(OSI)™ pharmaceuticals

2006 Annual Report

To Our Shareholders

We are delighted to be able to share this letter with you at a time when the Company has so recently achieved a seminal advance in our history — that of transitioning to profitability. During the first quarter of 2007 we delivered a strong $0.33 per share earnings from our continuing operations and fully expect to maintain this momentum through 2007.

This achievement comes nearly ten years after our decision to systematically build away from the technology platform services model — which allowed us to lay down a strong drug discovery sciences base in the early 1990's — and just 29 months since the U.S. approval of our flagship anti-cancer therapy Tarceva®.

Over the last decade we have been focused on ensuring that we bring Tarceva to cancer patients in desperate need of innovative next-generation molecular targeted therapies while simultaneously laying the foundation from which to build an outstanding biotechnology organization around this success. We continue today to be completely committed to meeting the needs of patients and shareholders alike. We firmly believe that striving for the optimal balance between financial performance and reinvestment in the discovery, development and commercialization of innovative therapies for patients suffering from cancer, diabetes and obesity is the best way to realize significant long term shareholder value.

Transitioning from a development stage organization to a more mature and commercially sustainable company has been a challenging journey for those — still relatively few — biotechnology companies who, like us, have achieved a major product success. In preparing for, and executing upon, this transition at OSI we have achieved many milestones including:

- The successful development and registration of Tarceva which is now available in over 100 countries around the world following the demonstration of a survival benefit in Phase III trials using Tarceva in treatment regimens for advanced non-small cell lung cancer and pancreatic cancer — two of the most difficult to treat and deadly forms of cancer;
- The treatment of well over 100,000 cancer patients with Tarceva — adding an estimated 20,000 years of life to these patients — translating to $650 million global sales in 2006 alone, just the second full year on the market in the U.S. and the first full year of sales in Europe;
- The execution of multiple successful financings and debt issuances to effectively capitalize the Company for future growth;
- The systematic addition of key development, registration and commercial assets and know-how that have allowed us to play a key role in maximizing the value of Tarceva within our global alliance for the brand with Genentech, Inc. and Roche;
- The evolution, through M&A and *de novo* investment, of a sound and differentiated R&D platform upon which to build in oncology;

- The highly successful $35 million acquisition of the DPIV intellectual property platform and lead compound (PSN9301) from Probiodrug in 2004. A transaction that we believe can potentially yield a royalty annuity worth hundreds of millions of dollars from this major emerging class of diabetes therapies spearheaded by the 2006/2007 approvals of Merck's Januvia™ and Janumet™; and

- A compounded annual appreciation in the stock price of OSIP of over 30% since we embarked upon the strategy to build away from the technology platform services model in 1998.

This journey to profitability has not been without missteps — the most noticeable of which has been the very disappointing consequences of the 2005 Eyetech acquisition. We made this acquisition based on the strategic rationale that a second source of appreciable top-line revenues would help fuel growth and expand our ability to fund R&D through our transition to profitability. The key asset acquired in the transaction, Macugen®, is a selective anti-VEGF agent that was the first of its class approved for neovascular age-related macular degeneration. Our decision to acquire Eyetech was based upon three critical assumptions that have proven to be erroneous — that the off-label use of the more promiscuous anti-VEGF agent, Avastin®, would not gain traction due to safety concerns; that the FDA would curtail the unregulated/unapproved reformulation of the Avastin anti-cancer formulation for injection in the eye; and that Macugen would have a sustainable niche — based on a preferential safety profile — in the market following the launch of Lucentis®, another more promiscuous anti-VEGF agent. Although Macugen recorded $107 million in sales in 2006 and we continue to believe that its safety profile will ultimately command a niche in the market place, there can be no doubt that this transaction was a significant miscue. We have recognized this and — in an industry that requires risk-taking but that also demands the aggressive management of risk — we have moved quickly to manage the situation. We have successively stripped costs out of the business (both the eye business and our expanding core operations in oncology and diabetes) and committed to divesting the eye business during the course of 2007. As a result we are reporting the financials of the Eyetech unit as discontinued operations through the completion of the divestiture.

As a result of this tactical miscue, we are more committed than ever to capitalize on the value we believe to be inherent in our core oncology and diabetes/obesity franchises and the last year has seen appreciable progress in this regard.

The competitive situation around Tarceva has improved noticeably with high profile Phase III failures for Telcyta™ in NSCLC and Avastin and Erbitux® in pancreatic cancer helping to reaffirm the value of Tarceva. We have also continued to execute on our joint label expansion clinical trials program with our colleagues at Genenetech and Roche. A crucial Phase III study using Tarceva as a maintenance therapy following front-line treatment regimens in NSCLC (the SATURN study) is enrolling on-track and we anticipate data from this study in the second half of 2008. The second-line (BETA) Avastin/Tarceva combination trial in NSCLC and maintenance study in ovarian cancer are also enrolling well. Our own clinical team has initiated a large Phase III trial (the RADIANT trial) which seeks to demonstrate the utility of Tarceva in an adjuvant setting following surgery and optional chemotherapy in stage I-IIIa NSCLC patients. In addition to this we have confirmed that the exposure levels of Tarceva in active smokers following regular dosing, 150mg/day, are approximately half those seen in non-smokers. Thus we will be seeking a dose modification to the package insert reflecting a new maximum tolerated dose of 300mg/day in this population of patients.

On the regulatory front, Tarceva was approved for use in pancreatic cancer in Europe in January of this year and we anticipate approval for NSCLC in Japan during 2007. Roche has successfully negotiated reimbursement agreements throughout Europe (with the exception of the U.K.'s NICE organization where they are appealing a

decision not to reimburse Tarceva in England and Wales) and the prospects continue to look good for expanding Tarceva use in ex-U.S. markets.

Tarceva sales in the U.S. have been stable in the latter part of 2006 and the early part of 2007. We believe that this is driven in part by active competition in the second/third line NSCLC market but that it is accentuated by changing reimbursement dynamics in the U.S. market. As a result of the Medicare reform, Part B (intravenously administered) drugs are no longer as favorably reimbursed as they have been in the past. However, we believe economic considerations remain an important factor in influencing choice of therapy in favor of Part B drugs especially in situations where the data may be perceived as equivocal. We believe this situation will adjust over time (as pressure on Part B reimbursement increases) and with the emergence of key new data such as that from the SATURN study.

We have also recently concluded an agreement with Genentech to realign our joint sales effort such that — effective April 1, 2007 — we will have, for the first time, a dedicated Tarceva sales force staffed 50:50 by OSI and Genentech sales representatives. This has a dual benefit to OSI in both increasing the proportion of total sales expenses for which we are reimbursed and — more importantly — providing a focused sales effort in support of the brand.

Our translational research efforts on Tarceva have continued to yield valuable insights into both the optimal use of this agent and the impact of cancer biology on targeted therapies in general. We are continuing to investigate the complex and intertwined interactions between smoking, dose, rash and aberrations in EGFR-related cell signaling such as those resulting from mutations in the k-ras gene on Tarceva therapy. More comprehensively, we are exploring the role of the phenomena of epithelial-to-mesenchymal transition (or EMT: a central biological process involved in the systematic spread and progression of human cancer) on the responsiveness of tumors to Tarceva and other targeted therapies. Indeed we have focused our oncology research efforts on exploiting our growing understanding of this process in order to develop optimal combinations of targeted therapies that exploit this complex tumor biology. Two of our emerging pipeline of follow-on therapies — OSI-906, which targets the insulin-like growth factor receptor (IGF1-R) and OSI-027, which targets the TORC1/TORC2 protein complexes and is a next generation mTOR pathway targeted agent — could allow us to optimize combination therapies with Tarceva that exploit aspects of EMT biology. Our most advanced follow-on oncology product, OSI-930, is in the latter stages of a Phase I trial in cancer patients. OSI-930 is an oral, small molecule, co-inhibitor of the receptor tyrosine kinases c-kit and VEGFR and is, as such, targeted to simultaneously inhibit an important proliferative pathway in certain tumors and the process of angiogenesis.

Our U.K. based diabetes and obesity Prosidion subsidiary has thrived as a focused R&D franchise built around PSN9301 — our own DPIV inhibitor acquired as part of the Probiodrug acquisition. PSN9301 is being developed with a view to mealtime or twice daily dosing (ultimately with metformin) and has demonstrated encouraging activity in Phase IIa trials. We believe its rapid absorption and clearance may allow for ''interprandial sparing'' whereby the inhibition of DPIV around major meals — where levels of the target glucose regulator GLP-1 are critical — can deliver the required efficacy without the potential side effects associated with sustained inhibition of other important DPIV substrates like Substance P. We expect to begin a Phase IIb trial program for PSN9301 during 2007.

Unlike the specialty market of oncology — where we expect to commercialize our future products directly in the U.S. — diabetes is a primary care market and our current model involves partnering our diabetes assets for commercialization. As such, and given the necessary constraints on our overall R&D spending as we strive to balance R&D reinvestment with financial performance, we chose to license our next most advanced diabetes

clinical program — the glucokinase activator PSN010 — to Eli Lilly and Company in a transaction that yielded $25 million in up-front fees, up to $360 million in potential milestones and competitive royalties upon successful development and commercialization. Lilly will also be responsible for all ongoing development and commercialization costs which has allowed us to contain our overall R&D spend in this critical transitional year for the Company.

Putting this all together, we believe that we have the Company well poised as we complete our journey to profitability. We have adjusted aggressively to the miscue of the Eyetech transaction, continued to build on the value of the Tarceva franchise and achieved what we believe is an appropriate balance between key R&D investments for the Company's longer term growth and disciplined cost-management allowing us to deliver credible earnings performance even as we build pipeline strength in oncology and diabetes/obesity.

We recognize the support of you, our shareholders, through this challenging time and remain confident in the near and long term prospects for success of our Company. We would also like to thank our employees and recognize their tremendous commitment to bringing new medicines and new hope to the millions of patients around the world who suffer from cancer, diabetes and obesity.

We thank you for your continued support and invite you to visit our new website at www.osip.com.

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, 2006 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, or a non-accelerated filer. See definition of ''accelerated filer and large accelerated filer'' in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐

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, 2006, the aggregate market value of the Registrant's voting stock held by non-affiliates was $816,902,229. 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, 2006 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, 2007, there were 57,505,252 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 2007 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 Form 10-K filed with the Securities and Exchange Commission on March 1, 2007. 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); Novantrone® (mitoxantrone for injection concentrate); and Gelclair® Bioadherent Oral Gel. 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 primary 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. 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. Tarceva achieved global sales of approximately $650 million for 2006. We co-promote Tarceva in the United States with Genentech, Inc. and receive royalties on sales outside of the United States from our international partner, Roche. Behind Tarceva, we have an emerging oncology pipeline of molecular targeted therapies in clinical and late-stage pre-clinical development.

We also have research and development programs in diabetes and obesity which are conducted through Prosidion Limited, our U.K. subsidiary. Our current business strategy in the diabetes and obesity area is to progress our research projects through clinical proof-of-concept studies followed by outlicensing or partnering these programs for upfront fees, milestones and royalties. In January 2007, we outlicensed our glucokinase activator, or GKA, program, including our clinical candidate PSN010, which is in Phase I studies, to Eli Lilly and Company for an upfront fee of $25 million and up to $360 million in potential development and sales milestones and other payments plus royalties on any compounds successfully commercialized from the program. We also generate revenues from our patent estate relating to the use of dipeptidyl peptidase IV, or DPIV, inhibitors for the treatment of type II diabetes and related indications. Nine pharmaceutical companies have taken non-exclusive licenses to these patents, which provide us with upfront payments as well as potential milestones and royalties. In the fourth quarter of 2006, one of our licensees, Merck & Co, Inc., received approval by the FDA for its DPIV inhibitor, Januvia® (sitagliptin phosphate), and commenced marketing of the drug, which triggered the payment of a milestone and royalties to us.

On November 6, 2006, we announced our intention to divest our eye disease business, a process which we expect to complete by mid-2007. Our eye disease business consists principally of Macugen (pegaptanib sodium injection), 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 because we believe 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 — will not be realized. Total U.S. net sales of Macugen in 2006 were approximately $103 million and were significantly impacted by the launch of a competitor's product. Given the financial constraints resulting from the decline in Macugen sales on our overall research and development budget, we do not believe that we can optimally develop the research and development assets in our eye disease business and continue to support Macugen in the face of competing priorities in the oncology, diabetes and obesity areas. We are currently negotiating with our partner, Pfizer, Inc. for the return of U.S. rights to Macugen to us in exchange for a royalty-free license to Pfizer to commercialize Macugen in the rest of the world. We believe this will help facilitate a successful divestiture of the eye business. We are currently in discussions with several parties regarding the divestiture of the eye disease business for an upfront fee and /or

future milestones and royalties. We intend to structure the divestiture in a manner which will allow us to be compensated for any future success of Macugen and the pipeline assets in the eye disease business — primarily our anti-platelet derived growth factor, or anti-PDGF, aptamer program. As a result of this decision to divest our eye disease business, we expect to record the financial information associated with these operations as discontinued operations starting in the first quarter of 2007 if we are able to finalize our plan to divest the business.

Strategy

Our major goals for 2007 are to:

- Together with our partners, Genentech and Roche, continue to drive Tarceva growth commercially and through investment in label expansion opportunities;
- Deliver full-year profitability for the first time; and
- Continue focused and selective investments in our research, pre-clinical and clinical assets to provide longer-term growth.

The growth of Tarceva in 2007 is centered on maximizing the near-term commercial impact in the United States, sustaining growth momentum outside of the United States and continuing to expand upon the science underlying the product. In addition to our promotional efforts, we also continue to support the publication of data from the pivotal trials of Tarceva in advanced NSCLC and pancreatic cancer, our BR.21 and PA.3 studies, respectively, in order to further educate the oncology community on the attributes of Tarceva.

Outside of the United States, Roche intends to build upon a successful first year launch for NSCLC in various key markets, including the EU. Worldwide sales of Tarceva for 2006, excluding U.S. sales, totaled approximately $248 million. We receive a 21% royalty on adjusted net sales of Tarceva outside of the United States (approximately 20.5% of net sales). In January 2007, the EU approved the sale of Tarceva in combination with gemcitabine for first line metastatic pancreatic cancer. In the second half of 2007, we expect action on the regulatory submission in Japan for Tarceva for NSCLC filed by Chugai Pharmaceuticals Co., Ltd., or Chugai, a subsidiary of Roche. We believe that continued uptake in the NSCLC market combined with the addition of sales for the pancreatic indication in the EU and sales for NSCLC in Japan, if approved, will help to sustain steady growth for Tarceva on a global basis.

Delivering full-year profitability in 2007 is a key goal that we believe can be attained through diligent management of our business and, in particular, our expenses. In addition to our decision to divest our eye business, we have taken several steps to carefully manage the interim costs related to the eye business, such as closing the headquarters for our eye disease business in Times Square, New York, at the end of 2006, and significantly reducing headcount related to this business. We also have minimized clinical development for Macugen and our other eye disease programs with the exception of our post-approval trial commitments and the LEVEL trial — our Phase IV trial to evaluate the safety of Macugen as a maintenance therapy for patients who have received prior treatment for wet AMD and experienced an improvement in the condition of their macular disease. We are decreasing our overall general and administrative expenses by resizing our corporate operations so that they are commensurate with our simplified business following the divestiture of our eye disease business. We also intend to decrease expenses related to certain activities, such as drug formulation, API manufacturing or toxicology studies, by outsourcing such functions in a cost-effective manner, including off-shoring.

In addition to careful management of our expenses, we expect that our patent portfolio around DPIV will begin to generate a valuable flow of royalty revenues from our licensees' products. One product, Merck's Januvia, is already on the market in the United States and received a positive opinion in January 2007 from the Committee for Medicinal Products for Human Use in relation to its EU regulatory approval application. With respect to a second product, Novartis AG's Galvus® (vildagliptin), Novartis announced on February 26, 2007 that it had received an

''approvable'' letter from the FDA. A third product candidate from Bristol-Myers Squibb Company, saxagliptin, is in the final stages of Phase III clinical trials. Merck's DPIV combination product, Janumet™, which is also covered by our DPIV license agreement with Merck, is expected to be approved in the United States in the second quarter of 2007.

We intend to continue to invest in clinical and pre-clinical programs for drug candidates in oncology and diabetes and obesity. We believe that these programs will provide an important foundation for long-term growth. In oncology, we will continue to advance OSI-930, a c-kit/VEGFR-2 inhibitor, through Phase I trials and, if justified, into Phase II trials. We plan on commencing Phase I studies for OSI-906, a novel small molecule inhibitor of the tyrosine kinase insulin growth factor 1 receptor, or IGF-1R, in the first half of 2007. OSI-027, our next-generation TORC1/TORC2 signaling inhibitor, is in advanced pre-clinical development and we anticipate that we will file an investigational new drug application, or IND, for this compound by the end of 2007. PSN602, a serotonin 1A agonist and monoamine reuptake, or S1RUP, inhibitor, is our first obesity candidate and should commence clinical trials by the fourth quarter of 2007. Our oncology research efforts are focused on the biology of epithelial-to-mesenchymal transition, or EMT, which we believe will allow us to exploit key molecular targets resulting in potentially synergistic molecular targeted therapy combinations with Tarceva.

Oncology

Tarceva

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 would result in tumor shrinkage. The HER1/EGFR gene is over-expressed, mutated or amplified in approximately 40% to 60% of all solid 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. While we believe that Tarceva is likely to have utility in many oncology disease settings, the initial focus of our development program has been on NSCLC and pancreatic cancer.

The American Cancer Society estimates that approximately 185,600 American cancer patients will be diagnosed with NSCLC in 2007. Based on data from the Tandem Oncology Monitor, a national audit in 2006 by Synovate, Inc. of cancer patients receiving therapy, approximately 63,000 subsequent courses of therapy were provided to NSCLC Stage IIIB/IV patients following a course of front-line chemotherapy. The American Cancer Society estimates that approximately 33,400 cancer patients in the United States will die from pancreatic cancer in 2007, 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 most common incident form of cancer in 2004 was lung cancer, with approximately 381,500 cases. Lung cancer was also the most common cause of cancer death in Europe, with approximately 341,800 deaths.

We have an ongoing collaboration with our partners, 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 21% royalty on adjusted net sales (approximately 20.5% of net sales). Tarceva research and development expenses that are part of the alliance's global development program generally are shared equally among the three parties.

We, together with Genentech and Roche, continue to invest in the future development of Tarceva. Large scale Phase III trials are underway which are designed to demonstrate the benefits of Tarceva as a maintenance therapy following the treatment of NSCLC and, separately, ovarian and colorectal cancer patients with first-line drug combination regimens; as a maintenance therapy adjuvant to surgery in stage I-IIIa NSCLC patients; and in combination with Avastin as a front-line and second-line treatment for NSCLC patients. We have also completed two phases of a study demonstrating that the maximum tolerated dose, or MTD, for Tarceva in smokers is 300 mg/day, which is twice the 150 mg/day MTD defined in previous studies. We intend to seek a change in the prescribing information for Tarceva reflecting the new MTD for smokers by the end of 2007.

We are also conducting a randomized Phase II study in front-line NSCLC patients who are positive for EGFR expression using one or both of two testing technologies (immunohistochemistry, or IHC, and fluorescent in situ hybridization, or FISH) using either Tarceva intercalated with chemotherapy or as a monotherapy. We believe that these selected patients may particularly benefit from Tarceva therapy. In addition, approximately 200 investigator-sponsored clinical trials and National Cancer Institute sponsored trials are ongoing and planned, investigating other Tarceva uses and regimens.

Commercial/Regulatory Milestones. 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 Commission for the EU 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. As of January 31, 2007, Tarceva has received approval in a total of 69 countries for NSCLC and 42 countries for pancreatic cancer. Chugai has filed a submission for approval of Tarceva in Japan which, if approved and following pricing approval, will result in the launch of Tarceva in Japan in the second half of 2007.

Lifecycle Plan. Our longer-term strategy for maximizing the Tarceva brand is to focus on progressing Tarceva use to the front-line and adjuvant settings in NSCLC, expanding Tarceva use to other cancers, and exploring the use of Tarceva in combination with other targeted therapies, including Avastin® (bevacizumab). Phase II data has shown good activity for Tarceva in the front-line setting in NSCLC. Anti-tumor activity has also been demonstrated in Phase II trials for ovarian, head and neck, brain, liver and breast cancers.

Together with Genentech and Roche, we have implemented a broad-based global development strategy for Tarceva comprised of simultaneous clinical programs designed to potentially expand the number of approved indications for Tarceva, evaluate its use in new and/or novel combinations and provide additional clinical data pertinent to our understanding of the drug. The studies are sponsored by us, Genentech, Roche or third parties through investigator-sponsored studies. Key studies are summarized below.

SATURN and TITAN Studies. The SATURN study is a double-blind randomized 850-patient Phase III study to evaluate the efficacy of Tarceva 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 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. Both the SATURN and TITAN studies are part of our post-marketing clinical studies agreed to with the FDA, and are currently enrolling. Those patients who do not progress on chemotherapy are enrolled in SATURN and randomized to Tarceva or placebo. This study, if positive, could provide a new label for Tarceva as a front-line maintenance therapy. We expect preliminary data from the SATURN

study in 2008. 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 head-to-head comparative data for Tarceva versus chemotherapy in the sub-set of patients who rapidly progress on front-line chemotherapy. In both SATURN and TITAN, tissue collection for analyses of molecular markers is mandatory and the information gained will be used to design future studies with Tarceva in NSCLC. The SATURN and TITAN studies are sponsored by Roche.

RADIANT Study (Adjuvant Tarceva after Surgery and Chemotherapy in Patients with Stage IB-IIIA NSCLC). Due to its demonstrated efficacy, favorable safety profile and convenience, 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 confirmed that certain patients with resectable NSCLC benefit from platinum-containing adjuvant chemotherapy. This treatment paradigm is becoming the standard of care in the United States. In the 945-patient RADIANT study, patients with fully resected NSCLC who are EGFR-positive by IHC and/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 and to increase the number of patients that may survive this disease. We began opening sites and enrolling patients to this study in late 2006. We hope to complete enrollment in 2009 with interim data available in 2010.

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. This is especially true in earlier stages of disease where multiple treatment choices are available. Results from our registrational study for NSCLC, the BR.21 study, suggest that patients with tumors that are EGFR positive by either FISH and/or IHC derive a larger survival benefit from Tarceva than those with EGFR negative tumors. 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. Patients with tumors that are EGFR-negative by both IHC and FISH are excluded from the study. 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. The study is currently enrolling.

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 who never smoked or were previous light smokers. 180 patients with Stage IIIB or IV disease will receive either Tarceva alone or in combination with the drugs carboplatin and paclitaxel. This study examines prospectively the results seen in retrospective analyses of the never-smoking patients in the TRIBUTE and BR.21 randomized Phase III studies. In TRIBUTE, 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 50 study centers which are part of the CALGB cooperative group network and has been endorsed by The Eastern Cooperative Oncology Group, or ECOG, and it is expected that ECOG-member institutions will soon be able to participate in this study.

Smoker Maximum Tolerated Dose Study. Pharmacokinetic analyses from our BR.21 study suggest 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 those observed in non-smokers. In 2006, OSI 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 MTD of Tarceva in this population as 300 mg/day. The second stage of the study has been initiated to compare the steady state pharmacokinetics of Tarceva at the 300 mg/day versus 150 mg/day. This stage of the study is currently enrolling.

Beta and Atlas Studies. Two additional studies in NSCLC are being conducted by our partner, Genentech. The first study, referred to as Beta Lung, is a Phase III, multicenter, placebo-controlled, double-blind, randomized trial to evaluate the efficacy of Avastin in combination with Tarceva compared with Tarceva alone for the treatment of advanced NSCLC in the second line setting. This trial is currently ongoing and has randomized 360 of the planned 650 patients. The study is a significant step toward an all targeted (non-chemotherapy) combination treatment option for NSCLC. Results of the trial are anticipated in 2008. The second study, referred to as ATLAS, is a randomized, double-blind, placebo-controlled, Phase IIIb study that compares Avastin therapy with Avastin plus Tarceva as a 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 2009.

Ovarian and Colorectal Cancer Studies. Additional collaborative 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 and follows a similar maintenance protocol to the one described above for NSCLC 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 four-arm study tests Tarceva as a maintenance therapy and also explores the use of Avastin in combination with the established front-line chemotherapy regimens FOLFOX and XELOX that are widely employed in the treatment of colorectal cancer. Both of these studies are currently enrolling patients.

Investigator Sponsored Studies. In addition to the studies listed above, there are approximately 200 investigator-sponsored studies and National Cancer Institute/Cancer Therapy Evaluation Program (CTEP) and Division of Cancer Prevention studies ongoing or planned in the Tarceva program. These studies are exploring monotherapy and combination uses of Tarceva, including with 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 partners 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. Under our agreement with Genentech, we are committed to provide at least 25% of the U.S. sales effort. 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. We believe that our sales team is a key contributor to the Tarceva sales effort.

The OSI/Genentech/Roche Alliance. We manage the ongoing development program for Tarceva with Genentech and Roche through a global development committee under a Tripartite Agreement among the parties. 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. 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. 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.

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 have also manufactured API for Tarceva clinical trials. Schwarz Pharma Manufacturing, Inc. is our manufacturer of Tarceva tablets and placebo product for clinical and commercial supplies. We have entered into long term supply agreements with our API and tablet manufacturers. We are working to qualify another manufacturer to serve as an alternative (i.e., back-up) provider of Tarceva tablets. Clinical supplies of Tarceva tablets are currently stored, labeled, packaged and distributed by Cardinal Health Clinical Services, and Cardinal Health Packaging Services 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 inventory on hand, to support the commercial sales of Tarceva.

Our Oncology Research and Development Strategy and Programs

The entire drug discovery and development process typically takes well over a decade and is subject to substantial risk and attrition. A significant majority of drug candidates which enter clinical trials fail to result in a successful product with typical metrics for the industry suggesting that only approximately one in eight drug

candidates that enter clinical trials will result in a successful product. We have built, over two decades, extensive expertise in the discovery and development of molecular targeted therapies — drugs designed to directly inhibit a biomolecule that we believe to be causally or mechanistically involved in the disease state we are addressing. Observations from our translational research on Tarceva coupled with our expertise in molecular targeted therapies has led to our focus on the biology of a process known as epithelial-to-mesenchymal transition, or EMT, which may allow us to identify key molecular targets for the development of optimal combination regimens that may enhance the treatment of certain types of solid tumors. The results from our research in this area may allow us to develop synergistic combination regimens that could enhance the likelihood of success of Tarceva in additional indications.

Translational Research. Translational research is an area of investigation designed to bridge our research knowledge base into the clinic and the marketplace, and one of the key goals for our translational research group has been to generate data that could enhance the quality of the clinical strategies for compounds within our development portfolio. The current emphasis of our translational research program is on Tarceva, and a series of collaborations and studies are ongoing. Our translational research group has pioneered research on Tarceva's effects on different types of cancer cells relative to EMT. 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. 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 acquire or gain the ability to migrate, invade and metastasize. These properties suggest the need to target distinctly different molecular targets in order to effectively treat these tumors. With this new insight, our development project teams are planning 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 respond to therapy.

Dual c-Kit/ VEGFR-2 Program. 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 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 is ongoing. We also have a second development candidate in our c-Kit/VEGFR-2 program, OSI-817, which serves as a back-up candidate to OSI-930.

The mutated Kit receptor is directly involved in tumor progression in the majority of gastrointestinal stromal tumors and certain leukemias, and over-expressed normal Kit is thought to play a role in small cell lung cancer. The inhibition of the tyrosine kinase activity of Kit is expected to result in reduced cancer cell proliferation and increased cellular apoptosis in tumor types driven by Kit, resulting in inhibition of tumor growth. In addition to inhibiting Kit activity, both OSI-930 and OSI-817 are also capable of inhibiting the VEGFR-2 receptor tyrosine kinase. This receptor is present on endothelial cells and is a key mediator of blood vessel growth in response to the angiogenic growth factor VEGF. This pathway is believed to be the single most important mechanism for recruitment of new blood vessels in nearly all solid tumors; hence, inhibition of this pathway should impact the growth and metastases of a wide range of angiogenesis-dependent malignancies. While the combination of Kit and VEGFR-2 inhibition would be expected to offer the greatest therapeutic benefit to patients bearing Kit expressing solid tumors, the VEGFR-2 component is considered an attractive target for all solid tumors. Targeting anti-angiogenesis is a very competitive arena in oncology today with two oral small molecules and one antibody therapeutic already approved

and being marketed. A key determinant of the success of our program will be our ability to differentiate OSI-930 from its competitors.

OSI-906. OSI-906 is a selective inhibitor of IGF-1R. IGF-1R stimulates proliferation, enables oncogenic transformation, and suppresses apoptosis. It has been one of the most widely pursued targets of drug discovery in the oncology arena over the last decade but efforts have been hampered by the close resemblance of IGF-1R to the insulin receptor. A key determinant of the success of this program will be our ability to block IGF-1R without causing extensive hyperglycemia indicating a co-inhibition of the insulin receptor. Inhibitors of IGF-1R are expected to have broad utility in oncology since the over-expression of IGF-1R and/or its ligands (IGF-I and IGF-II) or the down-regulation of ligand binding proteins, or IGFBPs, occurs in numerous human malignancies including lung, colon, breast, prostate, brain and skin cancers. Correlations of IGF-1R and ligand over-expression with increased risk and poor prognosis have been observed. In addition, signaling through the IGF system has been implicated in protecting tumor cells from apoptosis induced by a number of anti-cancer treatments such as EGFR inhibitors (e.g., Tarceva and the anti-HER2/erbB2 antibody Herceptin® (trastuzumab)) and cytotoxic agents. We believe that OSI-906 may be useful both as a single agent and in the potentiation of other molecularly targeted therapeutic agents such as Tarceva. We have found that the combination of an EGFR inhibitor with an IGF-1R inhibitor is synergistic in certain NSCLC cell lines. We filed the IND for OSI-906 in the fourth quarter of 2006 and we anticipate that Phase I clinical trials will commence in the first half of 2007.

OSI-027. OSI-027 is a next-generation mammalian target of rapamycin (mTOR) kinase inhibitor that inhibits the kinase activity associated with both the TORC1 and TORC2 complexes of mTOR. This dual TORC1 and TORC2 activity differentiates our compound from rapamycin and the various related analogs, or rapalogs, that are currently in clinical development in that these molecules only inhibit TORC1 activity. The PI-3 kinase/Akt/mTOR signaling pathway is thought to regulate cell growth, proliferation and survival and as a result mTOR has attracted much attention as a target for the treatment of cancer. The inappropriate activation of mTOR can occur via a variety of mechanisms including loss of PTEN protein function, the mutation or amplification of the p85 regulatory subunit of PI-3 kinase and the overexpression of receptor tyrosine kinases such as the ErbB family, PDGFR and IGF-1R. Numerous human tumors show loss of PTEN function, mutation of PI-3 kinase and/or overexpression of receptor tyrosine kinases, or RTKs, and may thus be susceptible to mTOR inhibition. The rapalogs have activity against human cancer; however, it is thought that their activity is limited by their inability to completely block phosphorylation of 4EBP1, one of the downstream targets of mTOR. Thus, the dual mTOR kinase inhibitor was developed as a means to maximize the pharmacological impact of mTOR blockade in comparison to that observed with the rapalogs. Moreover, we have found that the combination of an EGFR inhibitor with an inhibitor of mTOR is synergistic in certain tumor cell lines. We expect to file an IND for OSI-027 before the end of the fourth quarter of 2007.

Oncology Discovery. Given the importance and relevance of EMT to the therapeutic activity of Tarceva, we have focused our 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. This focus is an extension of our existing strategy to exploit signaling pathways involved in the control of the proliferation and/or modulation of tumor cell apoptosis. We are employing various processes from an EMT perspective in our oncology research, and such processes may allow us to identify compounds and appropriate combinations of targeted therapies that could have a broad range of activity in a disease indication for which there is strong biological support. Emerging data suggest that alternative pathways are operative in mesenchymal-type tumor cells that activate the key cell signaling protein Akt in an IGF-1R and EGFR independent manner, although the molecular mechanisms responsible for such Akt activation remain unclear at this time. These observations raise the possibility that new drug targets and new drug combinations can be identified through our research efforts on EMT. We believe that our continued focus on EMT

biology and rational molecular targeted therapy combinations will enable us to establish a uniquely differentiated platform within the biotechnology and pharmaceutical industries and will enhance the probability of technical success associated with our oncology discovery and development programs.

Novantrone

Novantrone (mitoxantrone concentrate for injection) is an anthracenedione used as an intravenous chemotherapy agent. Novantrone is approved by the FDA for the treatment of acute non-lymphocytic leukemia, and the relief of pain associated with advanced hormone refractory prostate cancer. We market and promote Novantrone for these approved oncology indications in the United States pursuant to a co-promotion agreement with an affiliate of Merck Serono, S.A. signed in March 2003. We receive commissions from Merck Serono on net oncology sales in this market. The patent for Novantrone expired in April 2006, which resulted in the loss of market exclusivity for Novantrone. Following the patent expiration, we experienced an anticipated significant decrease in our commissions related to Novantrone as a result of a large decrease in oncology sales due to generic competition. Under our agreement with Merck Serono, we are also no longer obligated to pay fees associated with the sales and marketing of Novantrone.

Collaborative Development Programs with Pfizer

From 1986 to 2001, our oncology drug discovery efforts in targeted therapies were conducted in collaboration with Pfizer. During the course of the alliance, several novel molecular targeted therapies, including Tarceva, were advanced to clinical development. Pfizer is continuing to develop two clinical stage targeted therapies from this prior alliance: CP-547,632, a VEGFR inhibitor in Phase II trials, and 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 either of these drug candidates, we will receive a royalty from Pfizer on the sales of these drugs. If Pfizer chooses to discontinue development of any of these drug candidates, we will have the right to pursue development of them. In 2006, Pfizer ceased development of CP-724,714, a small molecule HER-2 inhibitor, and rights to this compound were returned to us. We have chosen not to proceed with development of this compound at this time.

Outlicensing of Certain Clinical Programs

OSI-754. In December 2006, we outlicensed OSI-754, an oral farnasyl transferase inhibitor, to Link Medicine Corporation. Under the terms of the license, Link Medicine received an exclusive license to OSI-754 in all indications with the exception of oncology, and we received an upfront payment, along with potential fees, milestones and royalties upon successful development of this compound by Link Medicine.

OSI-211, Aptosyn® (exisulind), and OSI-461. We have entered into a letter of intent with The Channel Group, LLC to outlicense our clinical compounds Aptosyn and OSI-461, which we acquired from Cell Pathways, Inc., and OSI-211, which we acquired from Gilead Sciences, Inc. The transaction, if consummated, would provide us with an upfront payment, as well as potential future milestone and royalty payments.

Diabetes and Obesity

Diabetes and Obesity Clinical Programs and Discovery Research

Our diabetes and obesity research and development programs are carried out through our wholly-owned UK-based subsidiary, Prosidion. Our most advanced program, PSN9301, is a DPIV inhibitor, one of the most topical targets in diabetes drug development today. DPIV inhibitors are designed to regulate blood glucose by preventing the breakdown of GLP-1, a key glucose regulatory hormone that is cleaved and inactivated by DPIV. We acquired our DPIV program, together with a portfolio of patents and patent applications with claims covering DPIV as a target for anti-diabetes therapy and licensed rights to patent applications claiming combinations of DPIV inhibitors with

other oral anti-diabetes drugs such as metformin, from Probiodrug AG in July 2004 for approximately $35 million in cash plus future milestones relating to PSN9301.

PSN9301. PSN9301 is an oral, fast-acting inhibitor of DPIV, which cleaves and inactivates glucagon-like peptide-1, or GLP-1, an important mediator of blood glucose levels. Inhibition of DPIV leads to enhanced GLP-1 activity which leads to increased insulin secretion and decreased glucagon secretion resulting in significant lowering of both mean and post-prandial blood glucose levels. The increased insulin secretion has been shown to be glucose-dependent, providing a possible built-in safety mechanism against hypoglycaemia, or abnormally low blood sugar levels. The field for DPIV inhibitors is competitive. Merck's Januvia was approved for sale in the United States in late 2006 and Janumet, its combination of sitagliptin and metformin, is expected to be approved later in 2007. While numerous other pharmaceutical companies are currently developing DPIV inhibitors, we believe that PSN9301 is potentially differentiated from these competing products in that it has a very rapid onset of action and a relatively short duration of action and, therefore, is an ideal product candidate for prandial, or mealtime, dosing. It is anticipated that prandial dosing may result in less interference with other DPIV substrates between meals and overnight. PSN9301 has undergone a Phase IIa clinical trial which demonstrated that PSN9301 reduced blood glucose levels in type 2 diabetics by between 25% and 42% in oral glucose tolerance tests. As a result of the strong competitive environment for DPIV inhibitors, including the recent approval of Merck's Januvia, we are pursuing partnering opportunities to support the ongoing development of this compound.

PSN602. PSN602, a S1RUP inhibitor, is currently undergoing late-stage pre-clinical testing and we expect to begin clinical trials for this agent by the fourth quarter of 2007. The S1RUP program is a central nervous system targeted approach which targets satiety by serotonin 1A agonism and monoamine reuptake (S1RUP) inhibition and we are seeking to develop a compound that overcomes some of the cardiovascular side-effects associated with the marketed product sibutramine. PSN602 is the first anti-obesity molecule discovered by us to enter development.

PSN010. In January 2007, we outlicensed PSN010, an oral, small molecule activator of glucokinase, or GKA, 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 million and will potentially receive milestones of up to $360 million and a competitive royalty structure on net sales of any product arising from the licensed GKA program.

Discovery Research. We currently have one advanced project in discovery research which is focused on diabetes and/or obesity and targets selective agonists of the novel G-protein coupled receptor, GPR119. This program has potential utility both in the anti-obesity and diabetes area. We anticipate selecting a development candidate from this project during mid-2007. We also have several exploratory projects targeting diabetes and/or obesity.

Cessation of PSN357. In the fourth quarter of 2006, after a review of the preliminary Phase II data, we suspended further clinical development of PSN357, a glycogen phosphorylase inhibitor, which was in Phase IIa clinical trials for therapeutic intervention in type 2 diabetes.

Our DPIV Outlicensing Program

The DPIV assets we acquired from Probiodrug include issued and pending patents and patent applications with claims covering DPIV as a target for anti-diabetes therapy and licensed rights to patent applications claiming combinations of DPIV inhibitors with other oral anti-diabetes drugs such as metformin. Our rights to this patent estate of DPIV medical use patents provide us with a source of upfront payments, and milestone and royalty revenue through the issuance of non-exclusive licenses to the patent estate. Nine pharmaceutical companies,

including Novartis, Merck and Bristol-Myers Squibb, 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. 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 provides us with royalty payments. Merck also received a positive opinion for Januvia in January 2007 from the Committee for Medicinal Products for Human Use in relation to its EU regulatory approval application. Merck has filed an NDA for Janumet, its combination product, and could receive approval as early as March 2007. Further, Novartis recently received an ''approvable'' letter from the FDA for its DPIV inhibitor Galvus. An approval of Galvus would trigger milestone and royalty payments to us from commercial launch.

Eye Disease

On November 6, 2006, we announced our intention to divest our eye disease business, a process which we expect to complete by mid-2007. We made the decision to exit the eye disease business because we believe 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 — will not be realized. Given the resulting financial constraints on our overall research and development budget, we do not believe that we can optimally develop the research and development assets in our eye disease business and continue to support Macugen in the face of competing priorities in the oncology and diabetes and obesity areas. As we seek to divest our eye disease business, we have taken several steps to carefully manage the interim costs related to this business, such as closing the headquarters for our eye disease business in Times Square at the end of 2006, and significantly reducing headcount related to this business. We have also minimized clinical development for Macugen and our other eye disease programs with the exception of our post-approval trial commitments and the LEVEL trial.

We are currently negotiating with our partner, Pfizer, for the return of U.S. rights to Macugen to us in exchange for a royalty-free license to Pfizer to commercialize Macugen in the rest of the world. We believe this will help facilitate a successful divestiture of the eye business. We are also currently in discussions with several parties regarding the sale of the eye disease business for an upfront fee and/or future milestones and royalties. We intend to structure the sale in a manner which will allow us to be compensated for any future success of Macugen and the pipeline assets in the eye business — primarily our PDGF aptamer program. As a result of this decision to divest our eye disease business, we anticipate that we will record financial information associated with these operations as discontinued operations starting in the first quarter of 2007 if we are able to finalize our plan to divest the business.

Our eye disease business consists principally of Macugen, our marketed product for the treatment of wet AMD, which was launched in the United States in January 2005. Macugen is a novel therapeutic (a pegylated aptamer) that selectively binds to the VEGF-A isoform-165, the pathogenic isoform causing choroidal neovascularization associated with wet AMD. Macugen is administered inside the eye once every six weeks via an intravitreous injection, and addresses the abnormal blood vessel growth and blood vessel leakage that is believed to be the underlying cause of the disease. Total U.S. net sales for Macugen were approximately $103 million for the year ended December 31, 2006 and were significantly impacted by the launch of a competitor's product. Macugen is co-promoted in the United States by our specialty ophthalmology sales force as part of a co-development and marketing arrangement with Pfizer. We currently share with Pfizer on a 50/50 basis the gross profits of Macugen sales in the United States. We and Pfizer are responsible for our own sales costs and we share equally with Pfizer manufacturing, regulatory and marketing costs. Pfizer is responsible for all commercialization of Macugen outside of the United States. For sales of Macugen outside of the United States, we receive the greater of 20% of product operating profit or a 15% royalty.

Macugen's share of the wet AMD market has been significantly impacted by competition from two Genentech products: Lucentis, an anti-VEGF-A agent, which was approved in the United States in June 2006 and in the EU in January 2007, and off-label use of Genentech's anti-cancer agent Avastin, which is approved in the United States for the systemic, intravenous treatment of certain cancers. Unlike Macugen, Lucentis and Avastin are non-selective VEGF-A inhibitors designed to inhibit all isoforms of the VEGF molecule. Avastin has been re-packaged and/or re-formulated for intravitreous injection by independent compounding pharmacies and used extensively in an off-label manner by retinal specialists in the United States. However, there may be potential safety issues associated with the use of both Avastin and Lucentis for the treatment of wet AMD, including the potential for stroke. We therefore developed a strategy which contemplates the induction of therapy with agents like Lucentis and Avastin that may cause a gain in patients' vision, followed by maintenance of these vision gains with Macugen. This strategy is the basis of our ongoing LEVEL study, a Phase IV trial designed to demonstrate the safety of Macugen when used in this manner. The primary endpoint of the LEVEL study is the proportion of subjects losing less than three lines on the ETDRS chart at the end of 52 weeks, and the secondary endpoint is the measurement of retinal thickness and leakage. Enrollment of this study is targeted at 1,000 patients, with 277 patients enrolled as of January 31, 2007. We expect to complete enrollment in this trial by July 2007.

Other Macugen Clinical Programs

Phase II/ III Pivotal Trials. In December 2004 we announced that the FDA had approved Macugen for the treatment of wet AMD based on data from our VISION trials. We have completed approximately four and a half years of our Phase II/III pivotal clinical trials for the use of Macugen in the treatment of wet AMD. These Phase II/ III clinical trials are ongoing to generate long-term safety data for up to five years.

Wet AMD Post-Approval Commitment Study. We and Pfizer have agreed with the FDA that the original post-approval safety study, EOP1014, will be terminated. Instead, we will meet our post-approval safety study obligations to investigate corneal safety and neural retinal function in patients treated with Macugen through our other ongoing trials.

Macugen plus PDT Combination Study for Wet AMD. This Phase III combination trial, which was to compare Macugen and PDT with Visudyne versus Macugen alone, to determine if patients with the predominantly classic form of wet AMD benefit from combination therapy, is currently being wound down and will be terminated by the second quarter of 2007.

DME Clinical Study. A Phase III trial in diabetic macular edema, commenced in September 2005, has been amended in order to convert it into a 300-patient, single-dose study to support potential registration in the EU. This trial will be managed and funded solely by Pfizer.

Sales and Marketing

We commercialize Macugen with our collaboration partner, Pfizer. Under this arrangement, we and Pfizer co-promote Macugen in the United States. We have granted Pfizer the exclusive right to develop and commercialize Macugen outside the United States under a royalty-bearing license. As part of our decision to divest our eye disease business, we have streamlined our commercial organization in order to manage expenses in the interim while preserving a core operating group which can be transferred to a potential buyer. As of February 1, 2007, our commercial organization in ophthalmology was reduced to approximately 55 employees, 48 of whom were in sales and marketing and the remainder of whom were in medical affairs and reimbursement.

Collaboration with Pfizer

In December 2002, we entered into several concurrent agreements with Pfizer to jointly develop and commercialize Macugen for the prevention and treatment of diseases of the eye and related conditions. We are currently

negotiating with Pfizer to amend and/or terminate our various agreements to provide for the return of the U.S. rights to us in exchange for our grant of a royalty-free license to Pfizer to commercialize Macugen in the rest of the world.

Distribution and Pricing

We distribute Macugen in the United States primarily through three national distributors that specialize in pharmaceutical product distribution to specialty markets: McKesson Corporation, CuraScript Inc. and Besse Medical. Under these arrangements, we ship Macugen to our distributors and title and risk of loss pass upon shipment to the distributors. These distributors sell Macugen to physicians, physician group practices, hospitals, federal government buying groups and clinics. Our agreement with Pfizer provides that the parties will mutually agree on the pricing of Macugen.

Manufacturing

We currently depend on third parties to manufacture Macugen. We engaged a third party manufacturer, Degussa Canada, an independent operating subsidiary of Degussa AG, to produce the active pharmaceutical ingredient used in Macugen. Under the terms of our agreement with Degussa, we are obligated to purchase minimum specified percentages of our requirements for the API through 2008.

For our commercial and clinical trial supply of Macugen, we engaged Gilead in December 2003 as a separate fill and finish manufacturer to formulate the active pharmaceutical ingredient from a solid into a solution and to fill the solution into syringes. Under the terms of our agreement with Gilead, we are obligated to purchase minimum specified percentages of our requirements through January 2008.

Macugen License Agreements

We license key components of Macugen pursuant to the following license agreements:

Gilead. In March 2000, we entered into an agreement with Gilead and one of its subsidiaries for an exclusive worldwide license for the API for Macugen. In exchange for the rights licensed from Gilead, we pay royalties to Gilead based on net sales of Macugen by us or our affiliates or sublicensees and milestones triggered by certain events. Upon the expiration of the last-to-expire royalty term, the agreement expires and, at our option, our license from Gilead either (1) survives and remains exclusive, in which case we would be obligated to continue paying Gilead a reduced royalty on product sales or (2) survives and converts to nonexclusive, in which case we would not have any further royalty obligation to Gilead.

Nektar Therapeutics. In February 2002, we entered into a license, manufacturing and supply agreement with Nektar Therapeutics, formerly Shearwater Corporation, pursuant to which Nektar supplies us with the reagent that we link to the aptamer to create the API in Macugen. Under the terms of the agreement, Nektar granted us various exclusive and non-exclusive worldwide licenses, with the right to grant sublicenses, under patents and know-how related to the reagent controlled by Nektar, to develop, manufacture and commercialize Macugen. In exchange for these rights, we pay Nektar royalties based on net sales of Macugen by us or our affiliates or sublicensees. Nektar also has an exclusive right to supply us with the pegylation reagent for Macugen, subject to Nektar meeting its supply obligations. The agreement expires upon the expiration of the last-to-expire patent licensed by us from Nektar. The U.S. patent rights licensed to us by Nektar expire between 2013 and 2016.

Isis Pharmaceuticals. In December 2001, we entered into a non-exclusive license agreement with Isis Pharmaceuticals, Inc., which grants us rights under patents owned or controlled by Isis to commercialize Macugen worldwide. In exchange for this license, we pay Isis royalties based on net sales of Macugen and milestones triggered by certain events. The U.S. patent rights we license from Isis expire between 2010 and 2014.

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.

We have obtained patents for erlotinib, the API for Tarceva, in the United States, Europe, Japan, and a number of other countries. These patents expire in the major commercial markets in 2015. We are pursuing extensions of the patent term or of the data exclusivity term in the countries where such extensions are available. Significantly, we filed for patent term extensions that we anticipate will extend our U.S. patent for erlotinib to November 2018 and corresponding patents in Europe to March 2020. We also are currently pursuing U.S. and international patents for 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 key polymorphic forms of Tarceva in the United States, which we anticipate will provide us with added patent exclusivity for erlotinib through 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.

We have filed a number of U.S. and international patent applications relating to the OSI-930, OSI-817, OSI-906 and OSI-027 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 obtained patents for PSN9301 in the United States, Europe and six other countries. Corresponding patent applications are pending in Japan and a number of other countries. These patents will expire in 2019 with the possibility for patent term extensions of up to five years. We have also obtained patents for the specific salt form of PSN9301 in the United States and in Europe. Corresponding patent applications are pending in Japan and a number of other countries. These patents expire in 2022 and there may be the possibility for patent term extension in some of these countries. We are also pursuing patent applications for the use of PSN9301 in combination with other antidiabetic agents, such as metformin, and processes used in its manufacture. Uses of PSN9301 are also protected by our DPIV medical use patent estate.

The DPIV technology we acquired from Probiodrug includes a portfolio of medical use patents. This portfolio contains a number of patent families comprising issued and pending patents and patent applications with claims covering DPIV as a target for anti-diabetes therapy and related indications. We also have licensed sub-licensable rights to patents and patent applications claiming combinations of DPIV inhibitors with other oral anti-diabetes drugs such as metformin. Merck and Novartis are non-exclusive licensees under these medical use patents, together with seven other pharmaceutical companies. We are entitled to future potential milestones and royalties arising from the licenses under this patent portfolio. Patents which are the subject of these licenses will expire between 2017 and 2023. The earliest of these patents, which claims the use of DPIV inhibitors for lowering blood glucose levels, was revoked by the European Patent Office in May 2004. We are currently appealing the revocation of our patent by the European Patent Office, which has the effect of suspending the revocation of the patent until the appeal is decided. No date has yet been set for the hearing of the appeal proceedings. If we are unsuccessful in defending this opposition and the patent is revoked without the further possibility of appeal, this will potentially reduce the royalty revenue we derive from the non-exclusive licenses we have granted in those territories where the patent is revoked.

We have also sought patent protection for PSN602, our S1RUP inhibitor candidate, and potential back-up candidates for this compound, as well as for compounds arising from the GPR119 receptor project.

In the ophthalmology arena, we exclusively license from Gilead a patent portfolio related to Macugen which includes issued patents in the United States, Europe, Japan and a number of other countries. These patents expire between 2010 and 2017 in the United States. We are pursuing extensions of the patent term or of the data exclusivity term in the United States and in the countries where such extensions are available, which we anticipate will extend the patents in Europe to 2021. We also license exclusively and non-exclusively from Nektar patents related to the pegylation reagent, and license non-exclusively from Isis patents related to oligonucleotide modifications of the Macugen API. We are currently seeking U.S. and international patents for additional formulations and methods of use for Macugen, including a sustained release formulation of Macugen.

We license exclusively a patent portfolio related to E10030, an anti-PDGF aptamer, under our collaboration agreement with Archemix Corp. This patent portfolio includes patents which have issued in the United States and patent applications which are pending in Europe, Japan, Canada and Australia. We are also seeking U.S. and international patents for anti-VEGF/anti-PDGF combination therapies.

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 consisting of seven U.S. patents and additional U.S. and foreign applications, and Wyeth, consisting of four U.S. patents and additional foreign applications, 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 provides them with potentially greater flexibility in the development and marketing of their products and has led us, in the case of Tarceva to seek partnerships with leading biotechnology and pharmaceutical industry allies, like Genentech and Roche, in order to ensure our competitiveness on a global basis.

The market for oncology products is very competitive, with several 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 in the second and third line settings for the NSCLC indication includes existing chemotherapy options such as Alimta, Taxotere and Gemzar. In addition, in October 2006, the FDA approved Avastin in combination with chemotherapy for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC. Although Avastin in combination with chemotherapy is not approved for the treatment of second line NSCLC, off-label use of Avastin in this setting could limit the market share for Tarceva. A key factor for penetrating the second line setting is successfully convincing oncologists to switch from conventional chemotherapy to Tarceva and to employ Tarceva more extensively in the treatment of patients with good performance status prior to the use of additional chemotherapy agents. In limited markets where Iressa® (gefitinib) is available, such as Japan and Canada, Tarceva will compete against Iressa for market share. Other oncology drugs currently in clinical trials for treatment of NSCLC either as a single agent or in

combination, such as Erbitux® (cetuximab), Vectibix™ (panitumumab), Velcade® (bortezomib), Sutent® (sunitib malate), Nexavar® (sorafenib), Zactima™ (vandetanib), Xyotax™ (paclitaxel) and Telcyta™ (TLK286) could compete for market share in NSCLC in the future.

In the pancreatic setting, Tarceva may experience competition from Erbitux if ongoing studies for this drug produce positive results. Additionally, Roche announced favorable results for its chemotherapy product, Xeloda® (capecitabine), in pancreatic cancer in combination with gemcitabine. If Roche succeeds in gaining regulatory approval for Xeloda for the treatment of pancreatic cancer, it could impact Tarceva's market share in this indication.

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-2 targeted agents are in development, some of which are, like OSI-930, multi-targeted small molecule tyrosine kinase inhibitors.

In the diabetes and obesity arena, a number of pharmaceutical and biotechnology companies are conducting clinical trials of potential drugs in the same areas as our drug discovery and development programs. We are aware of at least six competitors, Merck, Novartis, Bristol-Myers Squibb, Takeda Pharmaceutical Company Limited, Merck KGaA and Pfizer with DPIV inhibitor clinical candidates for the treatment of diabetes. We believe that certain of these potential drugs are at a more advanced stage of development than our clinical candidate, PSN9301. In October 2006, Merck received FDA approval for Januvia, its DPIV inhibitor, and Novartis filed an NDA for its DPIV inhibitor, Galvus, in January 2006 and received an ''approvable'' letter from the FDA in late February 2007. Given that Januvia has reached the market earlier than PSN9301 and others may also receive regulatory approval prior to PSN9301, we may be at a competitive disadvantage at the time, if ever, that we receive regulatory approval to commercialize PSN9301. We must therefore clearly distinguish the profile of PSN9301 from other DPIV inhibitors if we are to successfully compete in the marketplace with this product. Additionally, if scientific developments change our understanding of the product differentiation of PSN9301 from that of our competitors' products, the competitive positioning and market potential of PSN9301 may be detrimentally affected. Our glucokinase activator, PSN010, which we have outlicensed to Eli Lilly, faces potential competition from Roche and Novo Nordisk A/ S, who have, at various times, announced similar GKA research and development activities.

Government Regulation

We and our collaborative partners are subject to, and any potential products discovered and developed by us must comply with, comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, 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 and promotion of pharmaceutical and diagnostic products.

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 a new drug application , or 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.

FDA Approval Process

FDA approval of our own and our collaborators' 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.

New indications or other changes to an already approved product also must be approved by the FDA. A supplemental new drug application, or 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 2003, 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 market 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 these requirements, 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 cGMPs 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 on the product, manufacturer or NDA holder, including withdrawal of the product from the market.

Tarceva and Macugen are protected by a portfolio of patents. Separate and apart from patent protection, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, entitles our products to various periods of non-patent statutory protection, known as marketing exclusivity. For Tarceva and Macugen, the five-year period of new chemical entity Hatch-Waxman exclusivity expires on November 18, 2008 and December 17, 2008, respectively. The patent system and marketing exclusivity work in tandem 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 Tarceva or Macugen until the respective marketing exclusivity periods end.

Four years into this marketing exclusivity period (*i.e.*, as of November 18, 2008 for Tarceva and December 17, 2008 for Macugen) however, 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 Tarceva's or Macugen's NDA are invalid 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 notification, FDA is then prevented from approving for 30 months an abbreviated new drug application, or ANDA, for a generic version, or any NDA for a modified version of either drug, where the applicant does not own or have a right of reference to all of the data required for approval, known as a 505(b)(2) application.

This 30-month stay may end early, however, if a court finds the patent invalid or not infringed. If, on the other hand, a court finds the patent valid and infringed, the ANDA or 505(b)(2) application may not be approved until the expiration of the patent. If we or the patent holder or NDA holder decides not to sue within 45 days, the FDA may approve the ANDA or 505(b)(2) application whenever the requirements for approval are met.

The Hatch-Waxman Act also provides for the restoration of a portion of a patent term lost during product development and FDA review of an application. However, the maximum period of restoration cannot exceed five years, or restore the total remaining term of the patent to greater than 14 years from the date of FDA approval of the product. The patent term restoration period 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 restoration and the patent holder must apply for restoration within 60 days of approval. The United States Patent and Trademark Office, in consultation with FDA, reviews and approves the application for patent term restoration. In the future, we may

consider applying for patent term restoration for some of our currently owned or licensed patents, depending on the expected length of clinical trials and other factors involved in the filing of an NDA.

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. Federal legislation enacted in December 2003 has altered the way in which physician-administered drugs covered by Medicare are reimbursed, generally leading to lower reimbursement for physicians. As of January 1, 2005, physicians are reimbursed for physician-administered drugs, such as Macugen, based on the average sales price of the drug plus 6%. The average sales price is the average net price of a drug to all non-federal purchasers. Price discounts will affect the drug reimbursement rates. We currently provide a discount on Macugen to a group purchasing organization. To date, we have not discounted the sale of Tarceva to non-federal purchasers, other than routine prompt payment discounts, although there can be no assurances that market pressures will not require us to provide such discounts in the future.

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, Part D plans establish formularies that govern the drugs and biologicals that will be offered and the out-of-pocket obligations for such products. Generally, such plans include Tarceva within the scope of the plan, with beneficiaries having to pay various amounts of copayments when obtaining Tarceva.

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. Some European governments, notably Germany and Italy, 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 Medicare-Medicaid Anti-Fraud and Abuse provisions in the federal Social Security Act, as amended, the 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 regulations.

We are also 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 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 laws and their implementation, our reporting actions could be subject to the enforcement and penalty provisions of the pertinent state authorities.

Our Employees

We believe that our success is largely dependant upon our ability to attract and retain qualified employees. As of December 31, 2006, we had a total of 611 full time employees worldwide. As of February 7, 2007, our number of employees decreased to 554, of which 276 primarily are involved in research, development and manufacturing activities and 140 primarily are involved in the commercialization of our products. We expect that an additional 89 employees will depart during 2007 as we streamline our overall operations as a result of our decision to divest our eye disease business.

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 much of our revenues from our principal marketed product, Tarceva, which provided approximately 55% of our total revenues for the year ended December 31, 2006. Going forward, we will rely to an even greater extent on Tarceva to generate revenues. Our ability to maintain or increase our revenues and overall market share for Tarceva will depend on, and may be limited by, a number of factors, including the following:

- We must maintain and seek to 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;
- Physicians may be reluctant to switch from existing treatment methods, including traditional chemotherapy agents, to Tarceva;
- The market for oncology products is very competitive, and there are marketed products and products which are currently in Phase III development that are or could be competitive with Tarceva;
- We must be successful in our clinical trials for additional indications and in receiving approval from the FDA and our foreign counterparts to market and sell Tarceva in such additional indications; and
- Third-party payors, including private health coverage insurers and health maintenance organizations, must continue to provide adequate coverage or reimbursement for Tarceva.

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 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 would negatively impact our revenues and harm our business.

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 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 on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

If we do not maintain a successful collaborative alliance with Genentech and 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.

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. We are presently working to qualify another manufacturer to serve as a back-up provider of 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.

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 in the United States to Tarceva in the second and third line settings for the NSCLC indication includes existing chemotherapy options such as Alimta, Taxotere and Gemzar. In addition, in October 2006, the FDA approved Avastin in combination with chemotherapy for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC. Although Avastin in combination with chemotherapy is not approved for the treatment of second or third line NSCLC, off-label use of Avastin in this setting could limit the market share for Tarceva. In certain markets where Iressa is available, Tarceva must compete for market share. Tarceva also currently competes, and may compete in the future, with a number of other cancer treatments, including Erbitux, Xeloda, Vectibix, Sutent, Nexavar and Zactima.

In the pancreatic setting, Tarceva may experience competition from Erbitux if ongoing studies for this drug produce positive results. Additionally, Roche announced favorable results for its chemotherapy product, Xeloda, in pancreatic cancer in combination with gemcitabine. If Roche succeeds in gaining regulatory approval for Xeloda for the treatment of pancreatic cancer, it could impact Tarceva's market share in this indication.

In the diabetes and obesity arena, a number of pharmaceutical and biotechnology companies are conducting clinical trials of potential drugs in the same areas as our drug discovery and development programs. We are aware of at least six competitors, Merck, Novartis, Bristol-Myers Squibb, Takeda, Merck KGaA and Pfizer with DPIV inhibitor clinical candidates for the treatment of diabetes. We believe that certain of these potential drugs are at a more advanced stage of development than our clinical candidate, PSN9301. In October 2006, Merck received FDA approval for Januvia, its DPIV inhibitor, and Novartis filed an NDA for its DPIV inhibitor, Galvus, in January 2006. Given that Januvia has reached the market earlier than PSN9301 and others may also receive regulatory approval prior to PSN9301, we may be at a competitive disadvantage at the time, if ever, that we receive regulatory approval to commercialize PSN9301. Additionally, if scientific developments change our understanding of the product differentiation of PSN9301 from that of our competitors' products, the competitive positioning and market potential of PSN9301 may be detrimentally affected. Our glucokinase activator, PSN010, faces potential competition from Roche and Novo Nordisk, who have, at various times, announced similar GKA research and development activities.

Macugen has experienced, and will continue to experience, significant competition in the market for the treatment of wet AMD from Lucentis and the off-label use of Avastin. Lucentis, an anti-VEGF-A humanized antibody fragment, was launched in the United States in July 2006. Clinicians are also engaging in widespread off-label intravitreous administration of Avastin for the treatment of patients with wet AMD. We estimate that Lucentis and Avastin comprise most of the market share of patients treated for wet AMD. While we are attempting to establish Macugen as the optimal product for the chronic management of wet AMD, this strategy depends on a clear understanding by ophthalmologists and retinal specialists of a potential higher risk for either ocular or systemic adverse events related to Avastin and Lucentis, as well as clinical data which support the ability of Macugen to sustain the vision gains resulting from the initial use of Lucentis or Avastin. If this strategy is not successful, Macugen's share of the wet AMD market may continue to decline.

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

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 received a positive opinion in January 2007 from the Committee for Medicinal Products for Human Use in relation to its European regulatory approval application. A second product covered by our DPIV license agreement with Merck, Janumet, is under review by the FDA. Novartis is also a licensee and it received an ''approvable'' letter from the FDA on February 26, 2007 with respect to its product, Galvus. There can be no assurance that Janumet, Galvus or any other DPIV inhibitors covered by license agreements with us will be approved by the FDA or other regulatory authorities or that we will derive royalty revenues from these agents. The extent to which we receive revenue under such licenses depends on our ability to enforce our patent rights in our DPIV portfolio and the progress and success of our licensees' products. If any of our licensees terminate their DPIV inhibitor programs or do not seek, or fail to receive, regulatory approval for their DPIV inhibitor products, the revenues we receive from such licensees will be reduced.

Although we have 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 of new drugs that we can commercialize. Our pipeline for our oncology and diabetes and obesity clinical programs is at an early stage. Other than the development of Tarceva for additional indications, there is currently one oncology candidate in clinical trials, OSI-930. This candidate, which is currently in Phase I trials, targets the co-inhibition of c-kit/VEGFR-2 receptor. Our lead clinical candidate for diabetes is PSN9301, a DPIV inhibitor that targets type 2 diabetes, which completed Phase IIa. We have temporarily suspended development of PSN9301 while we seek a partnering opportunity for this clinical candidate to offset development costs. Our oncology candidates, OSI-906, an IGF-1R inhibitor, and OSI-027, are currently in the pre-clinical stage of development. We are also developing PSN602, a S1RUP inhibitor, which is currently undergoing pre-clinical testing prior to entry into Phase I trials in the fourth quarter of 2007. 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.

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. Although we have not to date experienced any significant delays in enrolling clinical trial patients for our ongoing clinical trials, delays in patient enrollment for future trials may result in increased costs and delays, 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.

A component of our business strategy is to enter into collaborations with third parties to research, develop and commercialize certain of our products, or to outlicense clinical candidates, when we believe that doing so will maximize product value or when the products or candidates are no longer considered to be part of our core business. We may not be successful in establishing such collaborations or entering into such license agreements, which could adversely affect the prospects for these products to become commercialized.

A component of our business strategy is to enter into collaborations with third party collaborators for the research, development and commercialization of certain of our product candidates, or to outlicense our clinical candidates, when we believe that doing so will maximize the potential for the product. We 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 additional collaborations or outlicensing arrangements. If we are unable to reach such agreements, we may fail to meet our business objectives for the relevant product or program. The terms of any additional collaborations or license agreements that we establish for our product candidates may not be as favorable to us than if we had pursued independent development and commercialization. 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 certain of our products.

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 products subject to these arrangements. The risks that we face in connection with these arrangements include the following:

- Our collaborators and licensees may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of our arrangements with them; and
- Our collaborators and licensees may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of our products to reach their potential could be limited if our collaborators and licensees decrease or fail to increase spending relating to such products.

Our reliance on third parties, such as clinical research organizations, or 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, we may face delays in completing our clinical trials, as well as commercialization of our drug candidates. Furthermore, any loss or delay in obtaining contracts with such entities 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 long-term indebtedness when due, and therefore we may face liquidity problems.

Our long-term debt under our 3.25% convertible senior subordinated notes due 2023, or the 2023 Notes, and our 2.0% convertible senior notes due 2025, or the 2025 Notes, was $265 million as of December 31, 2006. Interest on the 2023 Notes accrues at the rate of 3.25% per annum and interest on the 2025 Notes accrues at a rate of 2% per annum. This amounts to interest payments of $2.4 million due and payable semi-annually on March 8 and September 8 of each year on the outstanding amount of the 2023 Notes. In addition, interest payments of $2.3 million are due and payable semi-annually on June 15 and December 15 of each year on the outstanding amount of the 2025 Notes. Cumulative interest payments of $80.4 million are scheduled to be paid between September 8, 2007 and September 8, 2023 on the 2023 Notes and $42.6 million between June 15, 2007 and December 15, 2025 on 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, for cash, or at our option, shares of our common stock, in September of 2008, 2013 and 2018 and the holders of the 2025 Notes have the right to require us to purchase all of the 2025 Notes, or a portion thereof, for cash in December of 2010, 2015 and 2020.

While we are currently generating sufficient net cash flow in excess of our operating budget to satisfy the our annual interest payments on the 2023 Notes and the 2025 Notes, there can be no assurances that we will be able to do so in the future. In addition, if the holders of the 2023 Notes or the 2025 Notes elect to require us to repurchase a significant portion of their notes in 2008 or 2010, respectively, we may not have sufficient net cash flow to repurchase these notes. While we are permitted to repurchase the 2023 Notes with our common stock in lieu of cash, the 2025 Notes must be repurchased with cash. This would require us 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 on favorable terms or at all. If we elect to repurchase our 2023 Notes with our common stock, our

stockholders will experience dilution and our stock price may decline. If we are unable to make our annual interest payments or repay the 2023 Notes or the 2025 Notes when due, we will default on our 2023 Notes and the 2025 Notes.

Our long-term debt also may make it more difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes and make us more vulnerable in the event of a downturn in our business.

Risks Relating to Regulatory Matters

The manufacture and packaging of pharmaceutical products such as Tarceva and Macugen 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 Macugen 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 partner, 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.

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. For example, with regard to Macugen, as a result of a post-approval commitment to the FDA to improve the control and environment for our finished drug product, we will change the final presentation or packaging for Macugen. Such a change, when implemented, will lead to an increase in our cost of goods for Macugen.

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 and Macugen in the United States and our collaboration partners have gained approval for Tarceva and Macugen in Canada, the EU and a number of other territories, there can be no guarantee of subsequent approvals either for Tarceva and Macugen 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 contra-indications, 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. Approved drugs can only be marketed 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 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.

Competitors could challenge our patents and file an ANDA or a 505(b)(2) new drug application for a generic or a modified version of Tarceva or Macugen and adversely affect our competitive position.

Products approved for commercial marketing by the FDA are subject to the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. The Hatch-Waxman Act provides companies with marketing exclusivity for varying time periods during which generic or modified versions of a drug

may not be marketed and allows companies to apply to extend patent protection for up to five additional years. It also provides a means for approving generic versions of a drug once the marketing exclusivity period has ended and all relevant patents have expired. The period of exclusive marketing, however, may be shortened if a patent is successfully challenged and defeated. Competitors with a generic or a modified version of Tarceva or Macugen may attempt to file an ANDA or a 505(b)(2) NDA and challenge our patents and marketing exclusivity. Such applications would have to certify that the patents in the Tarceva or Macugen NDA are invalid or not infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application under the Hatch-Waxman Act, referred to as a Paragraph IV certification. If successful, a competitor could come to market at an earlier time than expected. Since Tarceva and Macugen have five-year new chemical entity exclusivity, such a Paragraph IV challenge could not commence until at least late 2008. We can provide no assurances that we can prevail in a challenge or litigation related to our patents or exclusivity. Furthermore, regardless of the ultimate outcome of any litigation, the mere submission of such competitor application or the public announcement by a competitor that it intends to submit an application in the future may itself cause our stock price to decrease.

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 Medicare/Medicaid 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, with hospitals, physicians, and other potential purchasers 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 Claim Act, the federal Medicare/Medicaid 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.

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.

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.

The 2003 Medicare prescription drug coverage legislation, The Medicare Prescription Drug Improvement and Modernization Act, or the MMA, and 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 proposed at the federal and state levels that would result in significant changes to the healthcare system, either nationally or at the state level. Effective January 2004, the MMA changed the methodology used to calculate reimbursement for drugs such as Macugen that are administered in physicians' offices in a manner intended to reduce the amount that is subject to reimbursement. In addition, the legislation directs the Secretary of Health and Human Services to contract with procurement organizations to purchase physician-administered drugs from the manufacturers and to provide physicians with the option to obtain drugs through these organizations as an alternative to purchasing from the manufacturers, which some physicians may find advantageous. These changes may also cause private insurers to reduce the amounts that they will pay for physician-administered drugs.

Risks Related to Intellectual Property and Legal Matters

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 are 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 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 limit the length of term of patent protection we may have for our products. For example, our patent which claims the use of DPIV inhibitors for lowering blood glucose levels was revoked by the European Patent Office in May 2004. Although we are currently challenging the revocation of our patent by the European Patent Office, if we are unsuccessful in defending this opposition 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 revoked patent in those territories where the patent 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 a number of licenses that give us rights to third-party intellectual property that is 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 to

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

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.

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 alleging violations of securities laws which are described in our filings with the SEC. 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 U.S. Patent and Trademark Office, 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 our marketed products;
- a decline in our business operating results or prospects;
- 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 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;
- 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. On March 15, 2005, we purchased a facility located at 41 Pinelawn Road, Melville, New York, consisting of approximately 60,000 square feet. On March 6, 2006, we relocated our corporate headquarters from our leased premises at 58 South Service Road, Melville, New York to this new location. Our facility at 41 Pinelawn Road houses our principal executive, oncology, finance, legal and administrative offices. We terminated our 58 South Service Road lease in April 2006.

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 and pre-clinical 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 our regulatory, quality control and drug development operations for oncology and ophthalmology.

Boulder, Colorado. We occupy two facilities in Boulder, Colorado, which together house our clinical research, regulatory and drug development operations for oncology. The first facility we lease is located at 2860 Wilderness Place, and consists of approximately 60,000 square feet. The second facility we lease is located at 2970 Wilderness Place, and consists of approximately 31,000 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 us, 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 common stock during certain periods in 2004, which periods differed in the various complaints. The Court has now appointed a lead plaintiff, and on February 17, 2006, the lead plaintiff filed a consolidated amended class action complaint seeking to represent a class of all persons who purchased or otherwise acquired our common stock during the period from April 26, 2004 through November 22, 2004. The consolidated complaint alleges that defendants made material misstatements and omissions concerning the survival benefit associated with our 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. We have requested an oral argument on our motion and are awaiting a decision from the court. Based on the early stage of this litigation, the ultimate outcome cannot be determined at this time.

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 2006.

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 on the NASDAQ Global Select 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, 2005 through December 31, 2006 as reported on the NASDAQ Global Select Market:

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
2005 FISCAL YEAR	**HIGH**	**LOW**
First Quarter	$74.90	$41.25
Second Quarter	50.20	34.57
Third Quarter	47.65	28.15
Fourth Quarter	30.35	20.81
THREE-MONTH TRANSITION PERIOD	**HIGH**	**LOW**
October 1, 2004 through December 31, 2004	$74.95	$44.34

Holders and Dividends

As of February 21, 2007, there were approximately 2,947 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, 2006

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	6,661,780(c)	$36.24	807,446(e)
Equity compensation plans not approved by security holders	695,338(d)	$33.96	850,000(f)
Total	7,357,118	$36.01	1,657,446

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

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

c) Consists of five plans: the 1989 Incentive and Non-Qualified Stock Option Plan, the 1993 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 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 vest on the first anniversary of the date of grant and the remainder vests ratably monthly thereafter for twenty-four months.

In connection with the acquisition of Cadus, 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, 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 vest on the first anniversary and the remainder vest ratably monthly thereafter 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 402,206 shares reserved for issuance under the 1995 Employee Stock Purchase Plan and the stock purchase plan for employees of OSI-UK, and 405,240 shares reserved for issuance under the 1997 Incentive and Non-Qualified Stock Option Plan, 1999 Incentive and Non-Qualified Stock Option Plan, and the Amended and Restated Stock Incentive Plan.

f) On June 14, 2006, our Board of Directors adopted the OSI Stock Incentive Plan for New Hires. We adopted this plan to provide incentive equity grants to induce qualified individuals to accept employment with our company. At December 31, 2006, 850,000 shares of common stock were authorized and available for grant under the plan.

We have a policy of rewarding employees who achieve 10, 15, and 20 years of continued service with OSI 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 31. 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, 2006 and 2005, the three months ended December 31, 2004, and the years ended September 30, 2004, 2003 and 2002. 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, 2006(a)	Year Ended December 31, 2005(b)	Three Months Ended December 31, 2004(c)	Years Ended September 30, 2004(d)	2003(e)	2002(f)
Consolidated Statement of Operations Data:						
Revenues	$ 375,696	$ 174,194	$ 12,347	$ 42,800	$ 32,369	$ 21,816
Expenses:						
Cost of goods sold	79,223	18,882	(1,247)	8,985	157	—
Collaborative profit share	40,297	12,312	—	—	—	—
Net expense from unconsolidated joint business	—	—	7,661	—	—	—
Research and development	176,654	125,953	31,913	110,398	102,642	102,202
Acquired in-process research and development	—	64,442	—	32,785	31,451	130,200
Selling, general and administrative	158,617	98,393	20,313	98,909	70,532	28,146
Impairment of intangible assets	505,985	—	—	24,599	—	—
Amortization of intangibles	19,912	17,544	3,804	18,606	9,300	1,255
Loss from operations	(604,992)	(163,332)	(50,097)	(251,482)	(181,713)	(239,987)
Other income (expense) — net	762	6,209	1,702	(8,889)	356	7,904
Gain on sale of diagnostic business	—	—	—	—	—	1,000
Gain on early retirement of convertible senior subordinated notes — net	—	—	—	—	—	12,604
Loss before extraordinary gain	(604,230)	(157,123)	(48,395)	(260,371)	(181,357)	(218,479)
Extraordinary gain	22,046	—	—	—	—	—
Net loss	$(582,184)	$(157,123)	$(48,395)	$(260,371)	$(181,357)	$(218,479)
Basic and diluted net loss per common share:						
Loss before extraordinary gain	$ (10.61)	$ (3.02)	$ (1.02)	$ (6.50)	$ (4.87)	$ (6.07)
Extraordinary gain	0.39	—	—	—	—	—
Net loss	$ (10.22)	$ (3.02)	$ (1.02)	$ (6.50)	$ (4.87)	$ (6.07)
Weighted average number of shares of common stock outstanding	56,939	52,078	47,375	40,083	37,249	35,978

(In thousands, except per share data)	As of December 31,			As of September 30,		
	2006(a)	2005(b)	2004(c)	2004(d)	2003(e)	2002(f)
Consolidated Balance Sheet Data:						
Cash, cash equivalents and investment securities (unrestricted and restricted)	$216,368	$ 179,606	$656,239	$257,229	$404,147	$476,277
Receivables	80,075	152,482	14,077	12,112	11,654	6,981
Working capital	266,496	276,171	630,246	228,223	379,598	445,596
Total assets	457,732	1,058,582	780,116	388,029	591,502	579,044
Long-term liabilities	349,203	337,788	195,814	186,574	338,592	169,774
Stockholders' equity	28,946	578,466	539,390	154,233	218,057	379,108

(a) The calendar 2006 consolidated financial statements include $506.0 million of impairment charges related to Eyetech goodwill and Eyetech amortizable intangibles ($320.3 million and $185.7 million, respectively) and a $26.4 million charge for obsolete and expiring inventory, and a $22 million extraordinary gain recognized as a result of reversing the accrued contingent consideration recorded in connection with the acquisition of Cell Pathways in fiscal 2003.

(b) The calendar 2005 consolidated financial statements reflect the acquisition of Eyetech for aggregate consideration of $909.3 million ($637.4 million net of cash and investments acquired), including the 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 in November 2005; in-process research and development charge of $60.9 million related to the acquisition of Eyetech; in-process research and development charges of $3.5 million related to the acquisition of the minority interest in Prosidion; and the issuance of $115.0 million aggregate principle 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.

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

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

(e) The fiscal 2003 consolidated financial statements include 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; the acquisition of Cell Pathways for approximately $55.0 million in common stock, contingent value rights and cash; the issuance of $150.0 million of our 2023 Notes for net proceeds of approximately $145.1 million; and the purchase of 503,800 shares of our common stock for $19.0 million.

(f) The fiscal 2002 consolidated financial statements include the acquisition of certain assets from Gilead for approximately $175.7 million in cash and common stock; the receipt of $4.5 million from the phase-down of our collaboration with Anaderm Research Corporation, of which $1.8 million was recognized as revenue in accordance with SAB No. 101; the issuance of $200.0 million of convertible senior subordinated notes for net proceeds of approximately $192.9 million; and the early retirement of $40.0 million aggregate principal amount of convertible senior subordinated notes resulting in a net gain of approximately $12.6 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.

Our primary focus is oncology where our business is anchored by our flagship product, Tarceva, a small molecule inhibitor of EGFR. In November 2004, Tarceva was approved by the FDA for the treatment of advanced 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 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. Tarceva achieved global sales of approximately $650 million for 2006. We co-promote Tarceva in the United States with Genentech and receive royalties on sales from our international partner, Roche. Behind Tarceva, we have an emerging oncology pipeline of molecular targeted therapies in clinical and late-stage pre-clinical development.

We also have research and early development programs in diabetes and obesity which are conducted through Prosidion, our U.K. subsidiary. Our near term focus in the diabetes and obesity area is to progress our research projects through clinical proof-of-concept studies followed by outlicensing or partnering these programs for upfront fees, milestones and royalties. In January 2007, we outlicensed our GKA program, including our clinical candidate PSN010, which is in Phase I studies, to Eli Lilly for an upfront fee of $25 million and up to $360 million in potential development and sales milestones and other payments plus royalties on any compounds successfully commercialized from this program. We also generate revenues from our patent estate relating to the use of DPIV inhibitors for the treatment of type II diabetes and related indications. Nine pharmaceutical companies have taken non-exclusive licenses to these patents, which provide us with upfront payments as well as potential milestones and royalties. In the fourth quarter of 2006, one of our licensees, Merck, received approval by the FDA for its DPIV inhibitor, Januvia, and commenced marketing of the drug, which triggered the payment of a milestone and royalties to us.

On November 6, 2006, we announced our intention to divest our eye disease business, a process which we expect to complete in mid-2007. Our eye disease business consists principally of Macugen, our marketed product for the treatment of wet AMD, as well as research assets in the eye disease area. We made the decision to exit the eye disease business because we believe 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 — will not be realized. Total U.S. net sales of Macugen in 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 Macugen 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. Given the financial constraints resulting from the decline in Macugen sales on our overall research and development budget, we do not believe that we can optimally develop the research and development assets in our eye disease business and continue to support Macugen in the face of competing priorities in the oncology and diabetes and obesity areas. We are currently negotiating with our partner, Pfizer, for the return of U.S. rights to Macugen to us in exchange for a royalty-free license to Pfizer to commercialize Macugen in the rest of the world. We believe this will help facilitate a

successful divestiture of the eye disease business. We are currently in discussions with several parties regarding the divestiture of the eye disease business for an upfront fee and/or future milestones and royalties. We intend to structure the divestiture in a manner which will allow us to be compensated for any future success of Macugen and the pipeline assets in the eye disease business — primarily our PDGF aptamer program. As a result of our decision to divest this business, we expect to record the financial information associated with these operations as discontinued operations starting in the first quarter of 2007 if we are able to finalize our plan to divest the business.

Delivering full-year profitability in 2007 is a key goal that we believe can be attained through diligent management of our business and, in particular, our expenses. In addition to our decision to divest our eye business, we have taken several steps to carefully manage the interim costs related to the eye disease business, such as closing the headquarters for our eye disease business in Times Square at the end of 2006 and significantly reducing headcount related to this business. We also have minimized clinical development for Macugen and our other eye disease programs with the exception of our post approval trial commitments and the LEVEL trial. We are decreasing our overall general and administrative expenses by resizing our corporate operations so that they are commensurate with our simplified business following the divestiture of our eye disease business. We also intend to decrease expenses related to certain of our pre-clinical activities, such as drug formulation and toxicology studies, by outsourcing such functions in a cost-effective manner, including off-shoring.

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 costs incurred during the respective periods represent estimated costs of both parties and are subject to further adjustment based on each party's final review. Based on past experience, we do not believe that these adjustments, if any, will be significant to our consolidated financial statements. The partial 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.

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, future milestone payments received from Roche after March 2005 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.

During fiscal 2006, we received a $35 million milestone payment upon the launch of Macugen in Europe by Pfizer. In accordance with EITF 00-21, the milestone payment was recorded as unearned revenue and is being recognized as revenue on a straight-line basis over the expected term of our collaboration and licensing agreements with Pfizer which approximates the expected level of performance under these agreements with Pfizer.

Product Sales

Product sales consists primarily of sales of Macugen, and to a lesser extent, Gelclair Bioadherent Oral Gel, or Gelclair, a bioadherant oral gel for the relief of pain associated with oral mucositis, in the United States and its territories. 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 collectibility is reasonably assured.

Under an agreement with Pfizer dated February 2003, we share sales and marketing responsibility for sales of Macugen in the United States. We report product revenue on a gross basis for these sales. We have determined that we are qualified as a principal under the criteria set forth in EITF Issue 99-19, ''Reporting Gross Revenue as a Principal vs. Net as an Agent,'' or EITF 99-19, based on our responsibilities under our contracts with Pfizer, which include manufacture of product for sale in the United States, distribution, ownership of product inventory and credit risk from customers.

We record allowances for distribution fees, product returns and governmental rebates for all of our products sold in the United States at the time of sale, and report revenue net of such allowances. We must make significant judgments and estimates in determining these allowances. For instance:

- Our distributors have a limited right of return for unopened product during a specified time period based on the product's labeled expiration date. As a result, in calculating the allowance for product returns, we estimate the likelihood that product sold to distributors might be returned within a specific timeframe. We determine our estimates using actual product data from distributors, industry data on products with similar characteristics and the expiration dates of product sold.
- Certain government buying groups that purchase our product from wholesalers have the right to receive a discounted price from us. As a result, we estimate the amount of product which will ultimately be sold to these buying groups. We determine our estimates using actual product data from distributors and historical industry trends.

If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future.

Collaborative revenue

Collaborative program revenues represent funding arrangements for Macugen research and development with Pfizer and are recognized when earned in accordance with the terms of the contracts 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 are 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, in transactions where we act as a principal, with discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we have met the criteria to record revenue for the gross amount of the reimbursements.

Sales commissions

Sales commissions from Novantrone on net oncology sales are recognized in the period the sales occur and were based on the estimated split between oncology sales and multiple sclerosis sales, as determined on a quarterly basis by an external third party. Beginning in the third quarter of 2006, we agreed with Merck Serono on a fixed oncology split and therefore are no longer utilizing a third party to determine the split.

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, cost of goods sold includes a charge of $26.4 million related to the potential 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.

Included in inventory are raw materials and work-in-process for Tarceva and Macugen 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 the inventory that was partially produced and expensed prior to November 18, 2004.

In November 2005, we recorded a $55.0 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. As of December 31, 2006, $2.6 million of initial increase in fair value of the inventory was included in inventory and will be included in cost of goods sold when the acquired inventory is sold in the future.

The carrying value of Macugen raw material acquired on the date of the acquisition and Macugen inventory purchased and manufactured subsequent to the acquisition is stated at the lower of cost or market and is determined by the weighted average method.

Accruals for Clinical Research Organization and Clinical Site Costs

We make estimates of costs incurred to date but not yet invoiced in relation to external CROs and clinical site costs. We analyze the progress of 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.

Goodwill and Other Long-Lived Assets

We account for goodwill and other intangible assets in accordance with Statements of Financial Accounting Standards, or SFAS, No. 141, ''Business Combinations,'' or SFAS No. 141, and SFAS No. 142, ''Goodwill and Other Intangible Assets,'' or 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 discussed in Note 2(b) to the accompanying consolidated financial statements, due to 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.

Our identifiable intangible assets are subject to amortization. SFAS No. 142 requires that intangible assets with estimable 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 judgments 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.

As discussed in ''Impairment of Intangibles'' below, 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 the $185.7 million of Macugen intangible assets were impaired and consequently reduced their value to zero at December 31, 2006.

In October 2004, we determined that it was necessary to record an impairment charge as of September 30, 2004 related to our intangible asset for exclusive distribution rights to the marketed product, Gelclair, in North America.

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, 2006 and 2005

Results of Operations

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 loss increased in 2006 as we recognized $532 million of impairment charges in connection with Eyetech intangibles and inventory. Our results of operations for the year ended December 31, 2005 include 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

	(in thousands)		
	Year Ended December 31,		
	2006	2005	$ Change
Net revenue from unconsolidated joint business	$154,886	$ 84,727	$ 70,159
Product sales	104,276	32,411	71,865
Royalties on product sales	51,501	7,127	44,374
Sales commissions	11,755	29,684	(17,929)
License, milestone and other revenues	28,937	16,164	12,773
Collaborative program revenues	24,341	4,081	20,260
Total revenues	$375,696	$174,194	$201,502

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 $402 million and $275 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, 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.

Product Sales

Product sales for 2006 primarily consisted of sales of Macugen, and, to a lesser extent, Gelclair, in the United States and its territories. For the twelve months ended December 31, 2006, Macugen net sales totaled $103.3 million. Net sales of Macugen from November 14, 2005, the date we acquired Eyetech, through December 31, 2005, totaled $31.5 million, and are included in product sales for the twelve months ended December 31, 2005. Net Macugen sales represents gross product revenue less distribution service fees and estimates for allowances and returns.

Macugen sales declined from $50.6 million in the first quarter of 2006 to $7.2 million in the fourth quarter of 2006. We believe the decline was primarily due to the launch of Lucentis in July 2006 and the continued off-label use of Avastin for the treatment of wet AMD. On November 6, 2006, we announced our intention to exit our eye disease business, which consists principally of Macugen, as well as research assets in the eye disease area. Upon our exit of the eye disease business, which we expect to occur in mid-2007, we will no longer recognize product sales relating to Macugen.

Royalties on Product Sales

We receive royalties on the sales of Tarceva and Macugen outside of the United States and its territories. In September 2005, our partner 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 major markets in the EU. Tarceva sales are expected to increase outside the United States as additional reimbursement approvals are secured. For the years ended December 31, 2006 and 2005, Roche recorded $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. Macugen royalties from rest of world sales were $1.3 million and $141,000 for the years ended December 31, 2006 and 2005, respectively. Macugen was approved for marketing and sale in the EU in January 2006 and was launched in select EU countries by our partner, Pfizer, beginning in May 2006.

Sales Commissions

Sales commissions represent 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, and are expected to continue to decline 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.

License, Milestone and Other Revenues

We recognized $28.9 million and $16.2 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 include approximately $19 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 is 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 and a $35.0 million milestone payment from Pfizer as a result of the 2006 launch of Macugen in Europe. 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 were $5.4 million and $1.6 million, respectively. Our unrecognized deferred revenue related to these upfront fees and milestone payments was $72.6 million and $42.0 million as of December 31, 2006 and 2005, 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. As a result of the January 2007 marketing authorization by the European Commission for use of Tarceva in combination with gemcitabine as first-line therapy for metastatic pancreatic cancer we are entitled to a $4 million milestone payment from Roche. Additional milestone payments will be due from Genentech and Roche upon approval of adjuvant indications in the United States and Europe. Additional milestone payments will be due from Roche upon the approval of Tarceva in Japan. The ultimate receipt of these additional milestone payments is contingent upon the applicable regulatory approvals and other future events. In January 2007, we outlicensed our GKA program, including our clinical candidate PSN010, which is in Phase I studies, to Eli Lilly for an upfront fee of $25 million and up to $360 million in potential development and sales milestones and other payments plus royalties on any compounds successfully commercialized from this program. In addition, we may receive future milestone payments from the licensees of our DPIV patents.

Collaborative Program Revenues

Collaborative program revenues primarily represent reimbursement of a portion of research and development costs for Macugen under our collaboration agreement with Pfizer.

Expenses

	Year Ended December 31, (in thousands)		
	2006	**2005**	**$ Change**
Cost of goods sold	$ 79,223	$ 18,882	$ 60,341
Collaborative profit share	40,297	12,312	27,985
Research and development	176,654	125,953	50,701
Acquired in-process research and development	—	64,442	(64,442)
Selling, general and administrative	158,617	98,393	60,224
Impairment of intangible assets	505,985	—	505,985
Amortization of intangibles	19,912	17,544	2,368
	$980,688	$337,526	$643,162

Cost of Goods Sold

Total cost of goods sold for the years ended December 31, 2006 and 2005 were $79.2 million and $18.9 million, respectively. In 2006, cost of goods sold primarily consisted of $71.0 million related to Macugen and $8.2 million related to Tarceva. Cost of goods sold for the year ended December 31, 2005 included $4.9 million related to Tarceva and $14.0 million related to Macugen for the period between November 14, 2005 and December 31, 2005.

Also during the fourth quarter of 2006, we assessed our current level of Macugen finished goods 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 ultimate exit from the eye disease business. Our analysis of the carrying value of inventory relies 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. If actual results differ significantly from our expectations, it could lead to the write down of additional inventory or the benefit of selling inventory with zero cost basis.

In November 2005, in connection with the acquisition of Eyetech, we recorded the acquired Macugen inventory at its estimated fair value in accordance with SFAS No. 141. Included in cost of goods sold in 2006 and 2005 was approximately $19.9 million and $6.8 million, respectively, of the step-up in fair market value from the purchase accounting adjustments. We expect that approximately $2.6 million in fair market value purchase accounting adjustments related to Macugen will be included in future cost of goods sold or be recognized upon the possible sale of the eye disease business. The increase to fair market value is being recognized as cost of product sales when the acquired inventory is sold.

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.

Collaborative Profit Share

Collaboration profit share represents Pfizer's share of net product sales of Macugen less cost of goods sold within the United States for the year ended December 31, 2006 and the period between November 14, 2005 and December 31, 2005. Under our agreements with Pfizer, we share profits and losses from the commercialization of Macugen in the United States until the later of 15 years after commercial launch in the United States and the expiration of the United States patent rights for Macugen.

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 develop-

ment 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 $56.8 million and $48.3 million, respectively, in research and $119.9 million and $77.6 million, respectively, in pre-clinical and clinical development. We consider this level of investment suitable for a company with our pipeline of clinical and pre-clinical candidates.

Research and development expenses increased by $50.7 million for the year ended December 31, 2006 compared to the year ended December 31, 2005. The increase was primarily due to $45.9 million of research and development expenses related to the programs we acquired from Eyetech, $6.9 million increase in Tarceva related expenses, $5.0 million of severance related costs and $5.1 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 partners, Genentech and Roche, through a global development committee under a Tripartite Agreement among the parties. Together with our partners, 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. Since 2001, the partners have committed approximately $700 million combined in the global development plan to be shared by the three parties. As of December 31, 2006, we have invested in excess of $178 million in the development of Tarceva, representing our share of the costs incurred to date in the tripartite global development plan and additional investments outside of the plan.

On November 6, 2006, we announced our intention to exit our eye disease business. We expect to complete this process and exit the business in mid-2007 and therefore anticipate a significant decline in Eyetech research and development expenditures in 2007.

Acquired In-Process Research and Development

In connection with the acquisition of Eyetech in November 2005, we recorded an in-process R&D charge of $60.9 million in 2005 representing the estimated fair value of the acquired in-process technology that had not yet reached technological feasibility and had no alternative future use, as discussed in Note 2 to the accompanying consolidated financial statements.

We also recognized in-process R&D charges of $3.5 million in connection with the acquisition of the minority interest in Prosidion in 2005, and $32.8 million in connection with the acquisition of Probiodrug in July 2004.

Selling, General and Administrative

Selling, general and administrative expenses for the year ended December 31, 2006 increased by $60.2 million from $98.4 million for the year ended December 31, 2005. The increase in expenses was primarily attributable to $32.0 million of expenses related to the eye disease business, which was principally commercial expenses, recognition of $16.6 million of equity based compensation expense related to the adoption of SFAS No. 123(R), $5.9 million of charges related to facility consolidations, $2.5 million 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.

Impairment of Intangible Assets

For the year ended December 31, 2006, we recognized $506.0 million of impairment charges relating to Eyetech goodwill and other Eyetech intangibles with finite useful lives.

In accordance with SFAS No. 142, goodwill and other indefinite-lived intangible assets must be tested annually for impairment or in interim periods if events indicate there is a possible impairment. As a result of recent competitive developments relating to Macugen and the market for wet AMD treatments, we were required to assess the value of goodwill recorded in connection with the acquisition of Eyetech in November 2005. These developments included the widespread off-label use of Avastin to treat wet AMD and the launch of Lucentis, a competitive product to Macugen, in early July 2006. In performing this assessment, we considered the declining Macugen revenues, as well as our decision to suspend or curtail research activities in the eye disease area, which further limits the potential for future revenues from new eye disease products arising from Eyetech's research capabilities. Based on this assessment, we recorded an impairment charge of $320.3 million in the aggregate for the second and third quarters of 2006, reflecting the write-off of the full value of the Eyetech goodwill.

In accordance with SFAS No. 144, we are required to assess the recoverability of the long-lived assets relating to our eye disease business that existed on December 31, 2006, including the amortizable intangible assets related to Eyetech. This assessment included developing various estimates of 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. While we continue to believe that Macugen may achieve an important place in the wet AMD marketplace, it will be dependent on the outcome of the LEVEL trial and the emergence of additional safety signals with the use of other agents. In addition, it is probable that the ultimate outcome of our process to exit the eye disease business will result in a transaction with a combination of up-front consideration and contingent consideration. However, because of the current sales levels of Macugen and the uncertainty surrounding future sales levels of Macugen on which any contingent consideration would be based, there is significant risk relating to the value of any contingent consideration. After considering all of the aforementioned factors, we have concluded that all of the Macugen amortizable intangibles were impaired and have recorded a $185.7 million impairment charge in the fourth quarter of 2006.

Amortization of Intangibles

Amortization expense for the year ended December 31, 2006 and 2005 was $19.9 million and $17.5 million, respectively. In 2006, we recorded amortization expense of $18.1 million related to intangible assets of $201.4 million acquired in the Eyetech acquisition. 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	$11,315	$13,322	$(2,007)
Interest expense	(7,578)	(5,065)	(2,513)
Other (expense) income-net	(2,975)	(2,048)	(927)
Total other income (expense)	$ 762	$ 6,209	$(5,447)

The decrease in investment income for the year ended December 31, 2006 compared to the same period last year is primarily due to a decrease in our funds available for investment. This decrease was partially offset by $2.0 million of unrealized losses we recognized in the year ended December 31, 2005 relating to available-for-sale securities for which the impairment was deemed other then 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 last 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.

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 of these two clinical candidates and have entered into a letter of intent to outlicense these candidates. We have 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 have reversed the $22.0 million liability and recorded an extraordinary gain during the quarter ended June 30, 2006.

Years Ended December 31, 2005 and 2004

In December 2004, we changed our fiscal year end from September 30 to December 31. The first fiscal year affected by this change ended on December 31, 2005. Included in Item 8 of this annual report on Form 10-K are the consolidated balance sheets at December 31, 2006 and 2005 and the consolidated statements of operations, consolidated statements of stockholders' equity and consolidated statements of cash flows for the year ended December 31, 2006 and 2005, for the three-month transition period ending December 31, 2004, and for the year ended September 30, 2004. In order to provide the reader meaningful comparison, the following analysis provides comparison of the audited year ended December 31, 2005 with the unaudited year ended December 31, 2004 derived from the results of operations of the last nine months of fiscal year ended September 30, 2004 and the transition quarter ended December 31, 2004.

Results of Operations

Our net losses for the years ended December 31, 2005 and 2004 were $157.1 million and $268.6 million, respectively. Our results of operations for the year ended December 31, 2005 included the results of operations of our eye disease business for the period from November 14, 2005, the date of the acquisition of Eyetech, through December 31, 2005. On an overall basis, our net loss declined significantly in 2005 as we recognized the net profits

from our Tarceva partnership with Genentech and royalties from international sales of Tarceva from Roche. 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 in Prosidion. The 2004 net loss included an in process R&D charge of $32.8 million for the acquisition of certain assets of Probiodrug by Prosidion, a charge of $24.6 million related to the impairment of the Gelclair intangible asset and a charge of $7.2 million for excess inventory.

Revenues

	Year Ended December 31, (in thousands)		
	2005	2004	$ Change
Net revenue from unconsolidated joint business	$ 84,727	$ —	$ 84,727
Product sales	32,411	1,285	31,126
Royalties on product sales	7,127	—	7,127
Sales commissions	29,684	35,855	(6,171)
License, milestone and other revenues	16,164	6,616	9,548
Collaborative program revenues	4,081	—	4,081
Total revenues	$174,194	$43,756	$130,438

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 twelve months ended December 31, 2005, Genentech recorded $275 million in net sales of Tarceva in the United States and its territories. Our share of these net sales is reduced by the costs incurred for cost of goods sold and on the sales and marketing of the product. For the year ended December 31, 2005, we reported net revenues of $84.7 million from our unconsolidated joint business for Tarceva.

Product Sales

Product sales for 2005 primarily consisted of sales of Macugen, and, to a lesser extent, Gelclair, in the United States and its territories. For the twelve months ended December 31, 2005, Macugen net sales totaled $185 million. Net sales of Macugen from November 14, 2005, the date we acquired Eyetech, through December 31, 2005, totaled $31.5 million, and were included in product sales for the twelve months ended December 31, 2005. Net Macugen sales represents gross product revenue less distribution service fees and estimates for allowances and returns. Product sales also included sales of Gelclair of $917,000 and $1.3 million for years ended December 31, 2005 and 2004, respectively.

Royalties on Product Sales

We receive royalties on the sales of Tarceva and Macugen outside of the United States and its territories. In September 2005, 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. Tarceva was approved for this indication by the Swiss health authority, Swissmedic, in March 2005 and by Health Canada in July 2005. Our partner, Roche, began selling in Switzerland and Canada in March 2005 and July 2005, respectively. For the twelve months ended December 31, 2005, Roche recorded $36.0 million in net sales of Tarceva outside of the United States and its territories, of which we recorded $7.0 million in royalty revenues. Macugen royalties on rest of world sales were $141,000 from November 14, 2005, to December 31, 2005, and were included in royalties on product sales for the twelve months ended December 31, 2005.

Sales Commissions

Sales commissions represent commissions earned on the sales of Novantrone in the United States for oncology indications. Sales commissions for the years ended December 31, 2005 and 2004 were $29.7 million and $35.9 million, respectively. We believe the decrease was due to the patent expiration in April 2006 and the resulting loss of market exclusivity for the covered pharmaceutical product.

License, Milestone and Other Revenues

We recognized $16.2 million of license, milestone and other related revenues for the year ended December 31, 2005, of which $14.2 million related to upfront fees and milestone payments relating to 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. Also included in license and milestone revenues was the recognition of the ratable portion of the $25.0 million upfront fees from Genentech and the ratable portion of the $42.0 million of milestone payments received from Genentech and Roche in connection with various regulatory acceptances and approvals for Tarceva in the United States and Europe. These payments were initially deferred and were recognized as revenue in accordance with EITF 00-21. The ratable portion of these upfront fees and milestone payments for the years ended December 31, 2005 and 2004 were $1.6 million and $6.3 million, respectively. The unrecognized deferred revenue related to these upfront fees and milestone payments received from Genentech and Roche was $42.0 million and $18.7 million as of December 31, 2005 and 2004, respectively.

Collaborative Program Revenues

Collaborative program revenues represents reimbursement of a portion of research and development costs for Macugen under our collaboration agreement with Pfizer for the period from November 14, 2005 to December 31, 2005, and totaled $4.1 million.

Expenses

	Year Ended December 31, (in thousands)		
	2005	2004	$ Change
Cost of goods sold	$ 18,882	$ 7,627	$11,255
Collaborative profit share	12,312	—	12,312
Net expense from unconsolidated joint business	—	7,661	(7,661)
Research and development	125,953	118,204	7,749
Acquired in-process research and development	64,442	32,785	31,657
Selling, general and administrative	98,393	98,403	(10)
Impairment of intangible asset	—	24,599	(24,599)
Amortization of intangibles	17,544	17,572	(28)
	$337,526	$306,851	$30,675

Cost of Goods Sold

Total cost of goods sold for the years ended December 31, 2005 and 2004 were $18.9 million and $7.6 million, respectively. In 2005, cost of goods sold consisted of $14.0 million related to Macugen for the period between November 14, 2005 through December 31, 2005, $4.5 million related to Tarceva and $500,000 related to Gelclair. In 2004, cost of goods sold consisted of $11,000 related to Tarceva and $7.6 million related to Gelclair.

In November 2005, in connection with the acquisition of Eyetech, we recorded the acquired Macugen inventory at its estimated fair value in accordance with SFAS No. 141. Included in cost of goods sold in 2005 was approximately $6.8 million of the step-up in fair market value from the purchase accounting adjustments.

For the years ended December 31, 2005 and 2004, Tarceva cost of goods sold for manufacturing-related expenses associated with the sale of Tarceva to Genentech was $4.5 million and $11,000, respectively. 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. Although it is our policy to state inventory reflecting full absorption costs until we sell all of our existing inventory for which all or a portion of the costs were previously expensed, certain components of inventory will continue to reflect costs incurred to process into finished goods previously expensed raw materials and work in process. Cost of goods sold for the year ended December 31, 2005 and the three months ended December 31, 2004 would have been $4.2 million and $364,000 higher, respectively, if the Tarceva inventory sold had reflected the full absorption manufacturing costs. The increased costs presented in this manner are more reflective of our cost of goods sold going forward.

For the years ended December 31, 2005 and 2004, Gelclair cost of goods sold were $500,000 and $7.6 million, respectively. The decrease in cost of goods for the year ended December 31, 2005 compared to the prior year is primarily related to a provision of $7.2 million for Gelclair inventory that we deemed in excess of forecasted demand, based on the expiration date of the product.

Collaborative Profit Share

Collaboration profit sharing represents Pfizer's share of net product sales of Macugen less cost of goods sold within the United States for the period between November 14, 2005 and December 31, 2005. Under our agreements with Pfizer, we share profits and losses from the commercialization of Macugen in the United States until the later of 15 years after commercial launch in the United States and the expiration of the Unites States patent rights for Macugen.

Net Revenue (Expense) from Unconsolidated Joint Business

Net expense from unconsolidated joint business is related to our co-promotion and manufacturing agreements with Genentech for Tarceva. It consists of our share of the pretax co-promotion loss 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. For the period from the product launch on November 22, 2004, through December 31, 2004, Genentech recorded $13.3 million in net sales of Tarceva in the United States and its territories. The resulting net expense from unconsolidated joint business of $7.7 million was due to the significant costs we, along with Genentech, incurred on the sales and marketing of Tarceva during the period. In 2005, this joint business turned profitable, and was reflected in net revenue from unconsolidated joint business.

Research and Development

For the years ended December 31, 2005 and 2004, we invested a total of $48.3 million and $53.6 million, respectively, in research and $77.6 million and $64.6 million, respectively, in pre-clinical and clinical development. We considered this level of investment suitable for a company with our pipeline of clinical and pre-clinical candidates.

Research and development expenses increased $7.7 million for the year ended December 31, 2005 compared to the year ended December 31, 2004. The increase was primarily due to $9.3 million of research and development expenses related to the programs we acquired from Eyetech on November 14, 2005. These expenses reflected the expenses incurred between November 14, 2005 and December 31, 2005. The increase was also associated with

an increase in expenses related to our diabetes and obesity research, offset by a decrease in oncology expenses. Development costs associated with our diabetes pre-clinical and clinical pipeline, including PSN9301, PSN357, and PSN010, increased $20.7 million for the year ended December 31, 2005 over the prior year. In January 2005, we initiated a Phase II proof-of-concept and dose range finding study for our DPIV inhibitor, PSN9301. Offsetting this increase was a $19.7 million net decrease in our oncology research and development programs primarily associated with the decision to de-prioritize or cease development of our clinical candidates, OSI-7904L and OSI-461, and the consolidation of our U.K.-based oncology activities into our New York locations, and the $4.7 million of related realignment charges recorded in the year ended December 31, 2004.

With respect to our global development plan for Tarceva, as of December 31, 2005, we, together with our partners, had committed approximately $600 million in the aggregate since 2001 which costs are to be shared by the three parties. As of December 31, 2005, we had invested in excess of $141.0 million in the development of Tarceva, representing our share of the costs that we incurred in the tripartite global development plan and additional investments outside of the plan.

With respect to Macugen, for the period between November 14, 2005, the date of our Eyetech acquisition, and December 31, 2005, we expended $9.3 million in the development of Macugen, of which $4.1 million was reimbursed by Pfizer.

Acquired In-Process Research and Development

In connection with the acquisition of Eyetech in November 2005, we recorded an in-process R&D charge of $60.9 million representing the estimated fair value of the acquired in-process technology that had not yet reached technological feasibility and had no alternative future use.

We also recognized in-process R&D charges of $3.5 million in connection with the acquisition of the minority interest in Prosidion in calendar 2005, and $32.8 million in connection with the acquisition of Probiodrug in July 2004.

Selling, General and Administrative

Selling, general and administrative expenses for the years ended December 31, 2005 and 2004 remained constant at $98.4 million. However, expenses increased by $9.2 million as a result of the Eyetech acquisition on November 14, 2005. These expenses reflected the expenses incurred between November 14, 2005 and December 31, 2005. This increase was primarily offset by our share of Genentech's commercial expenses relating to Tarceva no longer being included in selling, general and administrative expense and instead were included as part of the co-promotion profit and included in the calculation of net revenues from unconsolidated joint business in the accompanying consolidated statement of operations for the year ended December 31, 2005. The year ended December 31, 2005 also included a charge of $4.2 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. The year ended December 31, 2004 included a charge of $1.8 million for the remaining rental obligations net of estimated sublease rental income for our Horsham, Pennsylvania facility which we assumed as part of the Cell Pathways acquisition in June 2003.

Impairment of Intangible Asset

In connection with our acquisition of Cell Pathways, we assumed the exclusive rights to market and distribute Gelclair in North America. We recorded an identifiable intangible asset of $29.0 million which was being amortized over eight and a half years, representing the remaining term of the agreement. We assess the potential impairment of our long-lived asset under the provisions of SFAS No. 144. In performing the recoverability test prescribed by

SFAS No. 144, we determined that the total of the expected future undiscounted cash flows directly related to the Gelclair asset were less than the carrying value of the Gelclair asset. As a result, an impairment charge was required. The amount of the impairment charge represents the difference between the fair value of the intangible asset and its associated carrying value. We calculated the fair value of the intangible asset using discounted cash flows. The discounted cash flows calculation was made utilizing various assumptions and estimates regarding future revenues and expenses, cash flow and discount rates. Based on these calculations, we determined that an impairment charge of $24.6 million, which represented the full unamortized balance of the Gelclair intangible asset, was necessary as of September 30, 2004. The impairment charge resulted from both the discontinuance of discussions with a replacement dental partner and slower than originally expected sales growth in the oncology marketplace.

Amortization of Intangibles

Amortization expense for the years ended December 31, 2005 and 2004 was $17.5 million and $17.6 million, respectively. In 2005, we recorded amortization expense of $2.3 million related to intangible assets of $201.4 million acquired in the Eyetech acquisition. The core technology is being amortized over the estimated useful life of 11 years. Amortization expense for our rights to Novantrone was $14.9 million in each of 2005 and 2004. At December 31, 2005, we revised the future recoverability period of Novantrone intangible asset to extend through the end of 2008, and amortized the remaining balance on a straight line basis.

Other Income and Expense

	Year Ended December 31, (in thousands)		
	2005	2004	$ Change
Investment income-net	$13,322	$ 6,152	$ 7,170
Interest expense	(5,065)	(11,835)	6,770
Other income (expenses)-net	(2,048)	146	(2,194)
Total other income (expenses)	$ 6,209	$ (5,537)	$11,746

The increase in investment income for the year ended December 31, 2005 over the prior year was primarily due to an increase in the funds available for investment, offset by $2.0 million of previously unrealized losses relating to available-for-sale marketable securities for which the impairment was deemed other than temporary. The increase in funds available for investment was the result of the public offering completed in November 2004 resulting in net proceeds to us of $419.5 million, and the offering of our 2025 Notes completed in December 2005 for net proceeds of $111.0 million. These cash inflows were significantly offset by net cash outflows of $430.2 million used in the Eyetech acquisition, $11.8 million for treasury stock repurchases, and $12.2 million for the call spread option purchase.

The decrease in interest expense resulted from the full conversion of the outstanding $160.0 million of our 2009 Notes in July 2004. As a result of the conversion, interest expense for the year ended December 31, 2005 primarily represented interest expense on our 2023 Notes and one-half month of interest expense on our 2025 Notes which were issued in December 2005. Interest expense for the year ended December 31, 2004 included interest expense on both the 2009 Notes and 2023 Notes, as well as a charge of $3.7 million representing the guaranteed interest on the 2009 Notes upon the conversion of the 2009 Notes in July 2004. Other income expense-net for the periods include the amortization of debt issuance costs related to the 2009, 2023 and 2025 Notes, losses on derivatives and other miscellaneous income and expense items.

Liquidity and Capital Resources

At December 31, 2006, cash and investments, including restricted securities, were $216.4 million compared to $179.6 million at December 31, 2005. The increase of $36.8 million was primarily due to the following changes: (i) net cash of $37.5 million from operating activities, and (ii) net cash of $9.1 million proceeds from stock option exercises; offset by (iii) cash used for capital expenditures of $10.7 million.

Included in cash used in 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, 2006, revenues were $201.5 million higher than prior periods primarily due to $154.9 million of revenues from Tarceva unconsolidated joint business revenue in the United States, $50.2 million of Tarceva rest of world royalties revenues, $103.3 million of Macugen sales, and $54 million of cash from collaborative agreements.

On November 12, 2004, during the transition quarter, we concluded a public offering of six million shares of our common stock at a price of $64.50 per share. Gross proceeds totaled $387.0 million with net proceeds of approximately $365.0 million after the payment of all related fees. In addition, on November 17, 2004, underwriters associated with the offering exercised their over-allotment option to purchase an additional 900,000 shares of our common stock at a price of $64.50 per share. Gross proceeds from the exercise of the over-allotment option totaled $58.1 million with net proceeds of approximately $54.9 million.

On November 14, 2005, we acquired all outstanding shares of Eyetech common stock at a purchase price of $15.00 in cash and 0.12275 shares of OSI common stock. The acquisition reduced the net cash and cash equivalents and investments by approximately $430.2 million.

On December 21, 2005, we issued our 2025 Notes in a private placement resulting in net proceeds to us of $96.5 million. On December 28, 2005, the investment bankers associated with this convertible debt offering exercised an option to purchase an additional $15.0 million of the 2025 Notes, resulting in additional net proceeds to us of $14.5 million. The 2025 Notes bear interest at 2.00% per annum, payable semi-annually in arrears, and mature on December 15, 2025. We used a part of the net proceeds to (i) purchase through the initial purchaser or its affiliates, concurrently with the offering, 500,000 shares of our common stock for $11.8 million, and (ii) pay approximately $12.2 million to purchase a call spread option with respect to our common stock. 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. This had the impact of increasing the effective conversion price of the 2025 Notes from our perspective to $40.00 per share, representing a conversion premium of approximately 70% to the per share closing price on December 21, 2005.

Delivering full-year profitability in 2007 is a key goal that we believe can be attained through careful and prudent management of our business and, in particular, our expenses. If we are able to execute on our internal plans, including exiting the eye disease business in mid-2007, we expect that our R&D investments and capital requirements over the next twelve to eighteen months can be funded from the generation of cash flow from our commercialized product and out licensing activities. If we are successful, we anticipate funding the majority, if not all of our liquidity and capital needs from the generation of cash flow from operations, with the potential exception of strategic acquisitions of products and/or businesses.

Commitments and Contingencies

Our major outstanding contractual obligations relate to our purchase obligations, our senior subordinated convertible notes and our facility leases. The following table summarizes our significant contractual obligations at December 31, 2006 and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	2007	2008	2009	2010	2011	2012 & Thereafter	Total
Contractual Obligations:							
Senior convertible debt(a)	$ 7,175	$ 7,175	$ 7,175	$ 7,175	$ 7,175	$355,700	$391,575
Operating leases	11,248	10,424	9,672	9,216	9,338	70,306	120,204
Capital commitments	285	—	—	—	—	—	285
Purchase obligations(b)	39,812	29,612	14,200	4,200	3,000	7,600	98,424
Obligations related to exit activities(c)	5,361	548	2,599	—	—	814	9,322
Total contractual obligations	$63,881	$47,759	$33,646	$20,591	$19,513	$434,420	$619,810

(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) Purchase obligations include inventory commitments, commercial and research commitments and other significant purchase commitments. Included in these purchase obligations is our share of the remaining future commitment related to the Tarceva global development cost of approximately $85 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 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 $9.0 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. Eligibility is determined based on age and years of service. We accrued post-retirement benefit costs of $8.1 million at December 31, 2006.
- 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, Inc. 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.
- We have a minor investment in a privately owned company, and are obligated to make an additional $1.7 million of capital contribution upon request.

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. 158, ''Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans,'' or SFAS No. 158. SFAS No. 158 requires employers to fully recognize the obligations associated with single-employer defined benefit pension, retiree healthcare and other post-retirement plans in their financial statements. We adopted the requirements of SFAS No. 158 as of December 31, 2006. The adoption did not have material impact on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, ''Fair Value Measurements,'' or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. The provisions of SFAS No. 157 are effective for our fiscal year ending December, 31, 2008. We are currently evaluating the impact of the provisions of SFAS No. 157.

In June 2006, the FASB issued Interpretation No. 48, ''Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109.'' This Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. This Interpretation is effective for our fiscal year ending December 31, 2007. We do not expect the adoption to have a material impact on our consolidated financial statements.

In February 2006, the FASB issued SFAS No. 155, ''Accounting for Certain Hybrid Financial Instruments'', or SFAS No. 155, which is an amendment of SFAS Nos. 133 and 140. This Statement (a) permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, (b) clarifies which interest-only strip and principal-only strip are not subject to the requirements of SFAS No. 133, (c) establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, (d) clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives, and (e) amends SFAS No. 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another

derivative financial instrument. This Statement is effective for financial statements for our fiscal year ending December 31, 2007. We are currently evaluating the impact of the provisions of SFAS No. 155.

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 DISCLOSURES ABOUT MARKET RISKS

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,'' or SFAS No. 115, 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, 2006, 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, 2006 would have resulted in a $1.1 million change in our net loss for 2006.

Periodically, we enter into forward exchange contracts to reduce foreign currency fluctuation risks relating to intercompany transactions for the funding of our research activities in the United Kingdom. We account for these derivative financial instruments in accordance with SFAS No. 133, ''Accounting for Derivative Instruments and Hedging Activities,'' which was amended by SFAS No. 137 and SFAS No. 138. Changes in the fair value of a derivative that is designated and documented as a cash flow hedge and is highly effective, are recorded in other comprehensive income until the underlying transaction affects earnings, and then are later reclassified to earnings. We formally assess, both at the inception and at each financial quarter thereafter, the effectiveness of the derivative instrument hedging the underlying forecasted cash flow transaction. Any ineffectiveness related to the derivative financial instruments' change in fair value will be recognized in the period in which the ineffectiveness was calculated. As of December 31, 2006, there were no foreign exchange contracts.

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.

Our long-term debt totaled $265.0 million at December 31, 2006 and was 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 Stockholders and Board of Directors
OSI Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of OSI Pharmaceuticals, Inc. and subsidiaries as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2006, for the three month period ended December 31, 2004, and for the year ended September 30, 2004. 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, 2006 and 2005, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2006, for the three months ended December 31, 2004, and for the year ended September 30, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of OSI Pharmaceuticals, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2006, 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 28, 2007 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

As discussed in Note 1 (j) and 11 to the consolidated financial statements, effective January 1, 2006, the Company adopted the fair value method of accounting for stock-based compensation as required by Statement of Financial Accounting Standards No. 123(R), *''Shared-Based Payment''*.

As discussed in Note 16 to the consolidated financial statements, the Company adopted the recognition and disclosure provisions of Statement of Financial Accounting Standards No. 158, *''Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans''* as of December 31, 2006.

/s/ KPMG LLP

Melville, New York
February 28, 2007

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2006 AND 2005
(In thousands except per share data)

	December 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,028	$ 164,084
Investment securities	164,786	5,061
Restricted investment securities — short-term	9,554	10,461
Accounts receivables — net	80,075	152,482
Inventory — net	36,860	75,715
Interest receivable	3,674	78
Prepaid expenses and other current assets	9,102	10,618
Total current assets	346,079	418,499
Property, equipment and leasehold improvements — net	56,223	61,947
Debt issuance costs — net	4,910	6,667
Goodwill	39,373	359,035
Other intangible assets — net	6,742	207,194
Other assets	4,405	5,240
	$ 457,732	$1,058,582
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 54,741	$ 80,467
Collaboration profit share payable	12,039	49,869
Unearned revenue — current	12,803	10,737
Other liabilities — current	—	1,255
Total current liabilities	79,583	142,328
Other liabilities:		
Rent obligations and deferred rent expense	10,044	6,337
Unearned revenue — long-term	66,089	39,051
Convertible senior subordinated notes	265,000	265,000
Contingent value rights	—	22,047
Accrued post-retirement benefit cost	8,070	5,353
Total liabilities	428,786	480,116
Stockholders' equity:		
Preferred stock, $.01 par value; 5,000 shares authorized; no shares issued at December 31, 2006 and 2005, respectively	—	—
Common stock, $.01 par value; 200,000 shares authorized, 59,179 and 58,728 shares issued at December 31, 2006 and 2005, respectively	592	587
Additional paid-in capital	1,616,874	1,592,155
Deferred compensation	—	(7,341)
Accumulated deficit	(1,553,653)	(971,469)
Accumulated other comprehensive income	2,354	1,755
	66,167	615,687
Less: treasury stock, at cost; 1,943 shares at December 31, 2006 and 2005	(37,221)	(37,221)
Total stockholders' equity	28,946	578,466
Commitments and contingencies (See Note 13)		
	$ 457,732	$1,058,582

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE
YEARS ENDED DECEMBER 31, 2006 AND 2005, THE THREE MONTHS ENDED
DECEMBER 31, 2004 AND THE YEAR ENDED SEPTEMBER 30, 2004
(In thousands except per share data)

	Year Ended December 31, 2006	Year Ended December 31, 2005	Three Months Ended December 31, 2004	Year Ended September 30, 2004
Revenues:				
Net revenue from unconsolidated joint business	$ 154,886	$ 84,727	$ —	$ —
Product sales	104,276	32,411	360	1,235
Royalties on product sales	51,501	7,127	—	—
Sales commissions	11,755	29,684	11,396	34,290
License, milestone and other revenues	28,937	16,164	591	7,275
Collaborative program revenues	24,341	4,081	—	—
	375,696	174,194	12,347	42,800
Expenses:				
Cost of goods sold	79,223	18,882	(1,247)	8,985
Collaborative profit share	40,297	12,312	—	—
Net expense from unconsolidated joint business	—	—	7,661	—
Research and development	176,654	125,953	31,913	110,398
Acquired in-process research and development (See Note 2)	—	64,442	—	32,785
Selling, general and administrative	158,617	98,393	20,313	98,909
Impairment of intangible assets (See Note 2)	505,985	—	—	24,599
Amortization of intangible assets	19,912	17,544	3,804	18,606
	980,688	337,526	62,444	294,282
Loss from operations	(604,992)	(163,332)	(50,097)	(251,482)
Other income (expense):				
Investment income — net	11,315	13,322	2,380	5,259
Interest expense	(7,578)	(5,065)	(1,219)	(13,436)
Other (expense) income — net	(2,975)	(2,048)	541	(712)
Net loss before extraordinary gain	(604,230)	(157,123)	(48,395)	(260,371)
Extraordinary gain	22,046	—	—	—
Net loss	$(582,184)	$(157,123)	$(48,395)	$(260,371)
Basic and diluted net loss per common share:				
Net loss before extraordinary gain	$ (10.61)	$ (3.02)	$ (1.02)	$ (6.50)
Extraordinary gain	0.39	—	—	—
Net loss	$ (10.22)	$ (3.02)	$ (1.02)	$ (6.50)
Weighted average shares of common stock outstanding	56,939	52,078	47,375	40,083

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005, THE THREE MONTHS ENDED DECEMBER 31, 2004 AND THE YEAR ENDED SEPTEMBER 30, 2004
(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 September 30, 2003	40,298	$ 403	$ 747,737	$ (216)	$ (505,580)	$1,164	$(25,451)	$218,057
Comprehensive income (loss):								
Net loss	—	—	—	—	(260,371)	—	—	(260,371)
Unrealized holding loss on investment securities, net of reclassification adjustment	—	—	—	—	—	(971)	—	(971)
Translation adjustment	—	—	—	—	—	1,204	—	1,204
Total comprehensive loss								(260,138)
Options exercised	1,493	15	38,673	—	—	—	—	38,688
Warrants exercised	6	—	—	—	—	—	—	—
Issuance of common stock for directors' annual retainer	11	—	474	(474)	—	—	—	—
Issuance of common stock for employee purchase plan and other	22	—	693	—	—	—	—	693
Issuance of common stock in connection with conversion of notes	3,200	32	159,968	—	—	—	—	160,000
Balance of unamortized debt issuance costs in connection with conversion of notes	—	—	(3,723)	—	—	—	—	(3,723)
Change in deferred compensation	—	—	(5)	5	—	—	—	—
Amortization of deferred compensation	—	—	—	479	—	—	—	479
Acceleration of director's options	—	—	177	—	—	—	—	177
Balance at September 30, 2004	45,030	450	943,994	(206)	(765,951)	1,397	(25,451)	154,233
Comprehensive income (loss):								
Net loss	—	—	—	—	(48,395)	—	—	(48,395)
Unrealized holding loss on investment securities, net of reclassification adjustment	—	—	—	—	—	(363)	—	(363)
Translation adjustment	—	—	—	—	—	2,224	—	2,224
Total comprehensive loss								(46,534)
Options exercised	450	5	11,189	—	—	—	—	11,194
Issuance of common stock for employee purchase plan and other	18	—	806	—	—	—	—	806
Issuance of common stock in connection with conversion of notes	6,900	69	419,497		—	—	—	419,566
Amortization of deferred compensation	—	—	—	125	—	—	—	125
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)

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005, THE THREE MONTHS ENDED DECEMBER 31, 2004 AND THE YEAR ENDED SEPTEMBER 30, 2004 — (Continued)
(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, 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 for directors' annual retainer	4	—	216	—	—	—	—	216
Issuance of restricted stock to employees	11	—	1,468	—	—	—	—	1,468
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
Balance at December 31, 2006	59,179	$ 592	$1,616,874	$ —	$(1,553,653)	$2,354	$(37,221)	$ 28,946

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005, THE THREE MONTHS ENDED DECEMBER 31, 2004 AND THE YEAR ENDED SEPTEMBER 30, 2004
(In thousands)

	Year Ended December 31, 2006	Year Ended December 31, 2005	Three Months Ended December 31, 2004	Year Ended September 30, 2004
Cash flow from operating activities:				
Net loss	$(582,184)	$(157,123)	$ (48,395)	$(260,371)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Gain from extraordinary item	(22,046)	—	—	—
Loss (gain) on sale of investments	—	2,188	4	(41)
Loss (gain) on sale and disposals of equipment	(5)	809	—	2
Depreciation and amortization	36,093	28,712	10,159	34,914
Impairment of intangible assets and goodwill	505,985	—	—	24,599
Provision for excess inventory — net	26,408	—	(3,368)	8,565
Impact of inventory step-up related to inventory sold	19,924	6,827	—	—
In-process research and development charge	—	64,442	—	32,785
Stock-based compensation expense	18,838	1,211	679	723
Other non-cash charges — net	865	816	(72)	493
Changes in assets and liabilities, net of the effects of acquisitions:				
Receivables	69,569	(45,062)	(3,602)	(459)
Inventory	(9,551)	(15,759)	2,684	(6,386)
Prepaid expenses and other current assets	1,715	386	3,628	594
Other assets	(3,755)	147	2	47
Accounts payable and accrued expenses	(17,017)	(34,271)	(4,014)	16,037
Collaboration profit share payable	(37,829)	949	—	—
Unearned revenue	29,104	29,760	10,203	2,795
Accrued post-retirement benefit cost	1,401	1,149	299	795
Net cash provided by (used in) operating activities	37,515	(114,819)	(31,793)	(144,908)
Cash flows from investing activities:				
Payments for acquisitions, net of cash acquired	—	(430,986)	—	(36,393)
Purchases of investments (restricted and unrestricted)	(239,268)	(447,443)	(192,104)	(250,714)
Maturities and sales of investments (restricted and unrestricted)	80,788	757,325	37,716	278,748
Net additions to property, equipment and leasehold improvements	(10,728)	(26,718)	(1,787)	(3,287)
Proceeds from sale of fixed assets	795	—	—	—
Purchase of compound library assets	(31)	(920)	214	(341)
Net cash used in investing activities	(168,444)	(148,742)	(155,961)	(11,987)
Cash flows from financing activities:				
Net proceeds from issuance of stock	—	—	419,566	—
Proceeds from the exercise of stock options, stock warrants, employee purchase plan, and other	9,138	12,471	11,445	39,315
Proceeds from the issuance of convertible senior subordinated notes	—	115,000	—	—
Call spread premium	—	(12,179)	—	—
Debt issuance costs	(102)	(3,902)	—	(118)
Payments on loans and capital leases payable	(640)	(180)	(4)	(63)
Purchase of treasury stock	—	(11,770)	—	—
Net cash provided by financing activities	8,396	99,440	431,007	39,134
Net (decrease) increase in cash and cash equivalents	(122,533)	(164,121)	243,253	(117,761)
Effect of exchange rate changes on cash and cash equivalents	477	(1,351)	1,705	(160)
Cash and cash equivalents at beginning of year	164,084	329,556	84,598	202,519
Cash and cash equivalents at end of year	$ 42,028	$ 164,084	$ 329,556	$ 84,598
Non-cash activities:				
Conversion of notes	$ —	$ —	$ —	$ 160,000
Reclassification of debt issuance costs in connection with notes	$ —	$ —	$ —	$ 3,723
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 Prosidion preferred stock to minority shareholders	$ —	$ —	$ —	$ 1,400
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	$ 4,869	$ —	$ 14,502

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. In December 2004, we changed our fiscal year end from September 30 to December 31. The first fiscal year affected by this change ended on December 31, 2005. 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, 2006 and 2005, for the three month transition period ended December 31, 2004, and for the year ended September 30, 2004. 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. partner for Tarceva (erlotinib). It consists of our share of the pretax co-promotion profit (loss) 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. For the year ended December 31, 2006, Genentech recorded $402 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 (loss) 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, selling and marketing expenses, and certain joint development expenses incurred by Genentech and us. The costs incurred during the respective periods represent estimated costs of both parties and are subject to further adjustment based on each party's final review. Based on past experience, we do not believe that these adjustments, if any, will be significant to our consolidated financial statements. The partial 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 $5.9 million and $7.0 million as of December 31, 2006 and 2005, 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, 2006	Year Ended December 31, 2005
Co-promotion profit and reimbursement of sales and marketing related costs	$143,692	$73,715
Reimbursement of manufacturing costs	11,194	11,012
Net revenue from unconsolidated joint business	$154,886	$84,727

(c) Product Sales

Product sales primarily consist of sales of Macugen (pegaptanib sodium injection) in the United States and its territories. For the twelve months ended December 31, 2006 and 2005, Macugen net sales totaled $103 million and $185 million, respectively. Net sales of Macugen from November 14, 2005, the date of our acquisition of Eyetech, through December 31, 2005, totaled $31.5 million, and are included in product sales for the year ended December 31, 2005. Net Macugen sales represents gross product revenue less distribution service fees and estimates for allowances and returns. 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 do not recognize revenue from product sales until 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 collectibility is reasonably assured.

Under an agreement dated February 2003 with Pfizer, Inc., we share sales and marketing responsibility with Pfizer for sales of Macugen in the United States. We report product revenue on a gross basis for these sales. We have determined that we are qualified as a principal under the criteria set forth in Emerging Issues Task Force, or EITF, Issue 99-19, ''Reporting Gross Revenue as a Principal vs. Net as an Agent,'' or EITF 99-19, based on our responsibilities under our contracts with Pfizer, which include manufacture of product for sale in the United States, distribution, ownership of product inventory and credit risk from customers.

We record allowances for distribution fees, product returns and governmental and other rebates for products sold in the United States at the time of sale, and report revenue net of such allowances. We must make significant judgments and estimates in determining these allowances. For instance:

- Our distributors have a limited right of return for unopened product during a specified time period based on the product's labeled expiration date. As a result, in calculating the allowance for product returns, we estimate the likelihood that products sold to distributors might be returned within a specific timeframe. We determine our estimates using actual product data from distributors, industry data on products with similar characteristics and the expiration dates of products sold.
- Certain government buying groups that purchase our product from wholesalers have the right to receive a discounted price from us. As a result, we estimate the amount of product which will ultimately be sold to these buying groups. We determine our estimates using actual product data from distributors and historical industry trends.

If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future.

In the fourth quarter of 2006 we discontinued sales of Gelclair Bioadherent Oral Gel, or Gelclair. Gelclair was sold in accordance with an exclusive distribution agreement with Helsinn Healthcare S.A., which allowed us to market and distribute Gelclair in North America. In late October 2004, we exercised our right to terminate the agreement with Helsinn, while continuing to exercise our right to sell off inventory. The discontinuance of Gelclair sales is not expected to have a material impact on our results since Gelclair sales were not material to our revenues for the years ended December 31, 2006 and 2005.

(d) 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 collaborative partners. 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.

(e) Sales Commissions

Sales commissions represent 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. (see Note 4(c)). 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, as determined by an external third party. Beginning in the third quarter of 2006, we agreed with Merck Serono on a fixed oncology split and therefore are no longer utilizing a third party to determine this amount. Based on past experience, we do not believe these adjustments, if any, will be significant to the consolidated financial condition or results of operations.

(f) 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 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 terms of a 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 $31.9 million as of December 31, 2006 of which $2.3 million is classified as short-term and the balance of $29.6 million is 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 $34.2 million as of December 31, 2005 of which $2.3 million is classified as short-term and the balance of $31.9 million was classified as long-term in the accompanying consolidated balance sheet.

In March 2005, the Tarceva alliance partners, 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, including Tarceva/ Avastin® (bevacizumab). The cost of the development plan will continue to be shared by the three partners. 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, future milestone payments received from Roche 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 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. 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 for the application of Tarceva for the treatment of advanced NSCLC. All of the payments have been included in deferred revenue. The unearned revenue related to the milestones earned from Roche was $7.9 million as of December 31, 2006 of which $983,000 is classified as short-term and the balance of $6.9 million was classified as long-term in the accompanying consolidated balance sheet. The unearned revenue related to the milestones earned from Roche was $7.8 million as of December 31, 2005 of which $868,000 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 second quarter of 2006, we received a $35 million milestone payment from Pfizer in connection with the launch of Macugen in select European countries. The milestone payment is being recognized over the term of our collaboration and license agreements with Pfizer, under which the last items of performance to be delivered to Pfizer are set forth, on a straight-line basis, which approximates the expected level of performance under the agreements. At December 31, 2006, we had unearned revenue of $32.9 million relating to Pfizer payments, of which $3.3 million was classified as short-term. Such unearned revenue may be reversed in the future if and when the Pfizer agreement is renegotiated or is transferred to a third-party in connection with a potential divestiture of the eye disease business.

During the year ended December 31, 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 agreements, we recognized upfront license and milestone revenue and royalties of $19 million for the year ended December 31, 2006.

All of the payments mentioned above in this Note 1(f) are included in license and milestone revenues on the accompanying consolidated statement of operations for the year ended December 31, 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.

(g) Collaborative Program Revenues

Collaborative program revenues represent funding arrangements for research and development in the field of biotechnology and are recognized when earned in accordance with the terms of the contracts and related research and development activities undertaken.

Based on the terms of our collaboration agreement with Pfizer, revenues derived from reimbursement of costs associated with the development of Macugen are recorded in compliance with EITF 99-19, and EITF Issue 01-14, ''Income Statement Characterization of Reimbursements Received For 'Out-of-Pocket' Expenses Incurred,'' or EITF 01-14. According to the criteria established by these EITF Issues, in transactions where we act as a principal, with discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we have met the criteria to record revenue for the gross amount of the reimbursements.

(h) 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 is our share of development expenses related to the Tripartite Agreement with Genentech and Roche (see Note 4(a)).

(i) 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 (see Note 2).

(j) Accounting for Share-Based Compensation

As discussed further in Note 11, ''Accounting for Share-Based Compensation,'' we adopted SFAS No. 123(R), ''Share Based Payment,'' or SFAS No. 123(R), on January 1, 2006 using the modified prospective method. Through December 31, 2005, we accounted for our stock option and employee stock purchase plans under the intrinsic value method of Accounting Principles Board, or APB, Opinion No. 25, and as a result no stock option related compensation costs had been recognized in our historical consolidated statements of operations.

We have used and expect to continue to use the Black-Scholes option-pricing model to compute the estimated fair value of stock options. 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 year ended December 31, 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.

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 are considered fully vested as of November 30, 2005, have 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) in fiscal 2006.

(k) Net Loss Per Share

Basic and diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the respective period. Common share equivalents (convertible senior subordinated notes, stock options, restricted stock and restricted stock units) are not included since their effect would be anti-dilutive. The contingent shares pursuant to the contingent value rights are not included since the contingency condition has not been satisfied.

Such common share equivalents and contingent shares for the years ended December 31, 2006 and 2005, the three months ended December 31, 2004, and the year ended September 30, 2004, amounted to (in thousands):

	Year Ended December 31, 2006	Year Ended December 31, 2005	Three Months Ended December 31, 2004	Year Ended September 30, 2004
Common share equivalents	7,688	4,948	4,752	7,152
Contingent shares	1,585	1,585	1,585	1,585

If the years ended December 31, 2006 and 2005, and three months ended December 31, 2004, had resulted in net income and had the common share equivalents for our 2% convertible senior subordinated notes due 2025, or 2025 Notes (3,908,240 shares), and our 3.25% convertible senior subordinated notes due 2023, or 2023 Notes (2,998,800 shares), been dilutive, interest expense related to the Notes would have been added back to net income to calculate diluted earnings per share. The related interest expense of these Notes for years ended December 31, 2006 and 2005 and the three months ended December 31, 2004 totaled $7.2 million, $4.9 million and $1.2 million, respectively. If the year ended September 30, 2004 had resulted in net income and had the common share equivalents for our convertible senior subordinated notes due 2009, or 2009 Notes (3,200,000 shares), and our 2023 Notes (2,998,800 shares) been dilutive, interest expense related to the Notes would have been added back to net income to calculate diluted earnings per share. The related interest expense of these Notes for the years ended September 30, 2004 and 2003 totaled $13.4 million and $6.7 million, respectively.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(l) Comprehensive Loss

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

	Year Ended December 31, 2006	Year Ended December 31, 2005	Three Months Ended December 31, 2004	Year Ended September 30, 2004
Net loss	$(582,184)	$(157,123)	$(48,395)	$(260,371)
Other comprehensive loss:				
Foreign currency translation adjustments	2,148	(2,431)	2,224	1,204
Unrealized gains on derivative instruments arising during period	—	—	—	131
Unrealized holding losses arising during period	(233)	(1,245)	(341)	(995)
Less: Reclassification adjustment for losses (gains) realized in net loss	—	2,173	(22)	(107)
	1,915	(1,503)	1,861	233
Total comprehensive loss	$(580,269)	$(158,626)	$(46,534)	$(260,138)

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

	As of December 31,	
	2006	2005
Cumulative foreign currency translation adjustment	$3,976	$1,828
Adjustment to initially apply SFAS 158	(1,316)	—
Unrealized losses on available-for-sale securities	(306)	(73)
Accumulated other comprehensive income	$2,354	$1,755

(m) 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 $13.0 million and $102.7 million as of December 31, 2006 and 2005, respectively.

(n) Investments

Investment securities at December 31, 2006 and 2005 consisted primarily of U.S. government securities, municipal obligations 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,'' or SFAS No. 115. 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 security below cost that is deemed to be other than temporary results in a reduction in carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. 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, 2006 were $9.6 million 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.

(o) 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 2, we recorded an impairment charge of $320.3 million to the Eyetech goodwill during the year ended December 31, 2006.

(p) 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.

Our most significant intangible asset was the acquired core and developed technology related to Macugen. As discussed in Note 2, 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.

In the fourth quarter of fiscal 2004, we determined it was necessary to record an impairment charge related to our intangible asset for exclusive distribution rights to the marketed product, Gelclair, in North America (see Note 7).

(q) Inventory

Tarceva 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 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. 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. 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.

At December 31, 2005, the cost reflected in a portion of the finished goods inventory for Tarceva consisted solely of cost incurred to package and label work-in-process inventory that had been previously expensed. During 2006, we had sold all of the inventory that was partially produced and expensed prior to November 2004.

As part of the acquisition of Eyetech, acquired finished goods and work-in-process was valued at fair value. Included in the finished goods at December 31, 2006 and 2005 was $2.2 million and $15.3 million, respectively, of step up in value assigned to Eyetech inventory as part of the acquisition. Included in work-in-process at December 31, 2006 and 2005 was $414,000 and $33.1 million, respectively, of step up in value assigned to Eyetech inventory. The carrying value of raw materials acquired on the date of the acquisition and post acquisition Macugen inventory is stated at the lower of cost or market, and our inventory costs are determined by weighted average method. Inventory is comprised of three components: raw materials, which are purchased directly by us, work-in-process, which is primarily API where title has transferred from our contract manufacturer to us, and finished goods, which is packaged product ready for commercial sale.

Also 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 relies 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. If actual results differ significantly from our expectations, it could lead to the write down of additional inventory or our sale inventory with zero cost basis.

Inventory, net of the reserve for excess inventory, at December 31, 2006 and 2005, consisted of the following (in thousands):

	December 31, 2006	December 31, 2005
Raw materials	$ 3,032	$ 5,905
Work-in-process	22,282	44,961
Finished goods on hand, net	6,088	19,533
Inventory subject to return	5,458	5,316
Total inventory	$36,860	$75,715

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)).

(r) 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.

(s) 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.

(t) 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.

(u) 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.

(v) Accounting for Derivatives

Periodically we enter into forward exchange contracts to reduce foreign currency fluctuation risks relating to intercompany transactions for the funding of our research activities in the United Kingdom. We account for these

derivative financial instruments in accordance with SFAS No. 133, ''Accounting for Derivative Instruments and Hedging Activities,'' which was amended by SFAS No. 137 and SFAS No. 138. When entered into, we designate and document these derivative instruments as a cash flow hedge of a specific underlying exposure, as well as the risk management objectives and strategies for undertaking the hedge transactions. Changes in the fair value of a derivative that is designated and documented as a cash flow hedge and is highly effective are recorded in other comprehensive income until the underlying transaction affects earnings, and then are later reclassified to earnings. We formally assess, both at the inception and at each financial quarter thereafter, the effectiveness of the derivative instrument hedging the underlying forecasted cash flow transaction. Any ineffectiveness related to the derivative financial instruments and changes in fair value will be recognized in the period in which the ineffectiveness was calculated. There were no foreign exchange contracts as of December 31, 2006 and 2005.

(w) 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 carryforwards. 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.

(x) Debt Issuance Costs

Costs incurred in issuing the 2025 Notes and the 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. Costs incurred in issuing the 2009 Notes were amortized using the straight-line method over a seven-year term. Upon conversion of the 2009 Notes in July 2004, the remaining unamortized costs of $3.7 million were reclassified to additional paid in capital (see Note 10(c)). The amortization of the debt issuance costs is included in other expense in the accompanying consolidated statements of operations.

(y) 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 U.S. generally accepted accounting principles. Actual results could differ from those estimates and assumptions.

(z) 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.

(2) Acquisitions

(a) Eyetech Pharmaceuticals, Inc. 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. immediately following the acquisition.

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, NY, Cedar Knolls, NJ, Woburn and Lexington, MA and Boulder, CO, as well as leasehold improvements and certain equipment; (c) inventory; and (d) certain other assets and liabilities.

As consideration for the acquisition, each share of Eyetech common stock was purchased for $15.00 cash and 0.12275 shares of our common stock. The aggregate consideration related to the acquisition totaled $909.3 million, including the cash consideration, value of OSI common stock issued, value of converted stock options issued, and deal related costs. We issued a total of approximately 5.65 million shares valued at $205.4 million, which was based on the average four-day closing price of our common stock around the date of the announcement of the acquisition, which occurred on August 21, 2005. In addition, each outstanding option to purchase shares of Eyetech common stock, other than options granted under Eyetech's 2001 Stock Plan, accelerated in full and became vested and exercisable prior to the closing date of November 14, 2005. Any of the Eyetech options that remained unexercised as of the effective time of the merger were terminated or cancelled in accordance with their terms. Each outstanding option granted under Eyetech's 2001 Stock Plan was assumed by OSI at the effective time and became an option to purchase shares of OSI common stock. The portion of the value assigned to options assumed and included in the purchase price was $1.9 million. Options issued to Eyetech employees that were in the money, but not yet vested, were converted into options for our common stock at a ratio of 0.491 OSI shares of common stock for each option to purchase one share of Eyetech common stock. Based on this ratio, we assumed approximately 153,000 options. In connection with the adoption of SFAS No. 123(R) effective January 1, 2006, the options are being amortized into expense over the remaining vesting period based on the fair value assigned to the options on the date of the acquisition. Outstanding unvested restricted shares and options to acquire restricted shares as of the acquisition date were converted into cash and shares of OSI common stock (restricted to the same extent as the restricted stock converted) on the same basis as the outstanding stock of Eyetech. The value assigned as of the acquisition date to these rights was $6.1 million which is being recognized as compensation expense in the accompanying financial statements over the remaining vesting period.

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 of December 31, 2005, the final determination for the disposition of equipment and other costs was not finalized. During the second and third quarters of 2006, we finalized our valuation of Eyetech related assets and liabilities and recognized adjustments to decrease the fair value of the acquired Eyetech assets by $3.9 million and decrease the assumed Eyetech liabilities by $3.7 million, resulting in a $0.3 million adjustment to increase the value assigned to Eyetech goodwill. 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 as determined as of September 30, 2006.

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 research and development (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.

The following unaudited pro forma financial information for the year ended December 31, 2005, the three-month transition period ended December 31, 2004 and the year ended September 30, 2004 combine the historical financial information of OSI and Eyetech giving effect to the merger as if it occurred on October 1, 2003, October 1, 2004 and January 1, 2005, reflecting only pro forma adjustments expected to have a continuing impact on the combined results. The unaudited pro forma financial information for the year ended September 30, 2004 combines the historical financial information of OSI for the year ended September 30, 2004 and Eyetech for the year ended December 31, 2004. In December 2004, OSI changed its fiscal year end to December 31 and filed a transition report on Form 10-QT for the three-month period ended December 31, 2004. The unaudited pro forma financial

information for the three-month period ended December 31, 2004 combines the historical financial information of OSI and Eyetech for the three-month period ended December 31, 2004. Accordingly, the historical financial information for Eyetech for the three months ended December 31, 2004 are included in the condensed pro forma financial information for both the year ended September 30, 2004 and the three months ended December 31, 2004. The unaudited pro forma financial information for the year ended December 31, 2005 combines the historical financial information of OSI and Eyetech for the year ended December 31, 2005. The unaudited pro forma financial information is as follows (in thousands, except per share information):

	Year Ended December 31, 2005	Three Months Ended December 31, 2004	Year Ended September 30, 2004
Revenues	$ 355,799	$ 22,209	$ 86,466
Net loss before non-recurring charge related to the acquisition	$(161,267)	$(92,715)	$(406,900)
Basic and diluted net loss per share before non-recurring charge related to the acquisition	$ (2.83)	$ (1.75)	$ (8.90)

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.

(b) 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 neovascular age-related macular degeneration, or 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, the Company recorded an impairment charge of $320.3 million during fiscal 2006, reflecting the full value of the Eyetech goodwill.

(c) 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. While we continue to believe that Macugen may achieve an important place in the wet AMD marketplace, it will be dependent on the outcome of the LEVEL trial, our trial to assess Macugen's ability to maintain the vision gain achieved by other non-selective VEGF-A agents used to treat wet AMD, and the emergence of additional safety signals with the use of these other agents. In addition, it is highly probable that the ultimate outcome of our process to exit the eye disease business will result in a transaction with a combination of up-front consideration and contingent consideration. We believe that the amount of the up-front consideration will only enable us to recover the value of certain tangible assets relating to our eye-disease business. However, because of the current sales levels of Macugen and the uncertainty surrounding future sales levels of Macugen on which any contingent consideration would be based, there is significant risk relating to the value of this contingent consideration. After considering all of the aforementioned factors, we have concluded that the Macugen intangibles are impaired and have reduced their value to zero at December 31, 2006 and recorded a $185.7 million charge in the fourth quarter of 2006.

(d) Probiodrug Assets

On July 26, 2004, our subsidiary, Prosidion, which is focused on the discovery and development of diabetes and obesity therapeutics, completed the acquisition of certain assets of Probiodrug AG, pursuant to the terms of an asset purchase agreement dated June 17, 2004. Probiodrug is a development company engaged in the research and development of drug candidates for various targets and various indications, including metabolic diseases. The assets acquired included a platform of DPIV technology, which includes PSN9301, a clinical candidate that is in Phase II clinical trials for the treatment of type 2 diabetes, and a portfolio of issued and pending patents and patent applications with claims covering DPIV as a target for anti-diabetes therapy and licensed rights to patent applications claming combinations of DPIV inhibitors with other oral anti-diabetes drugs such as metformin, that have been non-exclusively licensed to other companies for future milestones and royalty payments. Upon the closing of the acquisition, we paid $36.4 million in cash, including professional fees. The purchase price was allocated to the assets acquired based on the fair values as of the date of the acquisition. Of the $36.4 million purchase price, $32.8 million was assigned to the drug candidate in clinical development, PSN9301, and was expensed at the date of the acquisition and is included in acquired in-process research and development expenses in the accompanying consolidated statement of operations for the year ended September 30, 2004. The non-exclusive licenses issued to other companies, as well as the patent estate, were valued at $3.6 million and are included in other intangible assets-net on the accompanying consolidated balance sheets as of December 31, 2006 and 2005, and are being amortized on a straight-line basis through the earliest expiration of the related patents in April 2017. We will also be required to pay additional contingent milestone payments upon the achievement of certain milestones related to the development of PSN9301.

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 valued at $32.8 million and was assigned entirely to PSN9301. 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 product was 2010. Given the risks associated with the development of new drugs, the revenue and expense forecast was 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. The modeled cash flow was discounted back to the net present value. The projected net cash flows from such project 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 26% to reflect present value.

Prosidion also entered into a research agreement with Probiodrug whereby Probiodrug would provide services directed to the research and development of new lead molecules in the area of glucose-dependent insulinotropic peptide receptor, agonism and antagonism and DPIV inhibition. Prosidion agreed to fund the research and development services to be performed, up to $5.0 million dollars and would also be required to pay Probiodrug royalties on the net sales of products that arise from the research and development.

(e) 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 compound's 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.

(3) Investments

(a) Investment Securities

We invest our excess cash in U.S. government securities, municipal obligations and debt instruments of financial institutions and corporations with strong credit ratings. We have established guidelines relative to 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, 2006 and 2005 (in thousands):

	Costs	Gross Unrealized Losses	Fair Value
2006			
U.S. government securities	$137,089	$(274)	$136,815
Corporate and financial institutions debt	27,975	(3)	27,972
Investment securities	165,064	(277)	164,787
Restricted Investments	9,582	(29)	9,553
Total	$174,646	$(306)	$174,340

	Costs	Gross Unrealized Losses	Fair Value
2005			
U.S. government securities	$3,632	$(77)	$3,555
Corporate and financial institutions debt	1,514	(8)	1,506
Total	$5,146	$(85)	$5,061

Net realized gains (losses) on sales of investments during the years ended December 31, 2006 and 2005, the three months ended December 31, 2004 and the year ended September 30, 2004 were $170,000, ($2.2) million, ($5,700) and $5,000, respectively.

Maturities of securities classified as available-for-sale were as follows at December 31, 2006 (in thousands):

	Cost	Fair Value
2007	$117,105	$117,023
2008	41,074	40,982
2009	15,217	15,115
2010	—	—
2011	750	726
2012 and hereafter	500	494
	$174,646	$174,340

(4) Product Development/Commercialization Agreements

(a) Roche and Genentech

On January 8, 2001, we entered into an alliance with Genentech and Roche for the global co-development and commercialization of Tarceva. We received upfront fees of $25 million related to this alliance, and Genentech and Roche each purchased $35 million of our common stock at $75.66 per share. We are also entitled to up to $92 million upon the achievement of certain milestones under the terms of the alliance of which $44.8 million was received as of December 31, 2006. 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 approval 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 additional 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 which we 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 an amendment to the agreement effective as of June 4, 2004. Pursuant to this amendment, we co-promote Tarceva using a sales force equal to or greater than 25% 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 partial 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 had 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) Pfizer

In December 2002, Pfizer and Eyetech entered into several concurrent agreements to jointly develop and commercialize Macugen. The agreement became effective February 3, 2003 when government approval of the transaction was obtained. Pfizer has funded, and is obligated to continue to fund, a majority of the ongoing development costs incurred pursuant to an agreed upon development plan covering the development of Macugen for wet AMD, diabetic macular edema, or DME, central retinal vein occlusion, or CRVO, and other agreed upon ophthalmic indications. In the United States, we are co-promoting Macugen with Pfizer, we and Pfizer share in profits and losses from the sale of Macugen. Outside the United States, Pfizer markets the product under an exclusive license, for which we receive royalty payments based on net sales.

Under the agreement, the parties' sharing of gross profits and losses from the commercialization of Macugen in the United States extends until the later of 15 years after commercial launch in the United States or the expiration of the United States patent rights licensed to Pfizer. The payment of royalties to us by Pfizer based on

net sales of Macugen outside the United States extends, on a country-by-country basis, until the later of 15 years after commercial launch and the expiration of the patent rights licensed to Pfizer in each particular country. The royalty rate on net sales of Macugen outside the United States is reduced on a country-by-country basis to the extent that the patent rights in a particular country expire or a generic form of Macugen is marketed in that country. We commercially launched Macugen in January 2005. The United States patent rights licensed by us to Pfizer expire between 2010 and 2017. The corresponding foreign rights include patents that expire between 2011 and 2017 and patent applications which, if issued as patents, are expected to expire between 2011 and 2020. Pfizer may terminate the collaboration relationship without cause upon six to twelve months' prior notice, depending on when such notice is given. Either party may terminate the collaboration relationship based upon material uncured breaches by the other party. In addition, we may terminate the collaboration relationship if, during specified periods, net sales of Macugen do not reach specified levels. If we elect to terminate the collaboration in this situation, we would be required to pay royalties to Pfizer based on net sales of Macugen following such termination.

The collaboration is governed by a joint operating committee, consisting of an equal number of representatives of us and Pfizer. There are also subcommittees with equal representation from both parties that have responsibility over development and regulatory, manufacturing and commercialization matters. In the case of unresolved disagreement, ultimate decision-making authority is vested in us as to some matters and in Pfizer as to other matters. A third category of decisions requires the approval of both us and Pfizer. Outside the United States, ultimate decision-making authority as to most matters is vested in Pfizer.

Based on the achievement of certain specified worldwide regulatory submission and approvals, we would be eligible to receive up to an additional $55 million in license payments. We also have the potential to receive up to an additional $450 million in milestone payments, which are contingent upon successful commercialization of Macugen and which are based on attainment of agreed-upon sales levels.

(c) Merck Serono

On March 11, 2003, we entered into a co-promotion agreement with Ares Trading, an affiliate of Merck Serono, 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, 2006 and 2005, 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 $11.8 million, $29.7 million and $11.4 million for the years ended December 31, 2006 and 2005 and the three months ended December 31, 2004, respectively. Sales commissions totaled $34.3 million for the year ended September 30, 2004.

(d) Other

Under the terms of the aforementioned and other collaborative research agreements, with terms similar to the aforementioned agreements, certain collaborative partners will pay us royalties on net sales of products resulting from these research programs in addition to the research revenues described below. We or our collaborative partners may terminate each of the collaborative research programs upon the occurrence of certain events.

(5) License Agreements

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. 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. License, milestone and royalty payments were recognized as revenue for the year ended December 31, 2006 and 2005 for licenses of our DPIV patent estate was approximately $19 million and $14 million, respectively.

(6) 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 31, 2006	December 31, 2005
Land	—	$ 3,600	$ 3,600
Building and improvements	10-35	23,502	17,447
Laboratory equipment	5-15	25,663	25,872
Office furniture and equipment and computer equipment	3-7	15,319	14,004
Capitalized software	1-3	6,817	6,274
Manufacturing equipment	3-7	5,150	4,400
Leasehold improvements	Life of lease	34,260	33,262
Total		114,311	104,859
Less: accumulated depreciation and amortization		(58,088)	(42,912)
Property, equipment and leasehold improvements, net		$ 56,223	$ 61,947

Depreciation expense relating to these assets for the years ended December 31, 2006 and 2005 and the three months ended December 31, 2004 was $13.6 million, $10.6 million and $6.1 million, respectively. Depreciation expense relating to these assets for the year ended September 30, 2004 was $14.3 million. We had capitalized $6.8 million and $6.3 million of capitalized computer software costs as of December 31, 2006 and 2005, respectively, of which $5.3 million and $3.9 million was amortized as of December 31, 2006 and 2005, respectively.

(7) Goodwill and Other Intangible Assets

The carrying amount of goodwill was $39.4 million and $359.0 million as of December 31, 2006 and 2005, respectively. The balance of goodwill as of December 31, 2006 and 2005 included a $343,000 and $(132,000), respectively, effect from foreign currency exchange rate fluctuations during fiscal 2006 and 2005. The goodwill of $39.4 million as of December 31, 2006 is associated with our oncology operating segment and we completed our

annual impairment review of the goodwill as of December 31, 2006 and determined that no impairment charge was required. As discussed in Note 2, we recorded a $320.3 million impairment charge during 2006 relating to the Eyetech goodwill.

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

	December 31, 2006			December 31, 2005		
	Carrying Amount	Net Accumulated Amortization	Book Value	Carrying Amount	Net Accumulated Amortization	Book Value
Novantrone technology	$46,009	$(43,108)	$2,901	$ 46,009	$(41,657)	$ 4,352
Macugen	—	—	—	201,400	(2,263)	199,137
Acquired patent estate	760	(135)	625	668	(65)	603
Acquired licenses issued to other companies	3,932	(716)	3,216	3,458	(356)	3,102
Total	$50,701	$(43,959)	$6,742	$251,535	$(44,341)	$207,194

In connection with the acquisition of Eyetech on November 14, 2005, we recognized $201.4 million of intangible assets with determinable lives consisting of core and developed technology related to Macugen. These intangibles were being amortized straight-line over 11 years, the underlying life of the last to expire patent. As discussed in Note 2, we reviewed the Macugen intangibles for impairment at December 31, 2006 and recognized an impairment charge to reduce their carrying value to zero at December 31, 2006.

In connection with Prosidion's acquisition of certain assets of Probiodrug in fiscal 2004, we recorded intangible assets for the acquired patent estate ($515,000) and two non-exclusive licenses issued to Merck and Novartis ($3.1 million). 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 were being 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 will amortize the remaining balance on a straight-line basis.

In connection with the acquisition of Cell Pathways, we assumed the exclusive rights to market and distribute Gelclair in North America. These rights were being amortized over eight and a half years, the remaining term of the agreement. SFAS No. 142 requires that intangible assets with determinable 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. In September 2004, it was determined that the carrying value of the Gelclair rights exceeded the expected future undiscounted cash flows. The impairment charge resulted from both the discontinuance of discussions with a replacement dental partner, and slower than originally expected sales growth in the oncology marketplace. The discounted cash flows calculation was made utilizing various assumptions and estimates regarding future revenues and expenses, cash flow and discount rates. Based upon our analysis, we recognized an impairment loss for the remaining carrying value of the rights as of September 30, 2004. This impairment loss of $24.6 million is included as impairment of intangible asset expense in the accompanying consolidated statement of operations for the year ended September 30, 2004.

Amortization expense for these intangible assets for the years ended December 31, 2006 and 2005 was $19.9 million and $17.5 million, respectively. Amortization expense for the three months ended December 31, 2004 and year ended September 30, 2004 was $3.8 million and $18.6 million, respectively. Amortization expense is estimated to be $1.8 million for the years of 2007 and 2008, and $380,000 for the years 2009 through 2011.

(8) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses at December 31, 2006 and 2005 are comprised of (in thousands):

	December 31, 2006	December 31, 2005
Accounts payable	$ 3,543	$ 9,473
Accrued payroll and employee benefits	3,612	3,538
Accrued incentive compensation	—	3,963
Accrued exit costs (see Note 17)	8,128	10,241
Accrued interest	1,619	1,580
Accrued CRO and site costs	5,059	5,248
Accrued commercial and development costs	5,723	5,467
Accrued royalties	1,088	9,060
Accrued compensation related to Eyetech restricted shares (see Note 11)	221	3,910
Other accrued expenses	25,748	27,987
	$54,741	$80,467

Accrued royalties at December 31, 2006 represents royalties payable to other biopharmaceutical companies for patent licenses related to the sales of Macugen.

(9) Collaborative Profit Share Payable

In connection with the acquisition of Eyetech and our collaborative agreements with Pfizer, Macugen is co-promoted by us and Pfizer in the United States where we have an ophthalmology sales force, maintain the inventory and book all U.S. product sales. Pfizer and we share in gross profits and losses from the sale of Macugen products in the United States. As of December 31, 2006, we had a liability to Pfizer of $12.0 million related to their share of the Macugen gross profits.

(10) 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. 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 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, 2006 and 2005, the fair value of the outstanding 2025 Notes was approximately $147.9 million and $129.6 million, based on their quoted market value. As of January 1, 2007, 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, 2006. As a result, during the conversion period commencing January 1, 2007 and continuing through and including March 30, 2007, holders of the 2025 Notes may, if they elect, convert the 2025 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 2023 Noteholders 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 election 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 related debt issuance costs of $5.2 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 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, 2006 and 2005, the fair value of the outstanding 2023 Notes, was approximately $148.5 million and $144.3 million, respectively, based on their quoted market value.

(11) Stockholders' Equity

(a) Equity Plans

We have thirteen equity plans pursuant to which there are shares available for future grant and/or outstanding grants issued to our employees, officers, directors and consultants. Four of these plans still have shares available for future grant: the 1997 Incentive and Non-Qualified Stock Option Plan, the 1999 Incentive and Non-Qualified Stock Option Plan, the Amended and Restated Stock Incentive Plan, and Stock Incentive Plan for New Hires. 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 and Stock Incentive Plan for New Hires, restricted stock and restricted 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 11,609,500, of which 1,255,240 shares were available for future grant as of December 31, 2006.

Our Board of Directors adopted the 2001 Incentive and Non-Qualified Stock Option Plan, or the 2001 Stock Option Plan, effective June 13, 2001, which was approved by the stockholders on March 13, 2002. The 2001 Stock Option Plan permitted the grant of stock options to purchase up to 4.0 million shares as well as continuing automatic, formula-based grants of non-qualified stock options to directors who are not our employees. On December 11, 2002, our Board of Directors approved an amendment to the 2001 Stock Option Plan that only affected the automatic, formula-based grants of non-qualified stock options to directors who are not our employees. 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 4.0 million shares to 6.8 million shares. 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.

On November 12, 2005, our Board of Directors adopted 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.

Pursuant to the Eyetech merger agreement, 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 June 14, 2006, our Board of Directors adopted the Stock Incentive Plan for New Hires. The company adopted this Stock Incentive Plan for New Hires to provide incentive equity grants as an inducement to qualified individuals to accept employment with OSI. At December 31, 2006, 850,000 shares of common stock are authorized and available for grant under the 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. As of December 31, 2006, we had 322,090 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, 2006, we had 80,116 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.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

We recognized stock-based compensation for awards issued under our equity compensation plans, restricted stock, restricted stock units and options assumed in the acquisition of Eyetech and employee stock purchase plans in the following line items in the consolidated statement of operations for the year ended December 31, 2006 (in thousands):

	Share-based Compensation as a Result of the Adoption of SFAS 123(R)	Compensation Expense Related to Restricted Stock and Restricted Options	Total Share-based Compensation Expense
Cost of sales	$ 257	$ 414	$ 671
Research and development expenses	3,190	1,917	5,107
Selling, general and administrative expenses	11,344	5,231	16,575
Stock-based compensation expense	$14,791	$7,562	$22,353

As of December 31, 2005, we had recognized deferred compensation related to the intrinsic value of restricted stock and options assumed in connection with the acquisition of Eyetech. In connection with the adoption of SFAS No. 123(R) on January 1, 2006, we eliminated the caption deferred compensation by reducing accrued expenses by $3.9 million and additional paid in capital by $3.4 million. Upon adoption of SFAS 123(R), the fair value of these Eyetech awards is being recognized as compensation expense over the remaining vesting period of such restricted stock and options.

Total net stock-based compensation expense is attributable to the granting of, and the remaining requisite service periods of, stock options and restricted stock. Compensation expense attributable to net stock-based compensation for the year ended December 31, 2006 was $22.4 million (net of tax), or $.39 per share, for both basic and diluted earnings per share. At December 31, 2006, the total remaining unrecognized compensation cost related to unvested stock-based payment awards was $47.5 million. This cost is expected to be recognized over a weighted average period of approximately 3.8 years.

During the years ended December 31, 2005 and September 30, 2004 and the three months ended December 31, 2004, we recorded compensation expense for stock options based upon their intrinsic value on the date of grant pursuant to APB Opinion No. 25. 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, the three months ended December 31, 2004 and the year ended September 31, 2004 been determined in accordance with

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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	Three Months Ended December 31, 2004	Year Ended September 30, 2004
Net loss	$(157,123)	$(48,395)	$(260,371)
Add: stock-based compensation included in net loss	3,406	679	723
Compensation cost determined under fair value method	(61,714)	(7,395)	(25,854)
Pro forma net loss	$(215,431)	$(55,111)	$(285,502)
Basic and diluted net loss per common share:			
Net loss — as reported	$ (3.02)	$ (1.02)	$ (6.50)
Net loss — pro forma	$ (4.14)	$ (1.16)	$ (7.12)

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. We amortize the fair value of all awards on a straight-line basis over the total requisite service period.

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 during the year ended December 31, 2006. 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 value 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,		Three Months Ended December 31,	Year Ended September 30,
	2006	2005	2004	2004
Expected dividend yield	0%	0%	0%	0%
Expected volatility	54.53%	60.95%	80.16%	78.91%
Risk-free interest rate	4.53%	4.23%	3.22%	2.97%
Expected term (years)	4.51	4.49	3.00	3.00
Weighted average fair value of stock options grants	16.21	17.26	29.95	32.25

A summary of our stock option programs as of December 31, 2006 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 September 30, 2003	5,292	$28.01		
Granted at fair value	1,206	$61.40		
Exercised at fair value	1,489	$26.21		
Forfeitures	121	$36.97		
Outstanding at September 30, 2004	4,888	$36.61		
Granted at fair value	32	$55.06		
Exercised at fair value	454	$25.60		
Forfeitures	220	$49.68		
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	$35.6	5.96
Exercisable at December 31, 2006	4,660	$38.76	$21.7	5.80
Unvested at December 31, 2006	2,067	$29.81	$13.9	6.33

(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.

Information regarding stock options outstanding as of December 31, 2006 is as follows:

	Options Outstanding			Options Exercisable	
Price Range	Shares (In Thousands)	Weighted Average Exercise Price	Weighted Average Contractual Life	Shares (In Thousands)	Weighted Average Exercise Price
$ 0.00 - $ 9.77	177	$ 5.85	2.01	167	$ 5.78
$ 9.77 - $19.53	232	$16.03	5.54	232	$16.03
$19.53 - $29.30	1,970	$23.71	5.49	850	$23.04
$29.30 - $39.06	2,524	$35.17	6.25	1,686	$35.34
$39.06 - $48.83	810	$45.62	6.44	736	$45.51
$48.83 - $58.60	234	$52.84	5.09	234	$52.84
$58.60 - $68.36	720	$66.37	7.02	702	$66.33
$68.36 - $78.13	5	$72.30	8.01	5	$72.30
$78.13 - $87.89	55	$82.84	7.42	48	$82.83
	6,727	$36.02	5.96	4,660	$38.76

The total intrinsic value of stock options exercised during the years ended December 31, 2006 and 2005, the three months ended December 31, 2004 and the year ended September 30, 2004 was $6.1 million, $12.3 million, $17.6 million and $62.5 million, respectively.

In connection with the Company's adoption of SFAS No. 123(R), the Company uses the ''with-and-without'' approach described in EITF Topic No. D-32, Intraperiod Tax Allocation of the Tax Effect of Pretax Income from Continuing Operations to determine the recognition and measurement of excess tax benefits, accordingly, due to the Company's current tax loss no income tax benefit has been recognized with regard to excess tax benefits realized during the year ended December 31, 2006.

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, 2006, the historical forfeiture rate was 16.9% 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) in fiscal 2006.

Restricted Stock

We issued 191,250 shares of restricted common stock during the year ended December 31, 2006. These restricted shares vest annually over a two or four year period depending on the award and are valued at the stock price on date of grant and are subject to certain additional terms and conditions. As of December 31, 2006, 190,950 shares of our restricted stock remain outstanding representing $4.5 million of total remaining unrecognized compensation expense. We also assumed 339,439 shares of Eyetech restricted stock in connection with the acquisition of Eyetech. Pursuant to the terms of the merger agreement, each restricted share 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, 2006, 4,947 shares of our common stock and $604,000 in cash remained subject to these restricted shares, representing $730,000 of total remaining unrecognized compensation expense.

The following is a summary of the status of our restricted stock (excluding the restricted shares assumed in the Eyetech merger) as of December 31, 2006 and activity during the fiscal year then ended:

	No. Shares (In thousands)	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2005	16	$37.88
Granted at fair value	191	$30.79
Vested at fair value	4	$40.22
Forfeited	12	$31.29
Non-vested at December 31, 2006	191	$31.15

Restricted Stock Units

We issued 432,049 shares of restricted stock units to employees and directors during the year ended December 31, 2006. These restricted stock units vest annually over a four-year period, are valued at the stock price on date of grant, and are subject to the continued employment of the employee or status as a director. These awards are also subject to the provisions of the agreement under which the restricted stock units are granted. As of December 31, 2006, 432,049 of restricted stock units were outstanding representing $13.5 million of total remaining unrecognized compensation expense.

The following is a summary of the status of our restricted stock units as of December 31, 2006 and activity during the fiscal year then ended:

	No. Shares (In thousands)	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2005	0	$ —
Granted at fair value	432	$37.70
Vested at fair value	0	$ —
Forfeited	0	$ —
Outstanding at December 31, 2006	432	$37.70

(b) 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, at an exercise price of $500.00, one one-thousandth of a share of Series SRPA Junior Participating Preferred Stock upon the occurrence of specified triggering events, including the commencement of a tender offer or exchange offer for our common stock by a person or group or the acquisition of 17.5% or more of our outstanding common stock by a person or group.

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 become rights to purchase at the exercise price of $500.00 such number of shares of common stock (instead of rights to purchase preferred stock) as have a market value equal to double such exercise price. Furthermore, such rightholders will have the further right to purchase shares of our 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 triggering event occurs, with certain exceptions. The rights will expire on August 31, 2010 if not redeemed prior to such date.

(c) 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.

(d) 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 year ended December 31, 2006 and 2005, the quarter ended December 31, 2004, and the fiscal year ended September 30, 2004, approximately 38,000, 22,000, 3,000 and 16,000 shares, respectively, were issued with approximately 214, 161, 148, and 136 employees participating in the plan, respectively. At December 31, 2006, we had 322,090 shares of our authorized common stock available for future grant in connection with this plan.

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 (see Note 17(b)), 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 in

2005 and continued to offer the plan in 2006. 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 53 employees, 22 employees and six employees that participated in the plan during fiscal years 2006, 2005 and 2003, respectively. At December 31, 2006, we had 80,116 shares of our common stock available for future grant in connection with this plan.

(e) 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 (see Note 2(a)).

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 (see Note 2(c)).

On June 12, 2003, in connection with the acquisition of Cell Pathways, we issued approximately 2.2 million shares of our common stock valued at $31.2 million (see Note 2(d)).

(f) Public Offering

On November 12, 2004, during the transition quarter, we concluded a public offering of 6.0 million shares of our common stock at a price of $64.50 per share. Gross proceeds totaled $387.0 million with net proceeds of approximately $365.0 million after all related fees. In addition, on November 17, 2004, underwriters associated with the offering exercised their over-allotment option to purchase an additional 900,000 shares of our common stock at a price of $64.50 per share. Gross proceeds from the exercise of the over-allotment option totaled $58.1 million with net proceeds of approximately $54.9 million.

(g) Contingent Value Rights — 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 of these two clinical candidates and have entered into a letter of intent to outlicense these candidates. We have 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 have reversed the $22.0 million liability and recorded an extraordinary gain during the quarter ended June 30, 2006.

(12) Income Taxes

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

The tax effect of temporary differences, net operating loss carry forwards and research and development tax credit carry forwards as of December 31, 2006 and 2005 are as follows (in thousands):

	December 31, 2006	December 31, 2005
Deferred tax assets:		
Net operating loss carry forwards	$ 451,248	$ 415,413
Research and development tax credit carry forwards	29,422	26,093
Intangible assets	10,379	11,092
Unearned revenue	33,135	20,822
Purchased research and experimental expenditures	48,880	53,444
Capitalized research and experimental expenditures	9,467	11,742
Capitalized start-up costs	123	3,072
Other	26,820	17,428
	609,474	559,106
Valuation allowance	(607,961)	(453,937)
	1,513	105,169
Deferred tax liability:		
Other	(419)	(1,186)
Inventory fair value adjustment	(1,094)	(20,345)
Macugen intangible	—	(83,638)
	(1,513)	(105,169)
	$ —	$ —

As of December 31, 2006, we had available U.S. federal and foreign net operating loss carry forwards of approximately $1,093 million and $129 million, respectively, which will expire in various years from 2007 to 2025 and may be subject to certain annual limitations. Our research and development tax credit carry forwards expire in various years from 2007 to 2025. 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. The increase in the valuation allowance of $154 million in 2006 was primarily attributable to the impairment of Macugen intangibles and charges related to Macugen inventory.

Of the $608 million valuation allowance at December 31, 2006, $52 million relates to deductions for employee stock options for which the tax benefit will be credited to additional paid in capital if realized.

(13) Commitments and Contingencies

(a) Lease Commitments

We lease office, operating and laboratory space under various lease agreements. Rent expense was $10 million and $9.1 million for the years ended December 31, 2006 and 2005, $1.7 million for the three months ended December 31, 2004, and $8.8 million for the year ended September 30, 2004, respectively. Rent expense for fiscal 2006 includes the Oxford, England facility leases, Boulder, CO facility leases, the Farmingdale, NY facility lease, the Melville, NY facility lease, the Uniondale, NY facility lease, the Horsham, PA facility lease and the Eyetech facility leases acquired in November 2005. As further discussed in Note 17, we accrued for the remaining net lease rental payments for the Horsham, PA facility in fiscal 2004, and the remaining net lease rental payments for a portion of the Oxford, England facility in fiscal 2005. In addition, future lease costs for certain Eyetech facilities (Lexington and

a portion of the New York City facility) which were part of our exit plan were included in the determination of the purchase price of Eyetech. In December 2006, we exited the remaining portion of the New York City facility and recognized a charge for the expected net future lease payments.

The following is a schedule of future minimum rental payments for the next five fiscal years and thereafter required as of December 31, 2006, exclusive of sub-rental income from subleased facilities. Also included in the amounts below are commitments for equipment under various operating leases (in thousands).

2007	$ 11,248
2008	10,424
2009	9,672
2010	9,216
2011	9,338
2012 and thereafter	70,306
	$120,204

Rental obligations and deferred rent in the accompanying consolidated balance sheet reflects the SFAS No. 13 ''Accounting for Leases'' expense recorded 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 $4.1 million for rental obligations assumed in connection with the Eyetech acquisition. In connection with the Eyetech merger we recognized liabilities for certain leased facilities based upon the present value of the remaining lease payments, after exiting the facilities, offset by the estimated sublease rental income.

(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, 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) Borrowings

As of December 31, 2006, we had a line of credit with a commercial bank in the amount of $10 million. This line expires on March 31, 2007. There were no amounts outstanding under the line of credit as of December 31, 2006 and 2005.

(d) 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 us, 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 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 common stock during the period from April 26, 2004 through November 22, 2004. The consolidated complaint alleges that defendants made material misstatements and omissions concerning the survival benefit associated with our 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. We have requested an oral argument on our motion and are awaiting a decision from the court. Based on the early stage of this litigation, the ultimate outcome cannot be determined and accordingly, no provision has been recorded in the consolidated financial statements.

(14) 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, 2006 and 2005, the three months ended December 31, 2004 and the fiscal year ended September 30, 2004 were approximately $115,000 $299,000, $152,000, and $557,000 respectively. In addition, we have compensated other directors for services performed pursuant to consultant arrangements as follows: during the years ended December 31, 2006 and 2005, the three months ended December 31, 2004 and the fiscal year ended September 30, 2004, consulting fees in the amounts of $75,000, $154,000, $15,000, and $139,000, respectively, were paid by us pursuant to these arrangements. One member of our Board of Directors was an officer of Cold Spring Harbor Laboratory through December 2003. In fiscal 2003, we entered into a research agreement with Cold Spring Harbor Laboratory. A director is on the faculty of Vanderbilt University with which we had a collaborative research agreement through July 31, 2005, and also has a consulting agreement with our subsidiary, Prosidion. In 2006, a director who is now retired was an advisor to Roche, with which we have a collaboration agreement.

In connection with the acquisition of certain assets from Gilead on December 21, 2001, we assumed the loans of one of our officers and one of our vice presidents with an aggregate loan balance of $200,000. As of December 31, 2005, the loan balances were satisfied.

(15) 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. For each dollar an employee invests up to 6% of his or her earnings, we will contribute an additional 50 cents into the funds. Effective January 1, 2007, we will 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. During the twelve months ended

December 31, 2006 and 2005, the three months ended December 31, 2004 and the year ended September 30, 2004, our expenses related to the plan were approximately $1.4 million, $848,000, $168,000 and $625,000, respectively.

We also sponsor two 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 Biotech Pension Scheme covers employees retained from the acquisition of certain assets from British Biotech, as well as certain former employees of British Biotech 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, 2006 and 2005, the three months ended December 31, 2004, and the year ended September 30, 2004, respectively, our expenses related to the plans were $673,000, $560,000, $218,000 and $841,000, respectively.

(16) Employee Post-retirement Plan

We provide post-retirement medical and life insurance benefits to eligible employees, board members and qualified dependents. Eligibility is determined based on age and service requirements. These benefits are subject to deductibles, co-payment provisions 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,'' 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. In May 2004, the FASB issued FASB Staff Position, or FSP, No. FAS 106-2, ''Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003.'' FSP No. FAS 106-2 provides guidance on the accounting for the effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, or the Modernization Act, for employers that sponsor post-retirement health care plans that provide prescription drug benefits and requires those employers to provide certain disclosures regarding the effect of the federal subsidy provided by the Modernization Act. The accumulated post-retirement benefits obligation or net post-retirement benefits cost in the consolidated financial statements accompanying notes reflect the effects of the Modernization Act on our post-retirement benefit plan.

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 postretirement benefit obligation for other post-retirement plans).

Prior to the adoption of SFAS No. 158, accounting rules allowed for the delayed recognition of certain actuarial gains and losses caused by differences between actual and assumed outcomes, as well as charges or credits caused by plan changes impacting the benefit obligations which were attributed to participants' prior service. These unrecognized net actuarial gains or losses and unrecognized prior service costs or credits represented the difference between the plans' funded status and the amount recognized on the consolidated balance sheet. In accor-

dance with SFAS No. 158, we recorded an adjustment to accumulated other comprehensive loss of $1.3 million to recognize the funded status of our post-retirement benefit plan on our consolidated balance sheet. This adjustment represents the previously unrecognized net actuarial losses and unrecognized transition obligation. The effect of adopting SFAS No. 158 resulted in a $1.3 million increase of our post-retirement benefit obligation from $6.7 million to $8.1 million.

The adjustments recorded to accumulated other comprehensive loss liabilities will be recognized as components of post-retirement benefit cost and amortized over future periods in accordance with SFAS No. 106 in the same manner as prior to the adoption of SFAS No. 158. Actuarial gains and losses that arise in subsequent periods and are not recognized as other post-retirement benefit expense in the same period will now be recognized in other comprehensive income (loss). These amounts will be recognized subsequently as a component of post-retirement benefit cost following the same basis as the amounts recognized in accumulated other comprehensive loss upon adoption of SFAS No. 158.

The changes in the accumulated post-retirement benefit obligation during the year ended December 31, 2006 and 2005 were as follows (in thousands):

	Year Ended December 31, 2006	Year Ended December 31, 2005
Balance at beginning of year	$7,509	$6,186
Benefit payments	(134)	(111)
Loss experience	(768)	243
Service cost	1,054	839
Interest cost	409	352
Balance at end of year	$8,070	$7,509

The accrued accrued liability for post-retirement benefit cost at December 31, 2006 and 2005 consists of the following (in thousands):

	2006	2005
Accumulated post-retirement benefit obligation (accrued liability as of December 31, 2006)	$8,070	$7,509
Less: Unrecognized cumulative net loss		2,071
Less: Unrecognized transition obligation		85
Accrued post-retirement benefit costs as of December 31, 2005		$5,353

Net post-retirement benefit cost for the years ended December 31, 2006 and 2005, the three months ended December 31, 2004, and the year ended September 30, 2004, includes the following components (in thousands):

	Year Ended December 31, 2006	Year Ended December 31, 2005	Three Months Ended December 31, 2004	Year Ended September 30, 2004
Service cost for benefits earned during the period	$1,054	$ 839	$201	$572
Interest cost on accumulated post-retirement benefit obligation	409	352	82	262
Amortization of initial benefits attributed to past service	6	6	1	6
Amortization of loss	66	64	15	39
Net post-retirement benefit cost	$1,535	$1,261	$299	$879

For the year ended December 31, 2006, the health care cost trend decreased to an initial level of 10% (from an initial level of 11% in fiscal 2005), 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, 2006 by $2.0 million and the fiscal 2006 net post-retirement service and interest cost by $487,000. 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, 2006 by $1.5 million and the fiscal 2006 net post-retirement service and interest cost by $359,000. Benefits paid the year ended December 31, 2006 and 2005, the three months ended December 31, 2004, and the year ended September 30, 2004, respectively, were $134,000, $111,000, $21,000, and $83,000, respectively.

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

	2006	2005	2004
Discount rate	5.75%	5.5%	5.75%
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, 2006.

For the year ending December 31, 2007, we anticipate recognizing $6,000 and $22,000 of transition obligation and amortization of actuarial loss included in accumulated other comprehensive income in the December 31, 2006 Consolidated Balance Sheet. For the years ending 2007 through 2011, we anticipate paying benefits of $118,000, $129,000, $141,000, $153,000, and $162,000, respectively. We anticipate benefits of $932,000 for the years of 2012 through 2016. The estimated contributions expected to be paid to the plan are $118,000 for the 2007 fiscal year.

(17) Consolidation of Facilities

(a) Restructuring Plan

On November 6, 2006, we announced our intention to exit our eye disease business which consists principally of Macugen, our marketed product for the treatment of wet AMD. In connection with this decision, we committed

to a plan to re-scale the eye disease business and other OSI operations consistent with the streamlining of our overall business. The plan includes consolidation of facilities as well as a reduction in the workforce and is expected to cost between $11 million and $14 million. We recognized $5.7 million of this cost in the fourth quarter of 2006. Included in this charge is $3.2 million for severance payments, $1.7 million related to long term assets and their utilization and $1.2 million for lease obligations offset by previously accrued rent expense of $400,000. Of these costs, $2.2 million is included in R&D costs and $3.5 million is included in selling and administrative expenses. The remaining charges are expected to be incurred in the first and second quarters of 2007. The activity for the year ended December 31, 2006 was as follows (in thousands):

	Year Ended December 31, 2006
Opening liability	$ —
Accrual for severance, relocation and retention bonus	3,228
Accrual for rental obligations	1,255
Ending liability	$4,483

(b) Corporate Headquarters

During the first quarter of 2006, we relocated our corporate headquarters to our current facility in Melville, New York. As a result, in accordance with SFAS No. 146 ''Accounting for Costs Associated with Exit or Disposal Activities,'' or SFAS No. 146, during the first quarter of 2006, we recognized a liability of $2.7 million and net expense of $2.3 million for the exit cost associated with the termination of the lease for the old facility. During the second quarter of 2006, we recognized additional expense of $240,000 in connection with final lease settlement. The total recognized net expense of $2.6 million is comprised of the net lease obligations of $3.0 million, offset by previously accrued rent expense of $369,000. The activity for the year ended December 31, 2006 was as follows (in thousands):

	Year Ended December 31, 2006
Opening liability	$ —
Accrual for rental payments	2,974
Accretion expense	147
Cash paid for rent and other	(1,197)
Ending liability	$1,924

(c) Eyetech Integration

In connection with the acquisition of Eyetech on November 14, 2005, we implemented a plan to consolidate certain facilities and reduce the workforce. Included in the liabilities assumed in the acquisition, we recognized $6.2 million for the termination benefits and relocation cost of employees and $5.4 million for the present value of future lease commitments. The present value of the lease payments was determined based upon the date we plan to exit the facility and the remaining lease expiration, offset by estimated sublease income. Rental payments for the facilities prior to closure will be included in operating expense. Additional planned terminations occurred throughout 2006 for transition employees. In accordance with SFAS No. 146, these payments were deemed to represent retention bonuses associated with future service. For the year ended December 31, 2006, we recognized an additional $5.0 million of retention bonus costs. Of these costs, $3.2 million was included in R&D costs and

$1.8 million was included in selling and administrative expenses. The activity for the years ended December 31, 2006 and 2005 was as follows (in thousands):

	Year Ended December 31,	
	2006	2005
Opening liability	$10,261	$ —
Accrual for severance, relocation and retention bonus	4,998	7,147
Accrual for rental obligations	—	5,391
Accretion expense	329	—
Cash paid for severance	(7,790)	(2,277)
Cash paid for rent	(2,509)	—
Reversals related to severance (adjustment to goodwill)	(1,379)	—
Reversals related to lease accruals	(1,157)	—
Ending liability	$ 2,753	$10,261

(d) Oxford, England

During the fourth quarter of fiscal 2004, we consolidated all of our U.K.-based oncology R&D 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 year ended December 31, 2006 and 2005 was as follows (in thousands):

	Year Ended December 31,	
	2006	2005
Opening liability	$4,211	$ 1,380
Provision for rental adjustments	—	2,027
Provision for facility refurbishment	—	2,359
Cash paid for severance	—	(1,286)
Cash paid for rent	(701)	—
Other	552	(269)
Ending liability	$4,062	$ 4,211

(e) Horsham, Pennsylvania

During the second quarter of fiscal 2004, we committed to and approved an exit plan for our Horsham, PA facility, which we acquired in connection with our acquisition of Cell Pathways in June 2003. We have recognized the rent obligations for the remainder of the lease (through June 2008), offset by the sublease rental income. These exit costs are comprised of the net lease obligations of $2.1 million, offset by previously accrued rent expense of $338,000. In May 2004, we entered into a sublease agreement for the Horsham facility. We charge the rental

payments less the sublease rental income received against the accrued liability. The activity for the year ended December 31, 2006 and 2005 was as follows (in thousands):

	Year Ended December 31,	
	2006	2005
Opening liability	$1,160	$1,678
Cash paid for rent less sublease income received	(465)	(518)
Ending liability	$ 695	$1,160

(18) Subsequent Event

In January 2007, we outlicensed our GKA program, including our clinical candidate PSN010, which is in Phase I studies, to Eli Lilly for an upfront fee of $25 million and up to $360 million in potential development and sales milestones and other payments plus royalties on any compounds successfully commercialized from this program.

(19) 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 measures 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,'' or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. The provisions of SFAS No. 157 are effective for our fiscal year ending December 31, 2008. We are currently evaluating the impact of the provisions of SFAS No. 157.

In June 2006, FASB issued Interpretation No. 48, ''Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109.'' This Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. This Interpretation is effective for our fiscal year ending December 31, 2007. We do not expect the adoption to have a material impact on our consolidated financial statements.

In February 2006, the FASB issued SFAS No. 155, which is an amendment of FASB SFAS Nos. 133 and 140. This Statement (a) permits fair value re-measurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, (b) clarifies which interest-only strip and principal-only strip are not subject to the requirements of SFAS No. 133, (c) establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, (d) clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives, and (e) amends SFAS No. 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. This Statement is effective for financial statements for our fiscal year ending December 31, 2007. We are currently evaluating the effect that this statement will have on our consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(20) Quarterly Financial Data (unaudited)

The tables below summarize our unaudited quarterly operating results for the years ended December 31, 2006 and 2005.

	Three Months Ended (In thousands, except per share data)			
	March 31, 2006	June 30, 2006	September 30, 2006	December 31, 2006
Revenues	$116,442	$ 101,975	$ 73,993	$ 83,286
Net loss	$ (17,855)	$(319,929)	$(21,257)	$(223,143)
Basic and diluted net loss per weighted average share of common stock outstanding	$ (0.31)	$ (5.62)	$ (0.37)	$ (3.91)

	Three Months Ended (In thousands, except per share data)			
	March 31, 2005	June 30, 2005	September 30, 2005	December 31, 2005
Revenues	$ 19,067	$ 34,629	$ 33,988	$ 86,510
Net loss	$(32,504)	$(24,538)	$(20,037)	$(80,043)
Basic and diluted net loss per weighted average share of common stock outstanding	$ (0.64)	$ (0.48)	$ (0.39)	$ (1.47)

The basic and diluted net loss per common share calculation for each of the quarters are based on the weighted average number of shares outstanding in each period. Therefore, the sum of the quarters in a fiscal year does not necessarily equal the basic and diluted net 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 effective 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, 2006, our internal control over financial reporting was effective.

KPMG LLP, the independent registered public accounting firm that audits our consolidated financial statements, has issued its attestation report on management's assessment of internal control over financial reporting. This attestation report appears below.

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 2006 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 Stockholders and Board of Directors
OSI Pharmaceuticals, Inc.:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that OSI Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). OSI Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and 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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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, management's assessment that OSI Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, OSI Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

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. as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2006, for the three months ended December 31, 2004 and for the year ended September 30, 2004, and our report dated February 28, 2007 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Melville, New York
February 28, 2007

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, 2007

/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, 2007

/s/ MICHAEL G. ATIEH

Michael G. Atieh
Executive Vice President and Chief
Financial Officer

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, 2006 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, 2007

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, 2006 as filed with the Securities and Exchange Commission on the date hereof (the ''Report''), I, Michael G. Atieh, Executive Vice President and Chief Financial 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.

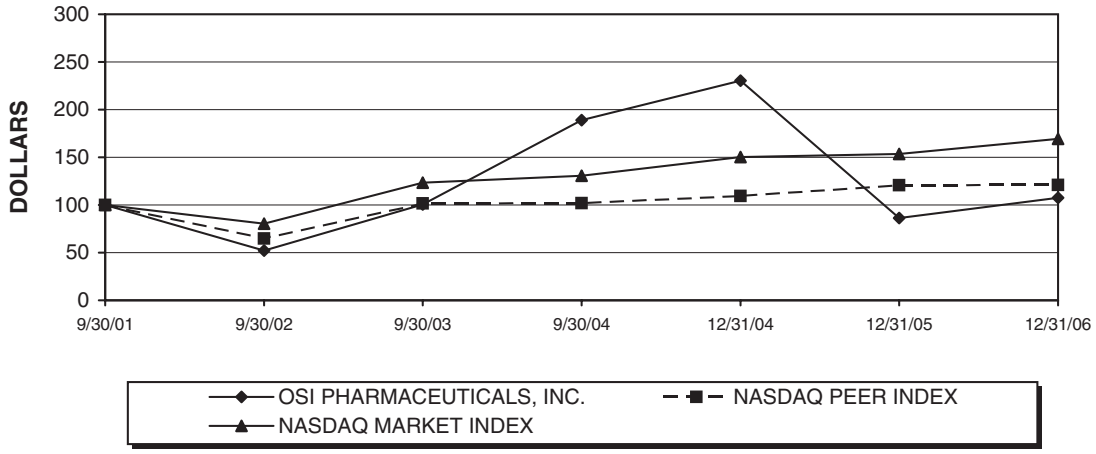
/s/ MICHAEL G. ATIEH

Michael G. Atieh
Executive Vice President and Chief
Financial Officer

Date: February 28, 2007

STOCK PRICE PERFORMANCE GRAPHS

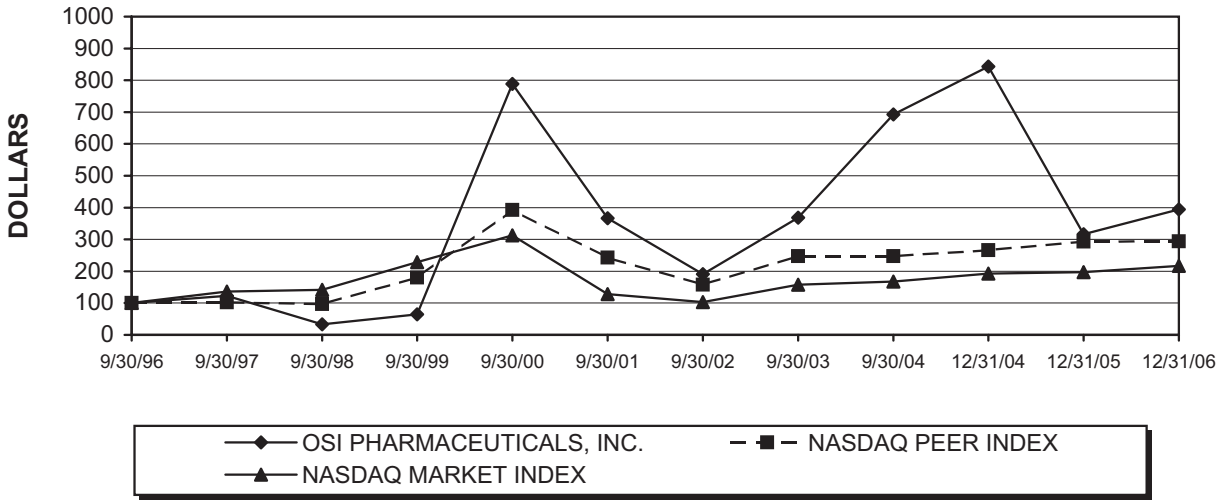
The following graph presents the cumulative return of our common stock with the cumulative total return of the Nasdaq Pharmaceutical Index (''Nasdaq Peer Index'') and the Nasdaq Global Select Market Index (''Nasdaq Market Index'') over a five-year period and three-month transition period due to the change in our fiscal year end from September 30 to December 31, based on an assumed investment of $100 on October 1, 2001, in each case assuming reinvestment of all dividends.



Company/Index/Market	As of						
	9/30/01	**9/30/02**	**9/30/03**	**9/30/04**	**12/31/04**	**12/31/05**	**12/31/06**
OSI PHARMACEUTICALS, INC	$100.00	52.22	100.46	189.11	230.31	86.28	107.63
NASDAQ PEER INDEX.....	100.00	64.85	101.63	101.85	109.34	120.58	120.93
NASDAQ MARKET INDEX	100.00	80.46	123.30	130.73	150.29	153.59	169.35

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 Peer Index and the Nasdaq Market Index over a 10-year and three-month transition period 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, 1996, in each case assuming reinvestment of all dividends.



Company/Index/Market	As of											
	9/30/96	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
OSI PHARMACEUTICALS, INC.	$100.00	122.54	32.75	64.08	788.73	366.20	191.21	367.89	692.51	843.38	315.94	394.14
NASDAQ PEER INDEX	100.00	102.36	96.69	179.76	392.37	243.13	157.68	247.11	247.64	265.85	293.17	294.02
NASDAQ MARKET INDEX	100.00	135.92	141.25	228.51	312.59	128.07	103.04	157.92	167.43	192.47	196.70	216.89

Board of Directors

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

Colin Goddard, Ph.D.
Chief Executive Officer

G. Morgan Browne
Former Chief Financial Officer and
Administrative Director
Cold Spring Harbor Laboratory

Santo J. Costa
Of Counsel, William Mullen Maupin
Taylor, P.A.

Daryl K. Granner, M.D.
Joe C. Davis Professor of Biomedical
Sciences; Professor, Molecular
Physiology and Biophysics
Vanderbilt University Medical Center

Joseph Klein, III
Managing Director
Gauss Capital Advisors, LLC

Walter M. Lovenberg, Ph.D.
President of Lovenberg Associates, Inc.
Former Executive Vice President
Marion Merrell Dow Inc.

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

Katharine B. Stevenson
Treasurer, Nortel Networks, Inc.

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

Paul G. Chaney
Executive Vice President and
President of OSI Eyetech

Neil Gibson, Ph.D.
Vice President,
Chief Scientific Officer

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,
Chemistry, Development &
Manufacturing

Barbara A. Wood, Esq.
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 Hanover Avenue
Cedar Knolls, NJ 07927

Transfer Agent & Registrar
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(800) 524-4458
http://stock.bankofny.com

Corporate Counsel
Saul Ewing LLP
Centre Square West
1500 Market Street
Philadelphia, PA 19102

General Counsel
Mintz, Levin
666 Third Avenue
New York, NY 10017

Patent Counsel
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 13, 2007 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 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.
41 Pinelawn Road
Melville, NY 11747
(631) 962-2000
www.osip.com

Stock Listing
Nasdaq: OSIP

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