know-how. We seek to protect this information in part by entering into confidentiality agreements with our employees, consultants and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

Our U.S. patents may be adversely affected by changes to patent-related U.S. statutes and the rules of the U.S. patent and trademark office.

The portfolio management strategy of our U.S. patents and pending patent applications may be adversely affected by proposed changes to patent-related U.S. statutes and to USPTO rules, especially changes to rules concerning the filing of continuation applications. The proposed USPTO rules were scheduled to go into effect on November 1, 2007, but were enjoined pursuant to an order issued on October 31, 2007 by the United States District Court for the Eastern District of Virginia. This injunction is expected to remain in effect until final judgment on the matter or as otherwise directed by the court. If implemented, the rules would limit to two the number of continuing applications that an applicant may file as a matter of right. The rules would also require that beyond such continuing applications, subsequent continuing application filings must be supported by a petition and a showing as to why the new amendments, claims, arguments or evidence presented could not have been previously submitted. An applicant may also file only one request for continued examination. Other proposed rules, if implemented, could limit the number of claims that we can include in a patent application to only five independent and 25 total claims per application, without submission of a document including a search and explanation of related patents and literature. The implementation of these rules will require significant changes in patent strategy and portfolio management in order to adequately protect our products in development and may result in less certainty with regard to the potential future value of our intellectual property assets.

The failure to prevail in litigation or the costs of litigation, including patent infringement claims, could harm our financial performance and business operations and could cause delays in product introductions.

We are susceptible to litigation. For example, as a public company, we are subject to claims asserting violations of securities laws and derivative actions. In particular, we currently face a securities class action filed in United States District Court for the Eastern District of New York alleging violations of securities laws which are described under Item 3 below, "Legal Proceedings." While the parties to this class action lawsuit have informed the Court that they have reached an agreement in principle to settle this action, the parties are still in the process of finalizing the settlement papers, which will then be subject to Court approval. In addition, as a biotechnology company, our processes and potential products may conflict with patents that have been or may be granted to competitors,

academic institutions or others. We cannot ensure that our products or methods do not infringe upon the patents or other intellectual property rights of third parties. As the biotechnology and pharmaceutical industries expand and more patents are filed and issued, the risk increases that our patents or patent applications for our product candidates may give rise to a declaration of interference by the USPTO, or to administrative proceedings in foreign patent offices, or that our activities lead to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal proceedings against us seeking substantial damages or seeking to enjoin us from researching, developing, manufacturing or marketing our products, which could result in substantial costs and harm our reputation. If any of these actions are successful, we may not only be required to pay substantial damages for past use of the asserted intellectual property but we may also be required to cease the infringing activity or obtain the requisite licenses or rights to use the technology, that may not be available to us on acceptable terms, if at all. Litigation and other proceedings may also absorb significant management time.

Litigation is inherently unpredictable and we may incur substantial expense in defending ourselves or asserting our rights in the litigation to which we are currently subject, or in new lawsuits or claims brought against us. Litigation can be expensive to defend, regardless of whether a claim has merit, and the defense of such actions may divert the attention of our management that would otherwise be engaged in running our business and utilize resources that would otherwise be used for the business. In the event of an adverse determination in a lawsuit or proceeding, or our failure to license essential technology, our sales could be harmed and/or our costs increase, which would harm our financial condition and our stock price may decline. While we currently maintain insurance that we believe is adequate, we are subject to the risk that our insurance will not be sufficient to cover claims.

The use of any of our potential products in clinical trials and the sale of any approved products exposes us to liability claims.

The nature of our business exposes us to potential liability risks inherent in the research, development, manufacturing and marketing of drug candidates and products. If any of our drug candidates in clinical trials or our marketed products harm people or allegedly harm people, we may be subject to costly and damaging product liability claims. Many patients who participate in clinical trials are already ill when they enter a trial. The waivers we obtain may not be enforceable and may not protect us from liability or the costs of product liability litigation. While we currently maintain product liability insurance that we believe is adequate, we are subject to the risk that our insurance will not be sufficient to cover claims. There is also a risk that adequate insurance coverage will not be available in the future on commercially reasonable terms, if at all. The successful assertion of an uninsured product liability or other claim against us could cause us to incur significant expenses to pay such a claim, could adversely affect our product development and could cause a decline in our product revenues. Even a successfully defended product liability claim could cause us to incur significant expenses to defend such a claim, could adversely affect our product development and could cause a decline in our product revenues.

Risks Related to Our Common Stock

Our stock price remains highly volatile which could make it difficult for our stockholders to resell our common stock.

If our stock price falls, our stockholders may not be able to sell their stock when desired or at desirable prices. When the stock prices of companies in the NASDAQ Biotechnology Index fall, our stock price will most likely fall as well. The stock price of biotechnology and pharmaceutical companies, including our stock price, has been volatile and may remain volatile for the foreseeable future.

The following factors, among others, some of which are beyond our control, may also cause our stock price to decline:

- a decline in sales of Tarceva;
- a decline in our business operating results or prospects;
- a general economic slowdown in the United States or the key international markets where Tarceva is sold;
- adverse events with respect to our intellectual property;
- announcement or launching of technological innovations or new therapeutic products by third parties;
- positive or negative clinical efficacy or safety results from our competitors' products;
- public concern as to the safety, or withdrawal, of our products and potential products;
- comments by securities analysts regarding us or our competitors and general market conditions;
- future sales of substantial amounts of our common stock by us or existing stockholders;
- negative developments concerning strategic alliance agreements;
- changes in government regulation, including pricing controls, that impact our products;
- negative or neutral clinical trial results, including clinical trial results for additional indications for Tarceva;
- delays with the FDA in the approval process for products and clinical candidates; and
- developments in laws or regulations that impact our patent or other proprietary rights.

Our governance documents and state law provide certain anti-takeover measures which will discourage a third party from seeking to acquire us and may impede the ability of stockholders to remove and replace our board of directors and, therefore, our management.

We have had a shareholder rights plan, commonly referred to as a "poison pill," since January 1999. The purpose of the shareholder rights plan is to protect stockholders against unsolicited attempts to acquire control of us that do not offer a fair price to our stockholders as determined by our board of directors. Under the plan, the acquisition of 17.5% or more of our outstanding common stock by any person or group, unless approved by our board of directors, will trigger the right of our stockholders (other than the acquiror of 17.5% or more of our common stock) to acquire additional shares of our common stock, and, in certain cases, the stock of the potential acquiror, at a 50% discount to market price, thus significantly increasing the acquisition cost to a potential acquiror.

The shareholder rights plan may have the effect of dissuading a potential hostile acquiror from making an offer for our common stock at a price that represents a premium to the then-current trading price. In addition, our certificate of incorporation and by-laws contain certain additional anti-takeover protective devices. For example,

- no stockholder action may be taken without a meeting, without prior notice and without a vote; solicitations by consent are thus prohibited;
- special meetings of stockholders may be called only by our board of directors, or by our stockholders holding 20% of our outstanding shares upon 90 days prior written notice;
- nominations by stockholders of candidates for election to the board of directors at our annual meeting of stockholders must be made at least 45 days prior to the anniversary of the date on which we first mailed our proxy materials for the prior year's annual meeting of stockholders; and
- our board of directors has the authority, without further action by the stockholders, to fix the rights and preferences, and issue shares, of preferred stock. An issuance of preferred stock with dividend and liquidation

rights senior to the common stock and convertible into a large number of shares of common stock could prevent a potential acquiror from gaining effective economic or voting control.

Further, we are subject to Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, restricts certain transactions and business combinations between a corporation and a stockholder owning 15% or more of the corporation's outstanding voting stock for a period of three years from the date the stockholder becomes a 15% stockholder. In addition to discouraging a third party from acquiring control of us, the foregoing provisions could impair the ability of existing stockholders to remove and replace our management and/or our board of directors.

ITEM 1B. UNRESOLVED STAFF COMMENTS

There are no unresolved staff comments.

ITEM 2. PROPERTIES

The following is a summary of the principal facilities which we utilize in our operations:

Melville, New York. We own a facility at 41 Pinelawn Road, Melville, New York, consisting of approximately 60,000 square feet. The facility houses our principal executive, oncology, finance, legal and administrative offices.

Farmingdale, New York. We lease a facility at One BioScience Park Drive, Farmingdale, New York, consisting of approximately 53,000 square feet. Our Farmingdale facility contains our drug discovery laboratories for oncology.

Cedar Knolls, New Jersey. We lease a facility at 140 Hanover Avenue, Cedar Knolls, New Jersey, consisting of approximately 25,000 square feet. Our Cedar Knolls facility contains certain of our regulatory, quality control and drug development operations for oncology and eye disease.

Boulder, Colorado. We lease two facilities in Boulder, Colorado, which together house our clinical and pre-clinical research, regulatory and drug development operations for oncology. One facility is located at 2860 Wilderness Place, and consists of approximately 60,000 square feet and the other one is located at 2970 Wilderness Place, and consists of approximately 29,000 square feet.

Oxford, England. We lease a facility at Windrush Court, Watlington Road, Oxford, England, consisting of approximately 88,000 square feet. This facility houses our diabetes and obesity corporate, research and development operations, as well as certain oncology development operations.

ITEM 3. LEGAL PROCEEDINGS

On or about December 16, 2004, several purported shareholder class action lawsuits were filed in the United States District Court for the Eastern District of New York against our company, certain of our current and former executive officers, and the members of our Board of Directors. The lawsuits were brought on behalf of those who purchased or otherwise acquired our company's common stock during certain periods in 2004, which periods differed in the various complaints. The Court appointed a lead plaintiff who, on February 17, 2006, filed a consolidated amended class action complaint seeking to represent a class of all persons who purchased or otherwise acquired our company's common stock during the period from April 26, 2004 through November 22, 2004. The consolidated complaint alleges that the defendants made material misstatements and omissions concerning the survival benefit associated with our company's product, Tarceva, and the size of the potential market of Tarceva upon FDA approval of the drug. It alleges violations of Sections 11 and 15 of the Securities Act of 1933, as amended, and Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The consolidated complaint seeks unspecified compensatory damages and other relief. On April 7, 2006, we filed a motion to dismiss the consolidated amended complaint. Briefing on this motion was completed on June 21, 2006. In an opinion dated March 31, 2007 (and entered on the docket on April 4, 2007), the Court granted in part and denied in part the motion to

dismiss. The Court dismissed claims against some of the individual defendants and dismissed the Section 11 and 15 claims, but granted the plaintiff 30 days leave to replead the Section 11 claim in accordance with the Court's order and to renew the Section 15 claim. The plaintiff did not amend, and thus those claims were dismissed with prejudice. The parties have now informed the Court that they have reached an agreement in principle to settle this action. The parties are in the process of finalizing the settlement papers, which will then be subject to Court approval.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of our security holders during the fourth quarter of fiscal 2007.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded in the over-the-counter market and is included for quotation on the NASDAQ National Market under the symbol OSIP. The following is the range of high and low sales prices by quarter for our common stock from January 1, 2006 through December 31, 2007 as reported on the NASDAQ National Market:

2007 FISCAL YEAR	HIGH	LOW
First Quarter	$36.89	$30.94
Second Quarter	38.37	33.09
Third Quarter	36.60	28.68
Fourth Quarter	52.00	33.27

2006 FISCAL YEAR	HIGH	LOW
First Quarter	$33.42	$26.50
Second Quarter	33.98	25.02
Third Quarter	38.17	30.17
Fourth Quarter	43.17	34.29

Holders and Dividends

As of February 21, 2008, there were approximately 2,712 holders of record of our common stock. We have not paid any cash dividends since inception and we do not intend to pay any cash dividends in the foreseeable future. Declaration of dividends will depend, among other things, upon future earnings, our operating and financial condition, our capital requirements and general business conditions.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information as of December 31, 2007

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(a)	Weighted-average exercise price of outstanding options, warrants and rights(b)	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	6,078,524(c)	$32.76	6,789,825(e)
Equity compensation plans not approved by security holders	413,735(d)	$41.60	—
Total	6,492,259	$33.32	6,789,825

a) Includes stock options, restricted stock, restricted stock units and deferred stock units.

b) The weighted-average exercise price of outstanding options, warrants and rights does not include restricted stock, restricted stock units and deferred stock units, as they are issued for no cash consideration.

c) Consists of four plans: the 1989 Incentive and Non-Qualified Stock Option Plan, the 1997 Incentive and Non-Qualified Stock Option Plan, the 1999 Incentive and Non-Qualified Stock Option Plan and the Amended and Restated Stock Incentive Plan.

d) In connection with the acquisition of certain oncology assets from Gilead Sciences, Inc. on December 21, 2001, we adopted a Non-Qualified Stock Option Plan for Former Employees of Gilead Sciences, Inc. We granted ten-year options to purchase an aggregate of 693,582 shares of our common stock at a purchase price of $45.01 per share, which represented the fair value of our stock at the date granted. With respect to each option grant, one-third of the options vested on the first anniversary of the date of grant and the remainder vested ratably monthly thereafter for 24 months.

In connection with the acquisition of Cadus in July 1999, we adopted a Non-Qualified Stock Option Plan for Former Employees of Cadus Pharmaceutical Corporation. We granted ten-year options to purchase an aggregate of 415,000 shares of our common stock at a purchase price of $5.00 per share, which represented the fair value of our stock at the date granted. These options became exercisable on July 30, 2000, one year from the date of the grant.

In connection with the acquisition of Eyetech Pharmaceuticals, Inc., or Eyetech, in November 2005, we adopted a Stock Incentive Plan for Pre-Merger Employees of Eyetech Pharmaceuticals, Inc. We granted seven-year options to purchase an aggregate of 625,810 shares of our common stock at a purchase price of $23.83, which represents the fair value of our stock at the date granted. With respect to each option grant, one-fourth of the options vested on the first anniversary and the remainder vest ratably thereafter on a monthly basis for 36 months.

Also in connection with the acquisition of Eyetech, we assumed Eyetech's 2001 Stock Plan and to facilitate such assumption, we adopted the Stock Plan for Assumed Options of Pre-Merger Employees of Eyetech Pharmaceuticals, Inc. The number of shares subject to each assumed option was determined by dividing the assumed Eyetech per share option exercise price by the conversion ratio of 0.491 and rounding that result down to the nearest whole number for a total of 153,290 shares. The exercise price was determined by dividing the assumed Eyetech per share option exercise price by the conversion ratio of 0.491 and rounding up to the nearest whole cent.

Includes options established for certain outside consultants related to clinical trial operations.

e) Consists of 378,823 shares reserved for issuance under the 1995 Employee Stock Purchase Plan and the stock purchase plan for our UK-based employees, and 6,411,002 shares reserved for issuance under the 1999 Incentive and Non-Qualified Stock Option Plan and the Amended and Restated Stock Incentive Plan.

We have a policy of rewarding employees who achieve 10, 15, and 20 years of continued service with our company with 100, 150, and 200 shares, respectively, of our common stock. We grant such shares of common stock on an annual basis to those individuals who meet the stated requirements.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Subsequent to the end of our 2004 fiscal year, we changed our fiscal year end to December 31st. On February 9, 2005, we filed a transition report on Form 10-QT for the three-month period ended December 31, 2004. The following table sets forth our selected consolidated financial data as of and for the years ended December 31, 2007, 2006 and 2005, the three months ended December 31, 2004, and the years ended September 30, 2004 and 2003. As a result of our decision to divest the eye disease business held by our wholly owned subsidiary, (OSI) Eyetech, Inc., the operating results for (OSI) Eyetech are shown as discontinued operations for all periods subsequent to our acquisition on November 14, 2005. The information below should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this report.

(In thousands, except per share data)	Year Ended December 31, 2007(a)	Year Ended December 31, 2006(b)	Year Ended December 31, 2005(c)	Three Months Ended December 31, 2004(d)	Year Ended September 30, 2004(e)	Year Ended September 30, 2003(f)
Consolidated Statement of Operations Data:						
Revenues	$341,030	$ 241,037	$ 138,423	$ 12,347	$ 42,800	$ 32,369
Expenses:						
Cost of goods sold	9,399	8,671	5,035	(1,247)	8,985	157
Net expense — unconsolidated joint business	—	—	—	7,661	—	—
Research and development	123,531	117,527	116,655	31,913	110,398	102,642
Acquired in-process research and development	9,664	—	3,542	—	32,785	31,451
Selling, general and administrative	99,159	107,458	89,205	20,313	98,909	70,532
Impairment of intangible assets	—	—	—	—	24,599	—
Amortization of intangibles	1,840	1,809	15,281	3,804	18,606	9,300
Income (loss) from operations	97,437	5,572	(91,295)	(50,097)	(251,482)	(181,713)
Other income (expense) — net	7,902	1,128	6,201	1,702	(8,889)	356
Income (loss) from continuing operations before income taxes	105,339	6,700	(85,094)	(48,395)	(260,371)	(181,357)
Income tax provision	(2,732)	—	—	—	—	—
Net income (loss) from continuing operations	102,607	6,700	(85,094)	(48,395)	(260,371)	(181,357)
Loss from discontinued operations — net of tax	(36,288)	(610,930)	(72,029)	—	—	—
Net income (loss) before extraordinary gain	66,319	(604,230)	(157,123)	(48,395)	(260,371)	(181,357)
Extraordinary gain — net of tax	—	22,046	—	—	—	—
Net income (loss)	$ 66,319	$(582,184)	$(157,123)	$(48,395)	$(260,371)	$(181,357)
Basic and diluted net earnings (loss) per common share:						
Basic earnings (loss):						
Income (loss) from continuing operations	$ 1.78	$ 0.12	$ (1.63)	$ (1.02)	$ (6.50)	$ (4.87)
Loss from discontinued operations — net of tax	(0.63)	(10.73)	(1.38)	—	—	—
Net income (loss) before extraordinary gain	1.15	(10.61)	(3.02)	(1.02)	(6.50)	(4.87)
Extraordinary gain — net of tax	—	0.39	—	—	—	—
Net income (loss)	$ 1.15	$ (10.22)	$ (3.02)	$ (1.02)	$ (6.50)	$ (4.87)
Diluted earnings (loss):						
Income (loss) from continuing operations	$ 1.70	$ 0.12	$ (1.63)	$ (1.02)	$ (6.50)	$ (4.87)
Loss from discontinued operations — net of tax	(0.58)	(10.60)	(1.38)	—	—	—
Net income (loss) before extraordinary gain	1.11	(10.48)	(3.02)	(1.02)	(6.50)	(4.87)
Extraordinary gain — net of tax	—	0.38	—	—	—	—
Net income (loss)	$ 1.11	$ (10.10)	$ (3.02)	$ (1.02)	$ (6.50)	$ (4.87)
Shares used in the calculation of income (loss) per common share:						
Basic	57,665	56,939	52,078	47,375	40,083	37,249
Diluted	62,241	57,645	52,078	47,375	40,083	37,249

(In thousands)	As of December 31, 2007(a)	2006(b)	2005(c)	2004(d)	As of September 30, 2004(e)	2003(f)
Consolidated Balance Sheet Data:						
Cash, cash equivalents and investment securities (unrestricted and restricted)	$305,098	$216,368	$ 179,606	$656,239	$257,229	$404,147
Receivables	87,523	80,075	152,482	14,077	12,112	11,654
Working capital	197,631	266,496	276,171	630,246	228,223	379,598
Total assets	558,380	457,732	1,058,582	780,116	388,029	591,502
Long-term liabilities	166,930	349,555	337,788	195,814	186,574	338,592
Stockholders' equity	138,956	28,594	578,466	539,390	154,233	218,057

(a) The calendar 2007 consolidated financial statements include a $9.7 million in-process research and development charge related to the payment made under our research collaboration with AVEO and the purchase of AdipoGenix intellectual property, and a $4.1 million gain, included in "Other income (expense) — net," related to our decision to curtail our post-retirement medical and life insurance plan. The 2023 Notes have been classified as current in the December 31, 2007 consolidated balance sheet.

(b) The calendar 2006 loss from discontinued operations includes $506.0 million of impairment charges related to (OSI) Eyetech goodwill and (OSI) Eyetech amortizable intangibles ($320.3 million and $185.7 million, respectively) and a $26.4 million charge for obsolete and expiring inventory. A $22.0 million extraordinary gain was recognized in the 2006 fiscal year as a result of reversing the accrued contingent consideration recorded in connection with the acquisition of Cell Pathways in the 2003 fiscal year.

(c) The calendar 2005 consolidated financial statements reflect: (a) the acquisition of Eyetech in November 2005 for aggregate consideration of $909.3 million ($637.4 million net of cash and investments acquired), including cash consideration of $702.1 million, the value of 5.6 million shares of our common stock issued to Eyetech shareholders, the value of converted stock options issued to Eyetech shareholders and transaction-related costs incurred; (b) an in-process R&D charge of $60.9 million related to the acquisition of Eyetech recorded as a loss from discontinued operations; (c) in-process R&D charges of $3.5 million related to the acquisition of the minority interest in Prosidion; and (d) the issuance of $115.0 million principle amount of our 2025 Notes in a private placement for net proceeds of $111.0 million, of which approximately $24.0 million was used to purchase, concurrently with the offering, 500,000 shares of our common stock and a call spread option with respect to our common stock.

(d) The three months ended December 31, 2004 includes: (a) the sale of 6.9 million shares of our common stock for net proceeds of $419.9 million; (b) net expense from unconsolidated joint business of $7.7 million related to our co-promotion and manufacturing agreements with Genentech for Tarceva; and (c) a net credit adjustment of $1.4 million to reduce a previously recorded provision for excess Gelclair® Bioadherent Oral Gel, or Gelclair, inventory.

(e) The fiscal 2004 consolidated financial statements include: (a) the acquisition of certain assets from Probiodrug for approximately $36.4 million in cash; (b) an impairment charge related to the Gelclair intangible asset of $24.6 million; (c) the conversion of $160.0 million aggregate principle amount of 4% convertible senior subordinated notes due 2009 into 3.2 million shares of our common stock; (d) the charge of $8.6 million relating to excess Gelclair inventory; and (e) the recognition of $3.0 million of Tarceva-related milestone revenues.

(f) The fiscal 2003 consolidated financial statements include: (a) the acquisition of the marketing and promotion rights to Novantrone for approved oncology indications in the United States for approximately $45.0 million in cash; (b) the acquisition of Cell Pathways for approximately $55.0 million in common stock, contingent value rights and cash; (c) the issuance of $150.0 million of our 2023 Notes for net proceeds of approximately $145.1 million; and (d) the repurchase of 503,800 shares of our common stock for $19.0 million.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a mid-cap biotechnology company committed to building a scientifically strong and financially successful top tier biopharmaceutical organization that discovers, develops and commercializes innovative molecular targeted therapies addressing major unmet medical needs in oncology, diabetes and obesity. In order to increase shareholder value, we must continue to grow our revenues and remain disciplined about our investments in R&D in an effort to achieve a higher rate of success than the biopharmaceutical industry average, while continuing to deliver strong financial performance.

2007 was our first full year of profitability — acheiving a three year goal we set when our flagship product, Tarceva, was approved for sale in the United States in November 2004. Tarceva, which is now approved for sale in 88 countries, is our primary source of revenue. We share 50% of the profits from U.S. sales of Tarceva (which are recorded by our collaborator for Tarceva, Genentech) and we receive royalties of approximately 20% on ex-U.S. sales of Tarceva by Roche, which is responsible for the marketing and sale of Tarceva outside of the United States. During 2007, we recorded approximately $268 million of Tarceva-related revenue, which represented approximately 79% of our total revenues. While this level of revenue resulted in substantial profitability for us in 2007, it remains critical to our future that Tarceva continue to grow on a worldwide basis. Tarceva's sales growth, especially in the United States where we retain approximately 47% of each new marginal sales dollar, results in additional earnings to us and, if achieved, would provide us the opportunity to make the necessary investments in our R&D portfolio in order to build a scientifically strong top-tier biopharmaceutical company. Oncology and diabetes/obesity research and development is an expensive and risky endeavor. We have a promising pipeline of early product candidates which we expect will require increasing levels of investment. However, we must continue to balance the need to invest in our pipeline with the need to deliver strong financial performance. Tarceva's continued growth, and our share of the resulting increased revenues, is critical for us to achieve this balance.

Tarceva's ability to grow in the future is dependent on a number of factors, including our and our collaborators' ability to expand market share for Tarceva both in the United States and the rest of the world, competitive developments in our industry and our ability to expand the approved indications for Tarceva by succeeding on key clinical trials. In the second half of 2008, we expect to receive data from two key label-expanding studies for Tarceva — SATURN, a Phase III study conducted by Roche to evaluate the efficacy of Tarceva as a maintenance therapy versus placebo, and Beta-Lung, a Phase III study conducted by Genentech to evaluate the efficacy of Avastin in combination with Tarceva as compared to Tarceva alone for the treatment of advanced NSCLC in the second line setting. This data, if positive, could result in label expansions for Tarceva, which, in turn, should drive future sales growth for Tarceva. The failure of these studies, coupled with success by our competitors, would result in a more limited role for Tarceva in the treatment of NSCLC and lower sales on a global basis.

Recognizing that we have limited resources, we have adopted a highly disciplined approach to research and development, prioritizing investment in a portfolio of differentiated and competitive drug candidates and technologies which we hope will enable us to deliver higher clinical success rates than the industry average. We have an emerging oncology pipeline of MTTs in clinical and late-stage pre-clinical development, which we intend to develop and commercialize independently in the United States and potentially other markets. These MTTs are small molecules designed to be administered orally as a tablet rather than by the less convenient intravenous infusion methods characteristic of many anti-cancer drugs. The focus of our proprietary oncology research efforts is the discovery and development of novel therapeutic agents that target the biological process of EMT, which is emerging significance in tumor development and disease progression. This research has grown out of our translational research efforts to understand which patients optimally benefit from Tarceva. We believe that our EMT research investment will allow us

to better design combinations of MTTs for specific sub-sets of cancer patients, which may allow us to improve patient outcomes, thereby enhancing our competitive position in the oncology marketplace.

We also have research and early development programs in diabetes and obesity which are conducted through Prosidion Limited, our U.K. subsidiary. Our research in diabetes and obesity is focused on novel targets where we believe that our expertise in chemistry will provide us with a competitive edge. The cost of investing in diabetes and obesity, including the cost of conducting the large Phase III clinical trials required to register these drugs for sale is significant and we will only be able to make these investments without a partner or collaborator if our revenues increases substantially. While we will ultimately need to select a partner with a global commercial infrastructure to help us commercialize our diabetes and obesity product candidates, we recognize that the longer we can maintain control of these product candidates from a development perspective, the greater the potential return to our shareholders will be, assuming we are successful.

Prosidion contributes an important second source of revenues to us from the licensing of our patent estate relating to the use of DPIV inhibitors for the treatment of type II diabetes and related indications. Twelve pharmaceutical companies have taken non-exclusive licenses to these patents, which provide us with upfront payments as well as potential milestones and royalties. During 2007, we earned approximately $35 million in revenue from this patent estate, including approximately $17 million in royalties. The royalty revenue from our DPIV patent estate has the potential to grow substantially over the next five years, assuming sales of licensed DPIV inhibitors continue on their current growth trajectory.

As we enter 2008, we are focused on delivering shareholder value by continuing the strong global growth of Tarceva, developing an innovative and differentiated research platform and pipeline while maintaining financial discipline around our R&D investments and controlling our spending on general and administrative expenses.

Critical Accounting Policies

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles. As such, we are required to make certain estimates, judgments and assumptions that we believe are reasonable based upon the information available. These estimates and assumptions affect the reported amounts of assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenues and expenses during the periods presented. Actual results could differ significantly from our estimates and the estimated amounts could differ significantly under different assumptions and conditions. We believe that the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and which require our most difficult and subjective judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Note 1 to the accompanying consolidated financial statements includes a summary of the significant accounting policies used in the preparation of the consolidated financial statements.

Revenue Recognition

Net Revenues from Unconsolidated Joint Business

Net revenues from unconsolidated joint business are related to our co-promotion and manufacturing agreements with Genentech for Tarceva. They consist of our share of the pretax co-promotion profit generated from our co-promotion arrangement with Genentech for Tarceva, the partial reimbursement from Genentech of our sales and marketing costs related to Tarceva and the reimbursement from Genentech of our manufacturing costs related to Tarceva. Under the co-promotion arrangement, all U.S. sales of Tarceva and associated costs and expenses, except for a portion of our sales related costs, are recognized by Genentech. We record our 50% share of the co-promotion pretax profit on a quarterly basis, as set forth in our agreement with Genentech. Pretax co-promotion profit under the co-promotion arrangement is derived by calculating U.S. net sales of Tarceva to third-party customers and deducting

costs of sales, distribution and selling and marketing expenses incurred by Genentech and us. The net sales recorded and costs incurred during the respective periods include estimates by both parties. If actual future results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of adjustment. We do not believe that these adjustments, if any, will be significant to our future results of operations. The reimbursement of sales and marketing costs related to Tarceva is recognized as revenue as the related costs are incurred. We defer the recognition of the reimbursement of our manufacturing costs related to Tarceva until the time Genentech ships the product to third-party customers at which time our risk of inventory loss no longer exists.

License Fees and Milestones

Our revenue recognition policies for all nonrefundable upfront license fees and milestone arrangements are in accordance with the guidance provided in the Securities and Exchange Commission, or SEC, Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," as amended by SEC Staff Accounting Bulletin No. 104, "Revenue Recognition." In addition, we follow the provisions of Emerging Issues Task Force Issue, or EITF 00-21, "Revenue Arrangements with Multiple Deliverables" for multiple element revenue arrangements entered into or materially amended after June 30, 2003. As a result of an amendment to our collaboration agreement with Genentech in June 2004, milestone payments received from Genentech after June 2004 and the remaining portion of the unearned upfront fee are being recognized in accordance with EITF 00-21.

Milestones received from Genentech after June 2004 and the remaining unearned upfront fee are being recognized over the term of our Manufacturing and Supply Agreement with Genentech, under which the last items of performance to be delivered to Genentech are set forth, on a straight line basis, which approximates the expected level of performance under the Manufacturing and Supply Agreement. In March 2005, we agreed to a further global development plan and budget with our partners, Genentech and Roche, for the continued development of Tarceva. For purposes of EITF 00-21, the revised development plan and budget for Tarceva was deemed a material amendment to our Roche agreement and therefore future milestones received from Roche will be recognized in accordance with EITF 00-21. Accordingly, milestone payments received from Roche after March 2005 have been, or will be initially recorded as unearned revenue and recognized over the expected term of the research collaboration on a straight-line basis, which approximates the expected level of performance under the development plan.

In January 2007, we licensed our glucokinase activator program, including our clinical candidate PSN010, to Eli Lilly for an upfront fee of $25.0 million and up to $360.0 million in potential development and sales milestones and other payments, plus royalties on any compounds successfully commercialized from this program. We deferred the initial recognition of the $25.0 million upfront fee based upon our obligation under the agreement to provide technical support during a transitional period of nine months from the date of execution. For the year ended December 31, 2007, we recognized all $25.0 million of the upfront fee.

Discontinued Operations

On November 6, 2006, we announced our intention to divest our eye disease business, a process which we expect to complete in 2008. During the first quarter of 2007, we finalized our exit plan and began to actively market our eye disease business assets. As discussed in Note 20 to the accompanying consolidated financial statements, as a result of the finalization of our plan to sell the business during the first quarter of 2007, in accordance with the provision of Statement of Financial Accounting Standards, or SFAS, No. 144 "Accounting for the Impairment or Disposal of Long Lived Assets," the results of operations of (OSI) Eyetech, Inc. for the current and prior period have been reported as discontinued operations. In addition, assets and liabilities of (OSI) Eyetech have been classified as assets and liabilities related to discontinued operations, including those held for sale. Net assets held for sale have been reflected at the lower of carrying amount or fair value, less cost to sell.

Critical accounting policies related to the eye disease business include the following:

(a) Macugen Product Sales

Macugen is sold primarily to distributors, who, in turn, sell to physicians, a limited number of specialty pharmacy providers and federal government buying groups. We recognize revenue from product sales when there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, we have no obligation to bring about sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured.

On April 20, 2007, we terminated our existing collaboration agreement with Pfizer with respect to the co-promotion of Macugen in the United States and amended and restated the license agreement pursuant to which we had originally granted to Pfizer a number of exclusive licenses or sublicenses to patents and other intellectual property related to Macugen on a world-wide basis. Under the terms of the amended and restated license agreement, Pfizer returned to us all rights to develop and commercialize Macugen in the United States, and we granted to Pfizer an exclusive right to develop and commercialize Macugen in the rest of the world. We and Pfizer have also agreed to provide each other with certain transitional services related to Macugen.

Prior to the April 2007 amendment, we shared sales and marketing responsibility for sales of Macugen in the United States and reported product revenue on a gross basis for these sales. We determined that we qualified as a principal under the criteria set forth in EITF 99-19, "Reporting Revenue Gross as Principal versus Net as an Agent," based on our responsibilities under our contracts with Pfizer, which included manufacture of product for sale in the United States, distribution, ownership of product inventory and credit risk from customers. Since April 20, 2007, we no longer share the gross profits of U.S. sales with Pfizer and no longer receive royalties from Pfizer from rest of the world sales.

(b) Macugen Collaborative Revenue

Collaborative program revenues related to Macugen represent funding arrangements for Macugen research and development with Pfizer and were recognized when earned in accordance with the terms of the agreements and related research and development activities undertaken.

Based on the terms of our collaboration agreement with Pfizer, revenues derived from reimbursements of costs associated with the development of Macugen were recorded in compliance with EITF 99-19 and EITF Issue 01-14, "Income Statement Characterization of Reimbursements Received for 'Out of Pocket' Expenses Incurred." According to the criteria established by these EITF Issues, we have met the criteria to record revenue for the gross amount of the reimbursements.

(c) Macugen Milestone Revenue

In the second quarter of 2006, we received a $35.0 million milestone payment from Pfizer upon the launch of Macugen in select European countries. In accordance with EITF 00-21, the milestone payment was recorded as unearned revenue and was being recognized as revenue on a straight-line basis over the expected term of our collaboration and license agreements with Pfizer, which approximated the expected level of performance under these agreements with Pfizer.

In April 2007, we terminated our collaboration and license agreements with Pfizer and entered into an amended and restated license agreement. Under the terms of this agreement, we continue to provide services, share certain expenses and collaborate in specified studies with Pfizer and, therefore, we are continuing to amortize the milestone payment over the term of the original agreement which corresponds to the term of the amended and restated license agreement. The amortization of the unearned revenue is included in loss from discontinued operations. Any remaining

balance of deferred revenue related to this milestone payment will be reversed upon the sale of the remaining eye disease business and the assignment to a third party of our obligations under the amended and restated agreement.

Inventory

The valuation of inventory requires us to make certain assumptions and judgments to estimate net realizable value. Inventories are reviewed and adjusted for obsolescence and aging based upon estimates of future demand, technology developments and market conditions. We determine the cost of raw materials, work in process and finished goods inventories using the weighted average method. Inventory costs include material, labor and manufacturing overhead. Inventories are valued at the lower of cost or market (realizable value) in accordance with Accounting Research Bulletin No. 43, or ARB 43. ARB 43 requires that inventory be valued at its market value where there is evidence that the utility of goods will be less than cost and that such write-down should occur in the current period. Accordingly, at the end of each period we evaluate our inventory and adjust to net realizable value the carrying value and excess quantities. During the fourth quarter of 2006, we assessed the current levels of Macugen sales, our current level of Macugen inventory with near term expiration dates and our progress on finalizing a new sterile syringe product presentation to satisfy our post-approval commitment to the FDA for Macugen. Based on this assessment, loss from discontinued operations includes a charge of $26.4 million related to the disposal of certain Macugen packaged syringes as well as the recoverability of work-in-process and raw materials. Our analysis of the carrying value of inventory relies upon known market trends and expectations for future sales. If actual sales results for Macugen differ significantly from our expectations, it could lead to the write down of additional inventory or the sale of inventory with zero cost basis.

As of December 31, 2007 inventory included raw materials and work-in-process for Tarceva that may be used in the production of pre-clinical and clinical product, which will be expensed to research and development cost when consumed for these uses. Tarceva is stated at the lower of cost or market, with cost being determined using the weighted average method. Prior to receipt of FDA approval of Tarceva for commercial sale on November 18, 2004, we had expensed all costs associated with the production of Tarceva to research and development expense in our consolidated statements of operations. Effective November 18, 2004, we began to capitalize the costs of manufacturing Tarceva as inventory, including the costs to label, package and ship previously manufactured bulk inventory which costs had already been expensed as research and development. As of September 30, 2006, we had sold all of the inventory that was partially produced and expensed prior to November 18, 2004.

Stock-Based Compensation

As discussed further in note 16 to the accompanying consolidated financial statements, we adopted SFAS No. 123(R), "Accounting for Stock-Based Compensation," on January 1, 2006 using the modified prospective method.

We have used and expect to continue to use the Black-Scholes option-pricing model to compute the estimated fair value of stock-based awards. The Black-Scholes option pricing model includes assumptions regarding dividend yields, expected volatility, expected option term and risk-free interest rates. We estimate expected volatility based upon a combination of historical, implied and adjusted historical stock prices. The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of grant. Commencing in the second quarter of fiscal 2005, the fair value of the options was estimated at the date of grant using a Black-Scholes option pricing model with the expected option term determined using a Monte Carlo simulation model that incorporates historical employee exercise behavior and post-vesting employee termination rates.

The assumptions used in computing the fair value of stock-based awards reflect our best estimates but involve uncertainties relating to market and other conditions, many of which are outside of our control. As a result, if other assumptions or estimates had been used, the stock-based compensation expense that was recorded for the years

ended December 31, 2007 and 2006 could have been materially different. Furthermore, if different assumptions are used in future periods, stock-based compensation expense could be materially impacted in the future.

Accruals for Clinical Research Organization and Clinical Site Costs

We record accruals for estimated clinical study costs. Clinical study costs represent costs incurred by clinical research organizations, or CROs, and clinical sites. These costs are recorded as a component of R&D expenses. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs, when evaluating the adequacy of our accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may not match the estimated costs for a given accounting period. Actual results could differ from those estimates under different assumptions.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In July 2006, the Financial Accounting Standards Board, or FASB, issued Financial Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109," or FIN 48, which clarifies the criteria that must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN 48 provides a benefit recognition model with a two-step approach consisting of a "more-likely-than-not" recognition criteria, and a measurement attribute that measures a given tax position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. FIN 48 also requires the recognition of liabilities created by differences between tax positions taken in a tax return and amounts recognized in the financial statements. FIN 48 is effective as of the beginning of the first annual period beginning after December 15, 2006, and became effective for us on January 1, 2007. The adoption of FIN 48 on January 1, 2007 had no impact on our financial condition, results of operations, or cash flows for the year ended December 31, 2007, as the Company has no unrecognized tax benefits.

We have accumulated approximately $1.1 billion in NOLs, which equates to approximately $413 million in deferred tax assets, relating to U.S. Federal, state and foreign income taxes through December 31, 2007. The U.S. NOLs, which we can use to offset future U.S. taxable income, expire between the years 2008 and 2026. The U.K. NOLs, which can be used to offset U.K. future taxable income, do not expire. However, utilization of the U.S. NOLs may be limited under U.S. Internal Revenue Code Section 382 and our ability to generate net income before they expire for both the U.S. and U.K. NOLs. We have also accumulated approximately an additional $150 million in other deferred tax assets based on temporary differences between book and tax reporting.

We continue to fully reserve our NOLs and other deferred tax assets despite achieving full-year profitability in 2007 and our expectation for continued future profitability, since, up until 2007, we have had a history of annual losses since inception. We will consider reversing a significant portion of the valuation reserve once we have demonstrated sustained profitability and our internal forecasts support the utilization of the NOLs prior to their expiration. If we determine that the reversal of a significant portion of the valuation reserve is appropriate, a significant one-time benefit will be recognized against our income tax provision in the period of the reversal. We do not expect to reverse the valuation allowance related to our U.K. NOLs for the foreseeable future and any NOLs that would be limited under the IRC Section 382. In addition, as of December 31, 2007, approximately $52 million of the deferred tax assets related to our NOLs consists of deductions for employee stock options for which the tax benefit will be credited to additional

paid-in capital if and when realized. At such time, we will also commence recognizing a current income tax provision at the existing U.S. statutory income tax rates. However, our ability to utilize the NOLs to offset taxable income will continue to provide us with significant cash savings until the NOLs are fully utilized or expire. We assess the appropriateness of the valuation allowance at the end of each reporting period.

Investments and Other-than-Temporary Impairments of Available-for-Sale Marketable Securities

Investment securities at December 31, 2007 and 2006 consisted primarily of U.S. government securities, U.S. government agency securities and debt securities of financial institutions and corporations with strong credit ratings. We classify our investments as available-for-sale securities, as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are recorded at their fair value. Unrealized holding gains and losses, net of the related tax effect, if any, on available-for-sale securities are excluded from earnings and are reported in accumulated other comprehensive income (loss), a separate component of stockholders' equity, until realized. The specific identification basis is utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities.

A decline in the market value of any available-for-sale marketable security below its cost that is deemed to be other-than-temporary results in a reduction in its carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is then established. The determination of whether an available-for-sale marketable security is other-than-temporarily impaired requires: (i) significant judgment and consideration of available quantitative and qualitative evidence in evaluating the potential impairment. Factors evaluated to determine whether the investment is other-than-temporarily impaired include: significant deterioration in the issuer's earnings performance, credit rating, or asset quality; (ii) the business prospects of the issuer; (iii) adverse changes in the general market conditions in which the issuer operates; (iv) the length of time that the fair value has been below our cost; (v) our expected future cash flows from the security; and (vi) our intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. Assumptions associated with these factors are subject to future market and economic conditions, which could differ from our assessment. During 2007 and 2006 we did not recognize any other-than-temporary impairments. During 2005, we recognized an impairment loss of $2.0 million which was recorded in interest and investment income, net.

Goodwill and Other Long-Lived Assets

We account for goodwill and other intangible assets in accordance with SFAS No. 141 and SFAS No. 142. SFAS No. 141 requires that the purchase method of accounting be used for all business combinations. It specifies the criteria which intangible assets acquired in a business combination must meet in order to be recognized and reported apart from goodwill. SFAS No. 142 requires that goodwill and intangible assets determined to have indefinite lives no longer be amortized but instead be tested for impairment at least annually and whenever events or circumstances occur that indicate impairment might have occurred. As a result of competitive developments relating to Macugen and the age related macular degeneration marketplace, we assessed the value of the $320.3 million of goodwill during fiscal 2006 and determined the goodwill was impaired. Consequently, the value was reduced to zero and the charge is included in loss from discontinued operations.

Our identifiable intangible assets are subject to amortization. SFAS No. 142 requires that intangible assets with finite useful lives be amortized over their respective estimated useful lives and reviewed for impairment in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 requires, among other things, that long-lived assets be measured at the lower of carrying amount or fair value, less cost to sell, whether reported in continuing operations or in discontinued operations. We review our intangibles with determinable lives and other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

Our judgment regarding the existence of impairment indicators are based on historical and projected future operating results, changes in the manner of our use of the acquired assets or our overall business strategy, and market and economic trends.

In December 2006, we assessed the recoverability of the long-lived assets relating to our eye disease business, including the Macugen intellectual property acquired in our acquisition of Eyetech, and determined that the $185.7 million of Macugen intangible assets were impaired and consequently reduced their value to zero at December 31, 2006. The related charge is included in loss from discontinued operations.

In the future, events could cause us to conclude that impairment indicators exist and that certain other intangibles with determinable lives and other long-lived assets are impaired which may result in an adverse impact on our financial condition and results of operations.

Years Ended December 31, 2007 and 2006

Results of Operations

Our net income from continuing operations for the years ended December 31, 2007 and 2006 was $102.6 million and $6.7 million, respectively. The increase in net income from continuing operations was primarily due to increases in revenue related to Tarceva, and milestones and upfront fees from our worldwide license agreements. Net income for the year ended December 31, 2007 was $66.3 million compared to a net loss of $582.2 million for the year ended December 31, 2006. Included in net income for 2007 and the net loss for 2006 are the losses from discontinued operations of $36.3 million and $610.9 million, respectively. Also included in the net loss for 2006 was a $22.0 million extraordinary gain relating to the reversal of the contingent value rights liability. As a result of our decision to exit the eye disease business and the finalization of our exit plan in March 2007, the results of the eye disease business are presented as discontinued operations for all periods subsequent to the Eyetech acquisition on November 14, 2005.

Revenues

	Year Ended December 31, (in thousands)		
	2007	2006	$ Change
Net revenue from unconsolidated joint business	$168,756	$154,886	$13,870
Royalties on product sales	95,243	50,174	45,069
License, milestone and other revenues	77,031	35,977	41,054
Total revenues	$341,030	$241,037	$99,993

Net Revenue from Unconsolidated Joint Business

Net revenue from unconsolidated joint business is related to our co-promotion and manufacturing agreements with Genentech for Tarceva. For the years ended December 31, 2007 and 2006, Genentech recorded net sales of Tarceva in the United States and its territories of approximately $417 million and $402 million, respectively. Our share of these net sales is reduced by the costs incurred for cost of goods sold and the sales and marketing expenses related to the product. For the years ended December 31, 2007 and 2006, we reported net revenue from our unconsolidated joint business for Tarceva of $168.8 million and $154.9 million, respectively. The increase in net revenue from unconsolidated joint business for the year ended December 31, 2007 was primarily due to higher sales related to price increases and higher reimbursement of marketing and sales costs. Despite relatively stable unit volume year over year, net sales of Tarceva for 2007 were negatively impacted by approximately $22 million of higher than anticipated product returns and returns reserve requirements recorded by Genentech in the second and third quarters of 2007.

Royalties on Product Sales

We receive royalties of approximately 20% on net sales of Tarceva outside of the United States and its territories. In September 2005, our collaborator Roche received approval from the European Commission for the sale of Tarceva in the EU for the treatment of patients with locally advanced or metastatic NSCLC, and in January 2007, as a first-line therapy for metastatic pancreatic cancer in combination with gemcitabine. Roche has also received approval for reimbursement in a number of EU countries and is pursuing approval in other markets in the EU. In October 2007, Tarceva was approved in Japan for the treatment of patients with non-resectable, recurrent and advanced NSCLC which is aggravated following chemotherapy, and the product was launched in Japan at the end of 2007. For the years ended December 31, 2007 and 2006, Roche reported U.S. dollar equivalent sales of approximately $470 million and $247 million, respectively, and we recorded $95.2 million and $50.2 million, respectively, in royalty revenue from these sales. The increase in royalty revenue was primarily due to increased demand outside the United States and, to some extent, changes in foreign exchange rates.

The royalty amount is calculated by converting the respective countries' Tarceva sales in local currency to Roche's functional currency (Swiss Francs) and then to U.S. dollars. The royalties are paid to us in U.S. dollars on a quarterly basis. As a result, fluctuations in the value of the U.S. dollar against foreign currencies will impact our earnings.

License, Milestone and Other Revenues

We recognized $77.0 million and $36.0 million of license, milestone and other related revenues for the years ended December 31, 2007 and 2006, respectively. The years ended December 31, 2007 and 2006 included $34.7 million and $20.4 million, respectively, of upfront payments, milestones and royalties, under the worldwide non-exclusive license agreements entered into by Prosidion under our DPIV patent portfolio covering the use of DPIV inhibitors for treatment of type 2 diabetes and related indications. The amount of license revenues generated from our DPIV patent estate can be expected to fluctuate significantly from quarter to quarter based on: (i) the level of future product sales by our licensees; (ii) the ability of our licensees to achieve specified events under the license agreements which entitle us to milestone payments; and (iii) our ability to enter into additional license agreements in the future.

In January 2007, we licensed our glucokinase activator program, including our clinical candidate PSN010, to Eli Lilly for an upfront fee of $25.0 million and up to $360.0 million in potential development and sales milestones and other payments, plus royalties on any compounds successfully commercialized from this program. We deferred the initial recognition of the $25.0 million upfront fee based upon our obligation under the agreement to provide technical support during a transitional period of nine months from the date of execution. For the year ended December 31, 2007, we had fulfilled our obligation and recognized the total amount of $25.0 million upfront fee.

Also included in license and milestone revenues was the recognition of the ratable portion of upfront fees from Genentech and milestone payments received from Genentech and Roche to date in connection with various regulatory acceptances and approvals for Tarceva in the United States, Europe and Japan. These payments were initially deferred and are being recognized as revenue in accordance with EITF 00-21. The ratable portion of the upfront fee and milestone payments recognized as revenue for the years ended December 31, 2007 and 2006 were $3.8 and $3.2 million, respectively. The unrecognized deferred revenue related to these upfront fees and milestone payments received was $41.0 million and $39.8 million as of December 31, 2007 and 2006, respectively. We also will be entitled to additional milestone payments from Genentech and Roche upon the occurrence of certain regulatory approvals and filings with respect to Tarceva. Additional milestone payments will be due from Genentech and Roche upon approval of adjuvant indications in the United States and Europe. The ultimate receipt of these additional milestone payments is contingent upon the applicable regulatory approvals and other future events.

During the third quarter of 2007, we received $7.5 million of license revenue from Renovo Group plc in connection with its license agreement with Shire plc for its transforming growth factor, or TGF, beta 3 drug candidate Juvista®.

Under our agreement with Renovo, we are entitled to a fixed percentage of any upfront payment, development and sales milestones and royalties that Renovo receives from Shire under the license agreement. We are contractually obligated under a cross-license to pay Novartis AG 15% of any amounts we receive from Renovo.

During the fourth quarter of 2007, we recognized $2.4 million of revenue from the consideration received as a result of outlicensing OSI-7904L, an oncology clinical candidate for which we had ceased development, to OncoVista Innovative Therapies, Inc. The consideration included cash of $500,000 and OncoVista common stock and warrants with a fair value of $1.9 million. The common stock is publicly traded and recorded as an available-for-sale security. The warrants are recorded at their estimated fair value in other assets.

Included in license, milestone and other revenues are sales commissions earned on the sales of Novantrone in the United States for oncology indications. Sales commissions for the years ended December 31, 2007 and 2006 were $2.5 million and $11.8 million, respectively. Sales commissions declined significantly subsequent to April 2006 due to the patent expiration of Novantrone in April 2006, which resulted in our loss of market exclusivity for this product and the launch of generic competitors.

Expenses

	Year Ended December 31, (in thousands)		
	2007	2006	$ Change
Cost of goods sold	$ 9,399	$ 8,671	$ 728
Research and development	123,531	117,527	6,004
Acquired in-process research and development	9,664	—	9,664
Selling, general and administrative	99,159	107,458	(8,299)
Amortization of intangibles	1,840	1,809	31
	$243,593	$235,465	$ 8,128

Cost of Goods Sold

Total cost of goods sold for the years ended December 31, 2007 and 2006 were $9.4 million and $8.7 million, respectively. In 2007, cost of goods sold related to Tarceva. Cost of goods sold for the year ended December 31, 2006 included $8.4 million related to Tarceva and a small amount related to Gelclair.

Prior to receipt of approval of Tarceva for commercial sale on November 18, 2004, we had expensed all costs associated with the production of Tarceva to research and development. Effective November 18, 2004, we began to capitalize the costs of manufacturing Tarceva as inventory, including the costs to label, package and ship previously manufactured bulk inventory whose costs had already been expensed as research and development. During 2006, we had sold all of the inventory partially produced and expensed prior to November 18, 2004. Cost of goods sold for the year ended December 31, 2006 would have been $1.4 million higher if the Tarceva inventory sold had reflected the full absorption of manufacturing costs.

Research and Development

We consider the active management and development of our clinical pipeline crucial to the long-term process of getting a clinical candidate approved by the regulatory authorities and brought to market. We manage our overall research, development and in-licensing efforts in a manner designed to generate a constant flow of clinical candidates into development to offset both the advancement of products to the market and the anticipated attrition rate of drug candidates that fail in clinical trials or are terminated for business reasons. The duration of each phase of clinical development and the probabilities of success for approval of drug candidates entering clinical development will be impacted by a variety of factors, including the quality of the molecule, the validity of the target and disease indication, early clinical data, investment in the program, competition and commercial viability. Because we manage our pipeline

in a dynamic manner, it is difficult to give accurate guidance on the anticipated proportion of our research and development investments assigned to any one program prior to the Phase III stage of development, or to the future cash inflows from these programs. For the years ended December 31, 2007 and 2006, we invested a total of $47.4 million and $46.4 million, respectively, in research and $76.0 million and $71.1 million, respectively, in pre-clinical and clinical development. We consider this level of investment suitable for a company of our size, taking into account our anticipated revenues and other non-R&D expenses, and the nature of our pipeline of clinical and pre-clinical candidates.

Research and development expenses increased by $6.0 million for the year ended December 31, 2007 compared to the year ended December 31, 2006. The increase was primarily due to an $8.9 million increase in research and development expenses related to non-Tarceva oncology programs, equity based compensation and severance costs, partially offset by minor declines in research and development expenses for Tarceva and for our diabetes and obesity programs.

We manage the ongoing development program for Tarceva with our partners, Genentech and Roche, through a global development committee under a Tripartite Agreement among the parties. Together with our collaborators, we have implemented a broad-based global development strategy for Tarceva that implements simultaneous clinical programs currently designed to expand the number of approved indications for Tarceva and evaluate the use of Tarceva in new and/or novel combinations. Our global development plan has included major Phase III clinical trials in lung and pancreatic cancer in the past, and currently includes additional major Phase III clinical trials in lung cancer in the maintenance and adjuvant settings. Since 2001, the partners have committed an aggregate of approximately $750 million to the global development plan to be shared by the three parties. As of December 31, 2007, we had invested in excess of $212 million in the development of Tarceva, representing our share of the costs incurred through December 31, 2007 under the tripartite global development plan and additional investments outside of the plan.

Acquired In-Process Research and Development

On September 28, 2007, we entered into a small molecule drug discovery and translational research collaboration with AVEO Pharmaceuticals, Inc. The purpose of this collaboration is the development of molecular therapies that target the underlying mechanisms of epithelial-to-mesenchymal transition, or EMT, in cancer. EMT is a process of emerging significance in tumor development and disease progression and the focal point of our proprietary oncology research efforts. We are collaborating with AVEO to develop proprietary target-driven tumor models for use in drug screening and biomarker validation, and intend to employ these models in support of our oncology drug discovery and clinical programs. Under the terms of our collaboration agreement, we delivered to AVEO a $10.0 million upfront cash payment (which includes $2.5 million of research funding for the first year of the collaboration) and purchased $5.5 million of AVEO preferred stock. We also agreed to provide AVEO with additional research funding, as well as milestones and royalties upon successful development and commercialization of products from the collaboration.

As with many early stage development efforts, we do not expect that this collaboration will result in a marketable product in the near term. As a result, $7.5 million of the upfront payment was recorded as an in-process R&D charge, since it was non-refundable and deemed to have no alternative future use. The $2.5 million of first-year research funding was recognized as a prepaid asset and is being amortized over one year, or the period that AVEO is expected to provide research efforts under the collaboration. The acquired preferred stock was recorded as a cost-based investment in other assets in the accompanying balance sheet as of December 31, 2007.

In the fourth quarter of 2007, Prosidion acquired intellectual property and laboratory equipment from AdipoGenix, Inc. for $2.3 million. Of the $2.3 million purchase price, $2.2 was recorded as an in-process R&D charge, since it was associated with the intellectual property which was deemed early stage with no alternative use. The remainder of the cost was allocated to the laboratory equipment acquired, based upon its fair value, and capitalized.

Selling, General and Administrative

Selling, general and administrative expenses for the year ended December 31, 2007 decreased by $8.3 million from $107.5 million for the year ended December 31, 2006. The decrease in expenses was primarily attributable to a $7.0 million decline in maintenance fees for Novantrone, costs savings and facility restructuring charges recorded in 2006. Partially offsetting these declines were an increase in commercial costs associated with Tarceva, a $1.1 million license fee due to Novartis as a result of the $7.5 million license fee we received from Renovo, and an increase in equity based compensation and severance related costs.

Other Income and Expense

	Year Ended December 31, (in thousands)		
	2007	2006	$ Change
Investment income-net	$12,830	$11,098	$1,732
Interest expense	(7,235)	(7,339)	104
Other income (expense)-net	2,307	(2,631)	4,938
Total other expenses/income	$ 7,902	$ 1,128	$6,774

The increase in investment income for the year ended December 31, 2007 compared to the same period last year was primarily due to an increase in funds available for investment and prevailing interest rates. The year ended December 31, 2006 included $2.6 million in interest earned on escrow funds for unexchanged shares in connection with the Eyetech acquisition.

Other income (expense)-net for the year ended December 31, 2007 included a $4.0 million curtailment gain related to our decision to curtail our post-retirement medical and life insurance plan. Other income (expense)-net for the years ended December 31, 2007 and 2006 included the amortization of debt issuance costs related to the convertible senior subordinated notes, and other miscellaneous income and expense items.

Income Taxes

For the year ended December 31, 2007, we recorded a provision for income taxes of $2.7 million related to income from continuing operations and a tax benefit of approximately $640,000 related to our loss from discontinued operations. Based on our ability to fully offset current taxable income by our net operating loss carry forwards, our estimated tax expense was principally related to alternative minimum tax.

We have accumulated approximately $1.1 billion in NOLs, which equates to approximately $413 million in deferred tax assets, relating to U.S. Federal, state and foreign income taxes through December 31, 2007. The U.S. NOLs, which we can use to offset future U.S. taxable income, expire between the years 2008 and 2026. The U.K. NOLs, which can be used to offset U.K. future taxable income, do not expire. However, utilization of the U.S. NOLs may be limited under U.S. Internal Revenue Code Section 382 and our ability to generate net income before they expire for both the U.S. and U.K. NOLs. We have also accumulated approximately an additional $150 million in other deferred tax assets based on temporary differences between book and tax reporting.

We continue to fully reserve our NOLs and other deferred tax assets despite achieving full-year profitability in 2007 and our expectation for continued future profitability, since, up until 2007, we have had a history of annual losses since inception. We will consider reversing a significant portion of the valuation reserve once we have demonstrated sustained profitability and our internal forecasts support the utilization of the NOLs prior to their expiration. If we determine that the reversal of a significant portion of the valuation reserve is appropriate, a significant one-time benefit will be recognized against our income tax provision in the period of the reversal. We do not expect to reverse the valuation allowance related to our U.K. NOLs for the foreseeable future and any NOLs that would be limited under the IRC Section 382. In addition, as of December 31, 2007, approximately $52 million of the deferred tax assets related to

our NOLs consists of deductions for employee stock options for which the tax benefit will be credited to additional paid-in capital if and when realized. At such time, we will also commence recognizing a current income tax provision at the existing U.S. statutory income tax rates. However, our ability to utilize the NOLs to offset taxable income will continue to provide us with significant cash savings until the NOLs are fully utilized or expire. We assess the appropriateness of the valuation allowance at the end of each reporting period.

Loss from Discontinued Operations

On November 6, 2006, we announced our intention to divest our eye disease business, a process which we are planning to complete in 2008. Our eye disease business consists principally of Macugen, our marketed product for the treatment of neovascular age-related macular degeneration, or wet AMD, as well as research assets in the eye disease area. We made the decision to exit the eye disease business based on our determination that a key strategic goal of the acquisition of the business in November 2005 — the generation of significant cash flow from the business in the 2006 through 2008 fiscal years — would not likely be realized.

We finalized our exit plan during the first quarter of 2007 and began to actively market our eye disease business. We explored several potential transactions to divest our entire eye disease business, but were unable to identify a transaction that would provide us with satisfactory terms for a complete sale of this business. Therefore, we switched to a strategy of separately divesting the assets. In July 2007, we entered into an agreement with Ophthotech Corporation to divest our anti-platelet derived growth factor, or PDGF, aptamer program for an upfront cash payment, shares of Ophthotech preferred stock and potential future milestones and royalties. Included in the loss from discontinued operations for the year ended December 31, 2007 was a gain of approximately $6.0 million recognized as a result of the agreement. We continue to pursue the divestiture of the remaining eye disease assets, including Macugen, and we are planning to complete this process in 2008.

As a result of our decision to divest the eye disease business, in accordance with the provision of SFAS No. 144 "Accounting for the Impairment or Disposal of Long Lived Assets," the results of operations of (OSI) Eyetech for the current and prior period have been reported as discontinued operations. In addition, assets and liabilities of (OSI) Eyetech have been classified as assets and liabilities related to discontinued operations, including those held for sale. Net assets held for sale have been reflected at the lower of carrying amount or fair value, less cost to sell.

Total revenue from (OSI) Eyetech was $37.4 million for the year ended December 31, 2007 compared to $134.7 million for the year ended December 31, 2006. Total U.S. net sales of Macugen in 2007 were approximately $18 million and were significantly impacted by the launch of a competitor's product. Losses declined $574.6 million to $36.3 million for the year ended December 31, 2007, compared to $610.9 million in the same period last year. The decline in losses was primarily attributable to the $532.4 million of impairment and inventory related charges we recognized in 2006, and lower operating expenses in 2007. As a result of the decline in revenues for Macugen and developments in the wet AMD marketplace, we recognized impairment charges in the second and third quarters of 2006 of approximately $320.3 million in the aggregate for the goodwill relating to our eye disease business, and additional charges in the fourth quarter of 2006 of $185.7 million relating to the Macugen intangible assets and $26.4 million relating to the Macugen obsolete and expiring inventory. In the third and fourth quarters of 2007, we assessed the net realizable carrying amount or fair value of the assets held for sale and recognized additional impairment charges of $5.6 million and $5.1 million, respectively, in order to reduce the carrying value of the assets.

Extraordinary Gain

In connection with the 2003 acquisition of Cell Pathways, Inc., we recognized contingent consideration of $22.0 million in the form of five-year contingent value rights pursuant to which each share of Cell Pathways common stock will be eligible for an additional 0.04 share of our common stock in the event of a filing of a new drug application by June 12, 2008 for either of the two clinical candidates acquired from Cell Pathways, OSI-461 or Aptosyn. We have

ceased our development efforts for these two clinical candidates and are pursuing outlicensing efforts with respect to these two candidates. During the second quarter of fiscal 2006, we concluded that, in our judgment, the milestone will not be met based upon the current progress of our outlicensing efforts and the technical hurdles for filing a new drug application by June 2008 and therefore, we reversed the $22.0 million liability and recorded an extraordinary gain during the year ended December 31, 2006.

Years Ended December 31, 2006 and 2005

Results of Operations

Our net income from continuing operations for the year ended December 31, 2006 was $6.7 million compared to a net loss of $85.1 million for the year ended December 31, 2005. Our net losses for the years ended December 31, 2006 and 2005 were $582.2 million and $157.1 million, respectively. Despite significant increases in net revenue from unconsolidated joint business from our Tarceva partnership with Genentech, royalties from international sales of Tarceva from Roche, and milestones and upfront fees from worldwide non-exclusive license agreements entered into for our DPIV patent portfolio, our net losses increased in 2006 as we recognized $532.4 million of impairment charges in connection with Eyetech intangibles and inventory. Our results of operations for the year ended December 31, 2005 included the results of operations of Eyetech for the period from November 14, 2005, the date of our acquisition of Eyetech, through December 31, 2005. The 2005 net loss included in-process R&D charges of $64.4 million in connection with the acquisition of Eyetech and the acquisition of the minority interest shares in Prosidion.

Revenues

	Year Ended December 31, (in thousands)		
	2006	2005	$ Change
Net revenue from unconsolidated joint business	$154,886	$ 84,727	$ 70,159
Royalties on product sales	50,174	6,986	43,188
License, milestone and other revenues	35,977	46,710	(10,733)
Total revenues	$241,037	$138,423	$102,614

Net Revenue from Unconsolidated Joint Business

Net revenue from unconsolidated joint business is related to our co-promotion and manufacturing agreements with Genentech for Tarceva. For the years ended December 31, 2006 and 2005, Genentech recorded net sales of Tarceva in the United States and its territories of approximately $402 million and $275 million, respectively. Our share of these net sales was reduced by the costs incurred for cost of goods sold and the sales and marketing expenses related to the product. For the years ended December 31, 2006 and 2005, we reported net revenue from our unconsolidated joint business for Tarceva of $154.9 million and $84.7 million, respectively. The increase in net revenue from unconsolidated joint business was primarily due to higher net sales related to the approval and launch of Tarceva for the pancreatic cancer indication in November 2005, an increase in market share penetration in the NSCLC indications and price increases.

Royalties on Product Sales

We receive royalties on the sales of Tarceva outside of the United States and its territories. In September 2005, our collaborator Roche received approval from the European Commission for the sale of Tarceva in the EU for the treatment of patients with locally advanced or metastatic NSCLC and, in January 2007 as a first-line therapy for metastatic pancreatic cancer in combination with gemcitabine. Roche has also received approval for reimbursement in a number of EU countries. For the years ended December 31, 2006 and 2005, Roche reported U.S. dollar equivalent

sales of approximately $248 million and $36 million, respectively, in net sales of Tarceva outside of the United States and its territories, and we recorded $50.2 million and $7.0 million, respectively, in royalty revenues from these sales.

License, Milestone and Other Revenues

We recognized $36.0 million and $46.7 million of license, milestone and other related revenues during the years ended December 31, 2006 and 2005, respectively. The years ended December 31, 2006 and 2005 included approximately $20 million and $14 million, respectively, of license, milestone and royalty payments under the worldwide non-exclusive license agreements entered into by Prosidion under our DPIV patent portfolio covering the use of DPIV inhibitors for treatment of type 2 diabetes and related indications. In October 2006, Merck announced that it had received FDA approval for its DPIV inhibitor, Januvia, which resulted in our receipt of a milestone payment and ongoing rights to royalties from sales of Januvia. Also included in license and milestone revenues was the recognition of the ratable portion of upfront fees from Genentech and milestone payments received from Genentech and Roche to date in connection with various regulatory acceptances and approvals for Tarceva in the United States, Europe and Japan. These payments were initially deferred and are being recognized as revenue in accordance with EITF 00-21. The ratable portion of the upfront fee and milestone payments recognized as revenue for the years ended December 31, 2006 and 2005 was $3.2 million and $1.6 million, respectively.

Also included in license, milestone and other revenues were sales commissions earned on the sales of Novantrone in the United States for oncology indications. Sales commissions for the years ended December 31, 2006 and 2005 were $11.8 million and $29.7 million, respectively. Sales commissions declined significantly in 2006 due to the patent expiration of Novantrone in April 2006, which resulted in our loss of market exclusivity for this product and the launch of generic competitors.

Expenses

	Year Ended December 31, (in thousands)		
	2006	2005	$ Change
Cost of goods sold	$ 8,671	$ 5,035	$ 3,636
Research and development	117,527	116,655	872
Acquired in-process research and development	—	3,542	(3,542)
Selling, general and administrative	107,458	89,205	18,253
Amortization of intangibles	1,809	15,281	(13,472)
	$235,465	$229,718	$ 5,747

Cost of Goods Sold

Total cost of goods sold for the years ended December 31, 2006 and 2005 were $8.7 million and $5.0 million, respectively. Cost of goods sold for the year ended December 31, 2006 included $8.4 million related to Tarceva and $255,000 related to Gelclair. Cost of goods sold for the year ended December 31, 2005 included $4.5 million related to Tarceva and $533,000 related to Gelclair.

Prior to receipt of approval of Tarceva for commercial sale on November 18, 2004, we had expensed all costs associated with the production of Tarceva to research and development. Effective November 18, 2004, we began to capitalize the costs of manufacturing Tarceva as inventory, including the costs to label, package and ship previously manufactured bulk inventory whose costs had already been expensed as research and development. During 2006, we had sold all of the inventory partially produced and expensed prior to November 18, 2004. Cost of goods sold for the years ended December 31, 2006 and 2005 would have been $1.4 million and $4.2 million higher, respectively, if the Tarceva inventory sold had reflected the full absorption of manufacturing costs. The increased costs presented in this manner are more reflective of our cost of goods sold going forward.

Research and Development

We consider the active management and development of our clinical pipeline crucial to the long-term process of getting a clinical candidate approved by the regulatory authorities and brought to market. We manage our overall research, development and in-licensing efforts in a manner designed to generate a constant flow of clinical candidates into development to offset both the advancement of products to the market and the anticipated attrition rate of drug candidates that fail in clinical trials or are terminated for business reasons. The duration of each phase of clinical development and the probabilities of success for approval of drug candidates entering clinical development will be impacted by a variety of factors, including the quality of the molecule, the validity of the target and disease indication, early clinical data, investment in the program, competition and commercial viability. Because we manage our pipeline in a dynamic manner, it is difficult to give accurate guidance on the anticipated proportion of our research and development investments assigned to any one program prior to the Phase III stage of development, or to the future cash inflows from these programs. For the years ended December 31, 2006 and 2005, we invested a total of $46.4 million and $45.9 million, respectively, in research and $71.1 million and $70.8 million, respectively, in pre-clinical and clinical development.

Research and development expenses increased by $872,000 for the year ended December 31, 2006 compared to the year ended December 31, 2005. The increase was primarily due to a $6.9 million increase in Tarceva related expenses, $255,000 of severance related costs and $2.9 million of equity based compensation expense related to the adoption of SFAS No. 123, "Share-Based Payment," or, SFAS 123(R). Partially offsetting these increases was a decline in research and development expenses for non-Tarceva related product candidates.

We manage the ongoing development program for Tarceva with our collaborators, Genentech and Roche, through a global development committee under a Tripartite Agreement among the parties. Together with our collaborators, we have implemented a broad-based global development strategy for Tarceva that implements simultaneous clinical programs currently designed to expand the number of approved indications of Tarceva and evaluate the use of Tarceva in new and/or novel combinations. Our global development plan has included major Phase III clinical trials in lung and pancreatic cancer in the past, and currently includes additional major Phase III clinical trials in lung cancer in the maintenance and adjuvant settings. As of December 31, 2006, the partners had committed approximately $700 million combined in the global development plan to be shared by the three parties.

As of December 31, 2006, we had invested in excess of $178 million in the development of Tarceva, representing our share of the costs incurred through December 31, 2006 under the tripartite global development plan and additional investments outside of the plan.

Acquired In-Process Research and Development

In connection with the acquisition of the minority interest in Prosidion in 2005, we recognized $3.5 million of in-process R&D charges.

Selling, General and Administrative

Selling, general and administrative expenses for the year ended December 31, 2006 increased by $18.3 million from $89.2 million for the year ended December 31, 2005. The increase in expenses was primarily attributable to recognition of $10.0 million of equity based compensation expense related to the adoption of SFAS No. 123(R), $4.5 million of charges related to facility consolidations, $400,000 of severance related costs, and an increase in corporate related expenses. Partially offsetting these increases was a $7.0 million decline in maintenance fees for Novantrone. The year ended December 31, 2005 also included a charge of $4.4 million for estimated facility lease return costs and the remaining rental obligations net of estimated sublease rental income for the unused portion of our Oxford facility resulting from the consolidation of our U.K.-based oncology operations.

Amortization of Intangibles

Amortization expense for the years ended December 31, 2006 and 2005 was $1.8 million and $15.3 million, respectively. Amortization expense for our rights to Novantrone were $1.5 million and $14.9 million for the years ended December 31, 2006 and 2005, respectively. At December 31, 2005, we revised the future recoverability period of the Novantrone intangible asset to extend through the end of 2008, and are amortizing the remaining balance on a straight line basis.

Other Income and Expense

	Year Ended December 31, (in thousands)		
	2006	2005	$ Change
Investment income-net	$11,098	$13,206	$(2,108)
Interest expense	(7,339)	(4,986)	(2,353)
Other income (expenses)-net	(2,631)	(2,019)	(612)
Total other expenses/income	$ 1,128	$ 6,201	$(5,073)

The decrease in investment income for the year ended December 31, 2006 compared to the same period in the prior year was primarily due to a decrease in our funds available for investment. This decrease was partially offset by $2.0 million of unrealized losses that we recognized in the year ended December 31, 2005 relating to available-for-sale securities for which the impairment was deemed other than temporary, and $2.6 million in interest earned during 2006 on escrow funds for unexchanged shares in connection with the Eyetech acquisition.

The increase in interest expense for the year ended December 31, 2006 compared to the same period in the prior year was primarily due to interest expense on our 2025 Notes, which were issued in December 2005. Other income expense-net for the periods included the amortization of debt issuance costs and other miscellaneous income and expense items.

Loss from Discontinued Operations

As a result of our decision to divest the Eyetech operations, the financial information associated with Eyetech has been reclassified and presented as discontinued operations in the accompanying consolidated statements of operations. Loss from discontinued operations was $610.9 million for the year ended December 31, 2006 compared to a loss of $72.0 million for the year ended December 31, 2005. The net loss from Eyetech is included in the 2005 results from November 14, 2005, the day we acquired Eyetech.

Total revenue from (OSI) Eyetech was $134.7 million for the year ended December 31, 2006 compared to $35.8 million from the period of our acquisition of Eyetech on November 14, 2005 through December 31, 2005. Total U.S. net sales of Macugen for the year ended December 31, 2006 were approximately $103 million and were significantly impacted by the launch of a competitor's product. U.S. net sales of Macugen declined significantly in 2006, from $50.6 million in the first quarter of 2006 to $7.2 million in the fourth quarter of 2006. As a result of the decline in revenues for Macugen and developments in the wet AMD marketplace, we recognized impairment charges in the second and third quarters of 2006 of approximately $320.3 million in the aggregate for the goodwill relating to our eye disease business and additional charges in the fourth quarter of 2006 of $185.7 million relating to the Macugen intangible assets and $26.4 million relating to the Macugen obsolete and expiring inventory. All of the charges are included in the loss from discontinued operations for the year ended December 31, 2006.

Extraordinary Gain

In connection with the 2003 acquisition of Cell Pathways, we recognized contingent consideration of $22.0 million in the form of five-year contingent value rights pursuant to which each share of Cell Pathways common stock will be

eligible for an additional 0.04 share of our common stock in the event of a filing of a new drug application by June 12, 2008 for either of the two clinical candidates acquired from Cell Pathways, OSI-461 or Aptosyn. We have ceased our development efforts for these two clinical candidates and have entered into a letter of intent to outlicense these candidates. During the second quarter of 2006, we concluded that, in our judgment, the milestone would not be met based upon the progress of our outlicensing efforts and the technical hurdles for filing a new drug application by June 2008 and therefore, we reversed the $22.0 million liability and recorded an extraordinary gain during the year ended December 31, 2006.

Liquidity and Capital Resources

The following table summarizes our cash flows for the years ended December 31, 2007 and 2006 (in thousands):

	Year Ended December 31,	
	2007	2006
Cash provided by (used in):		
Operating activities	$ 75,809	$ 37,515
Investing activities	19,879	(168,444)
Financing activities	24,755	8,396
Net increase (decrease) in cash and cash equivalents	$120,443	$(122,533)

At December 31, 2007, cash and investments, including restricted securities, were $305.1 million compared to $216.4 million at December 31, 2006. The increase of $88.7 million was primarily due to the following changes: (i) net cash of $75.8 million from operating activities; (ii) net cash of $24.8 million from proceeds from stock option exercises; (iii) net cash of $4.0 million from the sale of intellectual property, offset by cash used for capital expenditures of $4.3 million; and (iv) cash used for purchase of intellectual property of $9.7 million.

Included in cash provided by operating activities are fluctuations in the timing of cash disbursements and receipts, as well as increases in operating expenses, and increases in revenues. For the year ended December 31, 2007, revenues from continuing operations were $100.0 million higher than the same period in the prior year primarily due to an increase of $59.5 million of revenues related to Tarceva and an increase of $40.5 million of revenue from various licensing agreements.

On January 9, 2008, we issued $200.0 million aggregate principal amount of 3% convertible senior subordinated notes due 2038, or 2038 Notes, in a private placement resulting in net proceeds to us of approximately $193 million. We used a portion of the proceeds to repurchase approximately 1.5 million shares of our common stock concurrently with the offering for an aggregate price of $65.0 million. The 2038 Notes bear interest semi-annually in arrears through maturity at an annual rate of 3% and mature on January 15, 2038. We may redeem, for cash, all or part of the 2038 Notes at any time on or after January 15, 2013, at a price equal to 100% of the principal amount of the 2038 Notes, plus accrued and unpaid interest. Holders of the 2038 Notes have the right to require us to purchase, for cash, all or any portion of their 2038 Notes on January 15, 2013, 2018, 2023, 2028 and 2033 at a price equal to 100% of the principal amount of the 2038 Notes to be purchased, plus accrued and unpaid interest.

The 2038 Notes are unsecured and are subordinated to all of its existing and future senior indebtedness. The 2038 Notes rank equally in right of payment with all of our existing and future senior subordinated indebtedness. The 2038 Notes will be convertible, in certain circumstances, into our common stock based upon a base conversion rate, which, under certain circumstances will be increased pursuant to a formula that is subject to a maximum conversion rate. The initial base conversion rate is 13.5463 shares per $1,000 principal amount of notes (equivalent to an initial base conversion price of approximately $73.82 per share of our common stock). The initial base conversion price represents a premium of 65% to the $44.74 per share closing price of OSI's common stock on January 3, 2008. Upon conversion,

holders of the 2038 Notes will have the right to receive shares of our common stock, subject to our right to deliver cash in lieu of all or a portion of such shares.

Through diligent management of our business, in particular our expenses, we have achieved our goal of full year profitability for 2007. If we continue to execute on our internal plans, we expect that our research and development investments and capital requirements over the next 12 to 18 months will be funded from the generation of cash flow from Tarceva, our DPIV patent estate licenses and our out-licensing activities. Including the cash proceeds from our January 2008 sale of the 2038 Notes, we anticipate funding the majority, if not all of our liquidity and capital needs, as well as the potential redemption of the 2023 Notes or a portion thereof on or after September 2008, from our current cash position, and from the generation of cash flow from our operations, with the potential exception of strategic acquisitions of products and/or businesses.

Commitments and Contingencies

Our major outstanding contractual obligations relate to our senior subordinated convertible notes and our facility leases. The following table summarizes our significant contractual obligations at December 31, 2007 and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	2008	2009-2010	2011-2012	2013 & Thereafter
Contractual Obligations:				
Senior convertible debt(a)	$ 7,175	$14,350	$14,350	$348,525
Operating leases	13,040	22,648	21,871	82,364
Purchase obligations(b)	35,260	34,700	7,800	6,200
Obligations related to exit activities(c)	1,934	2,634	—	1,486
Total contractual obligations	$57,409	$74,332	$44,021	$438,575

(a) Includes interest payments at a rate of 3.25% per annum relating to the $150.0 million principal amount of the 2023 Notes and at a rate of 2% per annum relating to the $115.0 million principal amount of the 2025 Notes. The holders of the 2023 Notes have the right to require us to purchase all of the 2023 Notes, or a portion thereof, in September 2008. We may choose to pay the purchase price in cash or shares of our common stock. Holders of the 2025 Notes have the right to require us to purchase, for cash, all of the 2025 Notes, or a portion thereof, in December 2010.

(b) Includes inventory commitments, commercial and research commitments and other significant purchase commitments. Also includes our share of the remaining future commitment related to the Tarceva global development costs of approximately $76 million.

(c) Includes payments for termination benefits and facility refurbishments.

Other significant commitments and contingencies include the following:

- We are committed to share certain commercialization costs relating to Tarceva with Genentech. Under the terms of our agreement, there are no contractually determined amounts for future commercial costs.
- Under agreements with external clinical research organizations, or CROs, we will continue to incur expenses relating to clinical trials of Tarceva, Macugen and other clinical candidates. The timing and amount of these disbursements can be based upon the achievement of certain milestones, patient enrollment, services rendered or as expenses are incurred by the CROs and therefore we cannot reasonably estimate the potential timing of these payments.
- We have outstanding letters of credit of $7.7 million, which primarily serve as security for performance under various lease obligations.
- We have a retirement plan which provides post-retirement medical and life insurance benefits to eligible employees, board members and qualified dependents. We curtailed this plan in 2007, however, certain employees, board members and qualified dependents remain eligible for these benefits. Eligibility is

determined based on age and years of service. We had an accrued liability for post-retirement benefit costs of $3.2 million at December 31, 2007.

- Under certain license and collaboration agreements with pharmaceutical companies and educational institutions, we are required to pay royalties and/or milestone payments upon the successful development and commercialization of products. However, successful research and development of pharmaceutical products is high risk, and most products fail to reach the market. Therefore, at this time the amount and timing of the payments, if any, are not known.
- Under certain license and other agreements, we are required to pay license fees for the use of technologies and products in our research and development activities or milestone payments upon the achievement of certain predetermined conditions. These license fees are not deemed material to our consolidated financial statements and the amount and timing of the milestone payments, if any, are not known due to the uncertainty surrounding the successful research, development and commercialization of the products.
- In connection with the acquisition of Eyetech in November 2005, we assumed various contracts related to the in-licensing, development, manufacture and marketing of Macugen. These license agreements represent rights and obligations of our subsidiary, (OSI) Eyetech. Under the terms of the license agreements, we will be required to make additional milestone payments, and we are also required to pay royalties on net sales.

Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities." SFAS No. 159 permits entities to choose to measure many financial instruments and certain items at fair value that are not currently required to be measured at fair value. We will be subject to the requirements of SFAS No. 159 for our fiscal year ending December 31, 2008. We are currently evaluating the impact of the provisions of SFAS No. 159.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements," to clarify the definition of fair value, establish a framework for measuring fair value and expand the disclosures on fair value measurements. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. SFAS No. 157 also stipulates that, as a market-based measurement, fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability, and establishes a fair value hierarchy that distinguishes between: (a) market participant assumptions developed based on market data obtained from sources independent of the reporting entity, or observable inputs; and (b) the reporting entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances, or unobservable inputs. Except for the deferral for the implementation of SFAS No. 157 for other non-financial assets and liabilities, as defined, SFAS No. 157 will be effective for our fiscal year ended December 31, 2008. The FASB is expected to continue to further debate the aspects of SFAS No. 157 that relate to non-financial assets and liabilities, and the aforementioned accounting could change. We are currently evaluating SFAS No. 157 and are not yet in a position to determine what, if any, effect SFAS No. 157 will have on our consolidated financial statements.

On June 27, 2007, EITF 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities," or EITF 07-3, was issued. EITF 07-3 provides that nonrefundable advance payments made for goods or services to be used in future research and development activities are deferred and capitalized until such time as the related goods or services are delivered or are performed, at which point the amounts will be recognized as an expense. EITF 07-3 is effective for new contracts entered into after January 1, 2008. We are currently evaluating the potential impact, if any, of this EITF but do not expect it to be material to our financial position or results of operations.

In November 2007, EITF 07-01 "Accounting for Collaborative Arrangements" was issued. EITF 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF Issue 01-9, "Accounting for Consideration Given by a Vendor to a Customer." EITF 07-01 is effective for fiscal years beginning after December 15, 2008. We do not believe that this EITF will have a material impact on the results of operations, financial position or cash flows.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations," which replaces FASB Statement No. 141. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non controlling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combinations. SFAS 141R is effective as of the beginning of an entity's fiscal year that begins after December 15, 2008. We are currently evaluating the potential impact, if any, of the adoption of SFAS 141R on our financial statement.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statement amendments of ARB No. 51." SFAS 160 states that accounting and reporting for minority interests will be recharacterized as noncontrolling interests and classified as a component of equity. The Statement also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 applies to all entities that prepare consolidated financial statements, except not-for-profit organizations, but will affect only those entities that have an outstanding noncontrolling interest in one or more subsidiaries or that deconsolidate a subsidiary. This statement is effective as of the beginning of an entity's first fiscal year beginning after December 15, 2008. We are currently evaluating the potential impact, if any, of the adoption of SFAS 160 on our financial statement.

Forward Looking Statements

A number of the matters and subject areas discussed in this Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," in Item 1, "Business," and elsewhere in this report, that are not historical or current facts, deal with potential future circumstances and developments. The discussion of these matters and subject areas is qualified by the inherent risks and uncertainties surrounding future expectations generally, and these discussions may materially differ from our actual future experience involving any one or more of these matters and subject areas. These forward-looking statements are also subject generally to the other risks and uncertainties that are described in this report in Item 1A, "Business — Risk Factors."

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Our cash flow and earnings are subject to fluctuations due to changes in interest rates in our investment portfolio of debt securities and to foreign currency exchange rates. We maintain an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," and consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a component of accumulated other comprehensive income (loss) included in stockholders' equity. We consider our restricted investment securities to be held-to-maturity as defined by SFAS No. 115. These securities are reported at their amortized cost, which includes the direct costs to acquire the securities, plus the amortization of any discount or premium, and accrued interest earned on the securities. We have not used or held derivative financial instruments in our investment portfolio.

At December 31, 2007, we maintained a portion of our cash and cash equivalents in financial instruments with original maturities of three months or less. We also maintained an investment portfolio principally comprised of government and government agency obligations and corporate obligations that are subject to interest rate risk and will decline in value if interest rates increase.

A hypothetical 10% change in interest rates during the twelve months ended December 31, 2007 would have resulted in a $1.3 million change in our net income for 2007.

Our limited investments in certain biotechnology companies are carried on the equity method or cost method of accounting using the guidance of applicable accounting literature. Other-than-temporary losses are recorded against earnings in the same period the loss was deemed to have occurred.

The royalty revenue we receive from Roche is calculated by converting the respective countries' Tarceva sales in local currency to Roche's functional currency (Swiss Francs) and then to U.S. dollars. The royalties are paid to us in U.S. dollars on a quarterly basis. As a result, fluctuations in the value of the U.S. dollar against foreign currencies will impact our earnings. A hypothetical 10% change in current rates during the year ended December 31, 2007 would have resulted in an approximate $9 million change to our net income.

Our convertible senior subordinated notes totaled $265.0 million at December 31, 2007, and were comprised of our 2023 Notes which bear interest at a fixed rate of 3.25% and our 2025 Notes which bear interest at a fixed rate of 2.00%. Underlying market risk exists related to an increase in our stock price or an increase in interest rates which may make the conversion of the 2023 Notes or 2025 Notes to common stock beneficial to the holders of such notes. Conversion of the 2023 Notes or 2025 Notes would have a dilutive effect on any future earnings and book value per common share.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON THE CONSOLIDATED FINANCIAL STATEMENTS

To the Board of Directors and Stockholders
OSI Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of OSI Pharmaceuticals, Inc. and subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2007. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of OSI Pharmaceuticals, Inc. and subsidiaries as of December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 15 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans* as of December 31, 2006.

As discussed in Notes 1 and 16 to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R), *Shared-Based Payment.*

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), OSI Pharmaceuticals, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 27, 2008, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Melville, New York
February 27, 2008

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2007 AND 2006
(In thousands except per share data)

	December 31, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 162,737	$ 42,028
Investment securities	137,439	164,786
Restricted investment securities — short-term	4,922	9,554
Accounts receivables — net	87,523	80,075
Inventory — net	21,064	36,860
Interest receivable	1,116	3,674
Prepaid expenses and other current assets	9,882	9,102
Assets related to discontinued operations	25,442	—
Total current assets	450,125	346,079
Property, equipment and leasehold improvements — net	46,694	56,223
Debt issuance costs — net	3,047	4,910
Goodwill	39,411	39,373
Other intangible assets — net	4,966	6,742
Other assets	14,137	4,405
	$ 558,380	$ 457,732
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 45,843	$ 54,741
Collaboration profit share payable	—	12,039
Unearned revenue — current	10,912	12,803
Liabilities associated with discontinued operations	45,739	—
Convertible senior subordinated notes	150,000	—
Total current liabilities	252,494	79,583
Other liabilities:		
Rent obligations and deferred rent expense	10,812	10,044
Unearned revenue — long-term	37,075	66,089
Convertible senior subordinated notes	115,000	265,000
Accrued post-retirement benefit cost and other	4,043	8,422
Total liabilities	419,424	429,138
Stockholders' equity:		
Preferred stock, $.01 par value; 5,000 shares authorized; no shares issued at December 31, 2007 and 2006, respectively	—	—
Common stock, $.01 par value; 200,000 shares authorized, 60,352 and 59,179 shares issued at December 31, 2007 and 2006, respectively	604	592
Additional paid-in capital	1,658,737	1,616,874
Accumulated deficit	(1,487,686)	(1,554,005)
Accumulated other comprehensive income	4,522	2,354
	176,177	65,815
Less: treasury stock, at cost; 1,943 shares at December 31, 2007 and 2006	(37,221)	(37,221)
Total stockholders' equity	138,956	28,594
Commitments and contingencies (See Note 17)		
	$ 558,380	$ 457,732

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(In thousands except per share data)

	Year Ended December 31,		
	2007	2006	2005
Revenues:			
Net revenue from unconsolidated joint business	$168,756	$ 154,886	$ 84,727
Royalties on product sales	95,243	50,174	6,986
License, milestone and other revenues	77,031	35,977	46,710
Total revenues	341,030	241,037	138,423
Expenses:			
Cost of goods sold	9,399	8,671	5,035
Research and development	123,531	117,527	116,655
Acquired in-process research and development	9,664	—	3,542
Selling, general and administrative	99,159	107,458	89,205
Amortization of intangibles	1,840	1,809	15,281
Total expenses	243,593	235,465	229,718
Income from continuing operations	97,437	5,572	(91,295)
Other income (expense):			
Investment income — net	12,830	11,098	13,206
Interest expense	(7,235)	(7,339)	(4,986)
Other income (expense) — net	2,307	(2,631)	(2,019)
Income (loss) from continuing operations before income taxes	105,339	6,700	(85,094)
Income tax provision	2,732	—	—
Net income (loss) from continuing operations	102,607	6,700	(85,094)
Loss from discontinued operations	(36,288)	(610,930)	(72,029)
Net income (loss) before extraordinary gain	66,319	(604,230)	(157,123)
Extraordinary gain	—	22,046	—
Net income (loss)	$ 66,319	$(582,184)	$(157,123)
Basic and diluted income (loss) per common share:			
Basic earnings (loss)			
Continuing operations	$ 1.78	$ 0.12	$ (1.63)
Discontinued operations	(0.63)	(10.73)	(1.38)
Net income (loss) before extraordinary gain	1.15	(10.61)	(3.02)
Extraordinary gain	—	0.39	—
Net income (loss)	$ 1.15	$ (10.22)	$ (3.02)
Diluted earnings (loss)			
Continuing operations	$ 1.70	$ 0.12	$ (1.63)
Discontinued operations	(0.58)	(10.60)	(1.38)
Net income (loss) before extraordinary gain	1.11	(10.48)	(3.02)
Extraordinary gain	—	0.38	—
Net income (loss)	$ 1.11	$ (10.10)	$ (3.02)
Weighted average shares of common stock outstanding:			
Basic shares	57,665	56,939	52,078
Diluted shares	62,241	57,645	52,078

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005
(In thousands)

	Common Stock		Additional Paid-in	Deferred	Accumulated	Accumulated Other Comprehensive	Treasury	Total Stockholders'
	Shares	Amount	Capital	Compensation	Deficit	Income (Loss)	Stock	Equity
Balance at December 31, 2004	52,398	$524	$1,375,486	$ (81)	$ (814,346)	$ 3,258	$(25,451)	$ 539,390
Comprehensive income (loss):								
Net loss	—	—	—	—	(157,123)	—	—	(157,123)
Unrealized holding gain on investment securities, net of reclassification adjustment	—	—	—	—	—	928	—	928
Translation adjustment	—	—	—	—	—	(2,431)	—	(2,431)
Total comprehensive loss	—	—	—	—	—	—	—	(158,626)
Options exercised	469	5	10,221	—	—	—	—	10,226
Issuance of common stock for employee purchase plan and other	94	—	2,068	—	—	—	—	2,068
Issuance of common stock in connection with buyout of Prosidion minority interest	85	1	4,157	—	—	—	—	4,158
Issuance of common stock for directors' annual retainer	12	—	527	(527)	—	—	—	—
Amortization of deferred Compensation	—	—	—	1,739	—	—	—	1,739
Issuance of restricted stock to employees	16	—	613	(613)	—	—	—	—
Acceleration of stock options	—	—	816	—	—	—	—	816
Call spread purchased in connection with private offering	—	—	(12,179)	—	—	—	—	(12,179)
Issuance of common stock in connection with acquisition of Eyetech	5,654	57	205,336	—	—	—	—	205,393
Issuance of stock options and restricted rights in connection with Eyetech acquisition	—	—	5,110	(7,859)	—	—	—	(2,749)
Purchase of treasury stock, 500,000 shares	—	—	—	—	—	—	(11,770)	(11,770)
Balance at December 31, 2005	58,728	587	1,592,155	(7,341)	(971,469)	1,755	(37,221)	578,466
Comprehensive income (loss):								
Net loss	—	—	—	—	(582,184)	—	—	(582,184)
Unrealized holding gain on investment securities, net of reclassification adjustment	—	—	—	—	—	(233)	—	(233)
Translation adjustment	—	—	—	—	—	2,148	—	2,148
Total comprehensive loss	—	—	—	—	—	—	—	(580,269)
Adjustment to initially apply SFAS 158		—	—	—	—	(1,316)	—	(1,316)
Options exercised	391	4	7,888	—	—	—	—	7,892
Issuance of common stock for employee purchase plan and other	45	1	1,129	—	—	—	—	1,130
Issuance of common stock in connection with buyout of Prosidion minority interest	3	—	145	—	—	—	—	145
Issuance of common stock for directors' annual retainer	4	—	216	—	—	—	—	216
Issuance of restricted stock to employees	8	—	1,323	—	—	—	—	1,323
Reclassification of deferred compensation due to the adoption of SFAS 123(R)	—	—	(5,045)	7,341	—	—	—	2,296
Equity based compensation expense	—	—	19,063	—	—	—	—	19,063
Adjustment for EITF 06-02 (sabbatical leave)	—	—	—	—	(352)	—	—	(352)
Balance at December 31, 2006	59,179	592	1,616,874	—	(1,554,005)	2,354	(37,221)	28,594

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005 — (Continued)
(In thousands)

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity
	Shares	Amount						
Balance at December 31, 2006	59,179	592	1,616,874	—	(1,554,005)	2,354	(37,221)	28,594
Comprehensive income (loss):								
Net income	—	—	—	—	66,319	—	—	66,319
Unrealized holding gain on investment securities, net of reclassification adjustment	—	—	—	—	—	486	—	486
Curtailment of post-retirement plan	—	—	—	—	—	1,316	—	1,316
Translation adjustment	—	—	—	—	—	366	—	366
Total comprehensive income	—	—	—	—	—	—	—	68,487
Options exercised	1,052	11	25,622	—	—	—	—	25,633
Issuance of common stock under employee purchase plan	26	—	776	—	—	—	—	776
Issuance of restricted stock to employees	95	1	18	—	—	—	—	19
Equity based compensation expense	—	—	15,447	—	—	—	—	15,447
Balance at December 31, 2007	60,352	$604	$1,658,737	$ —	$(1,487,686)	$ 4,522	$(37,221)	$ 138,956

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005
(In thousands)

	Year Ended December 31,		
	2007	2006	2005
Cash flow from operating activities:			
Net income (loss)	$ 66,319	$(582,184)	$(157,123)
Adjustments to reconcile net income (loss) to net cash (provided by) used in operating activities:			
Extraordinary gain from reversal of contingent consideration	—	(22,046)	—
Loss on sale of investments	—	—	2,188
Loss (gain) on sale and disposals of equipment	1,471	(5)	809
Gain on sale of intellectual property	(7,892)	—	—
Depreciation and amortization	9,893	36,093	28,712
Impairment of intangible asset and goodwill	—	505,985	—
Impairment of assets held for sale	10,765	—	—
Provision for excess inventory— net	—	26,408	—
Impact of inventory step-up related to inventory sold	2,365	19,924	6,827
In-process research and development charge	9,664	—	64,442
Non-cash compensation charge	17,099	19,703	2,027
Changes in assets and liabilities, net of the effects of acquisitions:			
Receivables	(23,262)	69,569	(45,062)
Inventory	12	(9,551)	(15,759)
Prepaid expenses and other current assets	(1,054)	1,715	386
Other assets	(1,077)	(3,755)	147
Accounts payable and accrued expenses	6,038	(17,017)	(34,271)
Collaboration profit share payable	(9,257)	(37,829)	949
Unearned revenue	(1,331)	29,104	29,760
Accrued post-retirement benefit cost	(3,944)	1,401	1,149
Net cash provided by (used in) operating activities	75,809	37,515	(114,819)
Cash flows from investing activities:			
Payments for acquisitions, net of cash acquired	—	—	(430,986)
Purchases of investments (restricted and unrestricted)	(258,085)	(239,268)	(447,443)
Maturities and sales of investments (restricted and unrestricted)	287,628	80,788	757,325
Net additions to property, equipment and leasehold improvements	(4,332)	(10,728)	(26,718)
Purchase of intellectual property	(9,664)	—	—
Proceeds from sale of intellectual property	4,000	—	—
Proceeds from sale of fixed assets	335	795	—
Purchase of compound library assets	(3)	(31)	(920)
Net cash provided by (used in) investing activities	19,879	(168,444)	(148,742)
Cash flows from financing activities:			
Proceeds from the exercise of stock options, stock warrants, employee purchase plan, and other	26,409	9,138	12,471
Employees taxes paid related to equity awards	(1,654)	—	—
Proceeds from the issuance of convertible senior subordinated notes	—	—	115,000
Call spread premium	—	—	(12,179)
Debt issuance costs	—	(102)	(3,902)
Payments on loans and capital leases payable	—	(640)	(180)
Purchase of treasury stock	—	—	(11,770)
Net cash provided by financing activities	24,755	8,396	99,440
Net increase (decrease) in cash and cash equivalents	120,443	(122,533)	(164,121)
Effect of exchange rate changes on cash and cash equivalents	266	477	(1,351)
Cash and cash equivalents at beginning of year	42,028	164,084	329,556
Cash and cash equivalents at end of year	$ 162,737	$ 42,028	$ 164,084
Non-cash activities:			
Stock and warrants received from sale of intellectual property	$ 3,892	$ —	$ —
Post-retirement benefit obligation upon adoption of SFAS No. 158	$ —	$ 1,316	$ —
Issuance of common stock to acquire minority interest in Prosidion	$ —	$ —	$ 4,157
Issuance of equity securities in connection with Eyetech acquisition costs	$ —	$ —	$ 210,446
Liabilities assumed in connection with acquisitions	$ —	$ —	$ 124,000
Cash paid for interest	$ 7,175	$ 7,175	$ 4,869

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In this Annual Report on Form 10-K, "OSI," "our company," "we," "us," and "our" refer to OSI Pharmaceuticals, Inc. and subsidiaries.

(1) Summary of Significant Accounting Policies

(a) Principles of Consolidation

Our consolidated financial statements include the accounts of OSI Pharmaceuticals, Inc., and our wholly-owned subsidiaries, (OSI) Eyetech, Inc., Prosidion Limited and OSI Pharmaceuticals (UK) Limited, or OSI-UK. During fiscal 2003, we formed Prosidion, into which we transferred our diabetes and obesity research programs. On April 14, 2005, we completed the acquisition of the remaining minority interest of Prosidion and as a result, Prosidion became our wholly-owned subsidiary. On November 14, 2005, we acquired all outstanding shares of Eyetech Pharmaceuticals Inc., a biotechnology company with a focus on eye disease. The accompanying results of operations include Eyetech for the period from November 14, 2005 and are presented as discontinued operations in the accompanying statement of operations as discussed in Note 20. This report on Form 10-K includes the statement of operations, statement of cash flows and statement of stockholders' equity for the years ended December 31, 2007, 2006 and 2005. All intercompany balances and transactions have been eliminated in consolidation.

(b) Revenue Recognition

Net revenue from unconsolidated joint business

Net revenue from unconsolidated joint business is related to our co-promotion and manufacturing agreements with Genentech, Inc., our U.S. collaborator for Tarceva (erlotinib). It consists of our share of the pretax co-promotion profit generated from our co-promotion arrangement with Genentech for Tarceva, reimbursement from Genentech of our sales and marketing costs related to Tarceva, and the reimbursement from Genentech of our manufacturing costs related to Tarceva. Under the co-promotion arrangement, all U.S. sales of Tarceva and associated costs and expenses, except for a portion of our sales related costs, are recognized by Genentech. For the year ended December 31, 2007, Genentech recorded approximately $417 million in net sales of Tarceva in the United States and its territories. We record our 50% share of the co-promotion pretax profit on a quarterly basis, as set forth in our agreement with Genentech. Pretax co-promotion profit under the co-promotion arrangement is derived by calculating U.S. net sales of Tarceva to third-party customers and deducting costs of sales, distribution and selling and marketing expenses incurred by Genentech and us. The net sales recorded and costs incurred during the respective periods include estimates by both parties. If actual future results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of adjustment. We do not believe that these adjustments, if any, will be significant to our future results of operations. The reimbursement of our sales and marketing costs related to Tarceva is recognized as revenue as the related costs are incurred. We defer the recognition of the reimbursement of our manufacturing costs related to Tarceva until the time Genentech ships the product to third-party customers at which time our risk of inventory loss no longer exists. The unearned revenue related to shipments by our third party manufacturers of Tarceva to Genentech that have not been shipped to third-party customers was $7.0 million and $5.9 million as of December 31, 2007 and 2006, respectively, and is included in unearned revenue-current in the accompanying consolidated balance sheets.

Net revenues from unconsolidated joint business consist of the following (in thousands):

	Year Ended December 31, 2007	Year Ended December 31, 2006	Year Ended December 31, 2005
Co-promotion profit and reimbursement of sales and marketing related costs	$159,033	$143,692	$73,715
Reimbursement of manufacturing costs	9,723	11,194	11,012
Net revenue from unconsolidated joint business	$168,756	$154,886	$84,727

(c) Royalties on Product Sales

We estimate royalty revenue and royalty receivables in the periods these royalties are earned, in advance of collection. Our estimate of royalty revenue and receivables is based upon communication with our collaborators. Differences between actual revenues and estimated royalty revenue are adjusted for in the period which they become known, typically the following quarter. Historically, such adjustments have not been material to our consolidated financial condition or results of operations.

The royalty amount is calculated by converting the respective countries' Tarceva sales in local currency to Roche's functional currency (Swiss Francs) and then to U.S. dollars. The royalties are paid to us in U.S. dollars on a quarterly basis. As a result, fluctuations in the value of the U.S. dollar against foreign currencies will impact our earnings.

(d) Licenses, Milestones and Other Revenues

Our revenue recognition policies for all nonrefundable upfront license fees and milestone arrangements are in accordance with the guidance provided in the Securities and Exchange Commission's, or SEC's, Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," as amended by SEC Staff Accounting Bulletin No. 104, "Revenue Recognition." In addition, in fiscal 2004 we adopted the provisions of EITF Issue 00-21, "Revenue Arrangements with Multiple Deliverables", or EITF 00-21, for multiple element revenue arrangements entered into or materially amended after June 30, 2003.

We received a total of $25.0 million in upfront fees from Genentech and Roche, our ex-U.S. collaborator for Tarceva, in January 2001, which was being recognized on a straight-line basis over the expected term of our required research and development efforts under the tripartite agreement with Genentech and Roche. As a result of an amendment to our collaboration agreement with Genentech in June 2004, the remaining unearned upfront fee from Genentech of $1.8 million is being recognized in accordance with EITF 00-21, as discussed further below. The upfront fee from Roche was fully recognized as of December 31, 2004.

Since September 2004, we have received $34.0 million in milestone payments from Genentech based upon certain U.S. Food and Drug Administration, or FDA, filings and approvals of Tarceva in accordance with our agreement with Genentech. As a result of the amendment to our collaboration agreement with Genentech in June 2004, these payments are, and any future milestone payments will be, recognized in accordance with EITF 00-21. Milestones which have been received from Genentech after June 2004 and the remaining unearned upfront fee as of June 2004 are being recognized over the term of our Manufacturing and Supply Agreement with Genentech, under which the last items of performance to be delivered to Genentech are set forth, or on a straight-line basis, which approximates the expected level of performance under the Manufacturing and Supply Agreement. The unrecognized unearned revenue related to the milestones and upfront payment received from Genentech was $29.6 million as of December 31, 2007, of which $2.3 million was classified as short-term and the balance of $27.3 million was classified as long-term in the

accompanying consolidated balance sheet. The unrecognized unearned revenue related to the milestones and upfront payment received from Genentech was $31.9 million as of December 31, 2006, of which $2.3 million was classified as short-term and the balance of $29.6 million was classified as long-term in the accompanying consolidated balance sheet.

In March 2005, the Tarceva alliance collaborators, OSI, Genentech, and Roche, agreed to a further global development plan and budget for the continued development of Tarceva in earlier stage lung cancer, other cancer indications and in a variety of combinations with other oncology drugs. The cost of the development plan is being shared by the three collaborators. For purposes of EITF 00-21, the revised development plan and budget for Tarceva was deemed a material amendment to our Roche agreement, and, requires milestones received from Roche to be recognized in accordance with EITF 00-21. Accordingly, milestone payments received from Roche are initially recorded as unearned revenue and recognized over the expected term of the research collaboration on a straight-line basis, which approximates the expected level of performance under the development plan. In September 2005, we recorded a $4.0 million milestone payment from Roche upon approval of Tarceva by the European Commission for sale in the European Union, or EU. In November 2005, we recorded a $4.0 million milestone payment from Roche upon acceptance for review by the European Agency for the Evaluation of Medicinal Products for the application of Tarceva in combination with gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received previous chemotherapy. In May 2006, we recorded a $1.0 million milestone payment from Roche upon acceptance for review by the Japanese Ministry of Health of the application of Tarceva for the treatment of advanced non-small cell lung cancer, or NSCLC. In January 2007, we recorded a $4.0 million milestone payment from Roche upon the European Commission's marketing authorization for Tarceva in combination with gemcitabine as first-line therapy for metastatic pancreatic cancer. In November 2007, we recorded a $1.0 million milestone payment from Roche upon approval in Japan for the use of Tarceva in the treatment of advanced NSCLC. All of these payments have been included in deferred revenue. The unearned revenue related to the milestones earned from Roche was $11.3 million as of December 31, 2007, of which $1.6 million was classified as short-term and the balance of $9.7 million was classified as long-term in the accompanying consolidated balance sheet. The unearned revenue related to the milestones earned from Roche was $7.9 million as of December 31, 2006 of which $983,000 was classified as short-term and the balance of $6.9 million was classified as long-term in the accompanying consolidated balance sheet.

During the year ended December 31, 2007 and 2006, we entered into several worldwide non-exclusive license agreements under our dipeptidyl peptidase IV, or DPIV, patent portfolio covering the use of DPIV inhibitors for the treatment of type 2 diabetes and related indications. In addition to upfront fees received from these agreements, we are entitled to receive milestone payments upon the achievement of certain events and royalty payments on net sales. Under the terms of the new agreements executed and existing agreements, we recognized upfront license and milestone revenue and royalties of $34.7 million and $20.0 million for the years ended December 31, 2007 and 2006, respectively.

In January 2007, we licensed our glucokinase activator, or GKA, program, including our clinical candidate PSN010, to Eli Lilly and Company for an upfront fee of $25.0 million and up to $360.0 million in potential development and sales milestones and other payments, plus royalties on any compounds successfully commercialized from this program. We recognized the upfront fee as revenue in 2007 since we have no future performance obligation under the agreement beyond the end of 2007.

All of the payments mentioned above in this Note 1 are included in license and milestone and other revenues on the accompanying consolidated statement of operations for the years ended December 31, 2007 and 2006. We recognize revenue from license agreements where we have no future obligations upon the effective date of the agreements and the collection of payments is reasonably assured.

Other revenue includes sales commissions earned on the sales of the drug, Novantrone, in the United States for oncology indications pursuant to a co-promotion agreement dated March 11, 2003 with Ares Trading S.A., an affiliate of Merck Serono, S.A. Merck Serono markets Novantrone in multiple sclerosis indications and records all U.S. sales for all indications including oncology indications. Sales commissions from Novantrone on net oncology sales are recognized in the period the sales occur based on the estimated split between oncology sales and multiple sclerosis sales.

(e) Research and Development Costs

Research and development, or R&D, costs are charged to operations as incurred and include direct costs of R&D scientists and equipment, contracted costs, and an allocation of laboratory facility and other core scientific services. Included in R&D costs are our share of development expenses related to the Tripartite Agreement with Genentech and Roche (see note 2(a)).

(f) Acquired In-Process Research and Development

Costs to acquire in-process research and development projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are expensed as incurred.

(g) Cash and Cash Equivalents

We include as cash equivalents, treasury bills, commercial paper and time deposits with original maturities of three months or less. Such cash equivalents amounted to $81.9 million and $13.0 million as of December 31, 2007 and 2006, respectively.

(h) Investments

Investment securities at December 31, 2007 and 2006 consisted primarily of U.S. government securities, U.S. government agency securities and debt securities of financial institutions and corporations with strong credit ratings. We classify our investments as available-for-sale securities, as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are recorded at their fair value. Unrealized holding gains and losses, net of the related tax effect, if any, on available-for-sale securities are excluded from earnings and are reported in accumulated other comprehensive income (loss), a separate component of stockholders' equity, until realized. The specific identification basis is utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities. Dividend and interest income are recognized when earned.

Certain of our facility leases have outstanding letters of credit issued by commercial banks which serve as security for our performance under the leases. Included in restricted investment securities as of December 31, 2007 and 2006 were $4.9 million and $9.6 million, respectively, of investments to secure these letters of credit.

We have certain investments in privately-owned companies that are carried on the cost method of accounting. Other than temporary losses are recorded against earnings in the period the decrease in value of the investment is deemed to have occurred.

(i) Other-Than-Temporary Impairments of Available-For-Sale Marketable Securities

A decline in the market value of any available-for-sale marketable security below its cost that is deemed to be other-than-temporary results in a reduction in its carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is then established. The determination of whether an available-for-sale marketable security is other-than-temporarily impaired requires: (i) significant judgment and consideration of available quantitative and qualitative evidence in evaluating the potential impairment. Factors evaluated to determine whether the investment is other-than-temporarily impaired include: significant deterioration in the issuer's earnings performance, credit rating, or asset quality; (ii) the business prospects of the issuer; (iii) adverse changes in the general market conditions in which the issuer operates; (iv) the length of time that the fair value has been below our cost; (v) our expected future cash flows from the security; and (vi) our intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. Assumptions associated with these factors are subject to future market and economic conditions, which could differ from our assessment. During 2007 and 2006 we did not recognize any other-than-temporary impairments. During 2005, we recognized an impairment loss of $2.0 million which was recorded in interest and investment income, net.

(j) Goodwill and Intangible Assets

We account for goodwill and other intangible assets in accordance with SFAS No. 141, "Business Combinations," or SFAS No. 141, and SFAS No. 142, "Goodwill and Other Intangible Assets," or SFAS No. 142, which we adopted in fiscal 2003. SFAS No. 141 requires that the purchase method of accounting be used for all business combinations. It specifies the criteria which intangible assets acquired in a business combination must meet in order to be recognized and reported apart from goodwill. SFAS No. 142 requires that goodwill and intangible assets determined to have indefinite lives no longer be amortized but instead be tested for impairment at least annually and whenever events or circumstances occur that indicate impairment might have occurred. SFAS No. 142 also requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives and reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

As discussed in Note 20, we recorded an impairment charge of $320.3 million related to the Eyetech goodwill during the year ended December 31, 2006.

As a result of our R&D programs, including programs funded pursuant to R&D funding agreements (see note 8), we have applied for a number of patents in the United States and abroad. Costs incurred in connection with patent applications for our R&D programs have been expensed as incurred. Legal cost incurred related to defense of our Tarceva patents are capitalized and amortized over the remaining patent term.

(k) Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of

In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," or SFAS No. 144, we review long-lived assets to determine whether an event or change in circumstances indicates the carrying value of the asset may not be recoverable. We base our evaluation on such impairment indicators as the nature of the assets, the future economic benefit of the assets and any historical or future profitability measurements, as well as other external market conditions or factors that may be present. If such impairment indicators are present or other factors exist that indicate that the carrying amount of the asset may not be recoverable, we determine whether an impairment has occurred through the use of an undiscounted cash flows analysis at the lowest level for which identifiable cash flows exist. If impairment has occurred, we recognize a loss for the difference between the carrying amount and the fair value of the asset. Fair value is the amount at which the asset could be bought or sold in a current

transaction between a willing buyer and seller other than in a forced or liquidation sale and can be measured at the asset's quoted market price in an active market or, where an active market for the asset does not exist, our best estimate of fair value based on discounted cash flow analysis. Assets to be disposed of by sale are measured at the lower of carrying amount or fair value less estimated costs to sell.

In 2005, we acquired core and developed technology related to Macugen. As discussed in Note 20, at December 31, 2006, we assessed the carrying value of Macugen intangibles with definitive lives and determined that the assets were impaired and recorded a $185.7 million impairment charge.

(l) Inventory

Inventory is stated at the lower of cost or market, with cost being determined using the weighted average method. Included in inventory are raw materials and work-in-process that may be used in the production of pre-clinical and clinical product, which will be expensed to research and development cost when consumed for these uses. Prior to receipt of FDA approval of Tarceva for commercial sale on November 18, 2004, we had expensed all costs associated with the production of Tarceva to research and development expense in our consolidated statements of operations. Effective November 18, 2004, we began to capitalize the costs of manufacturing Tarceva as inventory, including the costs to label, package and ship previously manufactured bulk inventory which costs had already been expensed as R&D. Inventory is comprised of three components: raw materials, which are purchased directly by us, work-in-process, which is primarily active pharmaceutical ingredient, or API, where title has transferred from our contract manufacturer to us, and finished goods, which is packaged product ready for commercial sale.

(m) Depreciation and Amortization

Depreciation of fixed assets is recognized over the estimated useful lives of the respective asset groups on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the lesser of the estimated useful lives or the remainder of the lease term.

Amortization of compounds acquired by us (which are included in other assets on the accompanying consolidated balance sheets) is on a straight-line basis over five years.

(n) Computer Software Costs

We record the costs of computer software in accordance with the American Institute of Certified Public Accountants, Statement of Position 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use," or SOP 98-1. SOP 98-1 requires that certain internal-use computer software costs be capitalized and amortized over the useful life of the asset.

(o) Accrual for Clinical Research Organization and Clinical Site Costs

We record accruals for estimated clinical study costs. Clinical study costs represent costs incurred by clinical research organizations, or CROs, and clinical sites. These costs are recorded as a component of R&D expenses. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may or may not match the estimated costs for a given accounting period. Actual results could differ from those estimates under different assumptions.

(p) Foreign Currency Translation

The assets and liabilities of our non-U.S. subsidiaries, OSI-UK and Prosidion, which operate in their local currency, are translated to U.S. dollars at exchange rates in effect at the balance sheet date with resulting translation adjustments directly recorded as a separate component of accumulated other comprehensive income (loss). Income and expense accounts are translated at the average exchange rates during the year.

(q) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In July 2006, the Financial Accounting Standards Board, or FASB, issued Financial Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109," or FIN 48, which clarifies the criteria that must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN 48 provides a benefit recognition model with a two-step approach consisting of a "more-likely-than-not" recognition criteria, and a measurement attribute that measures a given tax position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. FIN 48 also requires the recognition of liabilities created by differences between tax positions taken in a tax return and amounts recognized in the financial statements. FIN 48 is effective as of the beginning of the first annual period beginning after December 15, 2006, and became effective for us on January 1, 2007. The adoption of FIN 48 on January 1, 2007 had no impact on our financial condition, results of operations, or cash flows for the year ended December 31, 2007, as the Company has no unrecognized tax benefits.

(r) Debt Issuance Costs

Costs incurred in issuing our 2% convertible senior subordinated notes due 2025, or our 2025 Notes, and our 3¼% senior subordinated notes due 2023, or our 2023 Notes, are amortized using the straight-line method over a five-year term, which represents the earliest date that we may redeem such notes. The amortization of debt issuance cost is included in other expense in the accompanying consolidated statements of operations.

(s) Stock-Based Compensation

As discussed further in Note 16 we adopted SFAS No. 123(R), "Accounting for Stock-Based Compensation," on January 1, 2006 using the modified prospective method.

We have used and expect to continue to use the Black-Scholes option-pricing model to compute the estimated fair value of stock-based awards. The Black-Scholes option-pricing model includes assumptions regarding dividend yields, expected volatility, expected option term and risk-free interest rates. We estimate expected volatility based upon a combination of historical, implied and adjusted historical stock prices. The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of grant. Commencing in the second quarter of fiscal 2005, the fair value of the options was estimated at the date of grant using a Black-Scholes option-pricing model with the expected option term determined using a Monte Carlo simulation model that incorporates historical employee exercise behavior and post-vesting employee termination rates.

The assumptions used in computing the fair value of stock-based awards reflect our best estimates but involve uncertainties relating to market and other conditions, many of which are outside of our control. As a result, if other assumptions or estimates had been used, the stock-based compensation expense that was recorded for the years ended December 31, 2007 and 2006 could have been materially different. Furthermore, if different assumptions are used in future periods, stock-based compensation expense could be materially impacted in the future.

(t) Segment Information

Operating segments are determined based on the Company's management approach. The management approach, as defined by SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information," is based on the way that the chief operating decision-maker organizes the segments within an enterprise for making decisions about resources to be allocated and assessing their performance. While the Company's results of operations are primarily reviewed on a consolidated basis, the chief operating decision-maker, effective January 1, 2006, manages the enterprise in three operating segments: (i) oncology; (ii) diabetes and obesity; and (iii) eye disease. In accordance with SFAS No. 131, given the similar economic characteristics of the three operating segments, the Company has deemed it to have one reportable segment.

(u) Use of Estimates

We have made a number of estimates and assumptions related to the reported amounts in our financial statements and accompanying notes to prepare these consolidated financial statements in conformity with generally accepted accounting principles. Actual results could differ from those estimates and assumptions.

(v) Eyetech Purchase Accounting

The purchase price related to our acquisition of Eyetech, as described in Note 20, was allocated to tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair market values as of the acquisition date. The determination of the fair values of in-process R&D, identifiable intangible assets and certain property, plant and equipment, requires significant estimates and assumptions including, without limitation, determining the timing and expected costs to complete the in-process projects, determining the product life and term of estimated future cash flows, and developing appropriate costs, expenses, depreciation and amortization assumptions, tax rates, discount rates and probability rates by project. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions.

On November 6, 2006, we announced our intention to divest our eye disease business, a process which we expect to complete in 2008. During the first quarter of 2007, we finalized our exit plan and began to actively market our eye disease business assets. As discussed in Note 20 to the accompanying consolidated financial statements, as a result of the finalization of our plan to sell the business during the first quarter of 2007, in accordance with the provision of Statement of Financial Accounting Standards, or SFAS, No. 144, "Accounting for the Impairment or Disposal of Long Lived Assets," the results of operations of (OSI) Eyetech, Inc. for the current and prior period have been reported as discontinued operations. In addition, assets and liabilities of (OSI) Eyetech have been classified as assets and liabilities related to discontinued operations, including those held for sale. Net assets held for sale have been reflected at the lower of carrying amount or fair value, less cost to sell.

Critical accounting policies related to the eye disease business include the following:

Macugen Product Sales

Macugen is sold primarily to distributors, who, in turn, sell to physicians, a limited number of specialty pharmacy providers and federal government buying groups. We recognize revenue from product sales when there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, we have no obligation to bring about sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured.

On April 20, 2007, we terminated our existing collaboration agreement with Pfizer with respect to the co-promotion of Macugen in the United States and amended and restated the license agreement pursuant to which we had originally granted to Pfizer a number of exclusive licenses or sublicenses to patents and other intellectual property related to Macugen on a world-wide basis. Under the terms of the amended and restated license agreement, Pfizer returned to us all rights to develop and commercialize Macugen in the United States, and we granted to Pfizer an exclusive right to develop and commercialize Macugen in the rest of the world. We and Pfizer have also agreed to provide each other with certain transitional services related to Macugen.

Prior to the April 2007 amendment, we shared sales and marketing responsibility for sales of Macugen in the United States and reported product revenue on a gross basis for these sales. We determined that we qualified as a principal under the criteria set forth in EITF 99-19, "Reporting Revenue Gross as Principal versus Net as an Agent," based on our responsibilities under our contracts with Pfizer, which included manufacture of product for sale in the United States, distribution, ownership of product inventory and credit risk from customers. Since April 20, 2007, we no longer share the gross profits of U.S. sales with Pfizer and no longer receive royalties from Pfizer from rest of the world sales.

Macugen Collaborative Revenue

Collaborative program revenues related to Macugen represent funding arrangements for Macugen research and development with Pfizer and were recognized when earned in accordance with the terms of the agreements and related research and development activities undertaken.

Based on the terms of our collaboration agreement with Pfizer, revenues derived from reimbursements of costs associated with the development of Macugen were recorded in compliance with EITF 99-19 and EITF Issue 01-14, "Income Statement Characterization of Reimbursements Received for 'Out of Pocket' Expenses Incurred." According to the criteria established by these EITF Issues, we have met the criteria to record revenue for the gross amount of the reimbursements.

Macugen Milestone Revenue

In the second quarter of 2006, we received a $35.0 million milestone payment from Pfizer upon the launch of Macugen in select European countries. In accordance with EITF 00-21, the milestone payment was recorded as unearned revenue and was being recognized as revenue on a straight-line basis over the expected term of our collaboration and license agreements with Pfizer, which approximated the expected level of performance under these agreements with Pfizer.

In April 2007, we terminated our collaboration and license agreements with Pfizer and entered into an amended and restated license agreement. Under the terms of this agreement, we continue to provide services, share certain

expenses and collaborate in specified studies with Pfizer, and therefore, we are continuing to amortize the milestone payment over the term of the original agreement which corresponds to the term of the amended and restated license agreement. The amortization of the unearned revenue is included in loss from discontinued operations. Any remaining balance of deferred revenue related to this milestone payment will be reversed upon the sale of the remaining eye disease business and the assignment to a third party of our obligations under the amended and restated agreement.

(2) Product Development/Commercialization Agreements/License Agreements

(a) Genentech and Roche

On January 8, 2001, we entered into an alliance with Genentech and Roche for the global co-development and commercialization of Tarceva. We have entered into separate agreements with both Genentech and Roche with respect to the alliance, as well as a Tripartite Agreement.

Under the Tripartite Agreement, we agreed with Genentech and Roche to optimize the use of each party's resources to develop Tarceva in certain countries around the world and share certain global development costs; to share information generated under a global development plan; to facilitate attainment of necessary regulatory approvals of Tarceva for commercial marketing and sale in the world; and to work together on such matters as the parties agree from time to time during the development of Tarceva. We, as well as Genentech and Roche, may conduct clinical and pre-clinical activities for additional indications for Tarceva not called for under the global development plan, subject to certain conditions. The Tripartite Agreement will terminate when either the OSI/ Genentech collaboration agreement or the OSI/Roche agreement terminates. Any reimbursement from or payments to Genentech or Roche for R&D costs under the cost sharing arrangement of the Tripartite Agreement are recorded as an increase or decrease to R&D expenses in the accompanying consolidated statements of operations.

Under the OSI/Genentech collaboration agreement, we agreed to collaborate in the product development of Tarceva with the goals of obtaining regulatory approval for commercial marketing and sale in the United States of products resulting from the collaboration, and, subsequently, supporting the commercialization of the product. Consistent with the development plan and with the approval of a joint steering committee, we agreed with Genentech as to who will own and be responsible for the filing of drug approval applications with the FDA other than the first new drug application, or NDA, which we owned and filed, and the first supplemental NDA, which we owned and filed. Genentech has primary responsibility for the design and implementation of all product launch activities and the promotion, marketing and sales of all products resulting from the collaboration in the United States, its territories and Puerto Rico.

We have certain co-promotion rights under the OSI/Genentech collaboration agreement, which are defined in amendments to the agreement effective as of June 4, 2004 and April 11, 2007. Pursuant to the amendments, we currently co-promote Tarceva using a sales force equal to 50% of the combined OSI/Genentech sales force. We share equally in the operating profits or losses on products resulting from the collaboration. Under the OSI/Genentech collaboration agreement, we granted to Genentech a royalty-free non-transferable (except under certain circumstances), non-sublicensable (except under certain circumstances), co-exclusive license under our patents and know-how related to Tarceva to use, sell, offer for sale and import products resulting from the collaboration in the United States, its territories and Puerto Rico. In addition, Genentech granted to us a royalty-free non-transferable (except under certain circumstances), non-sublicensable (except under certain circumstances), co-exclusive license to certain patents and know-how held by Genentech to use, make, have made, sell, offer for sale and import products resulting from the collaboration in the United States, its territories and Puerto Rico. We have primary responsibility for

patent filings for the base patents protecting Tarceva and, in addition, we have the right, but not the obligation, to institute, prosecute and control patent infringement claims relating to the base patents.

In connection with our collaboration with Genentech, Genentech recognizes all U.S. sales of Tarceva. We recognize revenues and losses from our alliance with Genentech, which consists of our 50% share of the pre-tax profits (loss) generated from the sales of Tarceva in the United States. We also recognize manufacturing revenue from the sale of inventory to Genentech for commercial sales of Tarceva in the United States and reimbursement from Genentech of our Tarceva-related commercial expenses. We receive royalties on sales of Tarceva outside of the United States by Roche.

The OSI/Genentech collaboration agreement continues until the date on which neither we nor Genentech are entitled to receive a share of the operating profits or losses on any products resulting from the collaboration, that is, until the date that we and Genentech mutually agree to terminate the collaboration or until either party exercises its early termination rights. The OSI/Genentech collaboration agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. The provisions of the amendment allowing us to co-promote are also subject to termination by Genentech upon a material breach by us of the amendment, which remains uncured, or upon a pattern of nonmaterial breaches which remains uncured. In addition, Genentech has the right to terminate the OSI/Genentech collaboration agreement with six months' prior written notice.

Effective June 4, 2004, we entered into a Manufacturing and Supply Agreement with Genentech that defined each party's responsibilities with respect to the manufacture and supply of clinical and commercial quantities of Tarceva. Under certain circumstances, if we fail to supply such clinical and commercial quantities, Genentech has the right, but not the obligation, to assume responsibility for such supply. The Manufacturing and Supply Agreement will terminate upon the termination of the OSI/Genentech collaboration agreement.

Under the OSI/Roche agreement, we granted to Roche a license to our intellectual property rights with respect to Tarceva. Roche is collaborating with us and Genentech in the continued development of Tarceva and is responsible for marketing and commercialization of Tarceva outside of the United States in certain territories as defined in the agreement. The grant is a royalty-bearing, non-transferable (except under certain circumstances), non-sublicensable (except under certain circumstances), sole and exclusive license to use, sell, offer for sale and import products resulting from the development of Tarceva worldwide, other than the territories covered by the OSI/Genentech collaboration agreement. In addition, Roche has the right, which it has exercised, to manufacture commercial supplies of Tarceva for its territory, subject to certain exceptions. Roche will pay us certain milestone payments and royalty payments on sales of products resulting from the collaboration. We have primary responsibility for patent filings for the base patents protecting Tarceva and, in addition, we have the right, but not the obligation, to institute, prosecute and control patent infringement claims relating to the base patents. The OSI/Roche agreement continues until the date on which we are no longer entitled to receive a royalty on products resulting from the development of Tarceva, that is, until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva or, in countries where there is no valid patent covering Tarceva, on the tenth anniversary of the first commercial sale of Tarceva in that country, or until either party exercises early termination rights. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, Roche has the right to terminate the agreement on a country-by-country basis with six months' prior written notice and we have the right to terminate the agreement on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

(b) AVEO

On September 28, 2007, we entered into a small molecule drug discovery and translational research collaboration with AVEO Pharmaceuticals, Inc. The purpose of this collaboration is the development of molecular therapies that target the underlying mechanisms of epithelial-to-mesenchymal transition, or EMT, in cancer. EMT is a process of emerging significance in tumor development and disease progression and the focal point of our proprietary oncology research services under the collaboration. We are collaborating with AVEO to develop proprietary target-driven tumor models for use in drug screening and biomarker validation, and intend to employ these models in support of our oncology drug discovery and clinical programs. Under the terms of our collaboration agreement, we paid AVEO a $10.0 million upfront cash payment (which included $2.5 million research funding for the first year of the collaboration) and purchased $5.5 million of AVEO preferred stock. We also agreed to provide AVEO with future research funding, as well as milestones and royalties upon successful development and commercialization of products from the collaboration.

As with many early stage development efforts, launch of an eventual product is not expected in the near term. As a result, $7.5 million of the upfront payment was recognized as an in-process R&D charge, since it was non-refundable and deemed to have no alternative future use. The $2.5 million of first year research funding was recognized as a prepaid asset and is being amortized over one year, or the period AVEO is expected to deliver research services under the collaboration. The acquired preferred stock was recorded as a cost based investment in other assets in the accompanying balance sheet as of December 31, 2007.

(c) Eli Lilly

In January 2007, we licensed our glucokinase activator, or GKA, program, including our clinical candidate PSN010, to Eli Lilly and Company for an upfront fee of $25.0 million and up to $360.0 million in potential development and sales milestones and other payments, plus royalties on any compounds successfully commercialized from this program. We recognized the upfront fee as license revenue in 2007 since we have no future performance obligation under the agreement beyond the end of 2007.

(d) OncoVista

During the fourth quarter of 2007, we recognized $2.4 million of revenue from the consideration received as a result of outlicensing OSI-7904L, an oncology clinical candidate for which we had ceased development, to OncoVista Innovative Therapies, Inc. The consideration included cash of $500,000 and OncoVista common stock and warrants with a fair value of $1.9 million. The common stock is publicly traded and recorded as an available-for-sale security. The warrants are recorded at their estimated fair value in other assets.

(e) Merck Serono

On March 11, 2003, we entered into a co-promotion agreement with Ares Trading SA, an affiliate of Merck Serono SA, to market and promote Novantrone for approved oncology indications in the United States through December 2017. In consideration for these exclusive rights, we paid $46.0 million in cash, including professional fees. The purchase price and related professional fees, net of related amortization, are included in other intangible assets-net in the accompanying consolidated balance sheets as of December 31, 2007 and 2006, and were initially amortized on a straight-line basis through expiration of the Novantrone patent in April 2006. At December 31, 2005, we revised the future recoverability period of the Novantrone intangible asset through the end of 2008 based upon revised estimates of future cash flows subsequent to the expiration of that patent. Under the terms of the co-promotion agreement, we

were required to pay quarterly maintenance fees until the later of the expiration of the last valid patent claim or the first generic date, as defined in the agreement. With introduction of generic competition in the marketplace, our last maintenance payment under the agreement was in April 2006. Such maintenance fees were expensed as incurred and included in selling, general and administrative expenses on the accompanying consolidated statements of operations. We receive commissions on net sales of the product in the United States for oncology indications. Sales commissions totaled $2.5 million, $11.8 million and $29.7 million for the years ended December 31, 2007, 2006 and 2005, respectively.

(f) DPIV Patent Estate

We have entered into various license agreements with third parties to grant the use of our proprietary assets. These licenses include the use of our patented gene transcription estate as well as the use of our DPIV patent estate acquired from Probiodrug AG in fiscal 2004. Licensees may be obligated to pay us license fees, annual fees, and milestones and royalties based on the development and sale of products derived from the licensed patents. Generally, the duration of each license is to be coextensive with the life of the last to expire of the underlying patents. For the years ended December 31, 2007 and 2006, we recognized as revenue $34.7 million and $20.4 million, respectively, of license, milestone and royalty payments from our DPIV patent estate.

(g) Other

Under the terms of the license and collaboration agreements discussed above, along with certain of our other license and collaboration agreements, we are entitled to royalties on net sales of products resulting from these agreements.

(3) Net Earnings (Loss) Per Share

Basic earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the reporting period. Diluted earnings per common share is computed by dividing net income by the weighted-average number of common shares outstanding during the reporting period, increased to include all additional common shares that would have been outstanding assuming potentially dilutive common share equivalents had been issued. Dilutive common share equivalents include the dilutive effect of in-the-money shares related to stock options, and are calculated based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an option, the average amount of compensation cost, if any, for future service that we have not yet recognized, and the amount of tax benefits that would be recorded in additional paid-in capital, if any, when the option is exercised, are assumed to be used to repurchase shares in the current period. Dilutive common share equivalents also reflect the dilutive effect of unvested restricted stock units, deferred stock units and restricted stock and the conversion of convertible debt which is calculated using the "if-converted" method. In addition, in computing the dilutive effect of convertible debt, the numerator is adjusted to add back the after-tax amount of interest and debt issuance cost recognized in the period. As of December 31, 2007, our outstanding convertible senior debt consisted of our 2023 Notes and our 2025 Notes.

The computations for basic and diluted income per share from continuing operations were as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2007	2006	2005
Net income (loss) from continuing operations — basic	$102,607	$ 6,700	$(85,094)
Add: Interest and issuance cost related to convertible debt	3,040	—	
Net income (loss) from continuing operations — diluted	$105,647	$ 6,700	$(85,094)
Weighted-average common shares outstanding — basic	57,665	56,939	52,078
Dilutive effect of options and restricted stock	668	706	—
Dilutive effect of 2025 Notes	3,908	—	—
Weighted-average common shares and dilutive potential common shares — diluted	62,241	57,645	52,078
Net income (loss) per share from continuing operations:			
Basic	$ 1.78	$ 0.12	$ (1.63)
Diluted	$ 1.70	$ 0.12	$ (1.63)

Under the "if-converted" method, 2,998,875 common share equivalents related to our 2023 Notes were not included in diluted earnings per share for the year ended December 31, 2007 because their effect would be anti-dilutive. For the year ended December 31, 2006, both the 2025 Notes and the 2023 Notes were not included in diluted earnings per share because their effect would be anti-dilutive. For the year ended December 31, 2005, the 2023 Notes, the 2025 Notes and our outstanding stock options were excluded because their effect would be anti-dilutive. The table below sets forth the common share equivalents related to convertible debt and equity plans; contingent shares; and the interest expense related to the convertible notes not included in dilutive shares because their effect was anti-dilutive.

	Year Ended December 31,		
(In thousands)	2007	2006	2005
Common share equivalents	2,999	6,907	4,948
Contingent shares	—	1,585	1,585
Convertible note interest and issuance expense not added back under the "if converted" method	$5,936	$9,038	$6,065

The contingent shares represent contingently issuable shares granted pursuant to contingent valued rights issued in connection with the acquisition of Cell Pathways, Inc. They were not included in dilutive shares since the contingency condition was not satisfied.

In connection with the 2003 acquisition of Cell Pathways, we recognized contingent consideration of $22.0 million in the form of five-year contingent value rights pursuant to which each share of Cell Pathways common stock will be eligible for an additional 0.04 share of our common stock in the event of a filing of a new drug application by June 12, 2008 for either of the two clinical candidates acquired from Cell Pathways, OSI-461 or Aptosyn. We have ceased our development efforts of these two clinical candidates and have entered into a letter of intent to outlicense these candidates. During the second quarter of fiscal 2006, we concluded that, in our judgment, the milestone will not be met based upon the current progress of our outlicensing efforts and the technical hurdles for filing a new drug application by June 2008 and therefore, we reversed the $22.0 million liability and recorded an extraordinary gain during the year ended December 31, 2006.

(4) Comprehensive Income (Loss)

Comprehensive income (loss) includes foreign currency translation adjustments, post-retirement adjustment and unrealized gains or losses on our available-for-sale securities (in thousands).

	Year Ended December 31,		
	2007	2006	2005
Net income (loss)	$66,319	$(582,184)	$(157,123)
Other comprehensive loss:			
Foreign currency translation adjustments	366	2,148	(2,431)
Curtailment of post-retirement plan	1,316	—	—
Unrealized holding gains (losses) arising during period	486	(233)	(1,245)
Less: Reclassification adjustment for losses realized in net loss	—	—	2,173
	2,168	1,915	(1,503)
Total comprehensive income (loss)	$68,487	$(580,269)	$(158,626)

The components of accumulated other comprehensive income were as follows (in thousands):

	As of December 31,	
	2007	2006
Cumulative foreign currency translation adjustment	$4,342	$ 3,976
Adjustment to initially apply SFAS No. 158	—	(1,316)
Unrealized gains (losses) on available-for-sale securities	180	(306)
Accumulated other comprehensive income	$4,522	$ 2,354

(5) Investments

(a) Investment Securities

We invest our excess cash in U.S. government securities, U.S. Government agency securities and debt instruments of financial institutions and corporations with strong credit ratings. We have established guidelines relative to the diversification of our investments and their maturities with the objective of maintaining safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

The following is a summary of available-for-sale securities as of December 31, 2007 and 2006 (in thousands):

2007	Costs	Gross Unrealized Gains	Fair Value
U.S. government and U.S. government agency securities	$128,416	$156	$128,572
Corporate and financial institutions debt	8,847	20	8,867
Total investment securities	137,263	176	137,439
Restricted investments	4,918	4	4,922
Total	$142,181	$180	$142,361

2006	Costs	Gross Unrealized Losses	Fair Value
U.S. government and U.S. government agency securities	$137,089	$(274)	$136,815
Corporate and financial institutions debt	27,975	(4)	27,971
Investment securities	165,064	(278)	164,786
Restricted investments	9,582	(28)	9,554
Total	$174,646	$(306)	$174,340

Net realized gains (losses) on sales of investments during the years ended December 31, 2007, 2006 and 2005 were $(4,000), $170,000 and $(2.2 million), respectively.

Maturities of securities classified as available-for-sale were as follows at December 31, 2007 (in thousands):

	Cost	Fair Value
2008	$ 51,732	$ 51,874
2009	46,098	46,112
2010	42,601	42,626
2011	1,750	1,749
	$142,181	$142,361

(6) Inventory

The December 31, 2006 inventory balances included both Tarceva and Macugen values. As of December 31, 2007, $5.1 million of Macugen inventories have been classified as assets related to discontinued operations.

During the fourth quarter of 2006, we assessed our current level of Macugen finished inventory with near term expiration dates, our progress on finalizing a new sterile syringe product presentation to satisfy our post-approval commitment to the FDA for Macugen, and the expected recoverability of Macugen work-in-process and raw material upon our planned disposal of the eye disease business. Our analysis of the carrying value of inventory relied upon known market trends and expectations for future sales. Based on this assessment, we concluded that an inventory charge of $26.4 million was required for the fourth quarter of 2006 related to the potential disposal of certain Macugen packaged syringes as well as the recoverability of work-in-process and raw materials. The inventory charge of $26.4 million is included in the loss from discontinued operations for the year ended December 31, 2006.

Inventory, net of the reserve for excess inventory, at December 31, 2007 and 2006, consisted of the following (in thousands):

	December 31, 2007	December 31, 2006
Raw materials	$ 1,704	$ 3,032
Work-in-process	8,595	22,282
Finished goods on hand, net	4,614	6,088
Inventory subject to return	6,151	5,458
Total inventory	$21,064	$36,860

Inventory subject to return represents the amount of Tarceva shipped to Genentech and Gelclair shipped to wholesale customers, which has not been recognized as revenue (see note 1(b)).

(7) Property, Equipment and Leasehold Improvements

Property, equipment and leasehold improvements are recorded at cost and consist of the following (in thousands):

	Estimated Life (years)	December 2007	December 2006
Land	—	$ 3,600	$ 3,600
Building and improvements	10-35	23,395	23,502
Laboratory equipment	5-15	26,478	25,663
Office furniture and equipment and computer equipment	3-7	16,025	15,319
Capitalized software	1-3	6,942	6,817
Manufacturing equipment	3-7	136	5,150
Leasehold improvements	Life of lease	34,525	34,260
Total		111,101	114,311
Less: accumulated depreciation and amortization		(64,407)	(58,088)
Property, equipment and leasehold improvements, net		$ 46,694	$ 56,223

Depreciation expense relating to continuing operations for the years ended December 31, 2007, 2006 and 2005 was $7.3 million, $9.6 million and $10.1 million, respectively. We had capitalized $6.9 million and $6.8 million of capitalized computer software costs as of December 31, 2007 and 2006, respectively, of which $6.3 million and $5.3 million was amortized as of December 31, 2007 and 2006, respectively. As of December 31, 2007, $1.5 million of property, plant and equipment related to (OSI) Eyetech is classified as assets related to discontinued operations. Depreciation expense related to discontinued operations for the years ended December 31, 2007, 2006 and 2005 was $929,000, $4.0 million and $484,000, respectively.

(8) Goodwill and Other Intangible Assets

The carrying amount of goodwill was $39.4 million as of December 31, 2007 and 2006. The balance of goodwill as of December 31, 2007 and 2006 included a $38,000 and $343,000, respectively, effect from foreign currency exchange rate fluctuations during fiscal 2007 and 2006. We completed our annual impairment review of goodwill as of December 31, 2007 and determined that no impairment charge was required. As discussed in Note 20, we recorded a $320.3 million impairment charge during 2006 related to the Eyetech goodwill.

The components of other intangible assets-net are as follows (in thousands):

	December 31, 2007			December 31, 2006		
	Carrying Amount	Net Accumulated Amortization	Book Value	Carrying Amount	Net Accumulated Amortization	Book Value
Novantrone technology	$46,009	$(44,558)	$1,451	$46,009	$(43,108)	$2,901
Acquired patent estate	770	(198)	572	760	(135)	625
Acquired licenses issued to other companies	3,984	(1,041)	2,943	3,932	(716)	3,216
Total	$50,763	$(45,797)	$4,966	$50,701	$(43,959)	$6,742

In connection with Prosidion's acquisition of certain assets of Probiodrug in July 2004, as discussed in Note 19, we recorded $515,000 of intangible assets related to the acquired patent estate and $3.1 million related to non-exclusive licenses issued to two pharmaceutical companies. In connection with the acquisition of the minority interest in Prosidion in fiscal 2005, the value of the patent estate and acquired licenses increased by $203,000 and $615,000, respectively. These intangible assets are being amortized on a straight-line basis over the term of the term of the patents. These intangible assets are recorded on the books of Prosidion and fluctuate based on changes in exchange rates.

We acquired the exclusive rights to market and promote Novantrone for approved oncology indications in the United States from Merck Serono in March 2003. These rights initially were amortized over the life of the underlying patent. At December 31, 2005, we revised the future recoverability period of the Novantrone intangible asset through the end of 2008, and therefore began amortizing the remaining balance on a straight-line basis.

Amortization expense related to continuing operations for our intangible assets for the years ended December 31, 2007, 2006 and 2005 was $1.8 million, $1.8 million and $15.3 million, respectively. Amortization expense is estimated to be $1.8 million for 2008 and $385,000 for the years 2009 through 2012. For the years ended December 31, 2006 and 2005, amortization expense related to discontinued operations was $18.1 million and $2.3 million, respectively. We did not recognize any amortization expense for discontinued operations for the year ended December 31, 2007.

(9) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses at December 31, 2007 and 2006 are comprised of (in thousands):

	December 31,	
	2007	2006
Accounts payable	$ 5,249	$ 3,543
Accrued payroll and employee benefits	3,398	3,612
Accrued exit costs (see note 10)	2,589	8,128
Accrued interest	1,619	1,619
Accrued CRO and site costs	4,969	5,059
Accrued commercial and development costs	6,566	5,723
Accrued royalties	—	1,088
Other accrued expenses	21,453	25,969
	$45,843	$54,741

As of December 31, 2007, $13.4 million of accounts payable and accrued expenses related to Eyetech have been classified as liabilities related to discontinued operations.

(10) Consolidation of Facilities

(a) Restructuring Plan

On November 6, 2006, we announced our intention to exit our eye disease business, and committed to a plan to re-scale our eye disease business and other operations consistent with the streamlining of our overall business. The plan as it related to ongoing operations included the consolidation of facilities, as well as a reduction in the workforce. We recognized $2.5 million of anticipated costs in the fourth quarter of 2006 related to our continuing operations which included a charge of $653,000 for severance payments, $654,000 related to long term assets and their utilization, and $1.2 million for lease obligations. During the year ended December 31, 2007, we recognized $1.3 million of additional severance charges, of which $719,000 was included in selling, general and administrative expenses, and $575,000 was included in research and development expenses and an additional $702,000 for lease obligations. The activity for the year ended December 31, 2007 and 2006 was as follows (in thousands):

	Year Ended December 31,	
	2007	2006
Opening liability	$ 1,897	$ —
Accrual for severance payments	1,292	653
Accrual for lease payments	702	1,254
Cash paid for severance	(1,525)	(10)
Cash paid for rent	(810)	—
Ending liability	$ 1,556	$1,897

(b) Corporate Headquarters

In 2006, we relocated our corporate headquarters to our newly acquired facility in Melville, New York. As a result, in accordance with SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," we recognized a liability of $3.0 million associated with the termination of the lease for the prior facility based on the net present value of future lease payments. The activity for the years ended December, 2007 and 2006 was as follows (in thousands):

	Year Ended December 31,	
	2007	2006
Opening liability	$ 1,924	$ —
Accrual for lease termination costs	—	2,974
Accretion expense	54	147
Cash paid for rent	(1,434)	(1,197)
Ending liability	$ 544	$ 1,924

(c) Oxford, England

In August 2004, we announced the decision to consolidate all of our U.K.-based oncology research and development activities into our New York locations. During the year ended December 31, 2005, we recorded a charge of $4.4 million, in selling, general and administrative expenses, for estimated facility lease return costs and the remaining rental obligation net of estimated sublease rental income in accordance with SFAS No. 146. The activity for the years ended December 31, 2007 and 2006 was as follows (in thousands):

	Year Ended December 31,	
	2007	2006
Opening liability	$ 4,062	$4,211
Cash paid for rent	(1,251)	(701)
Other	71	552
Ending liability	$ 2,882	$4,062

(11) Collaborative Profit Share Payable

In connection with the acquisition of Eyetech and prior to our amendment of our collaborative agreements with Pfizer in March 2007 discussed in Note 20, Macugen was co-promoted by us and Pfizer in the United States where we had an ophthalmology sales force, maintained the inventory and booked all U.S. product sales. Pfizer and we shared in gross profits and losses from the sale of Macugen products in the United States. As of December 31, 2007, we had a liability to Pfizer of $2.8 million which is included in liabilities related to discontinued operations.

(12) Convertible Senior Subordinated Notes

(a) 2.0% Convertible Senior Subordinated Notes

On December 21, 2005, we issued $100.0 million aggregate principal amount of 2025 Notes in a private placement for net proceeds to us of $96.5 million. On December 28, 2005, the bankers associated with this convertible debt offering exercised an option to purchase an additional $15.0 million of the 2025 Notes, for additional net proceeds to us of $14.6 million. The 2025 Notes bear interest at 2.0% per annum, payable semi-annually, and mature on December 15, 2025. The 2025 Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock based on an initial conversion rate, subject to adjustment, of 33.9847 shares per $1,000 principal amount of notes (which represents an initial conversion price of $29.43 per share), only in the following circumstances and to the following extent: (i) prior to December 15, 2020, during any fiscal quarter after the fiscal quarter ending March 31, 2006, if the closing sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding fiscal quarter exceeds 120% of the conversion price in effect on the last trading day of the immediately preceding fiscal quarter; (ii) prior to December 15, 2020, during the five business day period after any five consecutive trading day period, or the note measurement period, in which the average trading price per $1,000 principal amount of notes was equal to or less than 97% of the average conversion value of the notes during the note measurement period; (iii) upon the occurrence of specified corporate transactions, as described in the indenture for the 2025 Notes; (iv) if we call the notes for redemption; or (v) any time on or after December 15, 2020. Upon conversion, we will have the right to deliver, in lieu of shares of common stock, cash or a combination of cash and shares of common stock. At any time before the maturity date, we may irrevocably elect, in our sole discretion, to satisfy our conversion obligation in cash up to 100% of the principal amount of the notes converted, with any remaining amount to be satisfied in shares of our common stock. If

certain fundamental changes occur before December 15, 2010, the conversion rate may increase, or under certain circumstances, we may elect to change our conversion obligations to provide for conversion of the notes into the acquiring company's common stock. We may redeem the 2025 Notes, in whole or in part, for cash, at any time on or after December 15, 2010 for a price equal to 100% of the principal amount of the 2025 Notes to be redeemed, plus any accrued and unpaid interest. The holders of the 2025 Notes have the right to require us to purchase, for cash, all of the 2025 Notes, or a portion thereof, on December 15, 2010, December 15, 2015, on December 15, 2020 and under certain other circumstances as set out in the indenture, for a price equal to 100% of the principal amount of the 2025 Notes plus any accrued and unpaid interest. The related debt issuance costs of $3.9 million were deferred and are being amortized on a straight-line basis over a five-year term, which represents the earliest date that we may redeem the 2025 Notes. Concurrent with the sale of the 2025 Notes, we used $11.8 million of the net proceeds for the purchase of 500,000 shares of our common stock and we purchased a call spread overlay transaction from UBS, AG at a cost of $12.2 million. The call spread is a European-type option with a lower strike price of $29.425 and an upper strike price of $40.00 and involves an aggregate of 3.4 million shares of our common stock and expires on December 15, 2010. The call spread overlay agreement has the effect of increasing the effective conversion price of the 2025 Notes from our perspective to $40.00 per share on the intended sale of $100.0 million (excluding the sale of $15.0 million of 2025 Notes related to the exercise of the overallotment). The agreement calls for settlement using net shares. Under the agreement, bankers associated with the debt offering will deliver to us the aggregate number of shares we are required to deliver to a holder of 2025 Notes that presents such notes for conversion. If the market price per share of our common stock is above $40.00 per share, we will be required to deliver shares of our common stock representing the value in excess of the strike price. In accordance with EITF No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," and SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity," we recorded the purchase of the call spread overlay option agreement as a reduction in additional paid in capital, and will not recognize subsequent changes in fair value of the agreement.

At December 31, 2007 and 2006, the fair value of the outstanding 2025 Notes was approximately $195.5 million and $147.9 million, respectively, based on their quoted market value. As of January 1, 2008, the 2025 Notes were convertible as our common stock closed at or above $35.32 per share for twenty trading days within the thirty trading day period ending on December 29, 2007. As a result, during the conversion period commencing January 1, 2008 and continuing through and including March 31, 2008, holders of the Notes may, if they elect, convert the notes into shares of common stock, subject to the terms of the related indenture.

(b) 3.25% Convertible Senior Subordinated Notes

On September 8, 2003, we issued $135.0 million aggregate principal amount of 2023 Notes in a private placement for net proceeds to us of $130.3 million. On September 17, 2003, the bankers associated with this convertible debt offering exercised an option to purchase an additional $15.0 million of the 2023 Notes, for additional net proceeds to us of $14.5 million. The 2023 Notes bear interest at 3.25% per annum, payable semi-annually, and mature on September 8, 2023. The 2023 Notes are convertible into shares of our common stock at a conversion price of $50.02 per share, subject to normal and customary adjustments such as stock dividends or other dilutive transactions. We may redeem the 2023 Notes, in whole or in part, for cash, at any time after September 8, 2008 for a price equal to 100% of the principal amount of the 2023 Notes to be redeemed, plus any accrued and unpaid interest. The holders of the 2023 Notes have the right to require us to purchase all of the 2023 Notes, or a portion thereof, on September 8, 2008, September 8, 2013 and September 8, 2018 for a price equal to 100% of the principal amount of the 2023 Notes plus

any accrued and unpaid interest. If the holders of the 2023 Notes make this election, we can pay the purchase price in cash or by issuing our common stock. Upon a change in control, as defined in the indenture governing the 2023 Notes, the holders of the 2023 Notes will have the right to require us to purchase all of the 2023 Notes, or a portion thereof, not previously called for redemption at a purchase price equal to 100% of the principal amount of the 2023 Notes purchased, plus accrued and unpaid interest. Upon the exercise by the holders of the right to require us to purchase the 2023 Notes or upon a change of control, we may elect to pay the purchase price in common stock instead of cash. The number of shares of common stock a holder will receive will equal the purchase price divided by 95% of the average of the closing prices of our common stock for the five-trading day period ending on the third business day prior to the purchase date. The debt issuance costs of $5.2 million related to the 2023 Notes were deferred and are being amortized on a straight-line basis over a five-year term, which represents the earliest date that we may redeem the 2023 Notes. In connection with the issuance of the 2023 Notes, we used $19.0 million of the net proceeds for the purchase of 503,800 shares of our common stock. At December 31, 2007 and 2006, the fair value of the outstanding 2023 Notes, was approximately $163.5 million and $148.5 million, respectively, based on their quoted market value.

The 2023 Notes have been classified in current liability in the accompanying December 31, 2007 consolidated balance sheets, as holders have the right to require us to purchase all of the 2023 notes, or a portion thereof, on September 8, 2008. If holders of the 2023 Notes make this election, we can pay the purchase price in cash or by issuing shares of our common stock.

(13) Income Taxes

In July 2006, FASB issued FIN 48 which clarifies the criteria that must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN 48 provides a benefit recognition model with a two-step approach consisting of a "more-likely-than-not" recognition criteria, and a measurement attribute that measures a given tax position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. FIN 48 also requires the recognition of liabilities created by differences between tax positions taken in a tax return and amounts recognized in the financial statements. FIN 48 is effective as of the beginning of the first annual period beginning after December 15, 2006, and became effective for us on January 1, 2007. The adoption of FIN 48 on January 1, 2007 had no impact on the financial condition, results of operations, or cash flows for the year ended December 31, 2007 as the Company has no unrecognized tax benefits.

For the year ended December 31, 2007, we recorded a provision for income taxes of $2.7 million related to income from continuing operations and a tax benefit of approximately $640,000 related to our loss from discontinued operations. Based on our ability to fully offset current taxable income by our net operating loss carry forwards, our estimated tax expense is principally related to U.S. alternative minimum tax.

There is no provision (benefit) for federal or state income taxes for the years ended December 31, 2006 and 2005 because we incurred operating losses since inception and have established a valuation allowance equal to the net deferred tax assets.

The income tax provision for continuing operations for the year ended December 31, 2007 included the following (in thousands):

	Year Ended December 31, 2007
Current:	
Federal	$2,190
State and Local	196
Foreign	346
Total	$2,732

For the year ended December 31, 2007, our effective income tax rate for continuing operations differed from the statutory U.S. federal income tax rate as a result of the following:

	Year Ended December 31, 2007
Statutory U.S. Federal tax rate	35.0%
State and local taxes, net of federal benefit	0.2
Foreign taxes	0.3
Utilization of net operating loss carry forwards	(35.1)
Other, net	2.2
Total	2.6%

The tax effect of temporary differences, net operating loss carry forwards and research and development tax credit carry forwards as of December 31, 2007 and 2006 are as follows (in thousands):

	December 31, 2007	December 31, 2006
Deferred tax assets:		
Net operating loss carry forwards	$ 412,877	$ 451,248
Research and development tax credit carry forwards	35,243	29,422
Intangible assets	11,951	10,379
Unearned revenue	31,174	33,135
Purchased research and experimental expenditures	45,968	48,880
Capitalized research and experimental expenditures	7,235	9,467
Other	18,304	26,943
	562,752	609,474
Valuation allowance	(562,246)	(607,961)
	506	1,513
Deferred tax liability:		
Other	(409)	(419)
Inventory fair value adjustment	(97)	(1,094)
	(506)	(1,513)
	$ —	$ —

As of December 31, 2007, we had available U.S. federal and foreign net operating loss carry forwards of approximately $953 million and $116 million, respectively. The U.S. NOLs will expire in various years from 2008 to 2026 and may be subject to certain annual limitations. The U.K. NOLs do not have an expiration date. As of December 31, 2007, approximately $52 million of the deferred tax asset related to our U.S. net operating loss carry forwards consists of deductions for employee stock options for which the tax benefit will be credited to additional paid-in capital if and when realized. Our research and development tax credit carry forwards expire in various years from 2008 to 2027. A portion of our research and development tax credits relates to stock-based compensation and will be recorded as an increase to additional paid-in capital if and when realized. Certain of our net operating loss carry forwards and research and development tax credits may be subject to significant limitations under Section 382 of the Internal Revenue Code. We have also accumulated approximately an additional $150 million in other net deferred tax assets based on temporary differences between book and tax reporting. The decrease in the valuation allowance of approximately $46 million in fiscal 2007 was primarily attributable to the Company utilizing U.S. net operating loss carry forwards.

We continue to fully reserve our NOLs and other deferred tax assets despite achieving full-year profitability in 2007 and our expectation for continued future profitability, since, up until 2007, we have had a history of annual losses since inception. On a quarterly basis, we will reassess our valuation allowance for deferred income taxes. We will consider reversing a significant portion of the valuation reserve upon assessment of certain factors, including: (i) a demonstration of sustained profitability; (ii) the support of internal financial forecasts demonstrating the utilization of the NOLs prior to their expiration; and (iii) our reassessment of tax benefits recognition under FIN 48. If we determine that the reversal of a significant portion of the valuation reserve is appropriate, a significant one-time benefit will be recognized against our income tax provision in the period of the reversal. We do not expect to reverse the valuation allowance related to our U.K. NOLs for the foreseeable future and any NOLs that would be limited under IRC Section 382. In addition, the aforementioned $52 million of NOLs related to deductions for employee stock options will be credited to additional paid-in capital if and when realized. At such time, we will also commence recognizing an income tax provision at the existing U.S. Federal and state income tax rates. However, our ability to utilize our NOLs to offset taxable income will continue to provide us with significant cash savings until the NOLs are fully utilized or expire. The tax years from 1993 and forward remain open to examination by the Federal and most state authorities due to net operating loss and credit carry forwards.

(14) Employee Savings and Investment Plans

We sponsor an Employee Savings and Investment Plan under Section 401(k) of the Internal Revenue Code. The plan allows our U.S. employees to defer from 2% to 20% of their income on a pre-tax basis through contributions into designated investment funds. We match each employee's contribution to the plan on a dollar-for-dollar basis up to 4% of such employee's salary, and then match 50% of such employee's contribution from 4% to 6% of his or her salary. Prior to January 1, 2007, we matched 50% of the employees contributions up to 6% of his or her earnings. During the years ended December 31, 2007, 2006 and 2005, our expenses related to the plan were $2.0 million, $1.4 million and $848,000, respectively.

We also sponsor four pension plans covering the employees of OSI-UK and Prosidion. The Group Personal Pension Plan allows employees to contribute a portion of their income on a post-tax basis into designated investment funds. The tax paid on the contribution is then recovered from the Inland Revenue. We generally contribute from 4% to 9% depending on the employees' contributions. The British Biotechnology Limited Pension Scheme covers employees retained from the acquisition of certain assets from British Biotechnology Limited, as well as certain former

employees of British Biotechnology hired by us subsequent to the acquisition. The plan allows the employees to defer up to 15% of their income on a pre-tax basis through contributions into designated pension funds. For each period the employee invests, we will contribute up to 9% into the funds. For the year ended December 31, 2007, 2006 and 2005, our expenses related to the plans were $704,000, $673,000 and $560,000, respectively.

In addition, effective July 2007, we adopted a nonqualified deferred compensation plan which permits certain employees to elect annually to defer a portion of their compensation, and as of December 31, 2007, we had recorded a $456,000 liability. The employees select among various investment alternatives, with the investments held in a separate trust. The value of the participant's balance fluctuates based on the performance of the investments. The market value of the trust at December 31, 2007 was $443,000 and is included as an asset in the December 31, 2007 balance sheet because the trust's assets are available to the Company's general creditors in the event of our insolvency.

(15) Employee Post-retirement Plan and Other

(a) Employee Post-retirement Plan

Prior to April 18, 2007, we provided post-retirement medical and life insurance benefits to eligible employees, board members and qualified dependents. Eligibility was determined based on age and service requirements. These benefits are subject to deductibles, co-payment provisions and other limitations. On April 18, 2007, we curtailed our post-retirement medical and life insurance plan and grandfathered those employees, board members and qualified dependants who were eligible to participate in the plan on that date. As a result of the curtailment, we reduced our liability for this plan by $5.5 million and recognized a gain of $4.3 million and recorded an adjustment to accumulated other comprehensive income of $1.3 million. The curtailment had the effect of decreasing the accumulated benefit obligation at April 18, 2007 to $3.0 million. Only those grandfathered participants will continue to be entitled to receive benefits under the plan. These benefits are subject to deductibles, co-payments and other limitations. We follow SFAS No. 106, "Employers' Accounting for Post-Retirement Benefits Other Than Pensions" as amended by SFAS No. 132(R), "Employers' Disclosures About Pensions and Other Post-Retirement Benefits," or SFAS No. 106, to account for and disclose the benefits to be provided by the plan. Under SFAS No. 106, the cost of post-retirement medical and life insurance benefits is accrued over the active service periods of employees to the date they attain full eligibility for such benefits.

Effective December 31, 2006, we adopted the recognition and disclosure provisions of SFAS No. 158, "Employers' Accounting for Defined Benefit Pension and Other Post-retirement Plans, an amendment of FASB statements No. 87, 88, 106, and 132(R)," or SFAS No. 158. SFAS No. 158 requires employers to recognize in their balance sheets the overfunded or underfunded status of defined benefit post-retirement plans, measured as the difference between the fair value of plan assets and the benefit obligation (the projected benefit obligation for pension plans and the accumulated post-retirement benefit obligation for other post-retirement plans). Upon the adoption of SFAS No. 158, we recognized an accumulated post-retirement benefit obligation of $8.1 million. The adoption of SFAS No. 158 resulted in an increase in our liability of $1.3 million with offsetting charge to stockholders' equity as a component of accumulated other comprehensive income and as discussed above, the subsequent curtailment of the plan 2007 resulted in a $1.3 million adjustment to accumulated other comprehensive income.

Net post-retirement benefit cost (excluding the $4.3 million curtailment gain recognized in 2007) for the years ended December 31, 2007, 2006 and 2005, included the following components (in thousands):

	Year Ended December 31,		
	2007	2006	2005
Service cost for benefits earned during the period	$337	$1,054	$ 839
Interest cost on accumulated post-retirement benefit obligation	252	409	352
Amortization of initial benefits attributed to past service	2	6	6
Amortization of loss	6	66	64
Net post-retirement benefit cost	$597	$1,535	$1,261

The accrued post-retirement benefit cost at December 31, 2007 and 2006 totaled $3.2 million and $8.1 million, respectively.

The changes in the accumulated post-retirement benefit obligation during years ended December 31, 2007 and 2006 were as follows (in thousands):

	2007	2006
Balance at beginning of year	$ 8,070	$7,509
Benefit payments	(118)	(134)
Loss experience	128	(768)
Service cost	337	1,054
Curtailment gain	(5,506)	—
Interest cost	252	409
Balance at end of year	$ 3,163	$8,070

For the year ended December 31, 2007, the health care cost trend assumption decreased to an initial level of 9% (from an initial level of 10% in fiscal 2006), decreasing to an ultimate estimated rate of 5% by 2012 and thereafter. Increasing the assumed health care cost trend rates by one percentage point in each year and holding all other assumptions constant would increase the accumulated post-retirement benefit obligation as of December 31, 2007 by $315,000 and the fiscal 2007 net post-retirement service and interest cost by $18,000. Decreasing the assumed health care cost trend rate by one percentage point in each year and holding all other assumptions constant would decrease the accumulated post-retirement benefit obligation as of December 31, 2007 by $270,000 and the fiscal 2007 net post-retirement service and interest cost by $16,000. Benefits paid in the years ended December 31, 2007, 2006 and 2005 were $118,000, $134,000 and $111,000, respectively.

The weighted average assumptions used in determining benefit obligations and net periodic benefits costs are as follows:

	2007	2006	2005
Discount rate	5.72%	5.75%	5.5%
Expected long-term rate of return on plan assets	N/A	N/A	N/A

The discount rate was computed using Moodys Aa Corporate Bond Index and Merrill Lynch 10+ Bond Index as of December 31, 2007.

For the years ended 2008 through 2012, we anticipate paying benefits of $182,000, $196,000, $215,000, $231,000, and $232,000, respectively. We anticipate paying aggregate benefits of $1.2 million for the years of 2013 through 2017.

(b) Sabbatical Leave Accrual

Effective January 1, 2007, we adopted EITF 06-02, "Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to SFAS No. 43," or EITF 06-02. Sabbatical leave is generally defined as an employee's entitlement to paid time off after working for an entity for a specified period of time. The employee continues to be a compensated employee and is not required to perform any duties for the entity during the sabbatical leave. We provide a sabbatical leave of four weeks for employees who have achieved 15 years of service. We applied the consensus as a change in accounting principle through retrospective application to all prior periods in accordance with SFAS No. 154, "Accounting Changes and Error Corrections." The cumulative effect of the change in accounting principle is an increase of $352,000 in accrued expenses and a decrease in retained earnings of $352,000 as of December 31, 2006. The results of operations for the year ended December 31, 2006 and 2005 have not been restated for the retrospective impact of adopting the EITF 06-02 because the effect was insignificant. Included in accrued post-retirement benefit costs and other as of December 31, 2007 was $425,000 of accrued sabbatical leave.

(16) Stockholders' Equity

(a) Equity Plans

We have nine equity plans pursuant to which there are outstanding grants issued to our employees, officers, directors and consultants. Two of these plans still have shares available for future grant, the 1999 Incentive and Non-Qualified Stock Option Plan and the Amended and Restated Stock Incentive Plan. The plans are administered by the Compensation Committee of the Board of Directors, which may grant stock options and, in the case of the Amended and Restated Stock Incentive Plan, restricted stock, restricted stock units and deferred stock units. The Compensation Committee determines the terms of all equity grants under the plans. Our equity grants vest over various periods and expire no later than 10 years from date of grant. The total authorized shares under these plans are 21,388,777, of which 6,411,002 shares were available for future grant as of December 31, 2007.

On March 17, 2004, at our 2004 annual meeting of stockholders, our stockholders approved an amendment and restatement of the 2001 Stock Option Plan in the form of the Amended and Restated Stock Incentive Plan, or the Plan, which was adopted by the Board of Directors on January 23, 2004. On March 16, 2005 at our 2005 annual meeting of stockholders, our stockholders approved an amendment to the Plan to increase the number of equity awards issuable under the Plan from 4 million shares to 6.8 million shares. On June 13, 2007, our stockholders approved an amendment to the Plan to increase the number of equity awards issuable under the Plan from 6.8 million to 13.8 million. Participation in the Plan is limited to our directors, officers, employees and consultants of our parent or subsidiaries. The Plan permits the issuance of stock options, and the grant of restricted stock, restricted stock units, stock appreciation rights and stock bonus awards upon such terms and conditions as the Compensation Committee determines.

Pursuant to the Eyetech merger agreement, as discussed in Note 20, we assumed Eyetech's 2001 Stock Plan and, to facilitate such assumption, adopted the OSI Pharmaceuticals, Inc. Stock Plan for Assumed Options of Pre-Merger Employees of Eyetech Pharmaceuticals, Inc., or the Assumed Plan. Pursuant to the terms of the Assumed Plan and the merger agreement, we assumed all options and other awards granted to employees, outside directors and consultants outstanding under the Assumed Plan. The number of shares of OSI common stock subject to each assumed option was determined by multiplying the number of shares of the Eyetech common stock that were subject to each option prior to the effective time of the Eyetech acquisition by a conversion ratio of 0.491, and rounding that result down to the nearest whole number of shares of OSI common stock. The per share exercise price for the assumed options was determined by dividing the per share exercise price of the Eyetech common stock subject to

each option as in effect immediately prior to the effective time by the conversion ratio of 0.491 and rounding that result up to the nearest whole cent. Under the Assumed Plan, we granted non-qualified stock options to purchase up to 153,000 shares of our common stock in connection with the acquisition.

On November 12, 2005, our Board of Directors approved the OSI Pharmaceuticals, Inc. Stock Incentive Plan for Pre-Merger Employees of Eyetech Pharmaceuticals, Inc., or the Eyetech Plan. The Eyetech Plan was adopted to provide equity grants to certain Eyetech employees that we retained after the Eyetech merger.

We have an employee stock purchase plan under which eligible employees may contribute up to 10% of their base earnings toward the quarterly purchase of our common stock. The employee's purchase price is derived from a formula based on the fair market value of the common stock and a 15% discount. As of December 31, 2007, we had 298,397 shares of common stock available for future grant under these plans.

We sponsor a stock purchase plan for our UK-based employees. Under the terms of the plan, eligible employees may contribute between £5 and £250 of their base earnings, in 36 monthly installments towards the purchase of our common stock. As of December 31, 2007, we had 80,426 shares of our common stock available for future grant in connection with this plan.

Effective January 1, 2006, we adopted the provisions of SFAS No. 123(R), which establishes the accounting for employee stock-based awards. Under the provisions of SFAS No. 123(R), stock-based compensation is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the requisite employee service period (generally the vesting period of the grant). We adopted SFAS No. 123(R) using the modified prospective method and, as a result, periods prior to January 1, 2006 have not been restated.

Compensation expense related to continuing operations for the years ended December 31, 2007 and 2006 were as follows (in thousands):

	Year Ended December 31,	
	2007	2006
Cost of sales	$ 338	$ 251
Research and development expenses	4,683	2,973
Selling, general and administrative expenses	10,406	9,957
Stock-based compensation expense	$15,427	$13,181

Compensation expense related to discontinued operations for the year ended December 31, 2007 and 2006 was $2.2 million and $9.2 million, respectively. Total net stock-based compensation expense is attributable to the granting of, and the remaining requisite service periods of, stock options, restricted stock, restricted stock units and deferred stock units. Compensation expense attributable to net stock-based compensation for the years ended December 31, 2007 and 2006 was $17.7 million, or $0.28 diluted earnings per share, and $22.4 million or $0.39 diluted earnings per share, respectively. At December 31, 2007, the total remaining unrecognized compensation cost related to unvested stock-based payment awards was $61.3 million. This cost is expected to be recognized over a weighted average period of approximately 3.2 years.

During the year ended December 31, 2005, we recorded compensation expense for stock options based upon their intrinsic value on the date of grant pursuant to Accounting Principles Board, or APB, Opinion No. 25, "Accounting for Stock Issued to Employees." Since the exercise price for such options was equal to the fair market value of our stock at the date of grant, the stock options had no intrinsic value upon grant and, therefore, no expense associated with stock options was recorded in the consolidated statements of operations.

Had the compensation cost of our equity compensation plans for the year ended December 31, 2005 been determined in accordance with SFAS No. 123(R), our pro forma net loss and net loss per share would have been (in thousands except per share amounts):

	Year Ended December 31, 2005
Net loss	$(157,123)
Add: stock-based compensation included in net loss	3,406
Compensation cost determined under fair value method	(61,714)
Pro forma net loss	$(215,431)
Basic and diluted net loss per common share:	
Net loss — as reported	$ (3.02)
Net loss — pro forma	$ (4.14)

Under the modified prospective method, SFAS No. 123(R) applies to new awards and to awards outstanding on the effective date that are subsequently modified or cancelled. Compensation expense for outstanding awards for which the requisite service had not been rendered as of December 31, 2005 is being recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under SFAS No. 123(R). We amortize the fair value of all awards on a straight-line basis over the total requisite service period.

(b) Stock Options

We estimate the fair value of stock options using the Black-Scholes option-pricing model. We believe that the valuation technique and the approach utilized to develop the underlying assumptions are appropriate in calculating the fair value of our stock options granted. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by the employees who receive equity awards.

Historically, we have satisfied the exercise of options by issuing new shares. We estimate expected volatility based upon a combination of historical, implied and adjusted historical stock prices. The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of grant. We assumed an expected dividend yield of zero since we have not historically paid dividends and do not expect to pay dividends in the foreseeable future. Commencing in the second quarter of fiscal 2005, the fair value of the options was estimated at the date of grant using a Black-Scholes option pricing model with the expected option term determined using a Monte Carlo simulation model that incorporates historical employee exercise behavior and post-vesting employee termination rates. The fair values of the options was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions, and are based upon the weighted average for the periods reflected below:

	Year Ended December 31,		
	2007	2006	2005
Expected dividend yield	0%	0%	0%
Expected volatility	46.40%	54.53%	60.95%
Risk-free interest rate	3.83%	4.53%	4.23%
Expected term (years)	4.65	4.51	4.49
Per share weighted average fair value of stock options grants	19.26	16.21	17.26

A summary of our stock option programs at December 31, 2007, 2006, 2005 and 2004 and changes during the year is presented below:

	No. Shares (In thousands)	Weighted Average Exercise Price	Aggregate Intrinsic Value(1) (In millions)	Weighted Average Contractual Life Remaining in Years
Outstanding at December 31, 2004	4,246	$37.46		
Granted at fair value	3,573	$32.22		
Exercised at fair value	(463)	$21.76		
Forfeitures	(392)	$46.60		
Outstanding at December 31, 2005	6,964	$35.29		
Granted at fair value	777	$32.87		
Exercised at fair value	(391)	$20.22		
Forfeitures	(621)	$31.15		
Expired	(2)	$15.90		
Outstanding at December 31, 2006	6,727	$36.01		
Granted at fair value	665	$44.25		
Exercised at fair value	(1,042)	$24.65		
Forfeitures	(765)	$39.42		
Outstanding at December 31, 2007	5,585	$38.69	$68.5	5.24
Exercisable at December 31, 2007	3,896	$40.20	$46.0	4.97
Unvested at December 31, 2007	1,689	$35.22	$22.5	5.88

(1) The intrinsic value of a stock option is the amount by which the current market value of the underlying stock exceeds the exercise price of the option.

The total intrinsic value of stock options exercised during the years ended December 31, 2007, 2006 and 2005 was $15.9 million, $6.1 million, $12.3 million, respectively.

Options granted prior to June 1, 2005 have exercise prices equal to the fair market value of the stock on the date of grant, a contractual term of 10 years and a vesting period of three years. Options granted subsequent to May 31, 2005 have exercise prices equal to the fair market value of the stock on the date of grant, a contractual term of seven years and a vesting period of four years. For the year ended December 31, 2007 and 2006, the historical forfeiture rate was 21.84% and 16.9%, respectively, for non-executive employees and no forfeitures for executive employees was assumed for purposes of recognizing compensation expense based upon adjusted historical experience.

On November 30, 2005, the Compensation Committee of our Board of Directors approved the forward vesting of all unvested out-of-the-money stock options with an exercise price greater than $30.00 per share for all of our employees, other than executive officers. Options to purchase approximately 1.6 million shares of common stock were accelerated. Options held by executive officers and non-employee directors were not accelerated. The accelerated options, which were considered fully vested as of November 30, 2005, had grant prices ranging from $30.09 to $82.40 per share and a weighted average grant price of $45.44 per share. The primary purpose of the accelerated vesting was to enable us to reduce the future compensation expense associated with our out-of-the-money stock options upon adoption of SFAS No. 123(R).

(c) Restricted Stock, Restricted Stock Units, and Deferred Stock Units

Our outstanding shares of restricted stock, restricted stock units, and deferred stock units generally vest annually over a four-year period depending on the award, are valued at the stock price on date of grant, and are subject to certain additional terms and conditions, including but not limited to the continued service of the employee or director. An aggregate of 897,000 shares were outstanding for the year ended December 31, 2007, representing $35.0 million of unrecognized compensation expense which is expected to be recognized over a weighted average period of 3.4 years. The aggregate intrinsic value was $43.9 million as of December 31, 2007.

We also assumed 339,439 shares of Eyetech restricted stock in connection with our acquisition of Eyetech. Pursuant to the terms of the merger agreement, each share of restricted stock converted into the right to receive 0.12275 shares of our common stock and $15.00 cash payment upon vesting. As a result, on November 14, 2005, we reserved for issuance 41,666 shares of our common stock and $5.1 million in cash in connection with these restricted shares. As of December 31, 2007, 980 unvested shares of our common stock and $120,000 in cash remained subject to these restricted shares, representing $154,000 of unrecognized compensation expense.

The following is a summary of the status of our restricted stock, restricted stock units, and deferred stock units (excluding the assumed restricted shares in the Eyetech acquisition) for the years ended December 31, 2007 and 2006:

	No. Shares (In thousands)	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2005	16	$37.88
Granted	623	$35.58
Vested	(4)	$40.22
Forfeited	(12)	$31.29
Outstanding at December 31, 2006	623	$35.69
Granted	498	$46.77
Vested	(127)	$36.22
Forfeited	(97)	$35.59
Outstanding at December 31, 2007	897	$41.90

The total intrinsic value of restricted stock and restricted stock units that vested during the years ended December 31, 2007 and 2006 was $4.6 million and $169,000, respectively.

(d) Shareholder Rights Plan

On September 27, 2000, our Board of Directors adopted a shareholder rights plan, declared a dividend distribution of one Series SRPA Junior Participating Preferred Stock Purchase Right on each outstanding share of its common stock, and authorized the redemption of the rights issued pursuant to our then current shareholder rights plan. We distributed rights to all shareholders of record at the close of business on September 27, 2000, the record date. These rights entitle the holder to buy one one-thousandth of a share of Series SRPA Junior Participating Preferred Stock upon a triggering event as discussed below.

Upon the actual acquisition of 17.5% or more of our outstanding common stock by a person or group, the rights held by all holders other than the acquiring person or group will be modified automatically to be rights to purchase shares of common stock (instead of rights to purchase preferred stock) at 50% of the then market value of such

common stock. Furthermore, such rightholders will have the further right to purchase shares of common stock at the same discount if we merge with, or sell 50% or more of our assets or earning power to, the acquiring person or group or any person acting for or with the acquiring person or group. If the transaction takes the form of a merger of us into another corporation, these rightholders will have the right to acquire at the same percentage discount shares of common stock of the acquiring person or other ultimate parent of such merger party.

We can redeem the rights at any time before (but not after) a person has acquired 17.5% or more of our common stock, with certain exceptions. The rights will expire on August 31, 2010 if not redeemed prior to such date.

(e) Authorized Common and Preferred Stock

We have 200 million shares of authorized common stock, with a par value of $.01 per share, and five million shares of preferred stock with a par value of $.01 per share, with such designations, preferences, privileges, and restrictions as may be determined from time to time by our Board of Directors.

(f) Employee Stock Purchase Plan

We have an Employee Stock Purchase Plan under which eligible employees may contribute up to 10% of their base earnings toward the quarterly purchase of our common stock. The employee's purchase price is derived from a formula based on the fair market value of the common stock. During the years ended December 31, 2007, 2006 and 2005, approximately 24,000, 38,000 and 22,000 shares, respectively, were issued with approximately 150, 214 and 161 employees participating in the plan, respectively. At December 31, 2007, we had 298,397 shares of our authorized common stock available for future grant in connection with these plans.

We sponsor a stock purchase plan for our UK-based employees. Under the terms of the plan, eligible employees may contribute between £5 and £250 of their base earnings, in 36 monthly installments, towards the purchase of our common stock. The employee's purchase price is determined at the beginning of the 36-month period and compensation expense is recorded over the 36-month period. As a result of our decision in the fourth quarter of fiscal 2004 to consolidate all of our U.K.-based oncology research and development activities into our New York locations, we did not offer this plan to UK employees for fiscal 2004. As a result of the minority interest buyout of Prosidion in the second quarter of 2005, we offered this plan to our UK employees beginning in 2005 and continued to offer the plan in 2006 and 2007. During fiscal 2003, the maximum shares that could be issued under this plan were increased from 100,000 shares to 200,000 shares. There were 14 employees, 49 employees and 16 employees that participated in the 2007, 2006 and 2005 plans, respectively. At December 31, 2007, we had 80,116 shares of our common stock available for future grant in connection with this plan.

(g) Issuance of Common Stock for Acquisitions

On November 14, 2005, in connection with the acquisition of Eyetech, we issued a total of 5.65 million shares of our common stock valued at $205.4 million.

On April 14, 2005, in connection with the acquisition of the minority interest in Prosidion, we issued 84,940 shares of our common stock valued at $4.2 million.

(17) Commitments and Contingencies

(a) Lease Commitments

We lease office, operating and laboratory space under various lease agreements. Rent expense for continuing and discontinued operations was $5.9 million, approximately $10 million and $9.1 million for the years ended December 31,

2007, 2006 and 2005, respectively. Rent expense for fiscal 2007 includes the Oxford, England facility leases, Boulder, Colorado facility leases, Cedar Knolls, New Jersey lease and the Farmingdale, NY facility lease. As discussed in Note 10(c), we accrued the net remaining lease rental payments and refurbishment costs for a portion of the Oxford, England facility in fiscal 2005.

The following is a schedule of future minimum rental payments for the next five fiscal years and thereafter required as of December 31, 2007, exclusive of sub-rental income from subleased facilities. Also included in the amounts below are commitments for equipment under various operating leases (in thousands).

2008	$ 13,040
2009	11,569
2010	11,079
2011	11,073
2012	10,798
2013 and thereafter	82,364
	$139,923

Rental obligations and deferred rent in the accompanying consolidated balance sheet reflects the rent expense recognized on a straight-line basis in excess of the required lease payments in connection with our facility leases and the present value of net operating lease payments for exited facilities. Included in long-term rental obligations and deferred rent is $2.2 million related to deferred rental payments and $8.6 million of accruals related to exited facilities and refurbishment costs.

The table above includes future lease payments for Eyetech facilities (Lexington, Massachusetts, New York City) which we have subleased. We have recognized liabilities for these facilities based upon the period value of the remaining lease payments, offset by sublease rental income (see Note 20).

(b) Contingencies

Under certain license and collaboration agreements with pharmaceutical companies and educational institutions, we are required to pay royalties and/or milestones upon the successful development and commercialization of products.

From time to time, we have received letters from companies and universities advising us that various products under research and development by us may be infringing existing patents of such entities. These matters are reviewed by management, and if necessary, by our outside counsel. Where valid patents of other parties are found by us to be in place, management will consider entering into licensing arrangements with the universities and/or companies or modify the conduct of its research. Our future royalties, if any, may be substantially reduced if our licensees or collaborative partners are required to obtain licenses from third parties whose patent rights are infringed by our products, technology or operations. In addition, should any infringement claims result in a patent infringement lawsuit, we could incur substantial costs in defense of such a suit, which could have a material adverse effect on our business, financial condition and results of operations, regardless of whether we were successful in the defense.

(c) Litigation

On or about December 16, 2004, several purported shareholder class action lawsuits were filed in the United States District Court for the Eastern District of New York against our company, certain of our current and former executive officers, and the members of our Board of Directors. The lawsuits were brought on behalf of those who

purchased or otherwise acquired our company's common stock during certain periods in 2004, which periods differed in the various complaints. The Court appointed a lead plaintiff who, on February 17, 2006, filed a consolidated amended class action complaint seeking to represent a class of all persons who purchased or otherwise acquired our company's common stock during the period from April 26, 2004 through November 22, 2004. The consolidated complaint alleges that the defendants made material misstatements and omissions concerning the survival benefit associated with our company's product, Tarceva, and the size of the potential market of Tarceva upon FDA approval of the drug. It alleges violations of Sections 11 and 15 of the Securities Act of 1933, as amended, and Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The consolidated complaint seeks unspecified compensatory damages and other relief. On April 7, 2006, we filed a motion to dismiss the consolidated amended complaint. Briefing on this motion was completed on June 21, 2006. In an opinion dated March 31, 2007 (and entered on the docket on April 4, 2007), the Court granted in part and denied in part the motion to dismiss. The Court dismissed claims against some of the individual defendants and dismissed the Section 11 and 15 claims, but granted the plaintiff 30 days leave to replead the Section 11 claim in accordance with the Court's order and to renew the Section 15 claim. The plaintiff did not amend, and thus those claims were dismissed with prejudice. The parties have now informed the Court that they have reached an agreement in principle to settle this action. The parties are in the process of finalizing the settlement papers, which will then be subject to Court approval. In the opinion of our management, the ultimate outcome will not have a material impact on our financial position, results of operations or cash flows.

(18) Related Party Transactions

One member of our Board of Directors is a partner in a law firm which represents us on our patent matters. Fees paid to this firm during the years ended December 31, 2007, 2006 and 2005 were approximately $170,000, $115,000 and $299,000, respectively. In addition, we have compensated other directors for services performed pursuant to consultant arrangements. During the years ended December 31, 2007, 2006 and 2005, consulting fees in the amounts of $75,000, $75,000 and $154,000, respectively, were paid to such directors pursuant to these arrangements.

(19) Acquisitions

(a) Acquisition of AdipoGenix Assets

In the fourth quarter of 2007, Prosidion acquired intellectual property and laboratory equipment from AdipoGenix Inc. for $2.3 million. Of the $2.3 million purchase price, $2.2 million was recorded as an in-process research and development charge, since it was associated with the intellectual property which was deemed early stage and to have no alternative use. The remainder of the cost was allocated to the laboratory equipment acquired, based upon its fair value, and capitalized.

(b) Minority Interest in Prosidion

On April 14, 2005, we completed the acquisition of the minority interest held by the remaining shareholders of Prosidion. We issued a total of 84,940 shares of our common stock in exchange for 286,200 shares in Prosidion, representing approximately 2.8% of the Prosidion shares outstanding. In addition, we paid $176,000 in cash to one of the minority shareholders of Prosidion, who is a director of our company, in exchange for 11,000 shares of Prosidion. The 84,940 shares of our common stock were valued at $4.2 million, which was based on the average five-day closing price of our common stock around the date of the announcement of the proposed acquisition, which occurred on March 10, 2005. The acquisition of the minority interest resulted in Prosidion becoming our wholly-owned subsidiary. The acquisition of the minority interest was accounted for under the purchase method of accounting. The purchase

price was allocated to the assets acquired and assumed liabilities based on the fair value as of the acquisition date. We incurred direct costs of $650,000 in connection with the acquisition, resulting in a total acquisition cost of approximately $5.0 million.

The purchase price for the minority interest acquired was allocated as follows (in thousands):

License agreements	$ 615
Patent estate	203
Acquired in-process research and development	3,694
Minority interest	322
Goodwill	149
Common stock and cash paid	$4,983

In advance of the acquisition of the minority interest, we paid $1.4 million to Prosidion employees in exchange for all outstanding in-the-money Prosidion options. This compensation charge has been reflected in the statement of operations for the year ended December 31, 2005, of which $577,000 is included in research and development expense and $803,000 is included in selling, general and administrative expense.

The value assigned to the acquired in-process R&D was determined by identifying the acquired in-process research projects for which: (a) technological feasibility had not been established at the acquisition date; (b) there was no alternative future use; and (c) the fair value was estimable based on reasonable assumptions. The acquired in-process R&D was assigned entirely to three clinical candidates. The value of the acquired in-process R&D and the other identifiable intangible assets was determined by estimating the projected net cash flows, based upon the future revenues to be earned upon commercialization. In determining the value of the in-process R&D, the assumed commercialization date for the products ranged from 2010 to 2012. Given the risks associated with the development of new drugs, the revenue and expense forecasts were probability-adjusted to reflect the risk of advancement through the approval process. The risk adjustments applied were based on the compounds' stage of development at the time of assessment and the historical probability of successful advancement for compounds at that stage. The modeled cash flows were discounted back to the net present value. The projected net cash flows from such projects were based on management's estimates of revenues and operating profits related to such project. The value of the in-process R&D was based on the income approach that focuses on the income-producing capability of the asset. The underlying premise of this approach is that the value of an asset can be measured by the present worth of the net economic benefit (cash receipts less cash outlays) to be received over the life of the asset. Significant assumptions and estimates used in the valuation of in-process R&D included the stage of development for the project, future revenues, growth rates, product sales cycles, the estimated life of a product's underlying technology, future operating expenses, probability adjustments to reflect the risk of developing the acquired technology into commercially viable products, and a discount rate of 23.5% to reflect present value.

(20) Eyetech Acquisition and Discontinued Operations

(a) Discontinued Operations

On November 6, 2006, we announced our intention to divest our eye disease business, a process which we plan to complete in 2008. Our eye disease business consists principally of Macugen, our marketed product for the treatment of neovascular age-related macular degeneration, or wet AMD, as well as research assets in the eye disease area. We made the decision to exit the eye disease business based on our determination that a key strategic

goal of the acquisition of the business in November 2005 — the generation of significant cash flow from the business in the 2006 through 2008 fiscal years — would not likely be realized.

We finalized our exit plan during the first quarter of 2007 and began to actively market our eye disease business. We explored several potential transactions to divest our entire eye disease business, but were unable to identify a transaction that would provide us with satisfactory terms for a complete sale of this business. Therefore, we switched to a strategy of separately divesting the assets, and in July 2007, we entered into an agreement with Ophthotech Corporation to divest our anti-platelet derived growth factor, or PDGF, aptamer program for an upfront cash payment, shares of Ophthotech preferred stock and potential future milestones and royalties. Included in the loss from discontinued operations for the year ended December 31, 2007 was a gain of approximately $6.0 million recognized as a result of the agreement. We continue to pursue the divestiture of the remaining eye disease assets, including Macugen, and plan to complete this process by the end of 2008.

As a result of our decision to divest the eye disease business, in accordance with the provision of SFAS No. 144, the results of operations of (OSI) Eyetech for the current and prior period have been reported as discontinued operations. In addition, assets and liabilities of (OSI) Eyetech have been classified as assets and liabilities related to discontinued operations, including those held for sale. Net assets held for sale have been reflected at the lower of carrying amount or fair value, less cost to sell. In the third and fourth quarters of 2007, we assessed the net realizable carrying amount or fair value of the assets held for sale and recognized impairment charges of $5.6 million and $5.1 million, respectively, in order to reduce the carrying value of the assets.

Operating results of (OSI) Eyetech for the years ended December 31, 2007, 2006 and 2005 are summarized as follows (in thousands):

	Year Ended December 31,		
	2007	2006	2005
Net revenue	$ 37,435	$ 134,659	$ 35,771
Gain on sale of PDGF aptamer research program	6,012	—	—
Pretax loss	(36,930)	(610,929)	(72,029)
Net loss from discontinued operations	$(36,288)	$(610,929)	$(72,029)

In order to facilitate the divestiture of our eye disease business, on April 20, 2007, we terminated our existing collaboration agreement with Pfizer with respect to the co-promotion of Macugen in the United States and amended and restated the license agreement pursuant to which we had originally granted to Pfizer a number of exclusive licenses or sublicenses to patents and other intellectual property related to Macugen on a world-wide basis. Under the terms of the amended and restated license agreement, Pfizer returned to us all rights to develop and commercialize Macugen in the United States, and we granted to Pfizer an exclusive right to develop and commercialize Macugen in the rest of the world. We have also agreed with Pfizer to provide each other with certain transitional services related to Macugen.

Prior to the April 2007 amendment, we shared sales and marketing responsibility for sales of Macugen in the United States and reported product revenue on a gross basis for these sales. We determined that we qualified as a principal under the criteria set forth in EITF No. 99-19 based on our responsibilities under our original contracts with Pfizer, which included manufacture of product for sale in the United States, distribution, ownership of product inventory and credit risk from customers. Since April 20, 2007, we no longer share the gross profits of U.S. sales with Pfizer and no longer receive royalties from Pfizer from rest of the world sales.

In the second quarter of 2006, we received a $35.0 million milestone payment from Pfizer upon the launch of Macugen in select European countries. The milestone payment was recorded as unearned revenue and was being recognized as revenue on a straight-line basis over the expected term of our collaboration and license agreements with Pfizer, which approximates the expected level of performance under these agreements with Pfizer. The amortization of the unearned revenue and the related unrecognized revenue is included in discontinued operations. Under the amended and restated license agreement, we continue to provide services, share certain expenses and collaborate in specified studies with Pfizer, and therefore, we are continuing to amortize the milestone payment over the term of the original agreement which corresponds to the term of the amended and restated license agreement. Any remaining balance of deferred revenue related to this milestone payment will be reversed upon the sale of the eye disease business and the termination of our obligations under the agreement.

At December 31, 2007 certain assets and liabilities related to the eye disease business have been classified as assets or liabilities related to discontinued operations. The category includes not only assets which are held for sale, but also assets and liabilities which will no longer result in ongoing cash inflows or outflows after the divestiture.

The summary of the assets and liabilities related to discontinued operations as of December 31, 2007 is as follows:

Assets:	
Accounts receivable	$18,411
Prepaid expenses and other assets	470
Inventories (assets held for sale)	5,098
Property, plant and equipment (assets held for sale)	1,463
Assets related to discontinued operations	$25,442
Liabilities:	
Accounts payable and accrued expenses	$13,382
Collaboration profit share	2,783
Unearned revenue	29,574
Liabilities related to discontinued operations	$45,739

(b) (OSI) Eyetech Divestiture — Severance Costs

In connection with the acquisition of Eyetech on November 12, 2005, we implemented a plan to consolidate certain facilities and reduce the workforce. During 2006, we recognized an additional $3.6 million of termination benefits and relocation costs associated with this reduction.

As a result of our decision to exit our eye disease business in November 2006, we committed to a plan to re-scale the eye disease business. The plan included the consolidation of facilities as well as a reduction in the workforce for transitional employees throughout 2007 at a cost of $6.5 million. We recognized $2.6 million of severance and retention bonus costs in the fourth quarter of 2006, and the balance of $3.9 million in 2007.

In the third quarter of 2007, we implemented another reduction in workforce which resulted in recognizing $1.3 million of severance costs in 2007.

The activity for the years ended December 31, 2007 and 2006 was as follows (in thousands):

	Year Ended December 31,	
	2007	2006
Opening liability	$ 3,284	$ 4,871
Accrual for severance, relocation and retention bonuses	5,206	6,203
Cash paid for severance	(7,690)	(7,790)
Ending liability	$ 800	$ 3,284

(c) (OSI) Eyetech Integration — Facility Restructuring

In connection with the acquisition of Eyetech in November 2005, we implemented a plan to consolidate certain facilities. Included in the liabilities assumed in the acquisition, we recognized $5.4 million for the present value of future lease commitments. The facilities included in the accrual were Lexington, Massachusetts, a portion of the New York City office and one of our leased facilities in Boulder, Colorado. The present value of the lease payments was determined based upon the date that we plan to exit the facility and the remaining lease expiration, offset by estimated sublease income. Rental payments for the facilities prior to closure were included in operating expense. During 2006, the Boulder, Colorado facility was sold and we subleased a portion of the New York City office. The Lexington facility and the remaining portion of the New York City office also were closed during 2006, and subsequently subleased during 2007. In 2007, we recorded $3.7 million, of additional costs as a result of reevaluating our rental assumptions based upon the current rental market. These accruals are not included in the liabilities related to discontinued operations as of December 31, 2007 since the obligations will remain with us after the divestiture of the eye disease business.

The activity for the year ended December 31, 2007 and 2006 was as follows (in thousands):

	Year Ended December 31,	
	2007	2006
Opening liability	$ 2,054	$ 5,391
Accrual for lease costs	3,709	(1,157)
Accretion expense	248	329
Cash paid for rent	(2,729)	(2,509)
Ending liability	$ 3,282	$ 2,054

(d) Eyetech Acquisition

On November 14, 2005, we completed our acquisition of Eyetech, pursuant to the terms of an Agreement and Plan of Merger dated August 21, 2005. The acquisition was structured as a merger of a wholly-owned subsidiary of OSI with and into Eyetech, and Eyetech was renamed (OSI) Eyetech, Inc.

The assets purchased and liabilities assumed by us included: (a) one marketed product, Macugen, and the related technology platform and patent estate; (b) rights to Eyetech's leased facilities in New York, New York, Cedar Knolls, NJ, Woburn and Lexington, MA and Boulder, Colorado, as well as leasehold improvements and certain equipment; (c) inventory; and (d) certain other assets and liabilities.

The acquisition was accounted for under the purchase method of accounting. The purchase price was allocated to the acquired assets and assumed liabilities based on their estimated fair values. In connection with the merger, we

committed to and approved an exit plan for consolidation of certain Eyetech facilities. As a result of the exit plan, we recognized a liability of $5.4 million for rent obligations based upon the present value of the remaining lease payments, after exiting the facilities, offset by the potential sublease rental income. In addition, we recognized $6.2 million of liabilities associated with personnel reductions and relocation costs. As discussed below, we determined the Eyetech goodwill was impaired and recognized an impairment charge of $320.3 million, reflecting the entire amount of the value of Eyetech goodwill.

The final purchase price allocation is as follows (in thousands):

Cash and investments	$ 271,934
Accounts receivable	92,165
Inventory	62,587
Fixed assets	12,518
Prepaid expenses and other assets	7,955
Amortizable intangibles	201,400
Goodwill	320,261
In-process R&D	60,900
Total assets and in-process R&D acquired	1,029,720
Less liabilities assumed	120,327
Purchase price	$ 909,393

The value assigned to the acquired in-process R&D was determined by identifying those acquired in-process research projects for which: (a) technological feasibility had not been established at the acquisition date, (b) there was no alternative future use, and (c) the fair value was estimable based on reasonable assumptions. The acquired in-process R&D was valued at $60.9 million and expensed on the acquisition date, and included in the accompanying consolidated statements of operations for the year ended December 31, 2005. In determining the value of the in-process R&D, the assumed commercialization dates for the products ranged from 2007 to 2021. Given the risks associated with the development of new drugs, the revenue and expense forecasts were probability-adjusted to reflect the risk of advancement through the approval process. The risk adjustments applied were based on the compound's stage of development at the time of assessment and the historical probability of successful advancement for compounds at that stage. These modeled cash flows were discounted back to their net present value. The projected net cash flows from such projects were based on management's estimates of revenues and operating profits related to such projects. The value of the in-process R&D was based on the income approach that focuses on the income-producing capability of the assets. The underlying premise of this approach is that the value of an asset can be measured by the present worth of the net economic benefit (cash receipts less cash outlays) to be received over the life of the asset. Significant assumptions and estimates used in the valuation of in-process R&D included the stage of development for each of the two projects; future revenues; growth rates for each product; product sales cycles; the estimated life of a product's underlying technology; future operating expenses; probability adjustments to reflect the risk of developing the acquired technology into commercially viable products; and a discount rate of 16% to reflect present value.

In determining the fair value of the inventory, we recorded a $55 million step-up in value of finished goods and work-in-process inventory that we acquired from Eyetech. The step-up in fair value was determined based on the estimated selling price of the inventory, less costs of disposal and a reasonable selling profit to both complete and sell the product.

The following unaudited pro forma financial information for the year ended December 31, 2005, combine the historical financial information of OSI and Eyetech giving effect to the merger as if it occurred on January 1, 2005, reflecting only pro forma adjustments expected to have a continuing impact on the combined results. The unaudited pro forma financial information excluding the non-recurring in-process research and development charge related to the acquisition, was as follows (in thousands, except per share information):

	Year Ended December 31, 2005
Net loss	$(161,267)
Basic and diluted net loss per share	$ (2.83)

The pro forma financial information has been prepared for comparative purposes only. The pro forma financial information includes adjustments to the historical results to reflect the issuance of approximately 5.65 million shares of common stock and adjustments for amortization of Eyetech unearned revenue, interest expense related to assumed borrowings, recognition of deferred stock-based compensation, and amortization of the purchased intangibles. The pro forma financial information does not include the charge of approximately $60.9 million related to the acquired in-process R&D. The pro forma information does not purport to be indicative of operating results that would have been achieved had the acquisition taken place on the dates indicated or the results that may be obtained in the future.

(e) Eyetech Goodwill Impairment

In accordance with SFAS No. 142, goodwill and other indefinite-lived intangibles must be tested for impairment annually or in interim periods if events indicate there is a possible impairment. As a result of competitive developments relating to Macugen and the wet AMD marketplace, including competition from two Genentech products — Lucentis® (ranibizumab injection) and the widespread off-label use of Avastin — we were required to assess the value of the $320.3 million of goodwill recorded in connection with the acquisition of Eyetech. In our assessment, we considered the declining Macugen revenues and our decision to suspend or curtail research activities in the eye disease area, which further limits the potential for future revenues from new products. We determined the amount of the charge based on present value techniques using discounted cash flows in accordance SFAS No. 142. Based on this assessment, we recorded an impairment charge of $320.3 million during fiscal 2006, reflecting the full value of the Eyetech goodwill.

(f) Macugen Intangibles Impairment

In accordance with SFAS No. 144, the Company was required to assess the recoverability of the long-lived assets relating to the Company's eye disease business that existed on December 31, 2006, principally the amortizable intangible assets acquired in the Eyetech acquisition. This assessment included developing various estimates of probability-adjusted future cash flows relating to Macugen and weighing additional factors that could impact these future cash flows. Two critical factors were given significant weight in our assessment: the current sales level of Macugen; and our level of certainty regarding the ultimate structure of a transaction to exit the eye disease business. After considering all of the aforementioned factors, we concluded that the Macugen intangibles were impaired and reduced their value to zero at December 31, 2006 and recorded a $185.7 million charge in the fourth quarter of 2006.

(21) Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities," or SFAS No. 159. SFAS No. 159 permits entities to choose to measure many financial instruments and

certain items at fair value that are not currently required to be measured at fair value. We will be subject to the requirements of SFAS No. 159 for our fiscal year ending December 31, 2008. We are currently evaluating the impact of the provisions of SFAS No. 159.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements," to clarify the definition of fair value, establish a framework for measuring fair value and expand the disclosures on fair value measurements. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. SFAS No. 157 also stipulates that, as a market-based measurement, fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability, and establishes a fair value hierarchy that distinguishes between: (a) market participant assumptions developed based on market data obtained from sources independent of the reporting entity (observable inputs); and (b) the reporting entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances or (unobservable inputs). Except for the deferral for the implementation of SFAS No. 157 for other non-financial assets and liabilities, as defined, SFAS No. 157 will be effective for our fiscal year ended December 31, 2008. The FASB is expected to continue to further debate the aspects of SFAS No. 157 that relate to non-financial assets and liabilities, and the aforementioned accounting could change. We are currently evaluating SFAS No. 157 and are not yet in a position to determine what, if any, effect SFAS No. 157 will have on our consolidated financial statements.

On June 27, 2007, EITF 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities," or EITF 07-3, was issued. EITF 07-3 provides that nonrefundable advance payments made for goods or services to be used in future research and development activities are deferred and capitalized until such time as the related goods or services are delivered or are performed, at which point the amounts will be recognized as an expense. EITF 07-3 is effective for new contracts entered into after January 1, 2008. We are currently evaluating the potential impact, if any, of this EITF but do not expect it to be material to our financial position or results of operations.

In November 2007, the Emerging Issues Task Force issued EITF Issue 07-01 "Accounting for Collaborative Arrangements," or EITF No. 07-01. EITF No. 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF No. 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to Issue 01-9, "Accounting for Consideration Given by a Vendor to a Customer". EITF No. 07-01 is effective for fiscal years beginning after December 15, 2008. We do not believe that this EITF will have a material impact on the results of operations, financial position or cash flows.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations," or SFAS No. 141R, which replaces FASB Statement No. 141. SFAS No. 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non controlling interest in the acquiree and the goodwill acquired. SFAS No. 141R also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS No. 141R is effective as of the beginning of an entity's fiscal year that begins after December 15, 2008. We are currently evaluating the potential impact, if any, of the adoption of SFAS No. 141R on our financial statements.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statement — amendments of ARB No. 51, or SFAS No. 160." SFAS No. 160 states that accounting and reporting for minority interests will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS No. 160 also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 applies to all entities that prepare consolidated financial statements, except not-for-profit organizations, but will affect only those entities that have an outstanding noncontrolling interest in one or more subsidiaries or that deconsolidate a subsidiary. This statement is effective as of the beginning of an entity's first fiscal year beginning after December 15, 2008. We are currently evaluating the potential impact, if any, of the adoption of SFAS 141R on our financial statement.

(22) Subsequent Event

On January 9, 2008, we issued $200 million aggregate principal amount of 3% convertible senior subordinated notes due 2038, or 2038 Notes, in a private placement resulting in net proceeds to us of approximately $193 million. We used a portion of the proceeds to repurchase of approximately 1.5 million shares of our common stock concurrently with the offering for an aggregate price of $65 million. The 2038 Notes bear interest semi-annually in arrears through maturity at an annual rate of 3% and mature on January 15, 2038. We may redeem for cash, all or part of the 2038 Notes at any time on or after January 15, 2013, at a price equal to 100% of the principal amount of the 2038 Notes, plus accrued and unpaid interest. Holders of the 2038 Notes have the right to require us to purchase, for cash, all or any portion of their 2038 Notes on January 15, 2013, 2018, 2023, 2028 and 2033 at a price equal to 100% of the principal amount of the 2038 Notes to be purchased, plus accrued and unpaid interest. The 2038 Notes are unsecured and are subordinated to all of its existing and future senior indebtedness. The 2038 Notes rank equally in right of payment with all of our existing and future senior subordinated indebtedness. The 2038 Notes will be convertible, in certain circumstances, into our common stock based upon a base conversion rate, which, under certain circumstances will be increased pursuant to a formula that is subject to a maximum conversion rate. The initial base conversion rate is 13.5463 shares per $1,000 principal amount of notes (equivalent to an initial base conversion price of approximately $73.82 per share of our common stock). The initial base conversion price represents a premium of 65% to the $44.74 per share closing price of OSI's common stock on January 3, 2008. Upon conversion, holders of the 2038 Notes will have the right to receive shares of our common stock, subject to our right to deliver cash in lieu of all or a portion of such shares.

(23) Quarterly Financial Data (unaudited)

The tables below summarize our unaudited quarterly operating results for the years ended December 31, 2007 and 2006.

	Three Months Ended (In thousands, except per share data)			
	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007
Revenues from continuing operations	$77,469	$78,883	$100,370	$84,308
Net income from continuing operations	$19,695	$29,276	$ 35,904	$17,732
Net income	$ 6,641	$19,622	$ 29,628	$10,428
Basic earnings per share from continuing operations	$ 0.34	$ 0.51	$ 0.62	$ 0.31
Diluted earnings per share from continuing operations	$ 0.33	$ 0.48	$ 0.59	$ 0.29
Basic net income per share	$ 0.12	$ 0.34	$ 0.51	$ 0.18
Diluted net income per share	$ 0.12	$ 0.33	$ 0.49	$ 0.18

	Three Months Ended (In thousands, except per share data)			
	March 31, 2006	June 30, 2006	September 30, 2006	December 31, 2006
Revenues from continuing operations	$ 59,255	$ 55,652	$ 56,805	$ 69,325
Net income (loss) from continuing operations	$ 376	$ (2,440)	$ 159	$ 8,605
Net loss	$(17,855)	$(319,929)	$(21,257)	$(223,143)
Basic earnings (loss) per share from continuing operations	$ 0.01	$ (0.04)	$ 0.00	$ 0.15
Diluted earnings (loss) per share from continuing operations	$ 0.01	$ (0.04)	$ 0.00	$ 0.15
Basic net loss per share	$ (0.31)	$ (5.62)	$ (0.37)	$ (3.91)
Diluted net loss per share	$ (0.31)	$ (5.62)	$ (0.37)	$ (3.85)

The basic and diluted net income (loss) per common share calculation for each of the quarters are based on the weighted average number of shares outstanding and the effect of common stock equivalents in each period. Therefore, the sum of the quarters in a fiscal year does not necessarily equal the basic and diluted net income (loss) per common share for the fiscal year.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

CEO/CFO CERTIFICATIONS

Attached to this Annual Report on Form 10-K as Exhibits 31.1 and 31.2, there are two certifications, or the Section 302 Certifications, one by each of our Chief Executive Officer, or CEO, and our Chief Financial Officer, or CFO. This Item 9A contains information concerning the evaluation of our disclosure controls and procedures and internal control over financial reporting that is referred to in the Section 302 Certifications and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

Evaluation of Our Disclosure Controls and Procedures. The Securities and Exchange Commission requires that as of the end of the period covered by this Annual Report on Form 10-K, the CEO and the CFO evaluate the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Securities Exchange Act of 1934, or the Exchange Act, and report on the effectiveness of the design and operation of our disclosure controls and procedures. Accordingly, under the supervision and with the participation of our management, including our CEO and CFO, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K.

CEO/CFO Conclusions about the Effectiveness of the Disclosure Controls and Procedures. Based upon their evaluation of the disclosure controls and procedures, our CEO and CFO have concluded that our disclosure controls and procedures are at the reasonable assurance level to ensure that material information relating to OSI and our consolidated subsidiaries is made known to management, including the CEO and CFO, on a timely basis and during the period in which this Annual Report on Form 10-K was being prepared.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) of the Exchange Act).

Under the supervision of and with the participation of our CEO and our CFO, our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework and criteria established in *Internal Control — Integrated Framework,* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management has concluded that, as of December 31, 2007, our internal control over financial reporting was effective.

CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act), identified in connection with the evaluation of such internal control over financial reporting that occurred during the fourth quarter of fiscal 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Board of Directors and Stockholders
OSI Pharmaceuticals, Inc.:

We have audited OSI Pharmaceuticals, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2007, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). OSI Pharmaceuticals, Inc. and subsidiaries' management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, OSI Pharmaceuticals, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of OSI Pharmaceuticals, Inc. and subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2007, and our report dated February 27, 2008, expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Melville, New York
February 27, 2008

ITEM 9B. OTHER INFORMATION

Not applicable.

EXHIBIT 31.1

CERTIFICATION

I, Colin Goddard, Ph.D. certify that:

1. I have reviewed this annual report on Form 10-K of OSI Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2008

/s/ COLIN GODDARD, Ph.D.

Colin Goddard, Ph.D.
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Michael G. Atieh, certify that:

1. I have reviewed this annual report on Form 10-K of OSI Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2008

/s/ MICHAEL G. ATIEH

Michael G. Atieh
Executive Vice President,
Chief Financial Officer and Treasurer

EXHIBIT 32.1

OSI PHARMACEUTICALS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. § 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of OSI Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Colin Goddard, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ COLIN GODDARD, PH.D.

Colin Goddard, Ph.D.
Chief Executive Officer

Date: February 28, 2008

EXHIBIT 32.2

OSI PHARMACEUTICALS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. § 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of OSI Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael G. Atieh, Executive Vice President, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ MICHAEL G. ATIEH

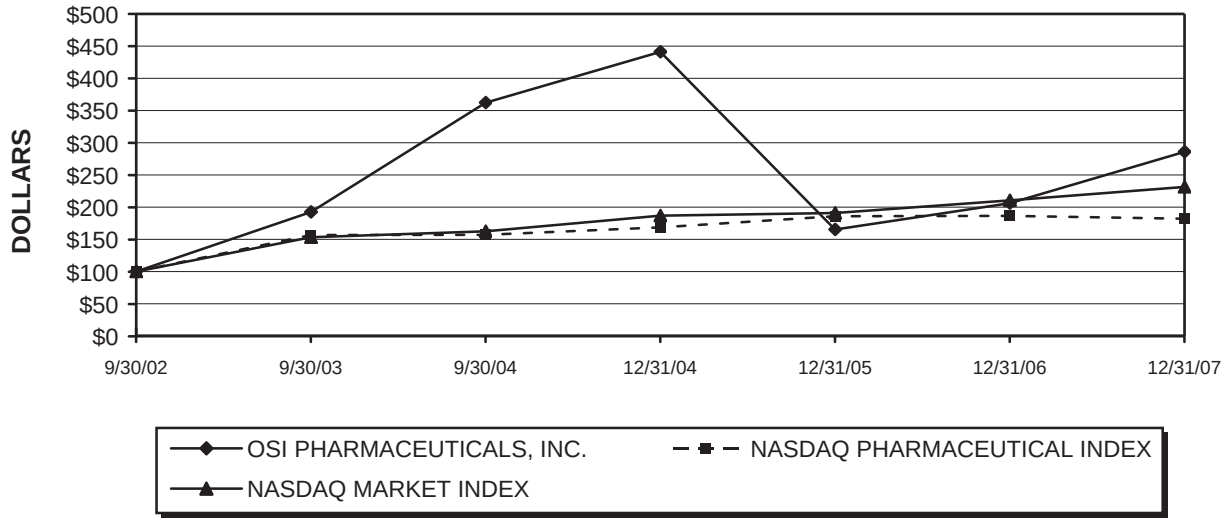
Michael G. Atieh
Executive Vice President,
Chief Financial Officer and Treasurer

Date: February 28, 2008

STOCK PRICE PERFORMANCE GRAPHS

The following graph presents the cumulative total return of our common stock with the cumulative total return of the Nasdaq Pharmaceutical Index and the Nasdaq Global Select Market Index ("Nasdaq Market Index") over a five-year period (including a three-month transition period ended December 31, 2004 due to the change in our fiscal year end from September 30 to December 31) based on an assumed investment of $100 on October 1, 2002, in each case assuming reinvestment of all dividends. The companies comprising the Nasdaq Pharmaceutical Index are available upon written request to Investor Relations at OSI's executive offices.

COMPARISON OF 5-YEAR CUMULATIVE TOTAL RETURN
AMONG OSI PHARMACEUTICALS, INC.,
NASDAQ PHARMACEUTICAL INDEX AND NASDAQ MARKET INDEX

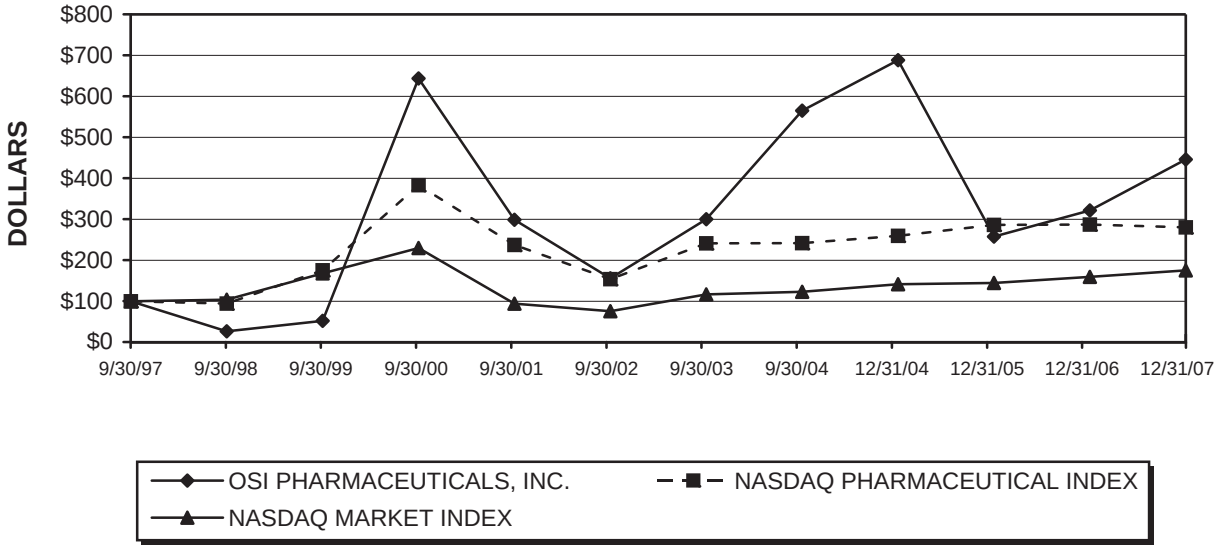


Company/Index/Market	As of						
	9/30/02	9/30/03	9/30/04	12/31/04	12/31/05	12/31/06	12/31/07
OSI PHARMACEUTICALS, INC.	$100.00	192.40	362.17	441.07	165.23	206.13	285.86
NASDAQ PHARMACEUTICAL INDEX . .	100.00	156.71	157.05	168.60	185.92	186.46	182.02
NASDAQ MARKET INDEX	100.00	153.26	162.48	186.79	190.90	210.49	231.39

STOCK PRICE PERFORMANCE GRAPHS — (Continued)

The following graph presents the cumulative total return of our common stock with the cumulative total return of the Nasdaq Pharmaceutical Index and the Nasdaq Market Index over a 10-year period (including a three-month transition period ended December 31, 2004 due to the change in our fiscal year end from September 30 to December 31) based on an assumed investment of $100 on October 1, 1997, in each case assuming reinvestment of all dividends. The companies comprising the Nasdaq Pharmaceutical Index are available upon written request to Investor Relations at OSI's executive offices.

COMPARISON OF 10-YEAR CUMULATIVE TOTAL RETURN
AMONG OSI PHARMACEUTICALS, INC.,
NASDAQ PHARMACEUTICAL INDEX AND NASDAQ MARKET INDEX



Company/Index/Market	As of											
	9/30/97	9/30/98	9/30/99	9/30/00	9/30/01	9/30/02	9/30/03	9/30/04	12/31/04	12/31/05	12/31/06	12/31/07
OSI PHARMACEUTICALS, INC.	$100.00	26.72	52.30	643.68	298.85	156.05	300.23	565.15	688.28	257.84	321.66	446.07
NASDAQ PHARMACEUTICAL INDEX	100.00	94.46	175.61	383.31	237.52	154.04	241.40	241.92	259.71	286.40	287.23	280.39
NASDAQ MARKET INDEX	100.00	103.92	168.12	229.98	94.23	75.81	116.18	123.18	141.61	144.72	159.58	175.42

BOARD OF DIRECTORS

Robert A. Ingram
Chairman of the Board
Vice Chairman, Pharmaceuticals
GlaxoSmithKline

Colin Goddard, Ph.D.
Chief Executive Officer

Santo J. Costa
Compensation Committee Chair
Of Counsel, Smith, Anderson,
Blount, Dorsett, Mitchell &
Jernigan, LLP

Daryl K. Granner, M.D.
Professor Emeritus, Molecular
Physiology and Biophysics
Vanderbilt University Medical Center

Joseph Klein, III
Managing Director
Gauss Capital Advisors, LLC

Kenneth B. Lee, Jr.
General Partner,
Hatteras Venture Partners

Viren Mehta
Mehta Partners, LLC

David W. Niemiec
Advisor
Saratoga Partners

Herbert Michael (Bob) Pinedo, M.D., Ph.D.
Professor of Medical Oncology at
Vrije University Medical Center
Vice Chairman of the Netherland
Organization for Health
Research & Development

Katharine B. Stevenson
Audit Committee Chair

John P. White, Esq.
Senior Partner
Cooper & Dunham LLP

EXECUTIVE OFFICERS

Colin Goddard, Ph.D.
Chief Executive Officer

Michael G. Atieh
Executive Vice President,
Chief Financial Officer and
Treasurer

Gabriel Leung
Executive Vice President and
President, Oncology Business

Anker Lundemose, M.D., Ph.D.
Executive Vice President and
President, OSI Prosidion

Robert L. Simon
Executive Vice President,
Pharmaceutical
Development & Manufacturing

Linda E. Amper, Ph.D.
Senior Vice President,
Human Resources

Barbara A. Wood, Esq.
Senior Vice President,
General Counsel and Secretary

CORPORATE HEADQUARTERS

OSI Pharmaceuticals, Inc.
41 Pinelawn Road
Melville, NY 11747

OTHER COMPANY LOCATIONS

Oncology Research – New York
1 Bioscience Park Drive
Farmingdale, NY 11735

Oncology Development –
Colorado
2860 Wilderness Place
Boulder, CO 80301

Prosidion – Diabetes Research
& Development
Watlington Road
Oxford, OX4 6LT
United Kingdom

CMC – Cedar Knolls
140 East Hanover Avenue
Cedar Knolls, NJ 07927

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http://stock.bankofny.com

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1500 Market Street
Philadelphia, PA 19102

Mintz, Levin
666 Third Avenue
New York, NY 10017

Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

AUDITORS

KPMG LLP
1305 Walt Whitman Road
Melville, NY 11747

ANNUAL MEETING

The annual meeting of
shareholders will be held
on June 11, 2008 at 10:00am
at OSI Pharmaceuticals, Inc.
(Corporate Headquarters)
41 Pinelawn Road
Melville, NY 11747

ANNUAL REPORT ON FORM 10-K

The Company's Annual Report
on Form 10-K, as amended,
filed with the Securities and
Exchange Commission and other
information may be obtained
without charge by writing,
phoning or visiting our website:

OSI Pharmaceuticals, Inc.
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(631) 962-2000
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STOCK LISTING

Nasdaq: OSIP

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