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[To Our Shareholders]

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In 2008, OSI Achieved Sustained Profitability

Tarceva Worldwide Sales	\$1.12 billion
Total Revenues	\$379 million
Pre-Tax Income from Continuing Operations	\$133 million
Net Income from Continuing Operations	\$467 million
Ending 2008 Cash	\$516 million

In order to provide additional, meaningful comparisons for our 2008 results, we provided the following adjusted, or non-GAAP, financial measures during our 2008 year-end earnings call:

In millions, except per share amounts

	<u>Net Income</u> <u>from</u> <u>continuing</u> <u>operations</u>	<u>Fully</u> <u>Diluted</u> <u>EPS</u>
2008 GAAP Results	\$467	\$7.34
<u>2008 Non-GAAP Adjustments</u>		
Valuation Allowance Gain	(\$337)	(\$5.20)
2008 Non-GAAP Results	\$130	\$2.14
<u>2008 Non-GAAP Pro Forma Adjustments</u>		
Retrospective Impact of APB 14-1	(\$13)	(\$0.12)
Imposition of 2009 Statutory Tax Rate	(\$44)	(\$0.78)
2008 Non-GAAP Pro Forma	\$73	\$1.24

Weighted Average Diluted Shares Outstanding

2008 GAAP Results	66.9
2008 Non-GAAP¹	64.3
2008 Pro Forma¹	60.4

¹The decrease in weighted shares outstanding is due to lower adjusted net income.

Use of Non-GAAP Financial Measures

The table above presents both generally accepted accounting principles (GAAP) and non-GAAP financial measures for the year ended December 31, 2008. The non-GAAP financial measures include adjusted net income from continuing operations and adjusted earnings per share from continuing operations, each of which has a GAAP equivalent. We have provided these non-GAAP financial measures to adjust for the impact of a \$337 million non-cash gain in the fourth quarter of 2008 related primarily to our expected utilization of net operating loss carryforwards. These non-GAAP financial measures also include certain proforma adjustments, which assume that the following items were in effect for the fiscal year ended December 31, 2008: (i) the adoption of FASB Staff Position APB 14-1 which required us to recognize additional non-cash interest expense related to our convertible debt instruments beginning in 2009; and (ii) the increase in our income tax expense to a 40% effective rate, even though we expect to continue to pay cash taxes at 2% to 4% alternative minimum tax rates. We believe that the non-GAAP financial measures included above provide investors with (i) financial measures that we use in the management of our business, and (ii) additional, meaningful comparisons of current results to prior periods' results by excluding the impact of significant non-cash items that we do not believe reflect our fundamental business performance. These non-GAAP measures should not be considered in isolation of, or as an alternative to, measurements required by GAAP.

To Our Shareholders

2008 was another year of real scientific progress and strong financial performance for our company. In November, Tarceva® crossed the \$1 billion annual sales mark – achieving this universally recognized metric for a “Blockbuster” medicine within four years of launch – and finished the year with annual global sales of \$1.12 billion, up 27% on 2007 sales. OSI corporate revenues of \$379 million fueled adjusted net income from continuing operations of \$130 million (up 26% from the prior year) and adjusted earnings per share from continuing operations of \$2.14, up from \$1.70 in 2007 (see accompanying chart on preceding page for reconciliation of all adjusted measures). Balance sheet “cash and short-term investments” ended 2008 at approximately \$516 million and have been conservatively managed throughout the ongoing financial crisis in the global economy. We have continued to manage our cost base judiciously and the emergence of significant DP-IV patent estate revenues – which contributed over 10% of 2008 revenues – has added important diversity to our revenue line. We expect this to be a major contributor to our revenue growth rate going forward as this class of diabetes drugs continues to expand in use.

We strive for an effective balance between financial performance and

the ability to re-invest in our mission of developing innovative and differentiated new medicines that deliver meaningful strides forward in the treatment of cancer and diabetes/obesity for patients around the world. In 2008, we invested approximately \$139 million in a research and development program that:

- (i) Yielded a major Phase III success for Tarceva in the SATURN trial (potentially allowing the expansion of its use to earlier stage lung cancer patients – a position reinforced by the subsequent success of the ATLAS trial in early 2009);
- (ii) Saw the continued expansion of our R&D efforts to explore Tarceva use beyond its core indications in second-/third-line non-small cell lung cancer (NSCLC) and first-line pancreatic cancer;
- (iii) Included the advancement of all four of our primary development candidates (OSI-906, OSI-027, PSN821 & PSN602) in clinical trials (creating a *bona fide* clinical pipeline of wholly owned assets arising from our internal *de novo* drug discovery research); and
- (iv) Continued to establish our research groups as recognized leaders in the areas of epithelial-to-mesenchymal transition (EMT) biology in cancer and in the

neuroendocrine control of body weight and glycemia in the diabetes/obesity arena.

None-the-less, all this progress has occurred against the back-drop of an unprecedented global economic downturn precipitated by the banking crisis at the end of 2008. Even within this bleak overall environment, the pharmaceutical and biotechnology industries are widely perceived to be in their own acute form of turmoil. The specter of uncertainty surrounding U.S. healthcare reform (and associated pricing and reimbursement pressures); widespread pending patent expirations and poor R&D productivity in the pharmaceutical sector; a financing crisis in the biotechnology sector (which could see widespread bankruptcies for the first time in the industry’s history); increasing and profligate generic industry challenge to essentially all valuable innovator intellectual property; and intense competition in new product development, has led to widespread pessimism and anxiety amongst industry analysts and commentators alike.

And yet, despite the fact that many of these macro developments impact our business to varying degrees, we enter 2009 with a sense of growing confidence in an organization that is anchored around a proven and



We strive for an effective balance between financial performance and the ability to re-invest in our mission of developing innovative and differentiated new medicines that deliver meaningful strides forward in the treatment of cancer and diabetes/obesity.

entrenched principal asset in Tarceva; possesses a high quality emerging clinical and pre-clinical pipeline; and has a solid financial strength that remains a rarity in the biotechnology sector – providing the company with appreciable strategic flexibility at a time when many biotech companies are in survival mode. The following commentary summarizes our progress as a business in 2008 and into the early part of 2009:

TARCEVA

Tarceva is commercialized in collaboration with Roche. We receive a 50% profit share on U.S. sales of Tarceva and a 21% royalty on sales in the rest of the world. Tarceva's significant global growth in 2008 was driven primarily by ex-U.S. sales which increased by nearly \$200 million from \$470 million in 2007 to \$665 million in 2008. The first full year of sales in the Japanese market was an important part of this growth. In addition, Tarceva was endorsed in November by the UK's National Institute for Health and Clinical Excellence (NICE) as an alternative treatment to the intravenous chemotherapy agent docetaxel for the second-line treatment of advanced NSCLC. Lung cancer patients in England, Wales and Northern Ireland will now have access to an oral targeted therapy

that has been approved throughout Europe for advanced NSCLC. Tarceva has received regulatory approval in a total of 94 countries for NSCLC and 70 countries for pancreatic cancer.

The more modest growth seen in the U.S. market (2008 sales of \$457 million versus 2007 sales of \$417 million) represents a credible achievement in the face of the continuing reimbursement imbalance between older cytotoxic (and newer biological) anti-cancer drugs reimbursed under the Medicare Part B regulations and the new generation of oral anti-cancer medicines like Tarceva, Gleevec®, Sutent® and Nexavar® which are reimbursed under the newer Part D regulations. Patients receiving oral medicines have higher effective co-payments and co-insurance obligations to meet – despite the fact that these oral drugs are more convenient to the patient and are often substantially cheaper than the competing cytotoxic and biological agents that are administered at the doctor's office by intravenous injection or infusion. This co-payment and co-insurance imbalance presents an even greater challenge in tough economic times when patients and their families struggle to make ends meet. We are proud of our U.S. partner Genentech's 'Access Solutions' and 'Access to Care Foundation' programs. They are

among the best in the industry and seek to provide access to Tarceva patients who can't afford their medicine. However, despite the fact that market analysis throughout 2008 and into early 2009 has shown that Tarceva has held its own in market share (and even grown share in certain settings), sales have inevitably been impacted by the downturn as a greater number of patients who have been prescribed Tarceva are failing to have their prescriptions filled – most likely due to the patients' inability to afford the co-payments and co-insurance.

We were pleased to announce in November 2008 that the large, randomized, placebo-controlled Phase III study, SATURN, met its primary endpoints and showed Tarceva extended the time patients with advanced NSCLC lived without their cancer getting worse when Tarceva is given immediately following initial treatment with platinum-based chemotherapy (as defined by progression-free survival). We believe that Tarceva, as a once-a-day oral therapy, is well suited for first-line maintenance treatment for patients with advanced NSCLC. The data will be formally presented to the medical community at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in Orlando, May 29 – June 2, 2009. Overall survival was one of the sec-



In 2008 Tarceva global sales exceeded \$1 billion, achieving "Blockbuster" status within 4 years of launch.

Tarceva is approved in 94 countries for NSCLC and in 70 countries for pancreatic cancer.

ondary endpoints and we anticipate mature survival data in the second half of 2009.

In March 2009, our regulatory team submitted a supplemental New Drug Application (sNDA) for the use of Tarceva as a first-line maintenance therapy in the treatment of NSCLC patients. Simultaneously, Roche filed an application in Europe with the European Medicines Agency (EMA). Assuming acceptance of the U.S. filing, we would expect a PDUFA date in or about mid-January 2010 and, if Tarceva is successfully registered, we would anticipate approval and launch in the first quarter of 2010.

Clinical data supporting the use of Tarceva in the NSCLC maintenance setting was enhanced in early 2009 when our partner Roche announced that a Phase III study, ATLAS, conducted by their U.S. Genentech organization was stopped early on the recommendation of an independent data safety monitoring board. A pre-planned interim analysis showed that combining Tarceva and Avastin® significantly extended the time NSCLC patients lived without their cancer getting worse, as defined by progression-free survival, compared with Avastin plus placebo following initial treatment with platinum-based chemotherapy and Avastin. In both

these key SATURN and ATLAS studies preliminary safety analyses showed adverse events were consistent with previous Tarceva studies as well as trials evaluating Tarceva and Avastin together, and no new safety signals were observed.

Unfortunately, a third major Phase III trial, The BeTa-Lung study, in which Tarceva and Avastin were compared to Tarceva and placebo in second-line NSCLC patients failed to meet its primary endpoint of overall survival. The BeTa study was noteworthy in that this was the first prospective, randomized study in which Tarceva was dosed to only a second-line NSCLC patient population, and the data in the Tarceva-only arm (which had a median survival of 9.2 months) were consistent with the earlier second-line subset findings from the pivotal second-/third-line NSCLC study, BR.21.

On a more positive note, our clinical and regulatory teams were successful in executing a clinical program and regulatory process that resulted in an important label update on Tarceva dose modification in those NSCLC patients who continue to smoke. The Tarceva label now states that "Cigarette smoking has been shown to reduce erlotinib exposure" and that a "cautious increase in the dose

of Tarceva, not exceeding 300mg" can be considered by physicians treating lung cancer patients who continue to smoke. Although the efficacy and long-term safety of a higher dose has not been established in a prospective trial for patients who continue to smoke, the update provides physicians with important information as they consider treatment options for this group of patients.

We continue to invest in a substantial ongoing life cycle plan for Tarceva which seeks to expand Tarceva use to the adjuvant setting in NSCLC (through an OSI conducted Phase III study known as RADIANT which is expected to complete enrollment in 2010) and to new disease indications like ovarian cancer (where an EORTC front-line maintenance Phase III study is expected to read-out top-line data in 2010) and hepatocellular carcinoma (where a collaborative Phase III study with Bayer/Onyx investigating the use of Tarceva in combination with Nexavar is due to start imminently). In addition, we continue to expect data from the CALGB study in "never-smoker," first-line NSCLC patients in 2009.

TARCEVA INTELLECTUAL PROPERTY

Tarceva's success also means that it

Tarceva patient, Ann Dudurich, finishes a 30-mile fundraiser bike ride after being diagnosed with Stage IV lung cancer in January 2007. Ann shared her inspirational story battling lung cancer with OSI employees in February 2009.



has attracted the interest of a global generics industry that is employing increasingly aggressive tactics toward innovator intellectual property (IP) rights around the world. We believe that the trend toward the erosion of innovator IP protection will ultimately undermine our industry's willingness and ability to invest in the next generation of breakthrough therapies like Tarceva and we are, together with Roche, taking proactive steps to defend our global IP rights surrounding Tarceva. These include taking legal action against companies producing a generic version of Tarceva in India (in the face of our issued Indian patent) and seeking a reissue of one of three Orange Book listed patents in the U.S. We remain confident in our ability to protect the unique inventiveness of Tarceva through its composition of matter patent expiry in 2018 (in the U.S.) and 2020 (in the EU and Japan).

We fully anticipated that, like virtually all valuable innovative small molecule therapies today, we would receive notice of the filing of one or more Abbreviated New Drug Applications (ANDAs) by generic companies at the earliest opportunity allowed under the 1984 Hatch-Waxman law. Generic companies can file an ANDA on the fourth anniversary of a NDA approval if they claim, among other things,

that they do not infringe the innovator company's IP (a so-called paragraph IV filing). Both Teva and Mylan submitted ANDAs following the fourth anniversary of the U.S. Tarceva approval in November 2004 and – within the 45-day period – we filed suit against both organizations in early 2009. Under the regulations, this triggers a 30-month stay at the FDA and no action on these ANDAs is possible in that period while the litigation plays out. We are confident in our Tarceva IP position and fully committed to prevailing in these lawsuits.

LOOKING BEYOND TARCEVA: OSI'S PIPELINE

The primary opportunity for significant long-term value creation in the business resides in the progress of our development pipeline and in the validation and credibility attached to the underlying discovery and translational research platforms that support this pipeline. In this respect we have made significant progress throughout the year where we were able to achieve the milestone of getting all four of our key development candidates into clinical development. We now have ongoing clinical programs for both oncology candidates (OSI-906 – an insulin-like growth factor-1 receptor, or IGF-1R inhibitor; and OSI-027 – our TORC1/TORC2 inhibitor) and both

diabetes/obesity candidates (PSN821 – our GPR119 agonist; and PSN602 – our next generation sibutramine competitor compound). We have inculcated an acute focus on the need for discipline in our R&D investments and have set a high standard on the differentiation and novelty of the molecular targeted therapies that we advance into clinical development.

We have also made considerable progress in building a leadership position in epithelial-to-mesenchymal transition (EMT) biology, the key area of research underlying our efforts in oncology, and in establishing neuroendocrine control of body weight and glycemia as an analogous area of focus in the diabetes/obesity arena. In December, we were able to take advantage of the current economic downturn in acquiring an attractive G-protein coupled receptor technology platform from the Danish company 7TM, which has considerably enhanced our early discovery capabilities in the neuroendocrine control area.

OSI-906: A recent robust partial response in a 35 year old woman with advanced adrenocorticoid carcinoma (ACC), along with a minor response in a NSCLC patient and multiple demonstrations of long-term disease stabilization from the ongoing Phase I program, have provided



An important part of our mission is to improve upon the available treatment options for cancer patients. OSI is at the forefront of a paradigm-shifting movement toward molecular targeted, better tolerated and personalized therapies.

encouraging indications of activity for this agent which is potentially a first-in-class oral inhibitor of the extensively targeted IGF-1R signaling axis. We are pursuing multiple aspects of the tumor biology surrounding this target including the potential for "onco-addiction" arising from over-expression of the IGF2 ligand in ACC and ovarian cancer. Our translational research programs have also investigated the phenomenon of compensatory signaling – whereby inhibition of, for example, the EGFR signaling pathway leads a tumor cell to up-regulate another signaling pathway such as IGF-1R. We believe simultaneous inhibition of tumor cell signaling through the EGFR, IGF-1R and insulin receptor pathways may provide synergistic benefits in the treatment of cancer patients whose tumors rely on this biology. We are planning to immediately follow an on-going Phase I OSI-906/Tarceva combination trial with a Phase II/III program in NSCLC to explore this opportunity. This registrationally oriented Phase II/III program could begin as soon as early 2010, if our Phase I data support the safe combination of OSI-906 and Tarceva.

OSI-027: We are continuing enrollment in our OSI-027 program and are now entering our third tier of dosing for this agent that is designed to be a next-generation mTOR inhibitor.

PSN821 and PSN602: Our GPR119 agonist, PSN821, has the potential to be the first orally available molecule which delivers both glucose control and weight loss, while PSN602 is designed to give greater weight loss efficacy without causing the cardiovascular side-effects seen with the anti-obesity agent Meridia®.

We recently completed the PSN821 single dose Phase I study in type II diabetes patients and are moving forward with the follow-on 14-day dosing study by mid-year (this study will include a first look at the impact of PSN821 on gastric emptying). Presuming continued success in this program, we expect to initiate the follow-on 28-day dosing Phase IIa study or possibly a 3-month dosing Phase IIb study, early in 2010. In keeping with our view that we be focused on establishing differentiation early in development programs, this study will include a sitagliptin active comparator.

On the PSN602 program, we have completed dosing in the 14-day Phase I program and have seen encouraging early data from key safety, tolerability and pharmacokinetics assessments. We also saw robust effects on appetite in standard meal tests that were included in this trial as preliminary indications of activity. We expect to begin the 28-day Phase IIa part of the

program by mid-year. This study will include a sibutramine comparator, again aimed at delivering key differentiation data as early in the development program as possible.

A CONFIDENT AND DISCIPLINED COMPANY WELL POSITIONED IN CHALLENGING TIMES

Although we are genuinely excited about our future prospects, we are also conscious of our fiscal responsibilities to our company and our shareholders. Thus, while we are confident in our pipeline and growth strategy, we have committed publicly to maintain a disciplined assessment of the risks inherent in our industry and to ensure that, should our aspirations fall short of our goals over the next 2-4 years, we will realize the financial value inherent in the Tarceva and DP-IV franchises for our shareholders before these assets begin to approach the end of their patent life.

Our industry is going through a period of significant consolidation. As a shareholder, you may believe that companies like OSI should be consolidated into larger corporations through acquisitions, or you may believe that those rare OSI's of the biotech world have a unique window through which substantial growth and shareholder

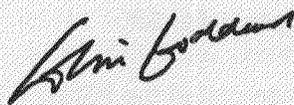
OSI is dedicated to turning the promise of innovative, targeted, personalized therapies into practice in the diabetes & obesity arena, two diseases with major unmet medical needs.



returns can be delivered as an independent entity. At OSI, we see the goal of delivering shareholder value via either outcome through the same strategic lens. Our strategy is predicated on the belief that creating a powerhouse innovator company that really moves the cause of personalized medicine forward by developing a portfolio of novel, differentiated, molecular targeted therapies to the better benefit of patients, shareholders and employees alike is the best template from which to turn the substantial success of OSI over the last decade into a period of equal success and value creation for our shareholders in the coming years.

Indeed, as we embark on perhaps the most exciting 2-4 year growth period in the company's history we do so with a justifiable sense of confidence in our people, our science and our financial strength, all of which is appropriately tempered with a sense of fiscal and strategic discipline that we believe makes OSI one of the few mid-cap biotechnology companies fully equipped to emerge from the current downturn as a strong and sustainable industry leader. In closing, we would like to take a moment to acknowledge that our past achievements and continued success are predicated on the talented team of employees that make up OSI; the

continued support of our stockholders; and, most importantly, to the physicians, patients and families from around the world for whom we constantly strive to improve their treatment options by innovating breakthrough medicines.



Colin Goddard, Ph.D.
Chief Executive Officer



Robert A. Ingram
Chairman of the Board



In 2008 we achieved a significant milestone by advancing four wholly-owned, highly differentiated and innovative product candidates into clinical development.

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, 2008

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

SEC
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MAY 06 2009

Washington, DC
122

OSI PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other Jurisdiction of
Incorporation or Organization)

13-3159796

(I.R.S. Employer Identification No.)

41 Pinelawn Road, Melville, N.Y.

(Address of Principal Executive Offices)

11747

(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
Series SRPA Junior Participating
Preferred Stock Purchase Rights

The NASDAQ Stock Market LLC

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

(Title of Class)

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

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

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

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

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

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

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

As of June 30, 2008, the aggregate market value of the Registrant's voting stock held by non-affiliates was \$1,372,090,100. 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, 2008 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 20, 2009, there were 57,920,762 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 2009 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K.

On the following pages, we have reproduced the first nine items of our annual report on the Form 10-K filed with the Securities and Exchange Commission on February 27, 2009. 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, Senior Director, Investor and Public Relations, 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. “(OSI) Eyetech” refers to Oldtech, Inc. (formerly, (OSI) Eyetech, Inc.), our wholly-owned subsidiary.

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

PART I

ITEM 1. BUSINESS

We are a profitable biotechnology company committed to building a scientifically strong and financially successful top tier biopharmaceutical organization that discovers, develops and commercializes innovative molecular targeted therapies, or MTTs, addressing major unmet medical needs in oncology, diabetes and obesity. Our strategic focus is in the area of personalized medicine. We are building upon the knowledge and insights from our flagship product, Tarceva, in order to establish a leadership role in turning the promise of personalized medicine into practice in oncology and in pioneering the adoption of personalized medicine approaches in diabetes and obesity. We are leveraging our targeted therapy expertise in drug discovery, development and translational research to deliver innovative, differentiated new medicines to the right patients, in the right combinations and at the right doses. We believe this approach optimally positions us to accomplish more rapid and cost-effective drug development aimed at providing substantial clinical benefit to the patients who can gain the most from our innovations. We further believe that, with increasing healthcare cost constraints and competition, leadership in personalized medicine approaches will define the successful biopharmaceutical companies of the future.

Our largest area of focus is oncology where our business is anchored by Tarceva, a small molecule inhibitor of the epidermal growth factor receptor, or EGFR, which is our primary source of revenues. In November 2004, Tarceva was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of advanced non-small cell lung cancer, or NSCLC, in patients who have failed at least one prior chemotherapy regimen and, subsequently, in November 2005, for the treatment of patients with locally advanced and metastatic pancreatic cancer in combination with the chemotherapy agent, gemcitabine. Tarceva was also approved for sale in the European Union, or EU, for the treatment of advanced NSCLC in September 2005 and, in January 2007, as a first-line therapy for metastatic pancreatic cancer in combination with gemcitabine. In October 2007, Tarceva was approved in Japan for the treatment of patients with nonresectable, recurrent and advanced NSCLC which is aggravated following therapy, and launched in Japan at the end of 2007. Tarceva, which as of January 2009, was approved for sale in 94 countries for advanced NSCLC after failure of chemotherapy and 70 countries for pancreatic cancer, achieved global sales of over \$1.1 billion for 2008. We co-promote Tarceva in the United States with Genentech, Inc., where we share profits equally, and receive royalties on sales outside of the United States from our international collaborator, Roche.

Prosidion Limited, our U.K. subsidiary which conducts our research and development programs in diabetes and obesity, contributes an important second source of revenues through the licensing of our patent estate relating to the use of dipeptidyl peptidase IV, or DPP-IV, inhibitors for the treatment of type II diabetes and related indications. As of February 15, 2009, twelve pharmaceutical companies have non-exclusive licenses to these patents, which provide us with upfront payments as well as potential milestones and royalties. As of December 31, 2008, this patent estate has generated approximately \$111 million in upfront license fees, milestones and royalties.

We expect that our revenues from Tarceva and our DPP-IV patent estate, combined with our diligent management of expenses, will continue to provide us with the capital resources necessary to make disciplined investments in research and development, or R&D, in order to support the continued growth of Tarceva and our internal pipeline of clinical and pre-clinical assets. As part of our lifecycle plan for Tarceva, we, together with Genentech and Roche, continue to invest in a broad clinical development program directed at maximizing Tarceva's long-term potential, including a number of large, randomized clinical trials designed to expand Tarceva's use in NSCLC and new disease settings, such as hepatocellular carcinoma. We have also prioritized investment in a portfolio of potentially differentiated and competitive drug candidates and technologies in oncology and diabetes and obesity. As a result, we have successfully advanced four drug candidates into clinical trials over the past two years, all of which were the result of our internal discovery efforts.

In oncology, we have a pipeline of MTTs in clinical and late-stage pre-clinical development which we intend to develop and commercialize independently. These include OSI-906 (an inhibitor of the insulin-like growth factor 1 receptor, or IGF-1R, with potential utility for the treatment of all major solid tumor types), which entered Phase I studies in June 2007, OSI-027 (a next generation mammalian target of rapamycin, or mTOR, kinase inhibitor), which entered Phase I studies in July 2008 and OSI-296 (a novel, potent tyrosine kinase inhibitor, or TKI, developed

as an epithelial-to-mesenchymal transition, or EMT, inhibitor), which is in late-stage pre-clinical development. In addition, we have two anti-angiogenesis agents, OSI-930 and OSI-632, for which we are seeking a development partner. Each of these MTTs, as well as Tarceva, are small molecules designed to be administered orally as a tablet rather than by the less convenient intravenous infusion methods characteristic of most anti-cancer drugs. The focus of our proprietary oncology research efforts is on understanding multiple elements of tumor biology — including the dependence of certain tumor cells on activated oncogenic signaling pathways, or onco-addiction, and compensatory signaling — but with a particular focus on the biological process of EMT, which is of emerging significance in understanding tumor development and disease progression. This research has grown out of our translational research efforts to understand which patients may optimally benefit from Tarceva. Our EMT research investment, together with related insights into mechanisms such as compensatory signaling, is the cornerstone of our personalized medicine approach in cancer, and should allow us to better design combinations of MTTs for specific sub-sets of cancer patients. This, in turn, may enable us to realize significant improvements in patient outcomes and to enhance our competitive position in the oncology marketplace.

We also have research and development programs in diabetes and obesity which are conducted through Prosidion. Our discovery efforts in diabetes and obesity are concentrated around the neuroendocrine control of bodyweight and glycemia, which focuses on central or peripheral nervous system or hormonal approaches to the control of bodyweight for the treatment of obesity, as well as the lowering of blood glucose together with meaningful weight loss for the treatment of type 2 diabetes. Two compounds from our diabetes and obesity research efforts, PSN821 and PSN602, entered clinical trials in 2008. PSN821 is an orally administered G protein-coupled receptor 119, or GPR119, agonist with potential anti-diabetic and appetite suppressing features, and PSN602 is an oral dual serotonin and noradrenaline reuptake inhibitor and 5-HT_{1A} agonist for the treatment of obesity.

Strategy

Our strategic focus is on turning the promise of innovative, personalized medicine into practice in our industry. This strategy, which is anchored around the continued growth of and reinvestment in Tarceva, seeks to appropriately balance our financial performance with disciplined, focused and selective investments in R&D designed to realize long term growth for our company. We anticipate that the continued growth of revenues from Tarceva and our DPIV patent estate, coupled with disciplined expense management, will allow us to support both a broad lifecycle plan for Tarceva and to continue to make R&D investments in those programs that we believe can produce novel, differentiated, “first-in-class” or “best-in-class” drug candidates. Our longer term growth strategy seeks to maintain significant ownership and control over these assets throughout their development and commercial lifecycles. We also believe that a key element to disciplined management of our R&D investment is the pursuit of an out-licensing or partnering strategy for any program or candidate that we determine no longer meets our criteria as a core asset. We further expect that our current financial resources and expected future cash flows will permit us to be a selective acquirer of attractive technologies, companies and pipeline assets where these types of acquisitions strongly supplement and complement our internal efforts in oncology and diabetes/obesity.

The goal of our R&D efforts is to pursue novel personalized medicine therapies by discovering and developing innovative, differentiated agents that deliver the right medicines, to the right patients, in the right combinations and at the right doses. We believe that this approach will lead to:

- More rapid and cost-effective drug development;
- The discovery and development of drugs that deliver meaningful clinical benefit to patients; and
- Increased availability of innovative medicines to the patients who can benefit from them the most.

Over the past decade or more, we have demonstrated our ability to discover MTTs in both oncology and diabetes/obesity, and this remains at the core of our efforts to build a differentiated pipeline. These discovery efforts have been guided by our translational research program, which seeks to accelerate the process of transforming scientific discoveries arising from the laboratory and the clinic into new drugs and treatment options for patients. Our translational research program has led us to explore the possibilities of using biomarkers to predict, detect and monitor disease, and has directed our research focus towards the biology of EMT in oncology and neuroendocrine control in diabetes and obesity. In oncology, we have learned from our translational research efforts for Tarceva that

developing and exploiting a comprehensive understanding of the biology of EMT may be a key to determining patient selection and combination of MTTs for the treatment of cancer. We have, therefore, invested internally and externally through collaborations, such as our alliance with AVEO Pharmaceuticals, Inc., or AVEO, in order to establish a leadership position in the understanding of this process and establish contextual models of human cancer biology in order to explore the implications of EMT and phenomena such as compensatory signaling mechanisms on oncology drug discovery and development. We believe that our EMT-driven approach to oncology research will provide us with a pathway to selecting responsive patient populations and obtaining the efficacy improvements that will be needed in order to compete in a growing and increasingly competitive market for oncology therapeutics. Similarly, in diabetes and obesity, we believe that our focus on the neuroendocrine control of bodyweight and glycemia may allow us to pioneer personalized medicine approaches in the future.

Our Marketed Product — Tarceva

Overview

Tarceva is an oral, once-a-day, small molecule therapeutic designed to inhibit the receptor tyrosine kinase activity of the protein product of the HER1/EGFR gene. HER1/EGFR is a key component of the HER signaling pathway, which plays a role in the abnormal growth of many cancer cells. EGFR inhibitors were designed to arrest the growth of tumors, referred to as cytostasis; however, under certain circumstances, EGFR inhibition can lead to apoptosis, or programmed cell death, which in turn results in tumor shrinkage. The HER1/EGFR gene is over-expressed, mutated or amplified in approximately 40% to 60% of all 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. The initial focus of our development program has been on NSCLC and pancreatic cancer. We, together with our collaborators or other third parties, are continuing to explore the use of Tarceva in other tumor types, including hepatocellular carcinoma, ovarian and colorectal cancers.

The American Cancer Society estimates that approximately 182,000 cancer patients in the United States were diagnosed with NSCLC in 2008. Tarceva is approved for the treatment of NSCLC patients in the second and third-line settings following a course of front-line chemotherapy. Based on data from the Tandem Oncology Monitor, a national audit in 2008 by Synovate, Inc. of cancer patients receiving therapy, approximately 65,000 subsequent courses of therapy were provided to NSCLC Stage IIIB/IV patients in the United States following a course of front-line chemotherapy. The American Cancer Society estimates that approximately 34,000 cancer patients in the United States died from pancreatic cancer in 2008, which makes it the fourth leading cause of cancer death in the United States. In Europe, based on information collected by the International Agency for Research on Cancer in Lyon, France, the third most common incident form of cancer in 2006 was lung cancer, with approximately 380,000 cases. The International Agency for Research on Cancer also reported that lung cancer was the most common cause of cancer death in Europe, with approximately 340,000 deaths in 2006.

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

Lifecycle Plan

We, together with Genentech and Roche, continue to invest in Tarceva through a broad development program. The goal of our lifecycle plan for Tarceva is to maximize the long-term market potential of our flagship product through a series of extensive and rationally-designed clinical trials. Our clinical trial strategy for Tarceva has three key objectives:

- Expand the use of Tarceva into other NSCLC treatment areas;
- Expand the use of Tarceva into other pancreatic cancer treatment areas and additional tumor types; and

- Develop therapies which combine Tarceva and other novel targeted agents for the treatment of NSCLC and other tumor types.

Studies to Expand Tarceva into other NSCLC Treatment Areas.

Tarceva Maintenance Therapy Studies. In November 2008, we and Genentech announced that a global Phase III study, SATURN, met its primary endpoint of progression free survival, or PFS, and showed with statistical significance that Tarceva extended the time that patients with advanced NSCLC lived without their disease advancing, referred to as PFS, when given immediately following initial treatment with platinum-based chemotherapy, compared to placebo. The SATURN study was a double-blind randomized 850-patient Phase III study to evaluate the efficacy of Tarceva as a maintenance therapy versus placebo following chemotherapy in patients with advanced, recurrent or metastatic NSCLC who have not experienced disease progression or unacceptable toxicity during four cycles of front-line chemotherapy. In February 2009, Genentech informed us that another global Phase III Tarceva study, ATLAS, was stopped early on the recommendation of an independent data safety monitoring board after a pre-planned interim analysis showed with statistical significance that combining Tarceva and Avastin extended the time that these patients lived without their disease advancing, compared with Avastin plus placebo. Genentech further informed OSI that a preliminary safety analysis showed adverse health events were consistent with previous Avastin or Tarceva studies as well as trials evaluating the two medicines together, and no new safety signals were observed. ATLAS was a randomized, double-blind, placebo-controlled, Phase IIIb study to evaluate the combination of Avastin plus Tarceva as a maintenance therapy for the treatment of locally advanced, recurrent, or metastatic NSCLC in patients whose cancer did not progress following initial treatment with Avastin and platinum-based chemotherapy. The results of both of these studies are currently being analyzed and will be presented at a future medical meeting.

We, together with Genentech and Roche, are currently discussing a potential new indication for Tarceva with the FDA and the European Health Authorities based on the results of the SATURN study. The SATURN study was conducted by Roche, and has been through the FDA's special protocol assessment, or SPA, process. The ATLAS study was funded by Genentech and Roche. Under terms of our co-development and commercialization alliance with Genentech and Roche, or the Tripartite Agreement, we may elect to make certain payments for the ATLAS study.

BeTa Lung Study. On October 6, 2008, we and Genentech announced that the BeTa Lung clinical trial, a randomized Phase III study evaluating Avastin® (bevacizumab) in combination with Tarceva in patients with advanced NSCLC whose disease had progressed following platinum-based chemotherapy, did not meet its primary endpoint of improving overall survival compared to Tarceva alone. The study did however provide evidence of clinical activity with improvements in the secondary endpoints of progression-free survival and response rate when Avastin was added to Tarceva compared to Tarceva alone. The BeTa Lung clinical trial was the first prospective randomized Phase III trial in which Tarceva was dosed to a purely second-line NSCLC patient population and data from the Tarceva plus placebo arm was consistent with prior sub-set analysis data from the pivotal BR.21 study showing a median survival of approximately nine months in those second-line patients.

RADIANT Study (Adjuvant Tarceva after Surgery and Chemotherapy in Patients with Stage IB-IIIa NSCLC). Due to its demonstrated efficacy, safety profile and convenience, we believe that Tarceva is well suited for testing in the adjuvant treatment of patients with fully resected stage IB through IIIa NSCLC. Over the last few years, it has been demonstrated that certain patients with resectable NSCLC may benefit from platinum-containing adjuvant chemotherapy. This treatment paradigm is becoming the standard of care in the United States. In the 945-patient RADIANT study, patients with fully resected NSCLC who are EGFR-positive by immunohistochemistry, or IHC, and/or fluorescent *in situ* hybridization, or FISH, and do or do not receive platinum-containing adjuvant chemotherapy, are randomized to receive Tarceva or placebo for up to two years. This study has the potential to change the standard of care for patients with early stage NSCLC. We expect to complete enrollment in the first half of 2010 and, assuming we meet this enrollment target, anticipate data from this trial by 2014. This study is an important component of our later stage lifecycle plan for Tarceva.

Smoker Maximum Tolerated Dose Study. Pharmacokinetic analyses from our BR.21 study for Tarceva in NSCLC which was the basis upon which Tarceva was approved by the FDA for NSCLC in November 2004,

suggested that patients that are current smokers have lower drug exposure. In addition, as judged by the lower incidence of rash and diarrhea, these patients appear to have a less marked biological effect from Tarceva. Retrospective analyses for the BR.21 study showed that the treatment effect of Tarceva on survival was less pronounced in this population. A Phase I study in healthy volunteers demonstrated that the plasma levels of Tarceva achieved in active smokers were approximately half of those observed in non-smokers. In 2006, we initiated a two-stage Phase I dose escalation study with Tarceva in NSCLC patients who continue to smoke. The first part of the study established the maximum tolerated dose, or MTD, of Tarceva in this population as 300 mg/day. The second stage of the study compared the steady state pharmacokinetics of Tarceva at 300 mg/day versus 150 mg/day. We filed a supplemental new drug application, or sNDA, with the FDA in the fourth quarter of 2007 seeking a change in the prescribing information for Tarceva to reflect the results from the study. The FDA approved this change and we issued a new package insert with updated dosage information for patients who smoke in September 2008.

Phase II Studies in Never-smokers. The Cancer and Leukemia Group B, or CALGB, is conducting a randomized Phase II study in previously untreated NSCLC patients with adenocarcinoma who have never smoked or were previous light smokers. For this study, 180 patients with Stage IIIB or IV disease will receive either Tarceva alone or in combination with the drugs carboplatin and paclitaxel. CALGB has indicated that accrual of this trial is nearing completion. In addition, the Eastern Cooperative Oncology Group has received approval from the Cancer Therapy Evaluation Program for a similar Phase II study which would randomize patients who have never smoked to either chemotherapy plus Avastin or chemotherapy plus Avastin in combination with Tarceva. The Southwest Oncology Group has also initiated a Phase II study of Avastin and Tarceva in never-smokers. These studies will add further insight to the results seen in retrospective analyses of the never-smoker patients in the prior TRIBUTE and BR.21 randomized Phase III studies. In TRIBUTE, a first-line NSCLC study, the sub-population of patients who were never-smokers receiving Tarceva in combination with chemotherapy had a median survival of 22.5 months, compared to 10.1 months for those receiving chemotherapy alone. In BR.21, the hazard ratio for benefit in never-smokers was 0.42, with a response rate of 24.7% for those patients who received Tarceva alone. 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 than one indicates a reduction in the risk of death.

TITAN Study. The TITAN study is a randomized 650-patient Phase III study to evaluate the efficacy of Tarceva compared to either of two chemotherapy agents, Alimta® (pemetrexed) or Taxotere® (docetaxel), following front-line chemotherapy in advanced, recurrent metastatic NSCLC patients who have experienced rapid disease progression or unacceptable toxicity. The TITAN study is part of our post-marketing commitments agreed to with the FDA upon the approval of Tarceva. 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). The study enrollment rate has been significantly lower than expected. As a result, it is difficult to predict when enrollment will be complete for this study. This study is designed to provide comparative data for Tarceva versus chemotherapy in the sub-set of patients who rapidly progress on front-line chemotherapy.

Phase II Study in Enriched Population. We recently completed a 143-patient Phase II study in which we prospectively selected patients with untreated NSCLC based on EGFR positivity using IHC and/or FISH. After enrollment, patients were randomized to either single agent Tarceva or Tarceva intercalated with chemotherapy. We elected not to proceed with a Phase III trial after the Phase II trial data demonstrated a six month PFS for each arm of the study that was lower than our targeted rate.

TASK Study. TASK is a 200-patient randomized, open label, Phase II study of Tarceva in combination with Avastin compared to standard chemotherapy regimens (gemcitabine plus cisplatin or paclitaxel plus carboplatin) plus Avastin in first-line NSCLC patients. Roche, the study sponsor elected to halt further enrollment on this study after data from a pre-planned interim analysis of the first 120 patients showed that it was unlikely that the study objective would be met.

Studies to Expand Tarceva into other Pancreatic Cancer Treatment Areas and Additional Tumor Types.

RACHEL Study. Sub-set analysis from the PA.3 study in pancreatic cancer suggests that those patients who have a grade 2 Tarceva-related rash have an approximately two-fold increase in their rate of survival. The RACHEL

study seeks to explore this observation in a prospective, randomized fashion. This Phase II study is part of Roche's post-marketing commitments agreed to with the EU regulatory authorities. Approximately 400 patients will be entered into the study and will receive four weeks of the standard gemcitabine plus 100 mg/day Tarceva regimen. Those patients who have not either progressed or demonstrated a grade 2 or 3 rash will be randomized to either continue the standard regimen or undergo a dose escalation protocol for the Tarceva component of the regimen. This study is currently enrolling.

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

Ovarian and Colorectal Cancer. Additional collaborative group Phase III trials are under way in both ovarian cancer and colorectal cancer. The ovarian cancer study, which completed enrollment in 2008, is an 830-patient Phase III trial being conducted by the European Organization for Research into the Treatment of Cancer, or EORTC, and follows a similar maintenance design to the SATURN study, in which Tarceva is used as a monotherapy following initial chemotherapy. The colorectal cancer study is a 640-patient study being conducted through a study group in the EU and also employs Tarceva in a maintenance setting. This study tests Tarceva in combination with Avastin as maintenance therapy compared to Avastin alone in patients who have had a partial response or stable disease after treatment in the first-line setting with modified FOLFOX 7 (folinic acid, fluorouracil and oxaliplatin) plus Avastin or modified XELOX (capecitabine plus oxaliplatin) plus Avastin, two widely employed treatment regimens for colorectal cancer.

Hepatocellular Cancer. Tarceva demonstrated clinical activity in patients with hepatocellular cancer, or HCC, in two small single arm Phase II trials. We anticipate that a randomized Phase III trial will commence in the first half of 2009 comparing Tarceva plus Nexavar® (sorafenib) with placebo plus Nexavar, for the treatment of advanced HCC. Nexavar is marketed and developed by Bayer AG and Onyx Pharmaceuticals, Inc. This trial will be primarily sponsored by Bayer and have a target enrollment of 700 patients.

Studies Which Combine Tarceva with other Targeted Agents.

We believe that there are a number of opportunities to combine Tarceva with other targeted agents to create improved patient outcomes, both for NSCLC as well as other tumor types. As discussed below, we initiated a Phase I study in the fourth quarter of 2008 exploring the combination of Tarceva with OSI-906, our oral small molecule IGF-1 receptor inhibitor. We also are actively exploring opportunities to combine Tarceva with other targeted therapies through investigator sponsored studies and partnerships with other pharmaceutical and biotechnology companies, including current partnerships with Novartis AG and ArQule, Inc. that combine Tarceva with an mTOR and mesenchymal-epithelial transition factor, or c-Met, inhibitor, respectively.

Treatment Beyond Progression. From an exploratory study conducted at Memorial Sloan Kettering Cancer Center, it has been reported that, in patients who progressed on EGFR TKI therapy, there appeared to be acceleration of disease progression when EGFR TKI therapy was discontinued. Upon reintroduction of EGFR TKI therapy, disease progression slowed. Based upon this observation, we believe further study is warranted as to whether continuing Tarceva therapy beyond disease progression by adding other drugs, and in particular, other targeted agents with a focus on EMT-driven combinations, provides a treatment benefit. Three investigator-sponsored studies are currently exploring this hypothesis, and an additional study is planned in the future.

Investigator Sponsored Studies.

In addition to the studies listed above, over 250 studies investigating other Tarceva uses and regimens are ongoing or planned, including both investigator-sponsored studies and studies sponsored by the National Cancer Institute. These studies are exploring monotherapy and combination uses of Tarceva, including with other novel agents, in various tumor types and with a variety of treatment modalities, such as radiation and surgery. Some studies are also examining the use of Tarceva earlier in the treatment paradigm in both the adjuvant and

chemoprevention settings. In general, many of these studies are carried out at minimal cost to us or our collaborators beyond the supply of Tarceva.

Sales and Marketing

In order to maximize the Tarceva brand and to ensure the optimal competitive positioning of Tarceva on a global basis, we entered into a co-development and commercialization alliance with Genentech and Roche in January 2001. Under the alliance, Genentech leads the marketing efforts in the United States and Roche sells and markets the drug in the rest of the world. In addition, we have agreed with Genentech that OSI employees will comprise 50% of the combined U.S. sales force through the end of the 2010 calendar year, after which time the size and composition of the sales force may be adjusted. 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 tradeshow.

OSI/Genentech/Roche Alliance

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

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

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 is responsible for the manufacture and supply of Tarceva tablets for sales outside of the United States.

Erlotinib is manufactured in a three-step process with high yield. Sumitomo Chemical Co., Ltd. and Dipharma S.p.A are our manufacturers of the API used for commercial supplies. Both of these manufacturers also manufacture API for Tarceva clinical trials. Schwarz Pharma Manufacturing, Inc. is our manufacturer of Tarceva tablets for clinical and commercial supplies, as well as placebo for blinded clinical studies. We have entered into long term supply agreements with our API and tablet manufacturers. Clinical supplies of Tarceva tablets are currently stored, labeled, packaged and distributed by Catalent Pharma Solutions LLC and Acculogix, Inc., a subsidiary of Fisher Clinical Services, Inc. Catalent Pharma Solutions also labels and provides secondary packaging services for commercial supplies of Tarceva tablets before their subsequent distribution to Genentech or a storage facility designated by Genentech. All manufacturers of the API and Tarceva tablets are required to comply with current good manufacturing practices, or cGMPs. We have produced sufficient quantities of Tarceva tablets to conduct our ongoing clinical trials, and we have a supply chain organization in place, with approximately six months or more of inventory on hand, to support the commercial sales of Tarceva.

Our Clinical Development Programs

We currently have four development candidates in Phase I clinical trials in oncology and diabetes/obesity, all of which are the result of our internal research efforts. Our immediate goal is to move these programs through Phase I trials to determine recommended doses and schedules, and if successful, commence later-Phase clinical trials for each of these compounds within the next twelve months. Longer term, we intend to maintain significant control over these assets and to commercialize them, in whole or in part, particularly in the United States.

OSI-906. OSI-906 is an oral small molecule IGF-1R inhibitor which we believe is among the first small molecule inhibitors against the IGF-1R target to enter clinical trials. In pre-clinical studies, OSI-906 has demonstrated synergy with Tarceva and potential utility in a number of different cancers, including NSCLC, breast, pancreatic, prostate, colorectal, adrenocortical, or ACC, and ovarian. We believe that OSI-906 is potentially more effective than antibodies, given its inhibition of the pAKT survival pathway and its ability to modulate potential compensatory signaling mechanisms in the tumor cell. We also believe that its oral administration will provide more scheduling flexibility and convenience than antibodies. OSI-906 is currently in Phase I studies exploring both continuous and intermittent dose schedules, and an additional Phase I study of OSI-906 in combination with Tarceva was initiated in the fourth quarter of 2008. As of January 2009, over 60 patients have been treated with OSI-906, and the drug has generally been well tolerated by these patients. Indications of anti-tumor activity have been seen in on-going Phase I program including a partial response in a patient with ACC, a minor response in a patient with NSCLC and disease stabilization in over 20% of evaluable patients. We are exploring a number of potential indications for OSI-906 both as a single agent and in combination with other targeted strategies.

PSN821. PSN821, a novel GPR119 agonist, is an oral small molecule drug with potential anti-diabetic and appetite suppressing effects, which is being developed for the treatment of type 2 diabetes. In pre-clinical models, PSN821 has been shown to release endogenous GLP-1 and increase beta-cell cAMP leading to improved glucose control, delayed gastric emptying, appetite suppression and weight loss. Based on the pre-clinical data set, we believe that PSN821 has the potential to be a “best-in-class” product. PSN821 is currently undergoing chemistry, manufacturing and control, or CMC, development, as well as drug metabolism and pharmacokinetics, or DMPK, and pre-clinical safety testing, to support Phase II clinical studies. The first-in-man Phase I clinical study commenced in the third quarter of 2008 and includes both healthy volunteers and patients with type 2 diabetes. Pre-clinical data on PSN821 was the subject of an oral presentation at the American Diabetes Association meeting in San Francisco, California in June 2008.

PSN602. PSN602 is a novel dual serotonin and noradrenaline reuptake inhibitor which also elicits 5HT_{1A} receptor agonism, which is being developed for the long-term treatment of obesity. Inclusion of 5HT_{1A} agonism has been shown in pre-clinical studies to counterbalance the undesirable cardiovascular effects of increased noradrenaline activity seen with other anti-obesity agents which inhibit the reuptake of noradrenaline and serotonin, while maintaining or improving upon efficacy. Because of this potential to demonstrate a favorable side-effect profile, and/or greater efficacy, relative to current therapies, we believe that PSN602 has the potential to be “best-in-class.” The first-in-man Phase I clinical study commenced in the second quarter of 2008 and includes single and multiple ascending dosing in both healthy lean and overweight/obese volunteers. Pre-clinical data on PSN602 was presented at the American Diabetes Association meeting in San Francisco, California in June 2008.

OSI-027. OSI-027 is a small molecule TORC1/TORC2 inhibitor which has the potential to supersede first generation mTOR inhibitors. Unlike existing agents targeting the mTOR pathway, OSI-027 inhibits both the TORC1 and TORC2 signaling complexes, allowing for the potential for complete truncation of aberrant cell signaling through this pathway. Inhibition of TORC1 and TORC2 has been shown in pre-clinical studies to elicit robust anti-tumor activity but to carry an appreciable toxicity burden. We commenced a Phase I clinical trial of OSI-027 in July 2008, which is currently enrolling. The Phase I study has shown indications of some toxicities that may limit the ability to optimally dose this agent.

Other Development Programs and Significant Outlicensing Activities

OSI-296. OSI-296, a novel, potent TKI developed to block compensatory signaling in epithelial tumor cells, is the first pre-clinical candidate to emerge from our EMT technology platform. In pre-clinical studies, OSI-296 has shown efficacy in a number of EMT ligand-driven tumor models and has blocked ligand-driven EMT and tumor growth.

PSN010. In January 2007, we outlicensed our glucokinase activator, or GKA, program, including the small molecule Phase I clinical candidate PSN010, to Eli Lilly and Company. GKAs have a dual effect in the pancreas and the liver resulting in increased hepatic glucose uptake in the liver and stimulated insulin secretion by the pancreas. Under the terms of our license with Eli Lilly, Eli Lilly is responsible for all aspects of clinical development, manufacturing and commercialization of PSN010 or any back-up compound included within the licensed GKA program. In return for such rights, we received an upfront payment of \$25.0 million and will potentially receive milestones and other payments of up to \$360.0 million and royalties based on net sales of any product arising from the licensed GKA program.

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

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

Our Oncology and Diabetes/Obesity Discovery Efforts

Oncology Research

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

Our early understanding of EMT emanated from work done by our translational research group, which observed that Tarceva's effects on different types of cancer cells appeared related to the EMT-status of these cancer cells. Pursuing EMT may allow us to better understand which patients might more optimally benefit from Tarceva or other MTT treatments. Retrospective analysis of tumor samples from the TRIBUTE Phase III study of Tarceva in combination with chemotherapy for the treatment of front-line NSCLC patients suggested that those patients whose tumors abundantly expressed E-cadherin responded better to Tarceva. By acquiring or co-opting a mesenchymal phenotype, we believe that epithelial derived tumor cells utilize different growth and survival pathways and become less dependent on EGFR signaling and ultimately acquire or gain the ability to migrate, invade and metastasize. These properties suggest the need to target distinctly different signaling pathways in order to effectively treat these tumors. As a result of our study of the signaling changes associated with EMT, we have deepened our understanding of compensatory signaling mechanisms associated with pharmacological inhibition of certain receptor tyrosine kinases, or RTKs. These RTKs regulate EMT and tumor growth processes and therefore are attractive therapeutic targets in oncology. For example, we have determined that inhibition of EGFR in tumor cells by Tarceva can lead to enhanced phosphorylation and/or activation of IGF-1R. Conversely, inhibition of IGF-1R can result in increased phosphorylation of EGFR. This observation provides the principal underpinning of our proposed development strategy combining OSI-906 and Tarceva. We believe that this phenomenon may also apply to other RTKs, and this has caused us to focus on identifying rational combinations of molecular-targeted agents directed at EMT-linked targets in order to confront compensatory signaling as a resistance mechanism in tumor cells. This new insight is leading our development project teams to plan and conduct studies of markers of EMT and EGFR signaling in retrospective and prospective clinical trials for Tarceva. These studies may enhance the likelihood of success of Tarceva in additional indications by selecting those patients most likely to better respond to therapy.

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

On September 28, 2007, we entered into a three-year oncology drug discovery and translational research collaboration with AVEO to help us to better understand the underlying mechanisms of the process of EMT in cancer. A main focus of the collaboration is the development of proprietary target-driven tumor models for use in drug screening, translational research and biomarker validation. As part of the collaboration, AVEO provides us with access to its databases of tumor targets identified from AVEO genetic screens focusing on tumor maintenance genes that drive EMT. AVEO uses its proprietary technology platform of genetically-defined mouse models of human cancer to develop for us *in vivo* tumor models that we believe more accurately portray contextual tumor biology than traditional xenograph models. These models are driven by EMT target genes of interest to us, which validate key EMT targets and create tools for our oncology discovery and translational research. Under the terms of the collaboration, we are responsible for the development and commercialization of all small molecule and non-antibody clinical candidates that arise from the collaboration. We own exclusively all small molecule intellectual property emanating from the collaboration and AVEO retains the rights to any antibodies and antibody-related biologics against targets from the collaboration. In addition to an upfront payment, we pay AVEO for ongoing research funding, and milestones and royalties upon successful development and commercialization of products from the collaboration. In 2008, we exercised our option on five targets evaluated as part of this collaboration, which provided us with exclusive rights to these targets for non-antibody-related therapeutic discovery and development. In addition, in 2007 and 2008 we exercised options on three tumor models developed for use in our translational research programs on the development of OSI-906 and OSI-027. OSI owns all translational research intellectual property emanating from the use of such tumor models.

Diabetes/Obesity Discovery

Prosidion's discovery efforts currently focus on innovative, small molecule, orally bioavailable MTTs for the treatment of diabetes and obesity. The International Diabetes Federation, or IDF, estimated in 2007 that up to

246 million people worldwide have diabetes and that this number will reach 380 million by 2025. The IDF also estimated that up to 3.8 million deaths worldwide each year are a result of diabetes, representing the fourth leading cause of death by disease globally. Diabetes is a chronic disease with multiple complications, including cardiovascular and renal disease, neuropathy, blindness and premature mortality. Type 2 diabetes accounted for approximately 90% of diabetes worldwide as of 2007 and, while historically considered a disease found in adults, it is increasingly occurring in obese children. As for obesity, the World Health Organization, or WHO, estimated in 2005 that over 1.6 billion adults worldwide were overweight, and over 400 million adults were obese. The WHO estimates that these figures will rise to 2.3 billion and 700 million, respectively, by 2015. Obesity is a major risk factor for type 2 diabetes, cardiovascular disease, musculo-skeletal disorders and certain cancers.

Beginning in 2008, Prosidion elected to concentrate its discovery efforts around the neuroendocrine control of bodyweight and glycaemia. This area covers central or peripheral nervous system or hormonal approaches to the control of bodyweight for the treatment of obesity, as well as the lowering of blood glucose together with meaningful weight loss for the treatment of type 2 diabetes. We believe that our focus in this area may ultimately lead to the development of a research platform that will allow us to identify biomarkers useful for the development of personalized medicines for diabetes and obesity. In December 2008, we acquired from 7TM Pharma A/S, a number of early stage research assets and a G-Protein coupled receptor, or GPCR, technology platform, which allows for the rapid identification of potent small molecule ligands for both orphan and known GPCRs. The purchase price was \$4 million. We expect that this platform will assist us in validating targets within the neuroendocrine focus area.

Divestiture of Eye Disease Business

On August 1, 2008, we completed the sale of the remaining assets of our eye disease business to Eyetech Inc., a newly formed corporation whose shareholders consist primarily of members of the Macugen[®] (pegaptanib sodium injection) sales team. These remaining assets consisted principally of the right to market and sell Macugen in the United States. We do not hold any equity or equity rights in Eyetech Inc. Under the terms of the transaction, the principal assets we transferred to Eyetech Inc. consisted of Macugen-related intellectual property and inventory, as well as \$5.8 million in working capital primarily in the form of Macugen trade receivables, in exchange for potential future milestone and royalty payments. Our consideration for the transaction also included payments in the event of any subsequent change-of-control affecting Eyetech Inc., as well as Eyetech Inc.'s agreement to assume certain obligations of (OSI) Eyetech. We also agreed to provide certain transition services to Eyetech Inc. for a period of time commencing with the closing of the transaction through December 31, 2009. Michael G. Atieh, our former Executive Vice President, Chief Financial Officer and Treasurer, joined Eyetech Inc. in a part-time executive chairman role upon his retirement from OSI in January 2009. Mr. Atieh also holds stock in Eyetech Inc. which became voting and participating with respect to dividends and distributions upon his retirement from our company.

Our Intellectual Property

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

Tarceva-Related Intellectual Property

We have obtained patents for erlotinib, the API for Tarceva, in the United States, Europe, Japan, and a number of other countries. We are pursuing extensions of the patent term and/or of the data exclusivity term in the countries where such extensions are available. We have been granted patent term extensions that extend our U.S. patent for erlotinib to November 2018 and corresponding patents in Europe to March 2020 and in Japan to June 2020. We also intend to seek pediatric exclusivity for Tarceva from the FDA, which, if granted, would extend the U.S. patent for

erlotinib by an additional six months. We are also currently pursuing U.S. and international patents for new inventions concerning various other formulations of erlotinib and related intermediate chemicals and processes. We have obtained patents covering a key polymorphic form of Tarceva in the United States and Europe, which expire in 2020. We are also currently seeking patent protection for additional methods of use for Tarceva, including the use of Tarceva in combination with other compounds.

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

We are currently reviewing Paragraph IV certifications received in February 2009 from two generic pharmaceutical companies — Teva Pharmaceuticals U.S.A., Inc., or Teva U.S.A., and Mylan Pharmaceuticals, Inc. If we commence lawsuits for patent infringement within 45 days of the date of receipt of these certifications, as we expect to do, the FDA cannot approve the ANDAs for either of these generic pharmaceutical companies until seven and one-half years have elapsed from the date of Tarceva's initial approval (i.e., May 18, 2012). This period of protection, referred to as the statutory litigation stay period, may end early however, in the event of an adverse court action, such as if we were to lose a patent infringement case against either Teva U.S.A. or Mylan before the statutory litigation stay period expires (i.e., the court finds the patent invalid, unenforceable, or not infringed) or if we fail to reasonably cooperate in expediting the litigation. On the other hand, if we were to prevail in an infringement action against Teva U.S.A. and/or Mylan, the ANDA with respect to such generic pharmaceutical company cannot be approved until the patent held to be infringed expires.

In light of the increasingly aggressive challenges by generic companies to innovator intellectual property, we, together with our collaborators, Genentech and Roche, are continually assessing the intellectual property estate for Tarceva around the world. On February 27, 2008, we filed with the U.S. Patent and Trademark Office, or USPTO, an application to reissue our composition of matter patent for Tarceva, U.S. Patent No. 5,747,498, or the '498 patent, in order to correct certain errors relating to the claiming of compounds, other than Tarceva, which fall outside of the scope of the main claim in the patent. The reissue application seeks to correct these errors by deleting surplus compounds from the claims. Like most composition of matter patents, the '498 patent claims many compounds in addition to Tarceva. Tarceva itself is accurately described in the '498 patent. We believe that eliminating these errors as an arguable basis for challenging the '498 patent is a prudent course of action given the aggressive strategy of generic companies in seeking to bring generic versions of innovator drugs to market at the earliest possible time, notwithstanding the patent protection of the innovator product. While we seek to correct these errors, the '498 patent remains listed in the Orange Book with the FDA and subject to Paragraph IV certification by potential ANDA filers and may be asserted by us in an infringement action. In the reissue application, we are also seeking narrower claims to the '498 patent. In addition, we also filed with the USPTO a request for a certificate of correction with respect to the '498 patent seeking to correct errors of a clerical or typographical nature. The USPTO granted the certificate of correction in September 2008.

We received the first office action from the USPTO in our reissue application on February 26, 2009. The office action includes an indication of allowability to composition of matter claims, including a claim specifically directed to Tarceva, while initially rejecting certain other claims. We are reviewing the issues raised by the USPTO examiner and will respond as appropriate. We believe this first step will allow us to substantially complete the reissue process by the end of 2009, however the process may take longer.

A patent corresponding to the '498 patent for Tarceva was granted in February 2007 in India and we, along with our collaborator Roche, successfully opposed a pre-grant opposition to this patent by Natco Pharma, Ltd. in July 2007. We also opposed Natco Pharma's request for a compulsory license to manufacture Tarceva in India for export to Nepal and Natco Pharma withdrew this request in September 2008. We and Roche are also currently seeking to enforce our composition of matter patent against CIPLA, Ltd. with respect to a generic form of Tarceva launched by CIPLA in India in January 2008. We and Roche filed a lawsuit against CIPLA in the High Court of Delhi in New Delhi, India in January 2008, which included a request that the court issue a preliminary injunction to prevent CIPLA from manufacturing and distributing Tarceva in India. The court denied this request in March 2008 and we subsequently appealed the decision. We completed our appeal in September 2008 and are awaiting a final decision. The court has also indicated that it will set the trial schedule for the infringement action in February 2009.

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

Other Intellectual Property

The DPIV assets we acquired from Probiodrug AG in 2004 include a portfolio of medical use patents. This portfolio contains a number of patent families comprising of issued and pending patents and patent applications with claims relating to the use of DPIV inhibitors for the treatment of diabetes and related indications. We also have licensed sub-licensable rights to patents and patent applications claiming the use of combinations of DPIV inhibitors with other anti-diabetic drugs such as metformin. Our rights to this patent estate provide us with a source of upfront payments, and milestone and royalty revenue through the issuance of non-exclusive licenses to the patent estate. As of February 15, 2009, twelve pharmaceutical companies, including Merck, Novartis and Bristol-Myers Squibb Company, or BMS, have licenses to this patent estate. These licenses provide us with upfront payments, milestones and royalties which vary according to the individual license agreements. As of December 31, 2008, we have generated approximately \$111 million in upfront license fees, milestones and royalties from the patent estate. In October 2006, Merck received FDA approval for its DPIV inhibitor, Januvia™ (sitagliptin). In March 2007, Merck received EU approval for Januvia and FDA approval for Janumet™, its combination product of sitagliptin and metformin. In July 2008, Merck also received EU approval for Janumet. In September 2007, Novartis received EU approval for its DPIV inhibitor, Galvus® (vildagliptin), and in November 2007, received EU approval for its combination product of vildagliptin and metformin, Eucreas®. We receive royalty payments from sales of Januvia, Janumet, Galvus and Eucreas.

The patents which are the subject of these DPIV licenses will expire between 2017 and 2027. In March 2008, we announced that the decision of Opposition Division of the European Patent Office to revoke one of our European patents relating to the use of DPIV inhibitors for lowering blood glucose levels had been upheld on appeal. As a result, royalties on sales of DPIV inhibitor products have been or will be reduced or eliminated in those territories where the patent has been revoked and where there is no other patent protection. Royalties may be restored, however, if certain currently pending patents, which are the subject of these licenses, are issued.

We have filed a number of U.S. and international patent applications relating to the OSI-906, OSI-027 and OSI-930 compounds, each of which we are developing as potential treatments for cancer. We have been granted a U.S. patent which protects the OSI-930 compound and method of use until 2024. We have also sought patent protection for PSN602, our oral dual serotonin and noradrenaline reuptake inhibitor and 5HT_{1A} agonist, and PSN821, our GPR119 agonist.

We have assembled a gene transcription patent portfolio which we have non-exclusively out-licensed to a number of pharmaceutical companies. We also have non-exclusive licenses from Cadus Pharmaceutical Corporation and Wyeth to a portfolio of patents and applications covering yeast cells engineered to express heterologous 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 the development of pharmaceutical products or therapies that are directly competitive with ours. Many of these competitors have greater capital resources than we do, which provide them with potentially greater flexibility in the development and marketing of their products. In the case of Tarceva, we chose to seek partnerships with leading biotechnology and pharmaceutical industry companies, Genentech and Roche, in order to ensure our competitiveness on a global basis.

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

The current competition to Tarceva for the treatment of NSCLC includes existing chemotherapy options such as Alimta, Taxotere and Gemzar® (gemcitabine), as well as Genentech's Avastin, which is approved in combination with chemotherapy for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC. Eli Lilly presented results at the June 2008 American Society of Clinical Oncology, or ASCO, conference demonstrating a positive outcome for a Phase III NSCLC maintenance therapy trial for Alimta. Eli Lilly has also announced that Alimta, in combination with cisplatin, has been approved by regulatory authorities in the United States and Europe for the first-line treatment of NSCLC.

Tarceva also competes with AstraZeneca plc's Iressa® (gefitinib) in the limited markets where it is available, such as Japan and Canada. AstraZeneca announced results in September 2007 from its international study comparing the use of Iressa versus Taxotere for the treatment of NSCLC after the failure of a first-line treatment showing that Iressa met the endpoint of non-inferiority to Taxotere. In July 2008, AstraZeneca also announced positive results for a sub-set of its patients in a study in Asia, IPASS, comparing the use of Iressa plus paclitaxel and carboplatin in the first-line treatment of advanced NSCLC. In May 2008, AstraZeneca announced that it had filed with the European Medicines Agency for the use of Iressa as a treatment for locally advanced or metastatic NSCLC in patients who have been pre-treated with platinum-containing chemotherapy, which, if successful, would result in additional competition for Tarceva in the EU. It is also possible that AstraZeneca may seek to amend Iressa's label in the United States.

Tarceva may compete in the future with ImClone Systems Incorporated and BMS's Erbitux® (cetuximab). In December 2008, ImClone Systems and BMS announced that they had submitted an application to the FDA to broaden the use of Erbitux to include first-line treatment of patients with advanced NSCLC in combination with platinum-based chemotherapy. The submission was based primarily on positive data from a Phase III study, referred to as FLEX, of the combination of Erbitux and chemotherapy in the treatment of first-line advanced NSCLC. ImClone Systems and BMS subsequently announced in January 2009 that they had withdrawn this application, but stated that they intend to resubmit the application in the future. A second study that evaluated Erbitux in combination with a different platinum containing chemotherapy, BMS-099, failed to meet its primary or secondary endpoints. In 2008, ImClone Systems was acquired by Eli Lilly.

Tarceva may also face competition in the future from AstraZeneca's Zactima™ (vandetanib). In November 2008, AstraZeneca announced preliminary results from three Phase III trials investigating Zactima use in NSCLC. In a head-to-head superiority trial versus Tarceva in the second-line advanced NSCLC setting, referred to as ZEST, AstraZeneca indicated that Zactima failed to meet its primary endpoint of demonstrating superior efficacy to Tarceva, but did meet the criteria of a pre-planned non-inferiority analysis. AstraZeneca also indicated that its trial combining Zactima with chemotherapy, referred to as ZODIAC, met its primary endpoint of PFS, but its study combining Zactima and Alimta, referred to as ZEAL, failed to meet its primary endpoint. AstraZeneca has indicated that it intends to file for FDA approval of Zactima in combination with chemotherapy as a treatment for second-line NSCLC in the second quarter of 2009. Other oncology drugs currently in clinical trials for the treatment of NSCLC either as a single agent or as a combination therapy, such as Amgen Inc.'s Vectibix™ (panitumumab), Millennium Pharmaceuticals, Inc.'s Velcade® (bortezomib), Pfizer's Sutent® (sunitinib malate) and Onyx's Nexavar, could

compete for market share in NSCLC in the future. We are aware of three current or planned Phase III clinical trials evaluating Sutent as a treatment for NSCLC, including a combination trial with Tarceva which is presently enrolling.

In the pancreatic cancer setting, Tarceva primarily competes with Gemzar monotherapy in the first-line setting. In addition, Tarceva's use in pancreatic cancer may be affected by experimental use of other products, such as Roche's Xeloda® (capecitabine) and Abraxis BioScience, LLC's Abraxane® (paclitaxel protein-bound particles for injectable suspension).

Our four Phase I development programs could face competition in the future if successful. OSI-906 could face competition from a number of other pre-clinical and clinical candidates which target IGF-1R, including more advanced antibody clinical candidates from Pfizer, ImClone Systems and Roche. OSI-027, a small molecule inhibitor of both mTOR complexes, TORC1 and TORC2, could compete with rapamycin analogs, such as Wyeth's Torisel™ (temsirolimus) and Novartis' Afinitor® (everolimus), which are known to inhibit the TORC1 complex. OSI-906 and OSI-027 may also compete in the future with therapeutic agents which target other molecular pathways or cellular functions, but potentially have similar clinical applications. PSN821, our GPR119 agonist for the treatment of type 2 diabetes, would potentially compete with current and future type 2 diabetes treatments, including GPR119 agonist Phase I clinical candidates from Metabolex, Inc. and from Arena Pharmaceuticals, Inc. in partnership with Ortho-McNeil-Janssen Pharmaceuticals, Inc. PSN602, a dual serotonin and noradrenaline reuptake inhibitor which also elicits 5HT_{1A} receptor agonism, is designed to compete with compounds such as Abbott Laboratories' Meridia® (sibutramine) and could compete with current and future obesity treatments, including Neurosearch A/S's tesofensine, a triple reuptake inhibitor currently in Phase III trials, and other therapies for the treatment of obesity.

Government Regulation

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

Key FDA Regulations

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

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

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

New indications or other changes to an already approved product also must be approved by the FDA. An sNDA is a supplement to an existing NDA that provides for changes to the NDA and therefore requires FDA approval. There are two types of sNDAs depending on the content and extent of the change: (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.

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. If the FDA cannot approve an NDA they will issue a "complete response" letter describing the specific deficiencies and, where possible, will outline recommended actions for the applicant to take before the NDA can be approved. This may include conducting additional studies.

Manufacturing procedures must conform to cGMPs, which must be followed at all times. In complying with this requirement, manufacturers, including a drug sponsor's third-party contract manufacturers, must continue to expend time, money and effort in the area of production, quality assurance and quality control to ensure compliance. Manufacturing establishments are subject to periodic inspections by the FDA in order to assess, among other things, compliance with cGMP. To supply products for use in the United States, foreign manufacturing establishments also must comply with 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 being placed on the product, manufacturer or NDA holder, including withdrawal of the product from the market.

The Hatch-Waxman Act

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

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

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

Pricing and Reimbursement

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

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

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

Other Regulation

In addition to regulations enforced by the FDA, we must also comply with regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements may apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. In addition, our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds, the handling and disposal of which are governed by various state and federal laws and regulations.

We are subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws. Anti-kickback laws generally make it illegal for a prescription drug manufacturer to knowingly and willfully solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the recommendation, purchase or prescription of a particular drug. 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. 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). In addition, under some of these laws, there is an ability for private individuals to bring similar actions. 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.

We are also subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from engaging in specified activities to obtain or retain business or to influence a person working in an official capacity. Under the FCPA, it is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

In addition, federal and state laws protect the confidentiality of certain health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information privacy and security rules under the Health Insurance Portability and Accountability Act of 1996. In addition, many state laws apply to the use and disclosure of health information.

In January 2009, we elected to adopt the revised voluntary Code on Interactions with Healthcare Professionals, or PhRMA Code, promulgated by the Pharmaceutical Research and Manufacturers of America. The updated PhRMA Code, which became effective in January 2009, addresses interactions with respect to marketed products and related pre-launch activities and reinforces the intention that interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine.

Our Employees

We believe that our success is largely dependent upon our ability to attract and retain qualified employees. As of December 31, 2008, we had a total of 491 full-time and 23 part-time employees worldwide.

Available Information

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

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

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business

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

We currently derive most of our revenues from our principal marketed product, Tarceva, which represented approximately 88% of our total revenues from continuing operations for the year ended December 31, 2008. For the next several years, we will continue to rely on Tarceva to generate the majority of our revenues. Our ability to maintain or increase our revenues for Tarceva will depend on, and may be limited by, a number of factors, including the following:

- Our ability to maintain and expand the market share, both in the United States and in the rest of the world, and revenues for Tarceva in the treatment of second-line and third-line NSCLC and for first-line pancreatic cancer in the midst of numerous competing products which are currently in late stage clinical development;
- Whether the positive data from the SATURN and ATLAS studies will be sufficient to achieve approval from the FDA and its foreign counterparts to market and sell Tarceva as a maintenance therapy in patients with advanced, recurrent or metastatic NSCLC who have not experienced disease progression following chemotherapy, and whether, if approved, Tarceva’s use in the setting will gain acceptance among prescribing physicians and result in increased Tarceva sales;
- Whether data from clinical trials for additional indications are positive and whether such data, if positive, will be sufficient to achieve approval from the FDA and its foreign counterparts to market and sell Tarceva in such additional indications;
- Whether physicians are willing to switch from existing treatment methods, including traditional chemotherapy agents (where certain reimbursement practices in the United States favor the use of intravenously administered drugs), to Tarceva;
- Current and future pricing pressures on Tarceva, including as a result of government-imposed price reductions, an increase in imports of Tarceva from lower cost countries to higher cost countries and pressure on physicians to reduce prescriptions of higher priced medicines like Tarceva;
- Adequate coverage or reimbursement for Tarceva by third-party payors, including private health coverage insurers and health maintenance organizations; and
- The ability of patients to afford any required co-payments for Tarceva. The risk that patients will not be able to afford the co-payments for Tarceva may become particularly acute if the recent global financial crisis is prolonged or worsens.

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;
- 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, including a “block box” warning that highlights significant safety concerns, or to the recall or withdrawal of Tarceva. In the event of a recall or withdrawal of Tarceva, our revenues would decline significantly.

Our strategy includes expanded use for Tarceva; however, there can be no assurance that the positive results from the SATURN or ATLAS trials will result in Tarceva receiving the required regulatory approvals for expanded use in NSCLC or that data from other clinical trials for additional indications will be positive or sufficient to achieve approval from the FDA and its foreign counterparts to market and sell Tarceva in such additional indications.

In November 2008, we and Genentech announced that our global Phase III study, SATURN, met its primary endpoint of PFS. The SATURN study is a double-blind randomized 850-patient Phase III study to evaluate the efficacy of Tarceva as a maintenance therapy versus placebo following four cycles of chemotherapy in patients with advanced, recurrent or metastatic NSCLC who have not experienced disease progression or unacceptable toxicity during the four cycles of front-line chemotherapy. In February 2009, Genentech informed us that another global Phase III study, ATLAS, was stopped early on the recommendation of an independent data safety monitoring board after a pre-planned interim analysis showed that combining Tarceva and Avastin extended with statistical significance the time that these patients lived without their disease advancing, compared with Avastin plus placebo. ATLAS was a randomized, double-blind, placebo-controlled, Phase IIIb study to evaluate the combination of Avastin plus Tarceva for the treatment of locally advanced, recurrent or metastatic NSCLC in patients whose cancer did not progress following initial treatment with Avastin and platinum-based chemotherapy.

While the SATURN and ATLAS studies have the potential to expand Tarceva use in NSCLC into the maintenance setting following first line treatment, there can be no assurance that Tarceva will receive approval from the FDA and its foreign counterparts for such an indication. The primary endpoint of the SATURN and ATLAS studies is PFS. Although SATURN has been through the FDA’s SPA process, there can be no guarantee that the PFS endpoint will not be subject to further scrutiny by the FDA. Overall survival was a secondary endpoint in the SATURN study and these data, when available, will also be included in the regulatory filings for this study. We do not anticipate that this data will be available until after the sNDA for SATURN has been submitted to the FDA. There can be no assurance that the PFS data, nor any additional data required by the FDA or its foreign counterparts, will be sufficient to support approval of Tarceva in the first line maintenance setting. If the FDA or its foreign counterparts do not approve Tarceva in this setting, it could have an adverse impact on our potential future revenues for Tarceva.

We are also conducting a number of other clinical trials which seek to expand the existing indications for Tarceva. The results from these clinical trials are difficult to predict; positive results from pilot studies or other similar studies, including subset analyses from prior studies, are not a guarantee of success in subsequent studies. In addition, there can be no guarantee that such studies, if positive, will result in approvals from the FDA and its foreign counterparts for new indications for Tarceva.

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

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

The OSI/Roche agreement continues until the date on which we are no longer entitled to receive a royalty on products resulting from the development of Tarceva, that is, until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva or, in countries where there is no valid patent covering Tarceva, on the tenth anniversary of the first commercial sale of Tarceva in that country. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, Roche has the right to terminate the agreement on a country-by-country basis with six months' prior written notice. We also currently have the right to terminate the agreement with respect to a particular country under certain circumstances if Roche has not launched or marketed a product in such country.

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

Roche is the majority shareholder in Genentech. However, in January 2009, Roche announced a tender offer to acquire the outstanding public shares of Genentech, which it does not currently own, for approximately \$42.1 billion. As the ultimate outcome of this proposed transaction is uncertain, we cannot presently determine its potential impact on the future commercialization and development of Tarceva and there can be no assurance that any subsequent integration activities associated with the transaction will not adversely affect the commercialization of Tarceva, particularly in the United States.

If we do not receive timely and accurate financial information from Genentech and Roche regarding the development and sale of Tarceva, we may be unable to accurately report our results of operations.

Due to our collaborations with Genentech and Roche for Tarceva, we are highly dependent on these companies for timely and accurate information regarding the costs incurred in developing and selling Tarceva, and any revenues realized from its sale, in order to accurately report our results of operations. If we do not receive timely and accurate information associated with the co-promotion and development of Tarceva, we may be required to record significant adjustments to our revenues or expenses in future periods and/or restate our results for prior periods. Such inaccuracies or restatements could cause a loss of investor confidence in our financial reporting or lead to legal claims against us.

Our business will be increasingly affected by pressures on drug pricing, which may limit or reduce the prices we can charge for Tarceva in the future and the pricing structure available to future products emanating from our pipeline.

The growth of overall healthcare costs in many countries means that governments and payors are under pressure to control spending even more tightly. As a result, our business and the pharmaceutical and biotechnology industries in general are operating in an increasingly challenging environment with very significant pricing pressures. These ongoing pressures include government-imposed industry-wide price reductions, mandatory pricing systems, an increase in imports of drugs from lower cost countries to higher cost countries, shifting of the payment burden to patients through higher co-payments and growing pressure on physicians to reduce prescriptions of higher priced medicines like Tarceva. We expect these efforts to continue as healthcare payors — in particular government-controlled health authorities, insurance companies and managed care organizations — increase their efforts to reduce the overall cost of healthcare, which may limit or reduce the prices we can charge in the future for Tarceva and any future products emanating from our pipeline. These pricing pressures could become particularly acute if the current global financial crisis is prolonged or worsens.

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

We are responsible for manufacturing and supplying Tarceva in the United States under the terms of a Manufacturing and Supply Agreement entered into with Genentech in 2004. We rely on two third-party suppliers to manufacture erlotinib, the API for Tarceva. We also currently rely on a single manufacturer to formulate the Tarceva tablets. If our relationships with any of these manufacturers with respect to Tarceva terminate or if these manufacturers are unable to meet their obligations, we would need to find other sources of supply. Such alternative sources of supply may be difficult to find on terms acceptable to us or in a timely manner, and, if found, would require FDA approval which could cause delays in the availability of erlotinib and ultimately Tarceva tablets, which, in turn, would negatively impact our revenues derived from Tarceva.

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

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

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

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

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

The current competition to Tarceva for the NSCLC indication includes existing chemotherapy options such as Alimta, Taxotere and Gemzar, as well as Genentech's Avastin, which is approved in combination with chemotherapy for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC. Eli Lilly presented results at the June 2008 ASCO conference demonstrating a positive outcome for a Phase III NSCLC maintenance therapy trial for Alimta. Eli Lilly has also announced that Alimta, in combination with cisplatin, has been approved by regulatory authorities in the United States and Europe for the first-line treatment of NSCLC.

Tarceva also competes with AstraZeneca's Iressa in the limited markets where it is available, such as Japan and Canada. AstraZeneca announced results in September 2007 from its international study comparing the use of Iressa versus Taxotere for the treatment of NSCLC after the failure of a first-line treatment, showing that Iressa met the endpoint of non-inferiority to Taxotere. In July 2008, AstraZeneca also announced positive results for a sub-set of its patients in a study in Asia, IPASS, comparing the use of Iressa versus paclitaxel and carboplatin in the first-line treatment of advanced NSCLC. In May 2008, AstraZeneca announced that it had filed with the European Medicines Agency for the use of Iressa as a treatment for locally advanced or metastatic NSCLC in patients who have been pre-treated with platinum-containing chemotherapy, which, if successful, would result in additional competition for Tarceva in the EU. It is also possible that AstraZeneca may seek to amend Iressa's label in the United States.

Tarceva may compete in the future with Erbitux. In December 2008, Imclone Systems, BMS and Merck KGaA announced that they had submitted an application to the FDA to broaden the use of Erbitux to include first-line treatment of patients with advanced NSCLC in combination with platinum based chemotherapy. The submission was based primarily on positive data from a Phase III study, referred to as FLEX, of the combination of Erbitux and chemotherapy in the first-line treatment of advanced NSCLC. Imclone Systems and BMS subsequently announced in January 2009 that they had withdrawn this application, but stated that they intend to resubmit the application in the future. A second study that evaluated Erbitux in combination with a different platinum containing chemotherapy, BMS-099, failed to meet its primary or secondary endpoints. In 2008, ImClone Systems was acquired by Eli Lilly.

Tarceva could also face competition in the future from AstraZeneca's Zactima. In November 2008, AstraZeneca announced preliminary results from three Phase III trials investigating Zactima use in NSCLC. In a head-to-head superiority trial versus Tarceva in the second-line advanced NSCLC setting, referred to as ZEST, AstraZeneca indicated that Zactima failed to meet its primary endpoint of demonstrating superior efficacy to Tarceva, but did not meet the criteria of a pre-planned non-inferiority analysis. AstraZeneca also indicated that its trial combining Zactima with chemotherapy, referred to as ZODIAC, met its primary endpoint of PFS but a study combining Zactima and Alimta, referred to as ZEAL, failed to meet its primary endpoint. AstraZeneca has indicated that it intends to file for FDA approval of Zactima in combination with chemotherapy as a treatment for second-line NSCLC in the second quarter of 2009. Other oncology drugs currently in clinical trials for the treatment of NSCLC either as a single agent or as a combination therapy, such as Amgen's Vectibix, Millennium's Velcade, Pfizer's Sutent and Bayer and Onyx's Nexavar, could compete for market share in NSCLC in the future. We are aware of three current or planned Phase III clinical trials evaluating Sutent as a treatment for NSCLC, including a combination trial with Tarceva which is presently enrolling.

In the pancreatic cancer setting, Tarceva primarily competes with Gemzar monotherapy in the first-line. In addition, Tarceva use in pancreatic cancer may be affected by experimental use of other products, such as Roche's Xeloda and Abraxis Bioscience's Abraxane® (paclitaxel protein-bound particles for injectable suspension).

Our four Phase I development programs could face competition in the future if successful. OSI-906, our oral small molecule IGF-1 receptor inhibitor, could face competition from a number of other pre-clinical and clinical candidates which target the IGF-1R, including more advanced antibody clinical candidates from Pfizer, ImClone Systems and Roche. OSI-027, a small molecule inhibitor of both mTOR complexes, TORC1 and TORC2, could compete with rapamycin analogs, such as Wyeth's Torisel and Novartis' Afinitor, which are known to inhibit the TORC1 complex. OSI-906 and OSI-027 may also compete in the future with therapeutic agents which target other molecular pathways or cellular functions, but potentially have similar clinical applications. PSN821, our GPR119

receptor agonist Phase I clinical candidate for the treatment of type 2 diabetes, would potentially compete with current and future type 2 diabetes treatments, including GPR119 agonist Phase I clinical candidates from Metabolex and Arena Pharmaceuticals in partnership with Ortho-McNeil-Janssen Pharmaceuticals. PSN602, our dual serotonin and noradrenaline reuptake inhibitor which also elicits 5HT_{1A} receptor agonism, is designed to compete with compounds such as Abbott Laboratories' Meridia and could compete with current and future obesity treatments, including Neurosearch's tesofensine, a triple reuptake inhibitor currently in Phase III trials, and other targeted therapies for the treatment of obesity.

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

We have licensed our DPIV medical use patent portfolio to pharmaceutical companies that develop and commercialize 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 October 2006 and in the EU in March 2007. Merck's combination product with metformin, Janumet, was approved by the FDA in March 2007 and in the EU in July 2008. Novartis is also a licensee and it received EU regulatory approval for its product, Galvus, in September 2007. Additionally, in November 2007, Novartis received EU regulatory approval for its combination product with metformin, Eucreas. There can be no assurance that Galvus, Eucreas or any other DPIV inhibitor products covered by license agreements with us will be approved by the FDA or other regulatory authorities. The amount of royalties and other payments that we derive from our DPIV patent estate is not only dependent on the extent to which products covered by the license agreements receive regulatory approval but is also dependent on how successful Merck, Novartis and other licensees are in expanding the global market for DPIV inhibitor products, as well as other factors that could affect their market share, such as safety issues. The extent to which we receive revenue under such licenses also depends on our ability to enforce our patent rights in our DPIV portfolio. As an example, in March 2008, we announced that the decision of the Opposition Division of the European Patent Office to revoke one of our European patents relating to the use of DPIV inhibitor products for lowering blood glucose levels had been upheld on appeal. As a result, royalties on sales of DPIV inhibitor products have been or will be reduced or eliminated in those territories where the patent has been revoked and where there is no other patent protection.

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

Successful research and development of pharmaceutical products is high risk. Most products and development candidates fail to reach the market. Our success depends on the discovery and development of new drugs that we can commercialize. Our pipeline for our oncology and diabetes and obesity clinical programs, including those that we deem to be core assets, is at an early stage. Our four core development candidates — OSI-906, OSI-027, PSN821 and PSN602 — are all in Phase I clinical trials. 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. As an example, in November 2007, we elected to discontinue development of our DPIV inhibitor, PSN9301, which had completed Phase IIa studies, after it failed to show an adequate safety margin in a three-month primate toxicology study.

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

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

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

Our reliance on third parties, such as clinical research organizations, or CROs, and manufacturers, 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 and to manufacture API and drug product. Because we have engaged and intend to continue to engage CROs and third-party manufacturers to help us conduct our clinical studies, obtain market approval for our drug candidates and manufacture API and drug product, many important aspects of this process have been, and will be, out of our direct control. If the CROs or third-party manufacturers 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, cGMPs, regulations and guidelines enforced by the FDA and similar foreign regulatory authorities, such trials may be materially delayed or terminated, adversely impacting our ability to commercialize our drug candidates. Furthermore, any loss or delay in obtaining contracts with such CROs and third-party manufacturers may also delay the completion of our clinical trials and the market approval of drug candidates.

Our operating results could be adversely affected by fluctuations in the value of the U.S. dollar against foreign currencies.

A significant percentage of our revenues are derived from royalties on sales of Tarceva outside of the United States by Roche, and our operating expenses relating to Prosidion are denominated in British pounds sterling, or GBP. As result, these Tarceva revenues and Prosidion operating expenses are affected by fluctuating foreign currency exchange rates. An increase in the U.S. dollar relative to other currencies in which we have revenues will cause our revenues to be lower than with a stable exchange rate. Changes in exchange rates between the GBP and the U.S. dollar can affect the recorded levels of the assets, liabilities and expenses relating to Prosidion. The primary foreign currencies in which we have exchange rate fluctuation exposure are the Euro, the GBP and the Swiss franc, but we also have exposure to exchange rate fluctuation in other currencies. Exchange rates between these currencies and U.S. dollars have fluctuated significantly in recent years, particularly as the current global financial crisis has unfolded, and may continue to do so in the future. We cannot predict the impact of future exchange rate fluctuations on our operating results.

We may not be able to make our required payments of interest and principal under our outstanding indebtedness when due, and may not be able to repurchase for cash our 2% convertible senior subordinated notes due 2025, or our 2025 Notes, or our 3% convertible senior subordinated notes due 2038, or our 2038 Notes, if required to do so in 2010 and 2013, respectively. If we elect to repurchase our 3¼% convertible senior subordinated notes due 2023, or our 2023 Notes, with our common shares, our shareholders would experience dilution and our stock price may decline.

Our aggregate debt under our 2023 Notes, 2025 Notes and 2038 Notes was approximately \$415 million as of December 31, 2008. While we are currently generating sufficient net cash flow to satisfy our anticipated annual interest payments on our outstanding convertible debt, there can be no assurance that we will be able to do so in the future. In addition, the holders of the 2023 Notes, the 2025 Notes and the 2038 Notes have the right to require us to repurchase their notes in September 2013, December 2010, and January 2013, respectively. While the 2023 Notes provide us with the option of delivering our common stock in lieu of cash in the event that the holders of the 2023 Notes require us to repurchase all or a portion of their 2023 Notes, the 2025 Notes and the 2038 Notes must be repurchased with cash. If we do not have sufficient resources at the time these obligations are due, we may be required to borrow additional funds or sell additional equity to meet these obligations, but there can be no guarantee that we will be able to raise such capital at the appropriate time on favorable terms or at all. If we are unable to make our annual interest payments or repay any of our convertible notes when due, we will default on our 2023 Notes, the 2025 Notes and the 2038 Notes, permitting the note holders to declare the notes immediately due and payable. There can be no assurance that we will have sufficient capital resources to repay our convertible notes in the event that such a default right is triggered.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents and investment securities.

Our cash and cash equivalents are maintained in highly liquid investments with maturities of 90 days or less at the time of purchase. Our investment securities consist of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. As of the date of this filing, we are not aware of any material losses or other significant deterioration in the fair value of our cash equivalents or investment securities since December 31, 2008; however, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents and investment securities and, as result, our financial condition.

Risks Relating to Regulatory Matters

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

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

We are currently reviewing a Paragraph IV certification that we received on February 9, 2009 from Teva U.S.A. If we commence a lawsuit for patent infringement within 45 days of the date of receipt of the certification, as we expect to do, the FDA cannot approve the ANDA until seven and one-half years have elapsed from the date of Tarceva's initial approval (*i.e.*, May 18, 2012). This period of protection, referred to as the statutory litigation stay

period, may end early, however, in the event of an adverse court action, such as if we were to lose the patent infringement case before the statutory litigation stay period expires (i.e., the court finds the patent invalid, unenforceable, or not infringed) or if we fail to reasonably cooperate in expediting the litigation. On the other hand, if we prevail in the infringement action, the ANDA cannot be approved until the patent held to be infringed expires. Tarceva is currently protected by three patents listed in the FDA's Approved Drugs Products List (Orange Book). A lawsuit brought with respect to one or more of those patents would restrict the FDA from approving Teva U.S.A.'s ANDA until May 18, 2012, unless an adverse ruling occurs prior to such time.

Additionally, following the conclusion of the statutory litigation stay period, or earlier date due to a loss of the statutory litigation stay protection, if the ANDA or 505(b)(2) NDA filing has been approved, a generic company may choose to launch a generic version of Tarceva notwithstanding the pendency of our infringement action or any appeal. This is referred to as an "at-risk launch" and is an aggressive strategy pursued by generic companies that has occurred more frequently in the last few years. Any launch of a generic version of Tarceva prior to the expiration of patent protection, whether as a result of the loss of the patent infringement litigation or due to an at-risk launch, will have a material adverse effect on our revenues for Tarceva and our results of operations.

If we do not receive adequate third-party reimbursement for the sales of Tarceva, we may see a reduction in the profitability of Tarceva.

Sales of Tarceva depend, in part, upon the extent to which the costs of Tarceva 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, state and foreign 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 Tarceva to be cost-effective, they may not reimburse providers of our products, or the level of reimbursement may reduce the profitability of Tarceva. As an example, while the U.K.'s National Institute of Health and Clinical Excellence recommended funding by the National Institute of Health for Tarceva in NSCLC, it still has not recommended reimbursement for Tarceva for the treatment of pancreatic cancer.

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.

Foreign government involvement and/or control over pricing of pharmaceutical products can have an effect on the revenues that we receive from Tarceva.

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

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

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

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

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

In addition, the U.S. federal government and several states impose drug pedigree law requirements designed to record the chain of custody of prescription drugs. Compliance with these pedigree laws may require implementation of tracking systems as well as increased documentation and coordination with our customers. Although there may be changes in these requirements and government enforcement may vary, failure to comply could result in fines or penalties, as well as supply disruptions that could have a material adverse effect on our business.

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

If government agencies do not grant us or our collaborators required approvals for any of our potential products in a timely manner or at all, we or our collaborators 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 collaborators, including the European Medicines Agency and the Japanese Ministry of Health, may delay or deny the approval of our potential products. Although we have been successful in gaining regulatory approval for Tarceva in the United States and our collaborators have gained approval for Tarceva in Canada, Japan, the EU and a number of other territories, there can be no guarantee of subsequent approvals for Tarceva in other territories or for other indications in the United States or for other products in the United States and other territories.

Delays or rejections may be encountered during any stage of the regulatory process based upon the failure of the clinical data to demonstrate compliance with, or upon the failure of the product to meet, a regulatory agency's requirements for safety, efficacy and quality. Any such delay could have a negative effect on our business. A drug candidate cannot be marketed in the United States until it has been approved by the FDA. Once approved, drugs, as well as their manufacturers, are subject to continuing and ongoing review, and discovery of previously unknown problems with these products or the failure to adhere to manufacturing or quality control requirements may result in restrictions on their distribution, sale or use, or their withdrawal from the market. The FDA also has the authority, when approving a product, to impose significant limitations on the product in the nature of warnings, precautions and 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. For example, the FDA's Amendments Act of 2007 provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA's authority with respect to post-marketing safety surveillance, including, among other things, the authority to require: (i) additional post-approval studies or clinical trials; (ii) the submission of a proposed risk evaluation and mitigation strategy; and (iii) label changes as a result of safety findings. These requirements may affect our ability to maintain marketing approval of our products or require us to make significant expenditures to obtain or maintain such approvals. This new law also enhances the FDA's enforcement authority, as well as civil and criminal penalties for violations.

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

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

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

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

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

Future legislative or regulatory reform of the healthcare system may limit the commercial prospects of certain of our products.

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

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

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

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

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

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

Changes in laws, regulations, accepted clinical procedures or social pressures could restrict our use of animals in testing and therefore adversely affect our R&D activities.

Certain of our R&D activities involve the use of laboratory animals. Changes in laws, regulations or accepted clinical procedures relating to the use of animals in testing may adversely affect our business by delaying or interrupting our R&D activities. In addition, social pressures that would restrict the use of animals in testing, or actions or protests against us or our collaborators by groups or individuals opposed to animal testing, could also delay or interrupt our R&D activities and could disrupt our U.S. and U.K. operations.

Risks Related to Intellectual Property and Legal Matters

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

We hold numerous U.S. and foreign patents as well as trademarks and trade secrets; we also have many pending applications for additional patents. We intend to continue to seek patent protection for, or maintain as trade secrets, the potentially valuable intellectual property arising from our research and development activities, including commercially promising product candidates that we have discovered, developed or acquired. Our success depends, in part, on our ability and our collaborators' ability to obtain and maintain patent protection for new product candidates, maintain trade secret protection and operate without infringing the valid and enforceable proprietary rights of third parties. As with most biotechnology and pharmaceutical companies, our patent position is highly uncertain and involves complex legal and factual questions. Without patent and other similar protection, other companies could offer the same or substantially identical products for sale without incurring the sizeable discovery and development costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished. The process of obtaining patents can be time-consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent may not issue or it may insufficiently protect the technology it was intended to protect. Even if issued, such issuance is not conclusive as to a patent's validity or its enforceability.

Our patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to prevent or stop competitors from marketing similar products or may limit the length of term of patent protection we may have for our products. Specifically, we are currently reviewing Paragraph IV certifications received in February 2009 from Teva U.S.A. and Mylan alleging that the three patents listed in the Orange Book for Tarceva are invalid, unenforceable, or will not be infringed by generic versions of erlotinib for which these generic pharmaceutical companies have sought FDA approval to commercialize in the United States. We, together with Genentech, are currently reviewing these certifications and expect to commence patent infringement lawsuits within the 45-day period triggered by our receipt of these certifications. In addition, a patent corresponding to the '498 patent was granted in February 2007 in India and survived a pre-grant opposition by Natco Pharma, Ltd. in July 2007. We, with our collaborator Roche, are currently seeking to enforce this patent against CIPLA with respect to a generic form of Tarceva launched by CIPLA in India. We and Roche filed a lawsuit against CIPLA in the High Court of Delhi in New Delhi, India in January 2008, which included a request that the court issue a preliminary injunction to prevent CIPLA from manufacturing and distributing Tarceva in India. The court denied this request in March 2008, and we subsequently appealed this decision. We completed our appeal in September 2008 and are awaiting a final decision. In addition, Teva Pharmaceuticals filed an opposition to the grant of a patent in Israel corresponding to our U.S. patent directed to a particular polymorph of Tarceva (U.S. Patent No. 6,900,221) in August 2007. This Israeli proceeding will be delayed until prosecution of a co-pending patent application in Israel is completed.

If we are unsuccessful in enforcing or defending our patents in any of these proceedings and the patents are revoked without possibility of appeal, this could reduce our future potential royalty revenue from sales of Tarceva in

these countries and increase the possibility that generic Tarceva will be unlawfully distributed and/or sold into countries where we have patent exclusivity which, in turn, would adversely impact our Tarceva revenues.

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

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

If we or our collaborators 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 collaborators will be forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our collaborators must obtain licenses from third parties, fees must be paid for such licenses, which would reduce the revenues and royalties we may receive on commercialized products.

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

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

The failure to prevail in litigation and/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 addition, as a biotechnology company, our processes and potential products may conflict with patents that have been or may be granted to competitors, academic institutions or others. We cannot ensure that our products or methods do not infringe upon the patents or other intellectual property rights of third parties. As the biotechnology and pharmaceutical industries expand and more patents are filed and issued, the risk increases that our patents or patent applications for our product candidates may give rise to a declaration of interference by the USPTO, or to administrative proceedings in foreign patent offices, or that our activities lead to

claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal proceedings against us seeking substantial damages or seeking to enjoin us from researching, developing, manufacturing or marketing our products, which could result in substantial costs and harm our reputation. If any of these actions are successful, we may not only be required to pay substantial damages for past use of the asserted intellectual property but we may also be required to cease the infringing activity or obtain the requisite licenses or rights to use the technology, that may not be available to us on acceptable terms, if at all. Litigation and other proceedings may also absorb significant management time.

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

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

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

Risks Related to Our Common Stock

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

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

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

- a decline in sales of Tarceva;
- a decline in our business operating results or prospects;
- a general economic slowdown in the United States, Europe or other key international markets where Tarceva is sold;
- adverse events with respect to our intellectual property;
- a prolonged interruption in the manufacture or supply of Tarceva;

- announcement or launching of technological innovations or new therapeutic products by third parties;
- positive or negative clinical efficacy or safety results from our competitors' products;
- public concern as to the safety, or withdrawal, of our products and potential products;
- comments by securities analysts regarding us or our competitors and general market conditions;
- future sales of substantial amounts of our common stock by us or existing stockholders;
- negative developments concerning strategic alliance agreements;
- changes in government regulation, including pricing controls, that impact our products;
- material delays in our key clinical trials;
- negative or neutral clinical trial results, including clinical trial results for additional indications for Tarceva;
- delays with the FDA in the approval process for products and clinical candidates; and
- developments in laws or regulations that impact our patent or other proprietary rights.

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

There are no unresolved staff comments.

ITEM 2. PROPERTIES

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

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

Farmingdale, New York. We lease a facility at One BioScience Park Drive, Farmingdale, New York, consisting of approximately 62,000 square feet. Our Farmingdale facility contains our drug discovery laboratories for oncology.

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

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

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

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

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 2008.

PART II

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

Market Information

Our common stock is traded in the over-the-counter market and is included for quotation on the NASDAQ National Market under the symbol OSIP. The following is the range of high and low sales prices by quarter for our common stock from January 1, 2007 through December 31, 2008 as reported on the NASDAQ National Market:

<u>2008 FISCAL YEAR</u>	<u>HIGH</u>	<u>LOW</u>
First Quarter	\$49.21	\$33.46
Second Quarter	\$42.10	\$32.10
Third Quarter	\$53.71	\$41.21
Fourth Quarter	\$48.98	\$31.33
<u>2007 FISCAL YEAR</u>	<u>HIGH</u>	<u>LOW</u>
First Quarter	\$36.89	\$30.94
Second Quarter	\$38.37	\$33.09
Third Quarter	\$36.60	\$28.68
Fourth Quarter	\$52.00	\$33.27

Holders and Dividends

As of February 20, 2009, there were approximately 2,663 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, 2008

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights(a)</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights(b)</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column)</u>
Equity compensation plans approved by security holders	6,491,465(c)	\$38.64	5,035,965(e)
Equity compensation plans not approved by security holders	<u>327,889(d)</u>	<u>\$46.20</u>	<u>—</u>
Total	<u>6,819,354</u>	<u>\$39.07</u>	<u>5,035,965</u>

- (a) Includes stock options, restricted stock, restricted stock units and deferred stock units.
- (b) The weighted-average exercise price of outstanding options, warrants and rights does not include restricted stock, restricted stock units and deferred stock units, as they are issued for no cash consideration.
- (c) Consists of four plans: the 1989 Incentive and Non-Qualified Stock Option Plan, the 1997 Incentive and Non-Qualified Stock Option Plan, the 1999 Incentive and Non-Qualified Stock Option Plan and the Amended and Restated Stock Incentive Plan.

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

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

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

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

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

- (e) Consists of 352,930 shares reserved for issuance under the 1995 Employee Stock Purchase Plan and the stock purchase plan for our U.K.-based employees, and 4,683,035 shares reserved for issuance under the 1999 Incentive and Non-Qualified Stock Option Plan and the Amended and Restated Stock Incentive Plan.

We have a policy of rewarding employees who achieve 10, 15, 20 and 25 years of continued service with our company with 100, 150 or 200 shares of our common stock depending on years of service. We grant such shares of common stock on an annual basis to those individuals who meet the stated requirements.

Recent Sales of Unregistered Securities

The following table reflects shares of common stock withheld from employees to satisfy their tax withholding obligations arising upon the vesting of restricted equity awards granted under our Amended and Restated Stock Incentive Plan.

<u>Period</u>	<u>Total Number Shares (or Units) Purchased</u>	<u>Average Price Paid per Share (or Unit)</u>	<u>Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Maximum Number (or Approximate Dollar Value) Shares (or Units) that May Yet Be Purchased Under the Plans or Programs</u>
October 1, 2008 –				
October 31, 2008	—	—	N/A	N/A
November 1, 2008 –				
November 30, 2008	—	—	N/A	N/A
December 1, 2008 –				
December 31, 2008	73,251(1)	\$33.41	N/A	N/A

- (1) Consists of shares of common stock withheld from employees to satisfy their tax withholding obligations arising upon the vesting of restricted equity awards granted under our Amended and Restated Stock Incentive Plan.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Subsequent to the end of our 2004 fiscal year, we changed our fiscal year end to December 31st. On February 9, 2005, we filed a transition report on Form 10-QT for the three-month period ended December 31, 2004. The following table sets forth our selected consolidated financial data as of and for the years ended December 31, 2008, 2007, 2006 and 2005, the three months ended December 31, 2004, and the year ended September 30, 2004. As a result of our decision to divest the eye disease business held by our wholly owned subsidiary, (OSI) Eyetechn, the operating results for (OSI) Eyetechn are shown as discontinued operations for all periods subsequent to our acquisition on November 14, 2005. The information below should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this report.

(In thousands, except per share data)	Year Ended December 31, 2008(a)	Year Ended December 31, 2007(b)	Year Ended December 31, 2006(c)	Year Ended December 31, 2005(d)	Three Months Ended December 31, 2004(e)	Year Ended September 30, 2004(f)
Consolidated Statement of Operations						
Data:						
Revenues	\$ 379,388	\$341,030	\$ 241,037	\$ 138,423	\$ 12,347	\$ 42,800
Expenses:						
Cost of goods sold	9,315	9,399	8,671	5,035	(1,247)	8,985
Net expense — unconsolidated joint business	—	—	—	—	7,661	—
Research and development	135,344	123,531	117,527	116,655	31,913	110,398
Acquired in-process research and development	4,000	9,664	—	3,542	—	32,785
Selling, general and administrative	94,930	99,159	107,458	89,205	20,313	98,909
Impairment of intangible assets	—	—	—	—	—	24,599
Amortization of intangibles	2,489	1,840	1,809	15,281	3,804	18,606
Income (loss) from operations	133,310	97,437	5,572	(91,295)	(50,097)	(251,482)
Other income (expense) — net	(166)	7,902	1,128	6,201	1,702	(8,889)
Income (loss) from continuing operations before income taxes	133,144	105,339	6,700	(85,094)	(48,395)	(260,371)
Income tax (benefit) provision business	(333,457)	2,732	—	—	—	—
Net income (loss) from continuing operations	466,601	102,607	6,700	(85,094)	(48,395)	(260,371)
Income (loss) from discontinued operations — net of tax business	4,884	(36,288)	(610,930)	(72,029)	—	—
Net income (loss) before extraordinary gain	471,485	66,319	(604,230)	(157,123)	(48,395)	(260,371)
Extraordinary gain — net of tax	—	—	22,046	—	—	—
Net income (loss)	<u>\$ 471,485</u>	<u>\$ 66,319</u>	<u>\$(582,184)</u>	<u>\$(157,123)</u>	<u>\$(48,395)</u>	<u>\$(260,371)</u>
Basic and diluted net earnings (loss) per common share:						
Basic earnings (loss):						
Income (loss) from continuing operations	\$ 8.14	\$ 1.78	\$ 0.12	\$ (1.63)	\$ (1.02)	\$ (6.50)
Income (loss) from discontinued operation	.09	(0.63)	(10.73)	(1.38)	—	—
Net income (loss) before extraordinary gain	8.23	1.15	(10.61)	(3.02)	(1.02)	(6.50)
Extraordinary gain	—	—	0.39	—	—	—
Net income (loss)	\$ 8.23	\$ 1.15	\$ (10.22)	\$ (3.02)	\$ (1.02)	\$ (6.50)
Diluted earnings (loss):						
Income (loss) from continuing operations	\$ 7.19	\$ 1.70	\$ 0.12	\$ (1.63)	\$ (1.02)	\$ (6.50)
Loss from discontinued operations	.07	(0.58)	(10.60)	(1.38)	—	—
Net income (loss) before extraordinary gain	7.26	1.11	(10.48)	(3.02)	(1.02)	(6.50)
Extraordinary gain	—	—	0.38	—	—	—
Net income (loss)	\$ 7.26	\$ 1.11	\$ (10.10)	\$ (3.02)	\$ (1.02)	\$ (6.50)
Shares used in the calculation of income (loss) per common share:						
Basic	57,316	57,665	56,939	52,078	47,375	40,083
Diluted	66,911	62,241	57,645	52,078	47,375	40,083

(In thousands)	As of December 31, 2008(a)	As of December 31, 2007(b)	As of December 31, 2006(c)	As of December 31, 2005(d)	As of December 31, 2004(e)	As of September 30, 2004(f)
Consolidated Balance Sheet Data:						
Cash, cash equivalents and investment securities (unrestricted and restricted)	\$ 515,511	\$305,098	\$216,368	\$ 179,606	\$656,239	\$257,229
Receivables	100,242	87,523	80,075	152,482	14,077	12,112
Working capital	629,260	197,631	266,496	276,171	630,246	228,223
Total assets	1,093,059	558,380	457,732	1,058,582	780,116	388,029
Long-term liabilities	460,392	166,930	349,555	337,788	195,814	186,574
Stockholders' equity	571,546	138,956	28,594	578,466	539,390	154,233

- (a) The calendar 2008 consolidated financial statements include a \$4.0 million in-process R&D charge related to the purchase of intellectual property and a \$336.6 million gain, included in the income tax provision related recognition of certain deferred tax assets. During 2008, we issued \$200.0 million principal amount of our 2038 Notes in a private placement for net proceeds of approximately \$193 million, of which \$65.0 million was used to purchase, concurrently with the offering, 1.5 million shares of our common stock. In addition, we repurchased approximately \$50 million of our 2023 Notes. The 2023 Notes have been reclassified as long-term in the December 31, 2008 consolidated balance sheet.
- (b) The calendar 2007 consolidated financial statements include a \$9.7 million in-process R&D charge related to the payment made under our research collaboration with AVEO and the purchase of AdipoGenix, Inc. intellectual property, and a \$4.1 million gain, included in "Other income (expense) — net," related to our decision to curtail our post-retirement medical and life insurance plan. The 2023 Notes were classified as current in the December 31, 2007 consolidated balance sheet.
- (c) The calendar 2006 loss from discontinued operations includes \$506.0 million of impairment charges related to (OSI) Eyetech goodwill and (OSI) Eyetech amortizable intangibles (\$320.3 million and \$185.7 million, respectively) and a \$26.4 million charge for obsolete and expiring inventory. A \$22.0 million extraordinary gain was recognized in the 2006 fiscal year as a result of reversing the accrued contingent consideration recorded in connection with the acquisition of Cell Pathways, Inc. in the 2003 fiscal year.
- (d) The calendar 2005 consolidated financial statements reflect: (a) the acquisition of Eyetech in November 2005 for aggregate consideration of \$909.3 million (\$637.4 million net of cash and investments acquired), including cash consideration of \$702.1 million, the value of 5.6 million shares of our common stock issued to Eyetech shareholders, the value of converted stock options issued to Eyetech shareholders and transaction-related costs incurred; (b) an in-process R&D charge of \$60.9 million related to the acquisition of Eyetech recorded as a loss from discontinued operations; (c) in-process R&D charges of \$3.5 million related to the acquisition of the minority interest in Prosidion; and (d) the issuance of \$115.0 million principal amount of our 2025 Notes in a private placement for net proceeds of \$111.0 million, of which approximately \$24 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.
- (e) The three months ended December 31, 2004 includes: (a) the sale of 6.9 million shares of our common stock for net proceeds of \$419.9 million; (b) net expense from unconsolidated joint business of \$7.7 million related to our co-promotion and manufacturing agreements with Genentech for Tarceva; and (c) a net credit adjustment of \$1.4 million to reduce a previously recorded provision for excess Gelclair® Bioadherent Oral Gel, or Gelclair, inventory.
- (f) The fiscal 2004 consolidated financial statements include: (a) the acquisition of certain assets from Probiobdrug for approximately \$36.4 million in cash; (b) an impairment charge related to the Gelclair intangible asset of \$24.6 million; (c) the conversion of \$160.0 million aggregate principal amount of 4% convertible senior subordinated notes due 2009 into 3.2 million shares of our common stock; (d) the charge of \$8.6 million relating to excess Gelclair inventory; and (e) the recognition of \$3.0 million of Tarceva-related milestone revenues.

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

Overview

We are a profitable 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 strategic focus is in the area of personalized medicine. We are building upon the knowledge and insights from our flagship product, Tarceva, in order to establish a leadership role in turning the promise of personalized medicine into practice in oncology and pioneering the adoption of personalized medicine approaches in diabetes and obesity. We are leveraging our targeted therapy expertise in drug discovery, development and translational research to deliver innovative, differentiated new medicines to the right patients, in the right combinations and at the right doses. We believe this approach is essential in order for us to accomplish more rapid and more cost-effective drug development aimed at providing substantial clinical benefit to the patients who can gain the most from our innovations. We further believe that, with increasing healthcare cost constraints and competition, leadership in personalized medicine approaches will define the successful biopharmaceutical companies of the future.

Tarceva, which, as of January 2009, was approved for sale in 94 countries for the treatment of advanced non-small cell lung cancer, or NSCLC, after failure of chemotherapy and 70 countries for the treatment of pancreatic cancer, is our primary source of U.S. revenue. We share 50% of the profits from U.S. sales of Tarceva (which are recorded by our collaborator for Tarceva, Genentech) and we receive royalties of approximately 20% on ex-U.S. sales of Tarceva by Roche, which is responsible for the marketing and sale of Tarceva outside of the United States. During 2008, we recorded \$335.0 million of Tarceva-related revenue, which represented approximately 88% of our total revenues. While this level of revenue resulted in substantial profitability for us in 2008, it remains important to our future that Tarceva sales continue to grow on a worldwide basis. Tarceva's sales growth, especially in the United States where we retain approximately 49% of each new marginal sales dollar, results in additional earnings to us and, if achieved, will continue to provide us with the opportunity to make the necessary investments in our research and development, or R&D, portfolio in order to build a scientifically strong, top-tier biopharmaceutical company. Oncology and diabetes/obesity R&D is an expensive and risky endeavor. We have a promising pipeline of Phase I and pre-clinical product candidates which we expect will require increasing levels of investment. However, we must continue to balance the ongoing investment in our pipeline with the need to deliver financial performance. Tarceva's continued growth, and our share of the resulting increased revenues, is critical for us to achieve this balance.

Tarceva's ability to grow in the future is dependent on a number of factors, including our and our collaborators' ability to expand market share for Tarceva both in the United States and the rest of the world, competitive developments in our industry, our ability to expand the approved indications for Tarceva by succeeding on key clinical trials and the changing reimbursement environment. As part of our lifecycle plan for Tarceva, we, together with Genentech and Roche, continue to invest in a broad clinical development program directed at maximizing Tarceva's long-term potential. This program includes a number of large, randomized clinical trials designed to expand Tarceva's use in both NSCLC and other treatment areas.

Recognizing that we have limited resources, we have adopted a highly disciplined approach to R&D, prioritizing investment in a portfolio of differentiated and competitive drug candidates and technologies which we hope will enable us to deliver higher clinical success rates than the industry average. In oncology, we have an emerging pipeline of molecular target therapies, or MTTs, in clinical and late-stage pre-clinical development which we intend to develop and commercialize independently. These include OSI-906 (an inhibitor of the insulin-like growth factor 1 receptor, or IGF-1R, with potential utility for the treatment of all major solid tumor types) which entered Phase I studies in June 2007, OSI-027 (a next generation mammalian target of rapamycin, or mTOR, kinase inhibitor) which entered Phase I studies in July 2008 and OSI-296 (a novel, potent tyrosine kinase inhibitor, or TKI, developed as an epithelial-to-mesenchymal transition, or EMT, inhibitor), which is in late-stage preclinical development. Each of these MTTs, as well as Tarceva, are small molecules designed to be administered orally as a tablet rather than by the less convenient intravenous infusion methods characteristic of most anti-cancer drugs. The focus of our proprietary oncology research efforts is on understanding multiple elements of tumor biology —

including the dependence of certain tumor cells on activated oncogenic signaling pathways, or onco-addiction, and compensatory signaling — but with a particular focus on the biological process of EMT, which is of emerging significance in understanding tumor development and disease progression. This research has grown out of our translational research efforts to understand which patients may optimally benefit from Tarceva. Our EMT research investment, together with related insights into mechanisms such as compensatory signaling, is the cornerstone of our personalized medicine approach in cancer, and should allow us to better design combinations of MTTs for specific sub-sets of cancer patients. This in turn may enable us to realize significant improvements in patient outcomes and to enhance our competitive position in the oncology marketplace.

We also have research and early development programs in diabetes and obesity which are conducted through our U.K. subsidiary, Prosidion Limited. Two compounds from our diabetes and obesity research efforts, PSN821 and PSN602, entered clinical trials in 2008. PSN821 is an orally administered G protein-coupled receptor 119, or GPR119, agonist with potential anti-diabetic and appetite suppressing features, and PSN602 is an oral dual serotonin and noradrenaline reuptake inhibitor and 5-HT_{1A} agonist for the treatment of obesity. Our discovery efforts in diabetes and obesity are concentrated around the neuroendocrine control of bodyweight and glycemia, which focuses on central or peripheral nervous system or hormonal approaches to the control of bodyweight for the treatment of obesity, as well as the lowering of blood glucose together with meaningful weight loss for the treatment of type 2 diabetes.

Prosidion contributes an important second source of revenues to us from the licensing of our patent estate relating to the use of DPIV inhibitors for the treatment of type 2 diabetes and related indications. As of February 15, 2009, twelve pharmaceutical companies had non-exclusive licenses to these patents, which have provided us with upfront payments as well as potential milestones and royalties. During 2008, we earned approximately \$41 million in royalty revenue from this patent estate. The royalty revenue from our DPIV patent estate has the potential to grow substantially over the next five years, assuming sales of licensed DPIV inhibitors continue on their current growth trajectory, and we believe our DPIV revenues will contribute to a significant portion of our overall anticipated revenue growth rate.

As we enter 2009, we are focused on delivering shareholder value by continuing to balance financial performance against the necessary reinvestment in R&D to further leverage our strong Tarceva franchise and develop an innovative and differentiated research platform and pipeline. By maintaining financial discipline around our R&D investments and controlling our spending on general and administrative expenses, we believe that we can deliver credible near term growth, while continuing to invest in attractive opportunities for long-term value creation.

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 revenue 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 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. Genentech is also responsible for estimating reserves for anticipated returns of Tarceva and monitoring the adequacy of these reserves. During 2008, in response to increased levels of Tarceva product returns, Genentech has modified its Tarceva returns policy and increased its reserve estimate for future Tarceva returns. 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. If actual future results differ from our estimates, we may need to adjust these estimates, which could have an effect on earnings in the period of adjustment. The reimbursement of sales and marketing costs related to Tarceva is recognized as revenue as the related costs are incurred. We defer the recognition of the reimbursement of our manufacturing costs related to Tarceva until the time Genentech ships the product to third-party customers, at which time our risk of inventory loss no longer exists.

Royalties

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

The royalty amount with respect to ex-U.S. Tarceva sales is calculated by converting the Tarceva sales for each country in their respective local currency into Roche's functional currency (Swiss francs) and then to U.S. dollars. The royalties are paid to us in U.S. dollars on a quarterly basis. As a result, fluctuations in the value of the U.S. dollar against foreign currencies will impact our royalty revenue.

License Fees and Milestones

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

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

Investments and Other-than-Temporary Impairments

Investment securities at December 31, 2008 and 2007 consisted primarily of U.S. government securities, U.S. government agency securities and debt securities of financial institutions and corporations with strong credit ratings. As of December 31, 2008, approximately 82% of our investment securities consisted of AAA rated and A1

rated securities, including our money market funds, which are AAA rated. We classify our investments as available-for-sale securities, as defined by Statement of Financial Accounting Standards, or, SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are recorded at their fair value. Unrealized holding gains and losses, net of the related tax effect, if any, on available-for-sale securities are excluded from earnings and are reported in accumulated other comprehensive income (loss), a separate component of stockholders' equity, until realized. The specific identification basis is utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities.

A decline in the market value of any available-for-sale marketable security below its cost that is deemed to be other-than-temporary results in a reduction in its carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is then established. The determination of whether an available-for-sale marketable security is other-than-temporarily impaired requires significant judgment and consideration of available quantitative and qualitative evidence in evaluating the potential impairment. Factors evaluated to determine whether the investment is other-than-temporarily impaired include: (i) whether there has been a significant deterioration in the issuer's earnings performance, credit rating, or asset quality; (ii) the business prospects of the issuer; (iii) adverse changes in the general market conditions in which the issuer operates; (iv) the length of time that the fair value has been below our cost; (v) our expected future cash flows from the security; and (vi) our intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. Assumptions associated with these factors are subject to future market and economic conditions, which could differ from our assessment. During 2007 and 2006 we did not recognize any other-than-temporary impairments. In the fourth quarter of 2008, we recorded a \$1.2 million impairment charge in other income (expense) — net related to an other-than-temporary decline in the fair value of common stock and warrants that we previously received as part of a licensing transaction.

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.

Inventory includes 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 R&D 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.

Stock-Based Compensation

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

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

The assumptions used in computing the fair value of stock-based awards reflect our best estimates, but involve uncertainties relating to market and other conditions, many of which are outside of our control. As a result, if other assumptions or estimates had been used, the stock-based compensation expense that was recorded for the years ended December 31, 2008, 2007 and 2006 could have been materially different. Furthermore, if different assumptions are used in future periods, stock-based compensation expense could be materially impacted in the future.

Accruals for Clinical Research Organization and Clinical Site Costs

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

Income Taxes

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

For the year ended December 31, 2008, we recorded a \$333.5 million income tax benefit from continuing operations, which included a favorable adjustment in the fourth quarter of 2008 of \$336.6 million resulting from the reversal of a significant portion of the valuation allowance. The reduction of the valuation allowance is based on the fact that we determined that it was more likely than not that we will generate sufficient taxable income to realize the benefits of our deferred assets, primarily resulting from our net operating losses, or NOLs. The determination was based upon our assessment of our cumulative profitability in the United States over the past three years and our expectation of future taxable income.

As of December 31, 2008, we had accumulated approximately \$949 million of NOLs related to our U.S. and foreign operations. The U.S. NOLs, which, subject to limitations, can be used to offset our future U.S. taxable income, expire between the years 2021 and 2026. Utilization of a portion of the U.S. NOLs may be limited under U.S. Internal Revenue Code Section 382. The U.K. NOLs, which can be used to offset our future U.K. taxable income, do not expire. Future utilization of the U.K. NOLs is uncertain based upon the historical results of our U.K. operations. As of December 31, 2008, we have recorded \$336.6 million net in deferred tax assets relating to the U.S. and foreign tax benefit from the potential future use of these NOLs. We have also accumulated an additional approximately \$100 million in other net deferred tax assets based on temporary differences between book and tax reporting.

On January 1, 2007, we adopted the provisions of Financial Accounting Standards Board, or FASB, Financial Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109," or FIN 48. FIN 48 clarifies the criteria that must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN 48 provides a benefit recognition model with a two-step approach consisting of a "more-likely-than-not" recognition criteria, and a measurement attribute that measures a given tax position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. FIN 48 also requires the recognition of liabilities created by differences between tax positions taken in a tax return and amounts recognized in the financial statements. As of December 31, 2008 and 2007, we did not have any liabilities relating to tax uncertainties.

Goodwill and Other Long-Lived 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. 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.

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

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

Discontinued Operations

On November 6, 2006, we announced our intention to divest our eye disease business. During the first quarter of 2007, we finalized our exit plan and began to actively market our eye disease business assets. As a result of the finalization of our plan to sell the business during the first quarter of 2007, in accordance with the provision of SFAS No. 144, the results of operations of (OSI) Eyetech for the current and prior periods have been reported as discontinued operations. In addition, assets and liabilities of (OSI) Eyetech have been classified as assets and liabilities related to discontinued operations, including those held for sale.

On August 1, 2008, we completed the sale of the remaining assets of our eye disease business to Eyetech Inc., a newly formed corporation whose shareholders consist primarily of members of the Macugen® (pegaptinib sodium injection) sales team. Under the terms of the transaction, the principal assets we transferred to Eyetech Inc. consisted of Macugen-related intellectual property and inventory, as well as \$5.8 million in working capital primarily in the form of Macugen trade receivables, in exchange for potential future milestone and royalty payments. We have determined that, under FASB Interpretation No. 46(R), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51," issued in January 2003, or FIN 46(R), Eyetech Inc. qualifies as a variable interest entity, or VIE, but as we are not its primary beneficiary, consolidation is not required. FIN 46(R) requires an entity to be classified as a VIE where (i) the reporting company, or its related parties, participated significantly in the design of the entity, or where substantially all of the activities of the entity either involve or are conducted on behalf of the reporting company or its related parties, and (ii) its equity investors do not have a controlling financial interest or where the entity is unable to finance its activities without additional financial support from other parties. Based on this test, we determined that Eyetech Inc. qualified as a VIE due to its inability at the time of its acquisition of the remaining assets of our eye disease business to finance its activities without additional financial support from third parties, and due to the fact that Mr. Atieh, our former Executive Vice President, Chief Financial Officer and Treasurer, is a stockholder in Eyetech Inc., participated in the design of the entity and agreed to serve as its part-time executive chairman upon his retirement from our company.

FIN 46(R) further requires the consolidation of entities which are determined to be VIEs when the reporting company determines itself to be the primary beneficiary — in other words, the entity that will absorb a majority of the VIEs expected losses or receive a majority of the VIEs expected residual returns. We determined that OSI is not the primary beneficiary of Eyetech Inc. as (i) OSI does not hold an equity position in Eyetech Inc., (ii) OSI's

ongoing interest in this entity is limited to OSI's contingent right to receive future royalties and milestones, and (iii) OSI does not have liability for the future losses.

Years Ended December 31, 2008 and 2007

Results of Operations

Net income for the year ended December 31, 2008 was \$471.5 million compared to \$66.3 million for the year ended December 31, 2007. Our net income from continuing operations for the years ended December 31, 2008 and 2007 was \$466.6 million and \$102.6 million, respectively. The increase in net income from continuing operations was primarily due to a \$336.6 million non-cash gain recorded in the fourth quarter of 2008 related to the recognition of certain deferred tax assets (primarily resulting from our NOLs) and an increase in Tarceva-related revenues and royalties from our DPIV patent estate. Included in net income for 2008 and 2007 are income from discontinued operations of \$4.8 million for 2008 and a net loss from discontinued operations of \$36.3 million for 2007. As a result of our decision to exit the eye disease business and the finalization of our exit plan in March 2007, the results of the eye disease business are presented as discontinued operations for all periods presented.

Revenues

	Year Ended December 31, (in thousands)		
	2008	2007	\$ Change
Tarceva-related revenues	334,653	267,799	66,854
Other revenues	44,735	73,231	(28,496)
Total revenues	<u>\$379,388</u>	<u>\$341,030</u>	<u>\$ 38,358</u>

Tarceva-Related Revenues

Tarceva-related revenues for the years ended December 31, 2008 and 2007 were \$334.7 million and \$267.8 million, respectively, and included net revenue from our unconsolidated joint business, Tarceva-related royalties and Tarceva-related milestones.

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, 2008 and 2007, Genentech recorded net sales of Tarceva in the United States and its territories of approximately \$457 million and \$417 million, respectively. The increase in net sales of Tarceva for the year ended December 31, 2008 was primarily a result of price increases and a lower level of reserve adjustments recorded in the year ended December 31, 2008 compared to the year ended December 31, 2007, partially offset by a slight decrease in demand. Our share of these net sales is reduced by the cost of goods sold for Tarceva and the costs related to the sales and marketing of the product. For the year ended December 31, 2008, we reported net revenues from our unconsolidated joint business for Tarceva of \$196.1 million compared to \$168.8 million for the same period last year. The increase in net revenue from unconsolidated joint business for the year ended December 31, 2008 was primarily due to higher sales, higher reimbursement of our sales and marketing costs and overall lower combined sales and marketing costs incurred by the collaboration.

Tarceva-Related Royalties

We receive royalties from Roche of approximately 20% on net sales of Tarceva outside of the United States and its territories. The royalty amount is calculated by converting the respective countries' Tarceva sales in local currency to Roche's functional currency (Swiss francs) and then to U.S. dollars. The royalties are paid to us in U.S. dollars on a quarterly basis. As a result, fluctuations in the value of the U.S. dollar against foreign currencies will impact our earnings. For the years ended December 31, 2008 and 2007, Roche reported U.S. dollar equivalent rest of world sales of approximately \$665 million and \$470 million, respectively. For the years ended December 31, 2008 and 2007, we recorded \$134.6 million and \$95.2 million in royalty revenue from these sales, respectively. The

increase in royalty revenue was primarily due to increased sales volume outside the United States, including sales in Japan, which has been a market for Tarceva since December 2007, and the net favorable impact of foreign exchange rates.

Tarceva-Related Milestones

Milestone revenues from Tarceva include the recognition of the ratable portion of upfront fees from Genentech and milestone payments received from Genentech and Roche in connection with various regulatory acceptances and approvals for Tarceva in the United States, Europe and Japan. These payments were initially deferred and are being recognized as revenue in accordance with EITF 00-21. The ratable portions of the upfront fees and milestone payments recognized as revenue for the years ended December 31, 2008 and 2007 were \$3.9 million and \$3.8 million, respectively. The unrecognized deferred revenue related to these upfront fees and milestone payments was \$37.1 million and \$41.0 million as of December 31, 2008 and 2007, respectively. We are also entitled to additional milestone payments from Genentech and Roche upon the occurrence of certain regulatory approvals and filings with respect to Tarceva. The ultimate receipt of these additional milestone payments is contingent upon the applicable regulatory approvals and other future events.

Other Revenues

Other revenues for the years ended December 31, 2008 and 2007 were \$44.7 million and \$73.2 million, respectively, and include non-Tarceva related license, milestone, royalty and commission revenues.

We recognized \$41.1 million and \$17.1 million of royalty revenue for the years ended December 31, 2008 and 2007, respectively, from previously granted 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. Our royalty revenue in 2008 and 2007 was principally derived from sales of Merck's DPIV inhibitor product, Januvia™, and its DPIV combination product with metformin, Janumet™. We also derived royalty revenue from sales of Novartis' DPIV inhibitor products, Galvus® and Eucreas®. The year ended December 31, 2007 also included \$17.7 million of upfront payments and milestones under the non-exclusive license for our DPIV patent portfolio. The amount of license revenues generated from our DPIV patent estate can be expected to fluctuate significantly from year to year based on: (i) the level of future product sales by our licensees; (ii) the ability of our licensees to achieve specified events under the license agreements which entitle us to milestone payments; and (iii) our ability to enter into additional license agreements in the future.

In February 2008, we licensed to a third party our transforming growth factor, or TGF β3, compound for certain indications, for an upfront fee of \$2.0 million. We recognized the \$2.0 million payment as license revenue in the first quarter of 2008 since we had no future performance obligations. Pursuant to the terms of a cross license with Novartis AG, approximately \$350,000 of the amount we received was paid to Novartis.

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

During the third quarter of 2007, we received \$7.5 million of license revenue from Renovo Group plc in connection with its license agreement with Shire plc for its TGF β3 drug candidate Juvista®. Under our agreement with Renovo, we are entitled to a fixed percentage of any upfront payment, development and sales milestones and royalties that Renovo receives from Shire under the license agreement. We are contractually obligated under a cross-license to pay Novartis 15% of any amounts we receive from Renovo.

During the fourth quarter of 2007, we recognized \$2.4 million of revenue from the consideration received as a result of outlicensing OSI-7904L, an oncology clinical candidate for which we had ceased development, to OncoVista Innovative Therapies, Inc. The consideration included cash of \$500,000 and OncoVista common stock and warrants with a fair value of \$1.9 million. The common stock is publicly traded and was recorded as an available-for-sale security. In the fourth quarter of 2008, we recorded a \$1.2 million impairment charge in other

income (expense)-net related to an other-than-temporary decline in fair value of the equity and warrants that we previously received as part of a licensing transaction.

Included in other revenues are sales commissions earned on the sales of Novantrone® (mitoxantrone for injection concentrate) in the United States for oncology indications. Sales commissions for the years ended December 31, 2008 and 2007 were \$171,000 and \$2.5 million, respectively. Sales commissions declined significantly subsequent to April 2006 due to the patent expiration of Novantrone in April 2006, which resulted in our loss of market exclusivity for this product and the launch of generic competitors.

Expenses

	Year Ended December 31, (in thousands)		
	2008	2007	\$ Change
Cost of goods sold	\$ 9,315	\$ 9,399	\$ (84)
Research and development	135,344	123,531	11,813
Acquired in-process research and development	4,000	9,664	(5,664)
Selling, general and administrative	94,930	99,159	(4,229)
Amortization of intangibles	2,489	1,840	649
	<u>\$246,078</u>	<u>\$243,593</u>	<u>\$ 2,485</u>

Cost of Goods Sold

Total cost of goods sold for the years ended December 31, 2008 and 2007 were \$9.3 million and \$9.4 million, respectively, and related to Tarceva sales.

Research and Development

R&D expenses increased by \$11.8 million for the year ended December 31, 2008 compared to the year ended December 31, 2007. The increase was primarily due to an increase in R&D expenses related to non-Tarceva oncology programs and equity-based compensation, partially offset by declines in R&D expenses for Tarceva and for our diabetes and obesity programs.

We manage the ongoing development program for Tarceva with our collaborators, Genentech and Roche, through a global development committee under a Tripartite Agreement among the parties. Together with our collaborators, we have implemented a broad-based global development strategy for Tarceva that implements simultaneous clinical programs currently designed to expand the number of approved indications for Tarceva and evaluate the use of Tarceva in new and/or novel combinations. Since 2001, the collaborators have committed an aggregate of approximately \$900 million to the global development plan to be shared by the three parties. As of December 31, 2008, we had invested in excess of \$245 million in the development of Tarceva, representing our share of the costs incurred through December 31, 2008 under the tripartite global development plan and additional investments outside of the plan.

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 highly disciplined manner designed to advance only high quality, differentiated agents into clinical development. The duration of each phase of clinical development and the probabilities of success for approval of drug candidates entering clinical development will be impacted by a variety of factors, including the quality of the molecule, the validity of the target and disease indication, early clinical data, investment in the program, competition and commercial viability. Because we manage our pipeline in a dynamic and disciplined manner, it is difficult to give accurate guidance on the anticipated proportion of our R&D 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, 2008 and 2007, we invested a total of \$54.3 million and \$47.4 million, respectively, in research and \$81.0 million and \$76.1 million, respectively, in pre-clinical and clinical

development. We believe that this represents an appropriate level of investment in R&D for our company when balanced against our goals of financial performance and the creation of longer-term shareholder value.

Acquired In-Process Research and Development

In the fourth quarter of 2008, our subsidiary, Prosidion, acquired intellectual property and other assets from 7TM Pharma A/S for \$4.0 million. The \$4.0 million was recorded as an in-process R&D charge, since it was associated with the intellectual property which was deemed early stage with no alternative future use in accordance with SFAS No. 2, "Accounting for Research and Development Costs."

In September 2007, we entered into a small molecule drug discovery and translational research collaboration with AVEO Pharmaceuticals, Inc., or AVEO. Under the terms of our collaboration, we delivered to AVEO an upfront cash payment of \$10.0 million, consisting of \$7.5 million for access to certain AVEO technology and \$2.5 million to fund the first year of research under the collaboration, and purchased \$5.5 million of AVEO's preferred stock. We are also obligated to provide AVEO with certain future research funding, as well as milestones and royalties upon successful development and commercialization of products from the collaboration. The AVEO technology is deemed to have no alternative future use in accordance with SFAS No. 2 since it was intended to be used to support our early development technologies. Accordingly, we expensed the \$7.5 million payment as acquired in-process R&D in the third quarter of 2007.

In the fourth quarter of 2007, Prosidion acquired intellectual property and laboratory equipment from AdipoGenix, Inc. for \$2.3 million. Of the \$2.3 million purchase price, \$2.2 million was recorded as an in-process R&D charge since it was associated with the intellectual property which was deemed early stage with no future alternative use in accordance with SFAS No. 2. The remainder of the cost was allocated to the laboratory equipment acquired, based upon its fair value, and capitalized.

Selling, General and Administrative

Selling, general and administrative expenses for the year ended December 31, 2008 were \$94.9 million, a decrease of \$4.2 million from the same period last year. The decrease was primarily attributable to a decline in license related fees and general corporate expenses, partially offsetting higher equity based compensation and salaries.

Other Income and Expense

	Year Ended December 31, (in thousands)		
	2008	2007	\$ Change
Investment income-net	\$ 12,961	\$12,830	\$ 131
Interest expense	(11,932)	(7,235)	(4,697)
Other income (expense)-net	(1,195)	2,307	(3,502)
Total other income (expense)	<u>\$ (166)</u>	<u>\$ 7,902</u>	<u>\$(8,068)</u>

Investment income for the year ended December 31, 2008 remained relatively constant to the same period last year. However, despite an increase in the funds available for investments, investment income was negatively impacted by lower rates of return on our investments.

Interest expense for the year ended December 31, 2008 increased by \$4.7 million compared to the same period last year, due to the additional interest expense resulting from the issuance of \$200.0 million 3% Convertible Senior Subordinated Notes due 2038, or our 2038 Notes, in January 2008. The increase was partially offset by the repurchase of \$50.0 million of our 3.25% Convertible Senior Subordinated Notes due 2023, or our 2023 Notes, through the first three quarters of 2008.

Other income (expense) — net was a \$1.2 million expense for the year ended December 31, 2008 compared to \$2.3 million of income for the same period last year. The year ended December 31, 2008 includes higher amortization of debt issuance cost, expenses associated with redeeming a portion of our 2023 Notes and a

\$1.2 million impairment charge related to common stock and warrants that we previously received as part of a licensing transaction for which we concluded the decline in market value was other- than-temporary. Partially offsetting the higher expenses in 2008 was \$3.4 million of foreign exchange gains recognized by our U.K. operations. The other income in the year ended December 31, 2007 was primarily a result of a \$4.0 million curtailment gain related to our decision to curtail our post-retirement medical and life insurance plan.

Income Taxes

For the year ended December 31, 2008, we recorded a \$333.5 million income tax benefit from continuing operations, which included a favorable adjustment of \$336.6 million in the fourth quarter of 2008 resulting from the reversal of a significant portion of the valuation allowance. In accordance with FAS 109, "Accounting for Income Taxes," the reduction of the valuation allowance is based on the fact that we determined that it was more likely than not that we will generate sufficient taxable income to realize the benefits of our deferred assets, primarily resulting from our NOLs. The determination was based upon our assessment of our cumulative profitability in the United States over the past three years and our expectation of future taxable income.

Income (loss) from Discontinued Operations

On November 6, 2006, we announced our intention to divest our eye disease business. During the first quarter of 2007, we finalized our exit plan and began to actively market our eye disease business assets. As a result of the finalization of our plan to sell the business during the first quarter of 2007, in accordance with the provision of SFAS No. 144, the results of operations of (OSI) Eyetech for the current and prior periods have been reported as discontinued operations. In addition, assets and liabilities of (OSI) Eyetech have been classified as assets and liabilities related to discontinued operations, including those held for sale.

On August 1, 2008, we completed the sale of the remaining assets of our eye disease business to Eyetech Inc. Under the terms of the transaction, the principal assets we transferred to Eyetech Inc. consisted of Macugen-related intellectual property and inventory, as well as \$5.8 million in working capital primarily in the form of Macugen trade receivables, in exchange for potential future milestone and royalty payments. Macugen net product revenues for the seven months ended July 31, 2008, or the last date that we held the remaining assets of our eye disease business, were \$7.2 million. Net income for the year ended December 31, 2008 was \$4.9 million compared to net losses of \$36.3 million, in the same period last year. As a result of the sale of the remaining assets of our eye disease business, during the year ended December 31, 2008 we incurred \$14.1 million of charges relating to the write-down of the assets held for sale to their net realizable value as well as transaction-related charges. We also recognized: (i) the remaining balance of the \$27.9 million of unearned revenue as income in the third quarter of 2008 as a result of the assignment to Eyetech, Inc. of certain obligations under our amended and restated license agreement with Pfizer; and (ii) a \$2.0 million expense in the third quarter of 2008 related to a third-party milestone obligation for Macugen.

Years Ended December 31, 2007 and 2006

Results of Operations

Our net income from continuing operations for the years ended December 31, 2007 and 2006 was \$102.6 million and \$6.7 million, respectively. The increase in net income from continuing operations was primarily due to increases in revenue related to Tarceva, and milestones and upfront fees from our worldwide license agreements. Net income for the year ended December 31, 2007 was \$66.3 million compared to a net loss of \$582.2 million for the year ended December 31, 2006. Included in net income for 2007 and the net loss for 2006 are the losses from discontinued operations of \$36.3 million and \$610.9 million, respectively. Also included in the net loss for 2006 was a \$22.0 million extraordinary gain relating to the reversal of the contingent value rights liability.

Revenues

	Year Ended December 31, (in thousands)		
	2007	2006	\$ Change
Tarceva-related revenues	267,799	208,298	59,501
Other revenues	73,231	32,739	40,492
Total revenues	<u>\$341,030</u>	<u>\$241,037</u>	<u>\$99,993</u>

Tarceva-Related Revenues

Tarceva revenues for the years ended December 31, 2007 and 2006 were \$267.8 million and \$208.3 million, respectively, and include net revenues from our unconsolidated joint business, Tarceva-related royalties and Tarceva-related milestones.

Net Revenue from Unconsolidated Joint Business

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

Tarceva-Related Royalties

We receive royalties from Roche of approximately 20% on net sales of Tarceva outside of the United States and its territories. The royalty amount is calculated by converting the respective countries' Tarceva sales in local currency to Roche's functional currency (Swiss francs) and then to U.S. dollars. Conversion from local currencies to Swiss francs occurs quarterly based on an average year-to-date exchange rate while the conversion from Swiss francs to U.S. dollars occurs quarterly based on the average exchange rate for the quarter. The royalties are paid to us in U.S. dollars on a quarterly basis. As a result, fluctuations in the value of the U.S. dollar against foreign currencies impact our earnings. For the years ended December 31, 2007 and 2006, Roche reported U.S. dollar equivalent sales of approximately \$470 million and \$247 million, respectively, and we recorded \$95.2 million and \$50.2 million, respectively, in royalty revenue from these sales. The increase in royalty revenue was primarily due to increased demand outside the United States and, to some extent, changes in foreign exchange rates.

Tarceva-Related Milestones

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

Other Revenues

Other revenues for the years ended December 31, 2007 and 2006 were \$73.2 million and \$32.7 million, respectively, and includes non-Tarceva related licenses, milestone, royalty and commission revenues.

We recognized \$17.1 million and \$0.9 million of royalty revenue for the years ended December 31, 2007 and 2006, respectively, from previously granted worldwide non-exclusive license agreements entered into by Prosidion under our DPIV patent portfolio covering the use of DPIV inhibitors for treatment of type 2 diabetes and related indications. The years ended December 31, 2007 and 2006 also included \$17.7 million and \$18.3 million, respectively, of upfront payments and milestones, under these license agreements. The amount of license revenues generated from our DPIV patent estate can be expected to fluctuate significantly from quarter to quarter based on: (i) the level of future product sales by our licensees; (ii) the ability of our licensees to achieve specified events under the license agreements which entitle us to milestone payments; and (iii) our ability to enter into additional license agreements in the future.

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

During the third quarter of 2007, we received \$7.5 million of license revenue from Renovo Group plc in connection with its license agreement with Shire plc for its transforming growth factor, or TGF β 3, drug candidate, Juvista[®]. Under our agreement with Renovo, we are entitled to a fixed percentage of any upfront payment, development and sales milestones and royalties that Renovo receives from Shire under the license agreement. We are contractually obligated under a cross-license to pay Novartis 15% of any amounts we receive from Renovo.

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

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

Expenses

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

Cost of Goods Sold

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

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 R&D. 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 R&D. During 2006, we had sold all of the inventory partially produced and expensed prior to November 18, 2004. Cost of goods sold for the year ended December 31, 2006 would have been \$1.4 million higher if the Tarceva inventory sold had reflected the full absorption of manufacturing costs.

Research and Development

R&D expenses increased by \$6.0 million for the year ended December 31, 2007 compared to the year ended December 31, 2006. For the years ended December 31, 2007 and 2006, we invested a total of \$47.4 million and \$46.4 million, respectively, in research and \$76.1 million and \$71.1 million, respectively, in pre-clinical and clinical development. The increase was primarily due to an \$8.9 million increase in R&D expenses related to non-Tarceva oncology programs, equity based compensation and severance costs, partially offset by minor declines in R&D expenses for Tarceva and for our diabetes and obesity programs.

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

Acquired In-Process Research and Development

On September 28, 2007, we entered into a small molecule drug discovery and translational research collaboration with AVEO. The purpose of this collaboration is the development of molecular therapies that target the underlying mechanisms of EMT in cancer. Under the terms of our collaboration agreement, we delivered to AVEO a \$10.0 million upfront cash payment (which includes \$2.5 million of research funding for the first year of the collaboration) and purchased \$5.5 million of AVEO preferred stock. We also agreed to provide AVEO with additional research funding, as well as milestones and royalties upon successful development and commercialization of products from the collaboration.

The \$7.5 million of the upfront payment was recorded as an in-process R&D charge, since it was non-refundable and deemed to have no alternative future use. The \$2.5 million of first-year research funding was recognized as a prepaid asset and is being amortized over one year, or the period that AVEO is expected to provide research efforts under the collaboration. The acquired preferred stock was recorded as a cost-based investment in other assets in the accompanying balance sheet as of December 31, 2007.

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

Selling, General and Administrative

Selling, general and administrative expenses for the year ended December 31, 2007 were \$99.2 million compared to \$107.5 million for the year ended December 31, 2006. The \$8.3 million decrease in expenses was primarily attributable to a \$7.0 million decline in maintenance fees for Novantrone, costs savings and facility restructuring charges recorded in 2006. Partially offsetting these declines were an increase in commercial costs associated with Tarceva, a \$1.1 million license fee due to Novartis as a result of the \$7.5 million license fee we received from Renovo and an increase in equity based compensation and severance related costs.

Other Income and Expense

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

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

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

Income Taxes

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

Loss from Discontinued Operations

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

Extraordinary Gain

In connection with the 2003 acquisition of Cell Pathways, Inc., we recognized contingent consideration of \$22.0 million in the form of five-year contingent value rights pursuant to which each share of Cell Pathways common stock was 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 ceased our development efforts for these two clinical candidates and pursued outlicensing efforts with respect to these two candidates. During the second quarter of fiscal 2006, we concluded that, in our judgment, the milestone would not be met based upon the progress of our outlicensing efforts and the technical hurdles for filing a new drug application by June 2008 and therefore, we reversed the \$22.0 million liability and recorded an extraordinary gain during the year ended December 31, 2006. The milestone was not met by the June 12, 2008 deadline.

Liquidity and Capital Resources

At December 31, 2008, cash and investments, including restricted securities, were \$515.5 million compared to \$305.1 million at December 31, 2007. The increase of \$210.4 million was primarily due to the following changes: (i) net cash of \$139.0 million generated from operating activities and \$200.0 million in proceeds from the issuance of our 2038 Notes in January 2008, offset by a \$65.0 million treasury stock buy back in January 2008 and cash used to repurchase \$50.0 million of the \$150.0 million in aggregate indebtedness that was outstanding under our 2023 Notes.

On January 9, 2008, we issued \$200.0 million aggregate principal amount of our 2038 Notes in a private placement, resulting in net proceeds to us of approximately \$193 million. We used a portion of the proceeds to repurchase approximately 1.5 million shares of our common stock concurrently with the offering for an aggregate price of \$65.0 million. The 2038 Notes bear interest semi-annually in arrears through maturity at an annual rate of 3% and mature on January 15, 2038. We may redeem, for cash, all or part of the 2038 Notes at any time on or after January 15, 2013, at a price equal to 100% of the principal amount of the 2038 Notes, plus accrued and unpaid interest. Holders of the 2038 Notes have the right to require us to purchase, for cash, all or any portion of their 2038 Notes on January 15, 2013, 2018, 2023, 2028 and 2033 at a price equal to 100% of the principal amount of the 2038 Notes to be purchased, plus accrued and unpaid interest. The 2038 Notes are unsecured and are subordinated to all of our existing and future senior indebtedness. The 2038 Notes rank equally in right of payment with all of our existing and future senior subordinated indebtedness. The 2038 Notes will be convertible, in certain circumstances, into our common stock based upon a base conversion rate, which, under certain circumstances will be increased pursuant to a formula that is subject to a maximum conversion rate. The initial base conversion rate is 13.5463 shares per \$1,000 principal amount of notes (equivalent to an initial base conversion price of approximately \$73.82 per share of our common stock). The initial base conversion price represents a premium of 65% to the \$44.74 per share closing price of OSI's common stock on January 3, 2008. Upon conversion, holders of the 2038 Notes will have the right to receive shares of our common stock, subject to our right to deliver cash in lieu of all or a portion of such shares.

Through diligent management of our business, in particular our expenses, we have sustained our profitability and strengthened our financial position. If we continue to execute on our internal plans, we expect over the next two years that our R&D investments, capital requirements and the potential redemption of our 2% Convertible Senior Subordinated Notes due 2025, or our 2025 Notes, in December 2010 could be funded from the generation of cash flow from Tarceva and our DPIV patent estate licenses. Certain potential exceptions to this include the possible need to fund strategic acquisitions of products and/or businesses should we identify any such strategic opportunities in the future.

Commitments and Contingencies

Our major outstanding contractual obligations relate to our senior subordinated convertible notes and our facility leases. The following table summarizes our significant contractual obligations at December 31, 2008 and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	<u>2009</u>	<u>2010-2011</u>	<u>2012-2013</u>	<u>2014 & Thereafter</u>
Contractual Obligations:				
Senior convertible debt(a)	\$11,548	\$23,097	\$23,097	\$622,034
Operating leases	11,074	21,543	20,303	66,619
Purchase obligations(b)	33,800	40,800	13,400	10,200
Obligations related to exit activities(c)	<u>1,817</u>	<u>—</u>	<u>1,409</u>	<u>—</u>
Total contractual obligations	<u>\$58,239</u>	<u>\$85,440</u>	<u>\$58,209</u>	<u>\$698,853</u>

- (a) Our senior convertible debt obligations assume the payment of interest on our senior convertible notes through their respective maturity dates and the payment of their outstanding principal balance at their respective maturity dates. The interest payments on our senior convertible notes are at a rate of (i) 3.25% per annum relating to the \$99.95 million principal amount of the 2023 Notes, (ii) 2% per annum relating to the

\$115.0 million principal amount of the 2025 Notes, and (iii) 3% per annum relating to the \$200.0 million principal amount of the 2038 Notes. The holders of the 2023 Notes have the right to require us to purchase, for cash, all of the 2023 Notes, or a portion thereof, in September 2013. In the event that the holders of the 2023 Notes exercise this right, we will have the option of delivering to the holders a specified number of shares of our common stock in lieu of cash as set forth in the indenture for the 2023 Notes. 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. Holders of the 2038 Notes have the right to require us to purchase, for cash, all of the 2038 Notes, or a portion thereof, in January 2013.

- (b) Includes commercial and research commitments and other significant purchase commitments. Also includes our share of the remaining future commitment related to the Tarceva global development costs of approximately \$93 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 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 \$1.9 million, which primarily serve as security for over performance under various lease obligations.
- We have a retirement plan which provides post-retirement medical and life insurance benefits to eligible employees, board members and qualified dependents. We curtailed this plan in 2007; however, certain employees, board members and qualified dependents remain eligible for these benefits. Eligibility is determined based on age and years of service. We had an accrued liability for post-retirement benefit costs of \$2.7 million at December 31, 2008.
- Under certain license and collaboration agreements with pharmaceutical companies and educational institutions, we are required to pay royalties, milestone and/or other 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 R&D 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.

Accounting Pronouncements

In May 2008, FASB issued FASB Staff Position, or FSP, No. APB 14-1, "Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)." This FSP clarifies that convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) are not addressed by paragraph 12 of APB Opinion No. 14, "Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants." Additionally, this FSP specifies that issuers of such instruments should separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. This FSP will be effective beginning with our financial statements issued for the first quarter of 2009. We are currently evaluating the impact this FSP will have on our financial position or results of operations and anticipate the adoption of this FSP will have a material impact on the carrying value and the interest expense associated with our 2025 Notes and 2038 Notes.

In April 2008, the FASB issued FSP No. FAS 142-3, "Determination of the Useful Life of Intangible Assets." FSP FAS 142-3 removes the requirement within SFAS No. 142 for an entity to consider, when determining the useful life of a recognized intangible asset, whether an intangible asset can be renewed without substantial cost or material modifications to the existing terms and conditions. FSP FAS 142-3 requires an entity to consider its own historical experience in developing renewal or extension assumptions. In the absence of entity specific experience, FSP FAS 142-3 requires an entity to consider assumptions that a marketplace participant would use about renewal or extension that are consistent with the highest and best use of the asset by a marketplace participant. FSP FAS 142-3 is effective prospectively for all intangible assets acquired after its effective date, for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, with additional disclosures required for all recognized intangible assets as of the effective date. We do not expect the adoption of FSB FAS 142-3 to have a material impact on our financial position, results of operations or cash flows.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities." SFAS No. 159 permits entities to choose to measure many financial instruments and certain items at fair value that are not currently required to be measured at fair value. Effective January 1, 2008, we elected to adopt the provisions of SFAS No. 159 for our fiscal year ending December 31, 2008. The adoption of SFAS No. 159 did not have a material impact on our financial position, results of operations or cash flows.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements," to clarify the definition of fair value, establish a framework for measuring fair value and expand the disclosures on fair value measurements. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. SFAS No. 157 also stipulates that, as a market-based measurement, fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability, and establishes a fair value hierarchy that distinguishes between: (a) market participant assumptions developed based on market data obtained from sources independent of the reporting entity, or observable inputs; and (b) the reporting entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances, or unobservable inputs. Except for the deferral for the implementation of SFAS No. 157 for specified other non-financial assets and liabilities, SFAS No. 157 is effective for our fiscal year ended December 31, 2008. The adoption of SFAS No. 157 did not have a material impact on our financial position, results of operations or cash flows.

In February 2008, the FASB issued FSP 157-2, "Effective Date of FASB Statement No. 157," which delays the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities. The delay is intended to allow the FASB and constituents additional time to consider the effect of various implementation issues that have arisen, or that may arise, from the application of SFAS No. 157. For items within the scope of FSP 157-2, this FSP defers the effective date of SFAS No. 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. We currently do not believe that the adoption of the deferred portion of SFAS No. 157 will have a material impact on our financial condition, results of operations or cash flows.

On June 27, 2007, EITF Issue 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities," was issued. EITF Issue 07-03 provides that nonrefundable advance payments made for goods or services to be used in future R&D activities are deferred and capitalized until such time as the related goods or services are delivered or are performed, at which point the amounts will be recognized as an expense. EITF Issue 07-03 is effective for new contracts entered into after January 1, 2008. The adoption of EITF Issue 07-03 did not have a material impact on our financial position, results of operations or cash flows in 2008.

In November 2007, EITF Issue 07-01, "Accounting for Collaborative Arrangements," was issued. EITF Issue 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. EITF Issue 07-01 is effective for fiscal years beginning after December 15, 2008. We currently do not believe that this EITF will have a material impact on the results of our operations, financial position or cash flows.

In December 2007, the FASB issued SFAS No. 141R, "Business Combinations." SFAS No. 141R replaces SFAS No. 141 and establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS No. 141R also provides guidance on how the acquirer should recognize and measure the goodwill acquired in the business combination and determine what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141R is effective for us in its fiscal year beginning January 1, 2009. Most of the requirements of SFAS No. 141R are only to be applied prospectively to business combinations entered into on or after January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51." SFAS No. 160 states that accounting and reporting for minority interests will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS No. 160 also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 applies to all entities that prepare consolidated financial statements, except not-for-profit organizations, but will affect only those entities that have an outstanding noncontrolling interest in one or more subsidiaries or that deconsolidate a subsidiary. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. We currently do not believe that the adoption of SFAS No. 160 will have a material impact on the results of our operations, financial position or cash flows.

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, "Risk Factors."

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Our cash flow and earnings are subject to fluctuations due to changes in interest rates in our investment portfolio of debt securities and to foreign currency exchange rates. We maintain an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale as defined by SFAS No. 115, 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. 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.

A hypothetical 10% change in interest rates during the twelve months ended December 31, 2008 would have resulted in a \$1.3 million change in our net income for 2008.

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

The royalty revenue we receive from Roche on net sales of Tarceva outside of the U.S. is calculated by converting the respective countries' Tarceva sales in local currency to Roche's functional currency (Swiss francs) and then to U.S. dollars. The royalties are paid to us in U.S. dollars on a quarterly basis. As a result, fluctuations in the value of the U.S. dollar against foreign currencies will impact our earnings. A hypothetical 10% change in current rates during the year ended December 31, 2008 would have resulted in an approximate \$13.5 million change to our net income.

Our convertible senior subordinated notes totaled \$414.95 million at December 31, 2008, and were comprised of our 2023 Notes which bear interest at a fixed rate of 3.25%, our 2025 Notes which bear interest at a fixed rate of 2% and our 2038 Notes which bear interest at a fixed rate of 3%. 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, 2025 Notes or 2038 Notes to common stock beneficial to the holders of such notes. Conversion of the 2023 Notes, 2025 Notes or 2038 Notes would have a dilutive effect on any future earnings and book value per common share.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS

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

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

We have audited the accompanying consolidated balance sheets of OSI Pharmaceuticals, Inc. and subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2008. 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, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, 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), OSI Pharmaceuticals, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 27, 2009 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Melville, New York
February 27, 2009

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2008 AND 2007

(In thousands except per share data)

	December 31,	
	2008	2007
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 272,936	\$ 162,737
Investment securities	240,328	137,439
Restricted investment securities	2,247	4,922
Accounts receivables — net	100,242	87,523
Inventory — net	20,139	21,064
Interest receivable	1,428	1,116
Prepaid expenses and other assets	6,719	9,882
Assets related to discontinued operations	917	25,442
Deferred tax assets — net	45,425	—
Total current assets	690,381	450,125
Property, equipment and leasehold improvements — net	43,443	46,694
Debt issuance costs — net	7,080	3,047
Goodwill	38,648	39,411
Other intangible assets — net	7,711	4,966
Other assets	14,591	14,137
Deferred tax assets — net	291,205	—
	\$ 1,093,059	\$ 558,380
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 49,052	\$ 45,843
Unearned revenue — current	10,547	10,912
Liabilities related to discontinued operations	1,522	45,739
Convertible senior subordinated notes	—	150,000
Total current liabilities	61,121	252,494
Other liabilities:		
Rent obligations and deferred rent expense	8,154	10,812
Unearned revenue — long-term	33,398	37,075
Convertible senior subordinated notes	414,950	115,000
Accrued post-retirement benefit cost and other	3,890	4,043
Total liabilities	521,513	419,424
Commitments and contingencies (See Note 17)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 5,000 shares authorized; no shares issued at December 31, 2008 and 2007, respectively	—	—
Common stock, \$.01 par value; 200,000 shares authorized, 61,124 and 60,352 shares issued at December 31, 2008 and 2007, respectively	611	604
Additional paid-in capital	1,693,263	1,658,737
Accumulated deficit	(1,016,201)	(1,487,686)
Accumulated other comprehensive income (loss)	(3,908)	4,522
	673,765	176,177
Less: treasury stock, at cost; 3,396 and 1,943 shares at December 31, 2008 and 2007, respectively	(102,219)	(37,221)
Total stockholders' equity	571,546	138,956
	\$ 1,093,059	\$ 558,380

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2008, 2007 AND 2006
(In thousands except per share data)

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Revenues:			
Tarceva-related revenues	\$ 334,653	\$267,799	\$ 208,298
Other revenues	<u>44,735</u>	<u>73,231</u>	<u>32,739</u>
Total revenues	<u>379,388</u>	<u>341,030</u>	<u>241,037</u>
Expenses:			
Cost of goods sold	9,315	9,399	8,671
Research and development	135,344	123,531	117,527
Acquired in-process research and development	4,000	9,664	—
Selling, general and administrative	94,930	99,159	107,458
Amortization of intangibles	<u>2,489</u>	<u>1,840</u>	<u>1,809</u>
Total expenses	<u>246,078</u>	<u>243,593</u>	<u>235,465</u>
Income from continuing operations	133,310	97,437	5,572
Other income (expense):			
Investment income — net	12,961	12,830	11,098
Interest expense	(11,932)	(7,235)	(7,339)
Other income (expense) — net	<u>(1,195)</u>	<u>2,307</u>	<u>(2,631)</u>
Income from continuing operations before income taxes	133,144	105,339	6,700
Income tax (benefit) provision	<u>(333,457)</u>	<u>2,732</u>	<u>—</u>
Net income from continuing operations	466,601	102,607	6,700
Income (loss) from discontinued operations — net of tax	<u>4,884</u>	<u>(36,288)</u>	<u>(610,930)</u>
Net income (loss) before extraordinary gain	471,485	66,319	(604,230)
Extraordinary gain — net of tax	<u>—</u>	<u>—</u>	<u>22,046</u>
Net income (loss)	<u>\$ 471,485</u>	<u>\$ 66,319</u>	<u>\$(582,184)</u>
Basic and diluted income (loss) per common share:			
Basic earnings (loss)			
Continuing operations	\$ 8.14	\$ 1.78	\$ 0.12
Discontinued operations	0.09	(0.63)	(10.73)
Net income (loss) before extraordinary gain	8.23	1.15	(10.61)
Extraordinary gain	—	—	0.39
Net income (loss)	\$ 8.23	\$ 1.15	\$ (10.22)
Diluted earnings (loss)			
Continuing operations	\$ 7.19	\$ 1.70	\$ 0.12
Discontinued operations	0.07	(0.58)	(10.60)
Net income (loss) before extraordinary gain	7.26	1.11	(10.48)
Extraordinary gain	—	—	0.38
Net income (loss)	\$ 7.26	\$ 1.11	\$ (10.10)
Weighted average shares of common stock outstanding:			
Basic shares	57,316	57,665	56,939
Diluted shares	66,911	62,241	57,645

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2008, 2007 AND 2006
(In thousands)

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity
	Shares	Amount						
Balance at December 31, 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 losses on investment securities — net	—	—	—	—	—	(233)	—	(233)
Translation adjustment	—	—	—	—	—	2,148	—	2,148
Total comprehensive loss	—	—	—	—	—	—	—	(580,269)
Adjustment to initially apply SFAS 158	—	—	—	—	—	(1,316)	—	(1,316)
Options exercised	391	4	7,888	—	—	—	—	7,892
Issuance of common stock for employee purchase plan and other	45	1	1,129	—	—	—	—	1,130
Issuance of common stock in connection with buyout of Prosidion minority interest	3	—	145	—	—	—	—	145
Issuance of restricted stock to employees	12	—	1,539	—	—	—	—	1,539
Reclassification of deferred compensation due to the adoption of SFAS 123(R)	—	—	(5,045)	7,341	—	—	—	2,296
Equity based compensation expense	—	—	19,063	—	—	—	—	19,063
Adjustment for EITF 06-02 (sabbatical leave)	—	—	—	—	(352)	—	—	(352)
Balance at December 31, 2006	<u>59,179</u>	<u>592</u>	<u>1,616,874</u>	<u>—</u>	<u>(1,554,005)</u>	<u>2,354</u>	<u>(37,221)</u>	<u>28,594</u>
Comprehensive income:								
Net income	—	—	—	—	66,319	—	—	66,319
Unrealized holding gains on investment securities — net	—	—	—	—	—	486	—	486
Curtailment of post-retirement plan	—	—	—	—	—	1,316	—	1,316
Translation adjustment	—	—	—	—	—	366	—	366
Total comprehensive income	—	—	—	—	—	—	—	68,487
Options exercised	1,052	11	25,622	—	—	—	—	25,633
Issuance of common stock under employee purchase plan and other	26	—	776	—	—	—	—	776
Issuance of restricted stock to employees	95	1	18	—	—	—	—	19
Equity based compensation expense	—	—	15,447	—	—	—	—	15,447
Balance at December 31, 2007	<u>60,352</u>	<u>604</u>	<u>1,658,737</u>	<u>—</u>	<u>(1,487,686)</u>	<u>4,522</u>	<u>(37,221)</u>	<u>138,956</u>
Comprehensive income:								
Net income	—	—	—	—	471,485	—	—	471,485
Unrealized holding losses on investment securities — net	—	—	—	—	—	(727)	—	(727)
Post-retirement plan	—	—	—	—	—	378	—	378
Translation adjustment	—	—	—	—	—	(8,081)	—	(8,081)
Total comprehensive income	—	—	—	—	—	—	—	463,055
Options exercised	568	5	15,733	—	—	—	—	15,738
Issuance of common stock under employee purchase plan and other	25	—	843	—	—	—	—	843
Issuance of restricted stock to employees	179	2	—	—	—	—	—	2
Equity based compensation expense	—	—	17,494	—	—	—	—	17,494
Purchase of treasury stock- 1,453 shares	—	—	—	—	—	—	(64,998)	(64,998)
Excess tax benefits from stock-based compensation	—	—	456	—	—	—	—	456
Balance at December 31, 2008	<u>61,124</u>	<u>\$611</u>	<u>\$1,693,263</u>	<u>\$ —</u>	<u>\$(1,016,201)</u>	<u>\$(3,908)</u>	<u>\$(102,219)</u>	<u>\$ 571,546</u>

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2008, 2007 AND 2006
(In thousands)

	Year Ended December 31,		
	2008	2007	2006
Cash flow from operating activities:			
Net income (loss)	\$ 471,485	\$ 66,319	\$(582,184)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Extraordinary gain from reversal of contingent consideration	—	—	(22,046)
Loss (gain) on sale and disposals of equipment	9	1,471	(5)
Gain on sale of intellectual property	—	(7,892)	—
Depreciation and amortization	13,198	12,471	34,235
Loss on sale of eye disease business and non-cash impairment charges	14,136	—	—
Impairment of assets	1,217	10,765	505,985
Provision for excess inventory — net	—	—	26,408
Impact of inventory step-up related to inventory sold	51	2,365	19,924
Amortization of premiums and discounts on investments	(1,151)	(2,578)	1,858
In-process research and development charge	4,000	9,664	—
Non-cash compensation charge	20,727	17,099	19,703
Gain on recognition of certain deferred tax assets	(336,629)	—	—
Changes in assets and liabilities:			
Accounts receivable	(4,895)	(23,262)	69,569
Inventory	536	12	(9,551)
Prepaid expenses and other current assets	2,994	(1,054)	1,715
Other assets	(67)	(1,077)	(3,755)
Accounts payable and accrued expenses	(12,925)	6,038	(17,017)
Collaboration profit share payable	—	(9,257)	(37,829)
Unearned revenue	(33,616)	(1,331)	29,104
Accrued post-retirement benefit cost and other	(134)	(3,944)	1,401
Net cash provided by operating activities	<u>138,936</u>	<u>75,809</u>	<u>37,515</u>
Cash flows from investing activities:			
Purchases of investments (restricted and unrestricted)	(337,355)	(258,085)	(239,268)
Maturities and sales of investments (restricted and unrestricted)	237,565	287,628	80,788
Net additions to property, equipment and leasehold improvements	(4,977)	(4,332)	(10,728)
Purchase of intangible assets	(8,000)	—	—
Purchase of intellectual property and capitalized patent defense costs	(4,886)	(9,664)	—
Proceeds from sale of intellectual property	—	4,000	—
Proceeds from sale of fixed assets	—	335	795
Purchase of compound library assets	(257)	(3)	(31)
Payments made in connection with disposal of eye disease business	(1,240)	—	—
Net cash provided by (used in) investing activities	<u>(119,150)</u>	<u>19,879</u>	<u>(168,444)</u>
Cash flows from financing activities:			
Proceeds from the exercise of stock options, employee purchase plan, and other	17,038	26,409	9,138
Employees taxes paid related to equity awards	(3,233)	(1,654)	—
Proceeds from the issuance of convertible senior subordinated notes	200,000	—	—
Debt issuance costs	(6,730)	—	(102)
Payments on loans and capital leases payable	—	—	(640)
Purchase of treasury stock	(64,998)	—	—
Repurchase of a portion of the 2023 Notes	(50,050)	—	—
Excess tax benefits from stock-based compensation	456	—	—
Net cash provided by financing activities	<u>92,483</u>	<u>24,755</u>	<u>8,396</u>
Net increase (decrease) in cash and cash equivalents	<u>112,269</u>	<u>120,443</u>	<u>(122,533)</u>
Effect of exchange rate changes on cash and cash equivalents	(2,070)	266	477
Cash and cash equivalents at beginning of year	<u>162,737</u>	<u>42,028</u>	<u>164,084</u>
Cash and cash equivalents at end of year	<u>\$ 272,936</u>	<u>\$ 162,737</u>	<u>\$ 42,028</u>
Cash paid for taxes	<u>\$ 2,108</u>	<u>\$ 1,400</u>	<u>\$ —</u>
Cash paid for interest	<u>\$ 9,770</u>	<u>\$ 7,175</u>	<u>\$ 7,137</u>
Non-cash activities:			
Stock and warrants received from sale of intellectual property	<u>\$ —</u>	<u>\$ 3,892</u>	<u>\$ —</u>
Post-retirement benefit obligation upon adoption of SFAS No. 158	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,316</u>

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

The consolidated financial statements are presented in accordance with accounting principles generally accepted in the United States. Our consolidated financial statements include the accounts of OSI Pharmaceuticals, Inc., and our wholly-owned subsidiaries, Oldtech Inc. (formerly known as (OSI) Eyetech), or (OSI) Eyetech, Prosidion Limited and OSI Pharmaceuticals (U.K.) Limited, or OSI U.K. 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, 2008, 2007 and 2006. All intercompany balances and transactions have been eliminated in consolidation.

(b) Reclassifications

Certain reclassifications have been made to the Consolidated Statements of Operations for the years ended December 31, 2007 and 2006 to conform to the presentation for the fiscal year ended December 31, 2008. These reclassifications include a reclassification of revenue categories within total revenues to conform to the 2008 fiscal year presentation.

(c) Revenue Recognition

Tarceva-related revenues includes net revenue from unconsolidated joint business and Tarceva-related milestones and royalties. Other revenues include license, milestone, royalty and commission from sources other than Tarceva. Our revenue recognition policies with respect to these revenue sources are described below.

(i) Net Revenue from Unconsolidated Joint Business

Net revenue from unconsolidated joint business is related to our co-promotion and manufacturing agreements with Genentech, Inc., our U.S. collaborator for Tarceva. It consists 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 and marketing costs, are recognized by Genentech.

Genentech is also responsible for estimating reserves for anticipated returns of Tarceva and monitoring the adequacy of these reserves. In response to increased levels of Tarceva product returns in 2008, Genentech has modified its Tarceva returns policy and increased its reserve for estimated future Tarceva returns.

For the year ended December 31, 2008, Genentech recorded approximately \$457 million in net sales of Tarceva in the United States and its territories. We record our 50% share of the co-promotion pretax profit on a quarterly basis, as set forth in our agreement with Genentech. Pretax co-promotion profit under the co-promotion arrangement is derived by calculating U.S. net sales of Tarceva to third-party customers and deducting costs of sales, distribution and selling and marketing expenses incurred by Genentech and us. If actual future results differ from our estimates and Genentech's, we may need to record an adjustment which could have an effect on earnings in the period containing the adjustment. The reimbursement of our sales and marketing costs related to Tarceva is recognized as revenue as the related costs are incurred. We defer the recognition of the reimbursement of our manufacturing costs related to Tarceva until the time Genentech ships the product to third-party customers, at which time our risk of inventory loss no longer exists. The unearned revenue related to shipments by our third party manufacturers of Tarceva to Genentech that have not been shipped to third-party customers was \$6.6 million and

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

\$7.0 million as of December 31, 2008 and 2007, respectively, and is included in unearned revenue-current in the accompanying consolidated balance sheets.

For the years ended December 31, 2008, 2007 and 2006, revenues from our share of the pretax co-promotion profit generated from our co-promotion arrangement with Genentech for Tarceva and the partial reimbursement from Genentech of our sales and marketing costs related to Tarceva were \$186.2 million, \$159.0 million and \$143.7 million, respectively, and revenues from the reimbursement of our manufacturing costs were \$9.9 million, \$9.7 million and \$11.2 million, respectively.

(ii) Royalties

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

The royalty amount with respect to ex-U.S. Tarceva sales is calculated by converting the Tarceva sales for each country in their respective local currency into Roche's functional currency (Swiss francs) and then to U.S. dollars. The royalties are paid to us in U.S. dollars on a quarterly basis. As a result, fluctuations in the value of the U.S. dollar against foreign currencies will impact our royalty revenue.

(iii) License, Milestones, and Commissions

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, 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.

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

Since September 2004, we have received \$34.0 million in milestone payments from Genentech based upon certain U.S. Food and Drug Administration, or FDA, filings and approvals of Tarceva in accordance with our agreement with Genentech. As a result of the amendment to our collaboration agreement with Genentech in June 2004, these payments are, and any future milestone payments will be, recognized in accordance with EITF 00-21. Milestones which have been received from Genentech after June 2004, and the remaining unearned upfront fee as of June 2004, are being recognized over the term of our Manufacturing and Supply Agreement with Genentech, under which the last items of performance to be delivered to Genentech are set forth, or on a straight-line basis, which approximates the expected level of performance under the Manufacturing and Supply Agreement. The unrecognized unearned revenue related to the milestones and upfront payment received from Genentech was \$27.3 million as of December 31, 2008, of which \$2.3 million was classified as short-term and the balance of \$25.0 million was classified as long-term in the accompanying consolidated balance sheet. The unrecognized unearned revenue related to the milestones and upfront payment received from Genentech was \$29.6 million as of December 31, 2007, of which \$2.3 million was classified as short-term and the balance of \$27.3 million was classified as long-term in the accompanying consolidated balance sheet.

In March 2005, 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

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

combinations with other oncology drugs. The cost of the development plan is being shared by the three collaborators. For purposes of EITF 00-21, the revised development plan and budget for Tarceva was deemed a material amendment to our Roche agreement and requires milestones received from Roche to be recognized in accordance with EITF 00-21. Accordingly, milestone payments received from Roche are initially recorded as unearned revenue and recognized over the expected term of the research collaboration on a straight-line basis, which approximates the expected level of performance under the development plan. In September 2005, we recorded a \$4.0 million milestone payment from Roche upon approval of Tarceva by the European Commission for sale in the European Union, or EU. In November 2005, we recorded a \$4.0 million milestone payment from Roche upon acceptance for review by the European Agency for the Evaluation of Medicinal Products for the application of Tarceva in combination with gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received previous chemotherapy. In May 2006, we recorded a \$1.0 million milestone payment from Roche upon acceptance for review by the Japanese Ministry of Health of the application of Tarceva for the treatment of advanced non-small cell lung cancer, or NSCLC. In January 2007, we recorded a \$4.0 million milestone payment from Roche upon the European Commission's marketing authorization for Tarceva in combination with gemcitabine as first-line therapy for metastatic pancreatic cancer. In November 2007, we recorded a \$1.0 million milestone payment from Roche upon approval in Japan for the use of Tarceva in the treatment of advanced NSCLC. All of these payments have been included in deferred revenue. The unearned revenue related to the milestones we received from Roche was \$9.7 million as of December 31, 2008, of which \$1.6 million was classified as short-term and the balance of \$8.1 million was classified as long-term in the accompanying consolidated balance sheet. The unearned revenue related to the milestones we received from Roche was \$11.3 million as of December 31, 2007, of which \$1.6 million was classified as short-term and the balance of \$9.7 million was classified as long-term in the accompanying consolidated balance sheet.

We have 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 \$41.1 million and \$34.7 million for the years ended December 31, 2008 and 2007, respectively.

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

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

(d) Research and Development Costs

R&D costs are charged to operations as incurred and include direct costs of R&D-related personnel and equipment, contracted costs and an allocation of laboratory facility and other core scientific services. Included in R&D costs are our share of development expenses related to the Tripartite Agreement with Genentech and Roche (see Note 2(a)). Our R&D costs related to the Tripartite Agreement include estimates by the parties to the agreement. If actual future results vary, we may need to adjust these estimates, which could have an effect on our

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

earnings in the period of adjustment. Historically such adjustments have not been material to our consolidated financial condition or results of operations.

(e) Acquired In-Process Research and Development

In accordance with SFAS No. 2, "Accounting for Research and Development Costs," costs to acquire in-process R&D 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.

(f) Cash and Cash Equivalents

We characterize money market funds, treasury bills, commercial paper and time deposits with original maturities of three months or less as cash equivalents. Such cash equivalents amounted to \$194.3 million and \$81.9 million as of December 31, 2008 and 2007, respectively.

(g) Investment Securities

Investment securities at December 31, 2008 and 2007 consisted primarily of U.S. government securities, U.S. government agency securities and debt securities of financial institutions and corporations with strong credit ratings. We classify our investments as available-for-sale securities, as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are recorded at their fair value. Unrealized holding gains and losses, net of the related tax effect, if any, on available-for-sale securities are excluded from earnings and are reported in accumulated other comprehensive income (loss), a separate component of stockholders' equity, until realized. The specific identification basis is utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities. Dividend and interest income are recognized when earned. A portion of our marketable investments have stated maturities greater than one year. We have classified these investments as current assets based upon the classification as available-for-sale and the underlying liquidity of the assets.

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, 2008 and 2007 were \$2.2 million and \$4.9 million, respectively, of investments to secure these letters of credit.

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

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

A decline in the market value of any available-for-sale marketable security below its cost that is deemed to be other-than-temporary results in a reduction in its carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is then established. The determination of whether an available-for-sale marketable security is other-than-temporarily impaired requires significant judgment and consideration of available quantitative and qualitative evidence in evaluating the potential impairment. Factors evaluated to determine whether the investment is other-than-temporarily impaired include: (i) significant deterioration in the issuer's earnings performance, credit rating or asset quality; (ii) the business prospects of the issuer; (iii) adverse changes in the general market conditions in which the issuer operates; (iv) the length of time that the fair value has been below our cost; (v) our expected future cash flows from the security; and (vi) our intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. Assumptions associated with these factors are subject to future market and economic conditions, which could differ from our assessment. During 2007 and 2006 we did not recognize any other-than-temporary impairments. In the fourth quarter of 2008, we recorded a \$1.2 million impairment charge in other income (expense) — net related to an

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

other-than-temporary decline in fair value of an equity investment and warrants received as part of a licensing transaction.

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

As discussed in Note 20, we recorded an impairment charge of \$320.3 million related to the goodwill initially recorded as part of our November 2005 acquisition of Eyetech Pharmaceuticals Inc. during the year ended December 31, 2006.

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

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

In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," or SFAS No. 144, we review long-lived assets to determine whether an event or change in circumstances indicates the carrying value of the asset may not be recoverable. We base our evaluation on such impairment indicators as the nature of the assets, the future economic benefit of the assets and any historical or future profitability measurements, as well as other external market conditions or factors that may be present. If such impairment indicators are present or other factors exist that indicate that the carrying amount of the asset may not be recoverable, we determine whether an impairment has occurred through the use of an undiscounted cash flows analysis at the lowest level for which identifiable cash flows exist. If impairment has occurred, we recognize a loss for the difference between the carrying amount and the fair value of the asset. Fair value is the amount at which the asset could be bought or sold in a current transaction between a willing buyer and seller other than in a forced or liquidation sale and can be measured at the asset's quoted market price in an active market or, where an active market for the asset does not exist, our best estimate of fair value based on discounted cash flow analysis. Assets to be disposed of by sale are measured at the lower of carrying amount or fair value less estimated costs to sell.

In 2005, we acquired core and developed technology related to Macugen. As discussed in Note 20, at December 31, 2006, we assessed the carrying value of Macugen intangibles with definitive lives and determined that the assets were impaired and we recorded a \$185.7 million impairment charge, which is included in the loss from discontinued operations for the year ended December 31, 2006.

(k) Inventory

Inventory is stated at the lower of cost or market, with cost being determined using the weighted average method. Included in inventory are raw materials and work-in-process that may be used in the production of pre-clinical and clinical product, which will be expensed to R&D cost when consumed for these uses. Inventory is comprised of three components: raw materials, which are purchased directly by us, work-in-process, which is

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

(l) 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.

(m) 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.

(n) 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 and/or patient visits, 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.

(o) Foreign Currency Translation

The assets and liabilities of our non-U.S. subsidiaries, OSI U.K. 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.

(p) Income Taxes

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

In July 2006, the Financial Accounting Standards Board, or FASB, issued Financial Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109," or FIN 48, which clarifies the criteria that must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN 48 provides a benefit recognition model with a two-step approach consisting of a "more-likely-than-not" recognition criteria, and a measurement attribute that measures a given tax position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. FIN 48 also requires the recognition of liabilities created by differences between tax positions taken in a tax return and amounts recognized

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
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in the financial statements. FIN 48 is effective as of the beginning of the first annual period beginning after December 15, 2006, and became effective for us on January 1, 2007. The adoption of FIN 48 on January 1, 2007 had no impact on our financial condition, results of operations, or cash flows for the year ended December 31, 2007, as the Company had no unrecognized tax benefits at that time.

(q) Debt Issuance Costs

Costs incurred in issuing our 3% Convertible Senior Subordinated Notes due 2038, or our 2038 Notes, our 2% Convertible Senior Subordinated Notes due 2025, or our 2025 Notes, and our 3.25% Convertible Senior Subordinated Notes due 2023, or our 2023 Notes, are amortized using the straight-line method over the five-year terms, which represents the earliest date that notes can be redeemed by the holders. The amortization of debt issuance cost is included in other expense in the accompanying consolidated statements of operations.

(r) Stock-Based Compensation

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

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

The assumptions used in computing the fair value of stock-based awards reflect our best estimates but involve uncertainties relating to market and other conditions, many of which are outside of our control. As a result, if other assumptions or estimates had been used, the stock-based compensation expense that was recorded for the years ended December 31, 2008, 2007 and 2006 could have been materially different. Furthermore, if different assumptions are used in future periods, stock-based compensation expense could be materially impacted in the future.

(s) 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. Prior to August 2008, while our results of operations were primarily reviewed on a consolidated basis, the chief operating decision-maker managed the enterprise in three operating segments: (i) oncology; (ii) diabetes and obesity; and (iii) eye disease. As of August 2008, we completed the sale of the remaining assets of our eye disease business, and therefore we have two remaining operating segments. In accordance with SFAS No. 131, given the similar economic characteristics of the remaining two operating segments, we determined that we have one reportable segment.

(t) Use of Estimates

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

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(2) Product Development/Commercialization Agreements/License Agreements

(a) Genentech and Roche

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

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

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

We have certain co-promotion rights under the OSI/Genentech collaboration agreement, which are defined in amendments to the agreement effective as of June 4, 2004 and April 11, 2007. We have agreed with Genentech that OSI employees will comprise 50% of the combined U.S. sales force through the end of the 2010 calendar year, after which time the size and composition of the sales force may be adjusted. We share equally in the operating profits or losses on products resulting from the collaboration. Under the OSI/Genentech collaboration agreement, we granted to Genentech a royalty-free non-transferable (except under certain circumstances), non-sublicensable (except under certain circumstances), co-exclusive license under our patents and know-how related to Tarceva to use, sell, offer for sale and import products resulting from the collaboration in the United States, its territories and Puerto Rico. In addition, Genentech granted to us a royalty-free non-transferable (except under certain circumstances), non-sublicensable (except under certain circumstances), co-exclusive license to certain patents and know-how held by Genentech to use, make, have made, sell, offer for sale and import products resulting from the collaboration in the United States, its territories and Puerto Rico. We have primary responsibility for patent filings for the base patents protecting Tarceva and, in addition, we have the right, but not the obligation, to institute, prosecute and control patent infringement claims relating to the base patents.

In connection with our collaboration with Genentech, Genentech recognizes all U.S. sales of Tarceva. We recognize revenues and losses from our alliance with Genentech, which consists of our 50% share of the pre-tax profits (loss) generated from the sales of Tarceva in the United States. We also recognize manufacturing revenue from the sale of inventory to Genentech for commercial sales of Tarceva in the United States and reimbursement from Genentech of our Tarceva-related commercial expenses. In addition, we are entitled to milestones under certain circumstances. 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

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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), and provides for the 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 is obligated to pay us certain milestone payments and royalty payments on sales of products resulting from the collaboration including Tarceva. We have primary responsibility for patent filings for the base patents protecting Tarceva and, in addition, we have the right, but not the obligation, to institute, prosecute and control patent infringement claims relating to the base patents. The OSI/Roche agreement continues until the date on which we are no longer entitled to receive a royalty on products resulting from the development of Tarceva, that is, until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva or, in countries where there is no valid patent covering Tarceva, on the tenth anniversary of the first commercial sale of Tarceva in that country, or until either party exercises early termination rights. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, Roche has the right to terminate the agreement on a country-by-country basis with six months' prior written notice and we have the right to terminate the agreement on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

(b) AVEO

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

As with many early stage development efforts, launch of an eventual product is not expected in the near term. As a result, \$7.5 million of the upfront payment was recognized as an in-process R&D charge since it was non-refundable and deemed to have no alternative future use. The \$2.5 million of first year research funding was

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recognized as a prepaid asset and was amortized over one year, or the period AVEO delivered research services under the collaboration. The acquired preferred stock was recorded as a cost based investment in other assets in the accompanying balance sheets as of December 31, 2008.

(c) Eli Lilly

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

(d) OncoVista

During the fourth quarter of 2007, we recognized \$2.4 million of revenue from the consideration received as a result of outlicensing OSI-7904L, an oncology clinical candidate for which we had ceased development, to OncoVista Innovative Therapies, Inc. The consideration included cash of \$500,000 and OncoVista common stock and warrants with a fair value of \$1.9 million. The common stock is publicly traded and recorded as an available-for-sale security. The warrants are recorded at their estimated fair value in other assets. In the fourth quarter of 2008, we concluded that the decline in the fair value of the common stock and warrants was other-than-temporary, which resulted in the recording of a \$1.2 million impairment charge, which is included in other income (expense) — net for the year ended December 31, 2008.

(e) Patent Licenses

We have entered into various license agreements with third parties to grant the use of our proprietary assets. These licenses include the use of our patented gene transcription estate as well as the use of our DPIV patent estate acquired from Probiodrug AG in fiscal 2004. Licensees may be obligated to pay us license fees, annual fees, and milestones and royalties on net sales of product based on the development and sale of products derived from the licensed patents. Generally, the duration of each license is to be coextensive with the life of the last to expire of the underlying patents. For the years ended December 31, 2008 and 2007 we recognized as revenue \$41.1 million and \$34.7 million, respectively, of license, milestone and royalty payments from our DPIV patent estate.

(f) TGF β 3

In February 2008, we licensed our transforming growth factor, or TGF β 3, compound for certain indications for an upfront fee of \$2.0 million. We recognized the \$2.0 million payment as license revenue in the first quarter of 2008 since we had no future performance obligations. Pursuant to the terms of a cross license with Novartis AG, approximately \$350,000 of the amount we received was paid to Novartis.

(3) Net Earnings (Loss) Per Share

Basic earnings per share is computed by dividing net income by the weighted average number of common shares outstanding during the reporting period. Diluted earnings per common share is computed by dividing net income by the weighted average number of common shares outstanding during the reporting period, increased to include all additional common shares that would have been outstanding assuming potentially dilutive common share equivalents had been issued. Dilutive common share equivalents include the dilutive effect of in-the-money shares related to stock options, and are calculated based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an option, the average amount of compensation cost, if any, for future service that we have not yet recognized and the amount of tax benefits that would be recorded in additional paid-in capital, if any, when the option is exercised, are assumed to be used to repurchase shares in the current period. Dilutive common share equivalents also reflect the dilutive effect of unvested restricted

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stock units, deferred stock units and restricted stock and the conversion of convertible debt which is calculated using the “if-converted” method. In addition, in computing the dilutive effect of convertible debt, the numerator is adjusted to add back the after-tax amount of interest and debt issuance cost recognized in the period. As of December 31, 2008, our outstanding convertible senior debt consisted of our 2023 Notes, 2025 Notes and our 2038 Notes.

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

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Net income from continuing operations — basic	\$466,601	\$102,607	\$ 6,700
Add: Interest and issuance cost related to convertible debt.	<u>14,351</u>	<u>3,040</u>	<u>—</u>
Net income from continuing operations — diluted	<u>\$480,952</u>	<u>\$105,647</u>	<u>\$ 6,700</u>
Weighted-average common shares outstanding — basic	57,316	57,665	56,939
Dilutive effect of options and restricted stock	729	668	706
Dilutive effect of 2025 Notes	3,908	3,908	—
Dilutive effect of 2023 Notes	2,308	—	—
Dilutive effect of 2038 Notes (issued in January 2008)	<u>2,650</u>	<u>—</u>	<u>—</u>
Weighted-average common shares and dilutive potential common shares — diluted.	<u>66,911</u>	<u>62,241</u>	<u>57,645</u>
Net income per share from continuing operations:			
Basic	\$ 8.14	\$ 1.78	\$ 0.12
Diluted	\$ 7.19	\$ 1.70	\$ 0.12

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

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Common share equivalents — convertible debt	—	2,999	6,907
Common share equivalents — equity plans	2,865	3,285	4,054
Contingent shares	—	—	1,585
Convertible note interest and issuance expense not added back under the “if converted” method	\$ —	\$5,936	\$9,038

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

In connection with the 2003 acquisition of Cell Pathways, we recognized contingent consideration of \$22.0 million in the form of five-year contingent value rights pursuant to which each share of Cell Pathways common stock was 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 ceased our development efforts of these two clinical candidates and sought to outlicense these

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candidates. During the second quarter of fiscal 2006, we concluded that, in our judgment, the milestone would not be met based upon the current progress of our outlicensing efforts and the technical hurdles for filing a new drug application by June 2008 and therefore, we reversed the \$22.0 million liability and recorded an extraordinary gain during the year ended December 31, 2006. The milestone was not met by the June 12, 2008 deadline.

(4) Comprehensive Income (Loss)

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

	Year Ended December 31,		
	2008	2007	2006
Net income (loss)	\$471,485	\$66,319	\$(582,184)
Other comprehensive income (loss):			
Foreign currency translation adjustments	(8,081)	366	2,148
Post-retirement plan	378	1,316	—
Unrealized holding gains (losses) arising during period.	(727)	486	(233)
	(8,430)	2,168	1,915
Total comprehensive income (loss)	\$463,055	\$68,487	\$(580,269)

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

	As of December 31,	
	2008	2007
Cumulative foreign currency translation adjustment	\$(3,739)	\$4,342
Post-retirement plan	378	—
Unrealized gains (losses) on available-for-sale securities	(547)	180
Accumulated other comprehensive income	\$(3,908)	\$4,522

(5) Investments

As of December 31, 2008, approximately 82% of our cash equivalents and investment securities consisted of AAA rated and A1 rated securities, including our money market funds, which are AAA rated. The remainder of our investment securities consisted primarily of investment grade corporate debt. The overall average credit rating of our portfolio of investment securities was AA+/Aa1 as of December 31, 2008. We have established guidelines relative to the diversification of our investments and their maturities with the principal objectives of capital preservation and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

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The following is a summary of available-for-sale securities as of December 31, 2008 and 2007 (in thousands):

<u>2008</u>	<u>Costs</u>	<u>Gross Unrealized Gains (Losses)</u>	<u>Fair Value</u>
U.S. government and U.S. government agency securities	\$ 66,007	\$ 607	\$ 66,614
Corporate and financial institutions debt	170,634	(1,173)	169,461
Municipal securities	<u>4,237</u>	<u>16</u>	<u>4,253</u>
Total investment securities	240,878	(550)	240,328
Restricted investments	<u>2,244</u>	<u>3</u>	<u>2,247</u>
Total	<u>\$243,122</u>	<u>\$ (547)</u>	<u>\$242,575</u>

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

Net realized gains (losses) on sales of investment securities during the years ended December 31, 2008, 2007 and 2006 were \$12,000, \$(4,000) and \$170,000, respectively.

The gross unrealized losses on our investments were \$1.2 million as of December 31, 2008, all of which occurred during 2008. Because we have the ability and intent to hold these investments until a recovery of fair value, which may be maturity, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2008. As of December 31, 2007, we did not have any unrealized losses on investment securities.

Maturities of investment securities classified as available-for-sale, were as follows at December 31, 2008 (in thousands):

	<u>Cost</u>	<u>Fair Value</u>
2009	\$157,885	\$158,049
2010	79,494	78,788
2011	<u>3,499</u>	<u>3,491</u>
	<u>\$240,878</u>	<u>\$240,328</u>

(6) Fair Value Measurements

On January 1, 2008, we adopted the provisions of SFAS No. 157, "Fair Value Measurements," which established a framework for measuring fair value in accordance with U.S. generally accepted accounting principles, or GAAP, and expanded on disclosures about fair value instruments. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (i.e., the exit price). SFAS No. 157 does not require assets and liabilities that were previously recorded at cost to be recorded at fair value. The adoption of SFAS No. 157 did not have an effect on our financial condition or results of operations for the year ended December 31, 2008.

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SFAS No. 157 established a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The three tiers include:

- (i) *Level 1* — quoted prices in active markets for identical assets and liabilities;
- (ii) *Level 2* — observable inputs other than quoted prices in active markets for identical assets and liabilities; and
- (iii) *Level 3* — unobservable inputs for which little or no market data exists, requiring management to develop its own assumptions.

Investment securities at December 31, 2008 consisted primarily of U.S. government agency securities and debt securities of financial institutions and corporations. The following table summarizes the fair value at December 31, 2008 and the classification by level of input within the fair value hierarchy, defined in SFAS. No. 157 above, of our cash equivalents, investment securities, restricted investments and convertible senior subordinated notes (in thousands):

	As Reflected on the Balance Sheet	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:					
Cash equivalents	\$250,380	248,181	\$ 2,201	—	\$250,382
Investment securities	240,328	—	240,328	—	240,328
Restricted investments	2,247	—	2,247	—	2,247
Other assets	1,104	—	1,104	—	1,104
Liabilities:					
2038 Notes	200,000	—	161,220	—	161,220
2025 Notes	115,000	—	157,010	—	157,010
2023 Notes	99,950	—	85,407	—	85,407

The \$272.9 million of cash and cash equivalents at December 31, 2008, included \$250.4 million of cash equivalents consisting of money market funds and commercial paper with original maturities of three months or less. In accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," our cash equivalents are carried at cost, and not marked-to-market.

The estimated fair value of our convertible senior subordinated notes is provided in accordance with SFAS No. 107 "Disclosures about Fair Value of Financial Instruments (as amended)." Our convertible senior subordinated notes are not marked-to-market and are shown in the accompanying consolidated balance sheets at their original issuance value.

Included in other assets in the accompanying balance sheets as of December 31, 2008 and 2007 are \$7.5 million of cost-based equity investments in non-public biotechnology companies. The determination of fair value of these investments was not deemed practical given that the cost of such determination would be excessive relative to the materiality of these investments to our financial position. We do not believe that any of these investments were impaired as of December 31, 2008 and 2007.

(7) Inventory

Tarceva is stated at the lower of cost or market, with cost being determined using the weighted average method. Inventory is comprised of three components: raw materials, which are purchased directly by us, work-in-process,

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which is primarily active pharmaceutical ingredient, or API, where title has transferred from our contract manufacturer to us, and finished goods, which are packaged product ready for commercial sale.

Inventory at December 31, 2008 and 2007 consisted of the following (in thousands):

	<u>December 31, 2008</u>	<u>December 31, 2007</u>
Raw materials	\$ 676	\$ 1,704
Work-in-process	8,532	8,595
Finished goods on hand, net	4,897	4,614
Inventory subject to return	<u>6,034</u>	<u>6,151</u>
Total inventory	<u>\$20,139</u>	<u>\$21,064</u>

Inventory subject to return represents the amount of Tarceva shipped to Genentech which has not been recognized as revenue.

(8) Property, Equipment and Leasehold Improvements

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

	<u>Estimated Life (years)</u>	<u>December</u>	
		<u>2008</u>	<u>2007</u>
Land	—	\$ 3,600	\$ 3,600
Building and improvements	10-35	23,249	23,395
Laboratory equipment	5-15	26,917	26,478
Office furniture and equipment and computer equipment	3-7	13,503	16,025
Capitalized software	1-3	7,114	6,942
Manufacturing equipment	3-7	135	136
Leasehold improvements	Life of lease	<u>30,634</u>	<u>34,525</u>
Total		105,152	111,101
Less: accumulated depreciation and amortization		<u>(61,709)</u>	<u>(64,407)</u>
Property, equipment and leasehold improvements, net		<u>\$ 43,443</u>	<u>\$ 46,694</u>

Depreciation expense relating to continuing operations for the years ended December 31, 2008, 2007 and 2006 was \$7.4 million, \$7.3 million and \$9.6 million, respectively. We had \$7.1 million and \$6.9 million of capitalized computer software costs as of December 31, 2008 and 2007, respectively, of which \$6.4 million and \$6.3 million was amortized as of December 31, 2008 and 2007, respectively. Depreciation expense related to discontinued operations for the years ended December 31, 2008, 2007 and 2006 was \$751,000, \$929,000 and \$4.0 million, respectively.

(9) Goodwill and Other Intangible Assets

The carrying amount of goodwill was \$38.6 million and \$39.4 million as of December 31, 2008 and 2007, respectively. The balance of goodwill as of December 31, 2008 and 2007 included a \$(764,000) and \$38,000, respectively, effect from foreign currency exchange rate fluctuations during fiscal 2008 and 2007. We completed our annual impairment review of goodwill as of December 31, 2008 and determined that no impairment charge was required.

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

	December 31, 2008			December 31, 2007		
	Carrying Amount	Accumulated Amortization	Net Book Value	Carrying Amount	Accumulated Amortization	Net Book Value
Novantrone technology	\$46,009	\$(46,009)	\$ —	\$46,009	\$(44,558)	\$1,451
Acquired intangibles	9,386	(1,675)	7,711	4,754	(1,239)	3,515
Total	<u>\$55,395</u>	<u>\$(47,684)</u>	<u>\$7,711</u>	<u>\$50,763</u>	<u>\$(45,797)</u>	<u>\$4,966</u>

In the first quarter of 2008, we entered into an amended license agreement pursuant to which we terminated our obligation to pay royalties to a licensor of certain intellectual property with whom we had a cross-license related to our DPIV patent estate in consideration for an \$8.0 million upfront payment and potential future milestones. The upfront payment has been recorded as an intangible asset and is being amortized on a straight-line basis from February 2008 through February 2019, the last to expire patent covered under the license agreement. Future milestones, if any, will be recognized when paid and amortized from the date of payment.

A certain portion of our intangible assets are recorded on the books of Prosidion and denominated in British pounds sterling. As a result, the balance reported fluctuates based upon the changes in exchange rates.

Amortization expense related to continuing operations for our intangible assets for the years ended December 31, 2008, 2007 and 2006 was \$2.5 million, \$1.8 million and \$1.8 million, respectively. Amortization expense is estimated to be \$916,000 for each of the years 2009 through 2014. For the year ended December 31, 2006, amortization expense related to discontinued operations was \$18.1 million. We did not recognize any amortization expense related to discontinued operations for the years ended December 31, 2008 and 2007.

(10) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses at December 31, 2008 and 2007 are comprised of (in thousands):

	December 31,	
	2008	2007
Accounts payable	\$ 6,659	\$ 5,249
Accrued payroll, incentive compensation and employee benefits	11,766	3,398
Accrued exit costs	492	2,589
Accrued interest	3,856	1,619
Accrued CRO and site costs	4,094	4,969
Accrued commercial and development costs	7,272	6,566
Other accrued expenses	<u>14,913</u>	<u>21,453</u>
	<u>\$49,052</u>	<u>\$45,843</u>

As of December 31, 2008 and 2007, \$1.5 million and \$13.4 million, respectively, of accounts payable and accrued expenses related to (OSI) Eyetech have been classified as liabilities related to discontinued operations.

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(11) Consolidation of Facilities

(a) Restructuring Plan

In November 2006, we committed to a plan to re-scale our operations. The plan included the consolidation of facilities, as well as a reduction in the workforce. We recognized \$2.5 million of anticipated costs in 2006 related to our continuing operations. During the year ended December 31, 2007, we recognized \$1.3 million of additional severance charges and an additional \$702,000 for lease obligations. As of December 31, 2008, all of the costs have been paid. The activity for the years ended December 31, 2008 and 2007 was as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Opening liability	\$ 1,556	\$ 1,897
Accrual for severance payments	—	1,292
Accrual for lease payments	(51)	702
Cash paid for severance	(410)	(1,525)
Cash paid for rent, net of buildout allowance	(1,095)	(810)
Ending liability	<u>\$ —</u>	<u>\$ 1,556</u>

(b) Oxford, England

In August 2004, we announced the decision to consolidate 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, "Accounting for Costs Associated with Exit or Disposal Activities." The activity for the years ended December 31, 2008 and 2007 was as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Opening liability	\$2,882	\$ 4,062
Accrual for lease payments	390	—
Cash paid for rent	(906)	(1,251)
Other	(467)	71
Ending liability	<u>\$1,899</u>	<u>\$ 2,882</u>

(c) Eyetech Acquired Facilities

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

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December 31, 2007 since the obligations were not transferred to Eyetech Inc. in connection with the divestiture of the remaining assets of the eye disease business.

The activity for the year ended December 31, 2008 and 2007 was as follows (in thousands):

	<u>Year Ended December 31,</u>	
	<u>2008</u>	<u>2007</u>
Opening liability	\$ 3,282	\$ 2,054
Accrual for lease termination cost	—	3,709
Accretion expense	159	248
Cash paid for rent	(5,698)	(4,601)
Sublease income	<u>4,552</u>	<u>1,872</u>
Ending liability	<u>\$ 2,295</u>	<u>\$ 3,282</u>

(12) Income Taxes

The income tax (benefit) provision from continuing operations for the years ended December 31, 2008, 2007 and 2006 included the following (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Current:			
Federal	\$ 2,007	\$2,190	\$ —
State and Local	1,033	196	—
Foreign	<u>132</u>	<u>346</u>	<u>—</u>
Total	<u>\$ 3,172</u>	<u>\$2,732</u>	<u>\$ —</u>
Deferred:			
Federal	\$(300,578)	\$ —	\$ —
State and Local	(36,051)	—	—
Foreign	<u>—</u>	<u>—</u>	<u>—</u>
Total	<u>\$(336,629)</u>	<u>\$ —</u>	<u>\$ —</u>
Total	<u>\$(333,457)</u>	<u>\$2,732</u>	<u>\$ —</u>

Based on our ability to fully offset current taxable income by our NOLs, our current provision for both the 2008 and 2007 years is principally related to U.S. alternative minimum tax. For the year ended December 31, 2008, we recorded a current provision for income taxes of approximately \$3.2 million related to income from continuing operations and a tax benefit of approximately \$1.3 million related to discontinued operations. For the year ended December 31, 2007, we recorded a current provision for income taxes of approximately \$2.7 million related to income from continuing operations and a tax benefit of approximately \$640,000 related to our loss from discontinued operations. There is no current provision or benefit for federal, state or foreign income taxes for the year ended December 31, 2006 because we were not subject to the alternative minimum tax during the period.

The deferred tax provision for 2008 includes the recognition of \$336.6 million of net tax benefits as a result of reducing certain valuation allowances previously established in the United States as further discussed below.

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The components of earnings before income taxes from continuing operations were as follows (in thousands):

	Year Ended December 31,		
	2008	2007	2006
United States	\$133,180	\$ 93,471	\$ 25,904
Foreign	(36)	11,868	(19,204)
Earnings before income taxes	<u>\$133,144</u>	<u>\$105,339</u>	<u>\$ 6,700</u>

Our effective tax rate differs from the statutory U.S. Federal income tax rate as a result of the following:

	Year Ended December 31,	
	2008	2007
Statutory U.S. federal tax rate	35.0%	35.0%
State and local taxes, net of federal benefit	0.5	0.2
Foreign taxes	0.1	0.3
Current utilization of net operating losses and other deferred tax assets	(33.6)	(35.1)
Reversal of valuation allowance	(252.8)	—
Other, net	<u>0.4</u>	<u>2.2</u>
Total	<u>(250.4)%</u>	<u>2.6%</u>

The tax effect of NOLs, R&D tax credit carry forwards and temporary differences as of December 31, 2008 and 2007 was as follows (in thousands):

	December 31,	
	2008	2007
Deferred tax assets:		
Net operating loss carry forwards	\$333,443	\$ 412,877
R&D tax credit carry forwards	12,115	35,243
Intangible assets	11,021	11,951
Unearned revenue	17,108	31,174
Purchased R&D	39,498	45,968
Capitalized R&D	5,278	7,235
Other	<u>26,992</u>	<u>18,304</u>
	445,455	562,752
Valuation allowance	<u>(96,801)</u>	<u>(562,246)</u>
	348,654	506
Deferred tax liability:		
Depreciation	(7,385)	—
Contingent bond interest	(3,479)	—
Other	<u>(1,161)</u>	<u>(506)</u>
	<u>(12,025)</u>	<u>(506)</u>
	<u>\$336,629</u>	<u>\$ —</u>

As of December 31, 2008, we had available U.S. federal and foreign NOLs of approximately \$859 million and \$90 million, respectively. The U.S. NOLs will expire in various years from 2021 to 2026 and may be subject to

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certain annual limitations. The U.K. NOLs do not have an expiration date. Included in the \$333.4 million of deferred tax asset NOLs noted in the table above, as of December 31, 2008, was approximately \$67 million of deductions for equity-based compensation for which the tax benefit will be credited to additional paid-in capital, if and when realized. Our R&D tax credit carry forwards expire in various years from 2009 through 2028. Approximately \$3 million of the \$12.1 million of R&D tax credit carry forwards relates to equity-based compensation and will be recorded as an increase to additional paid-in capital, if and when realized. In accordance with SFAS No. 123(R), we recorded a valuation allowance of approximately \$70 million against the \$67 million of deductions for equity-based compensation and \$3.0 million of equity-based R&D tax credits as these tax benefits can only be recognized when realized. Certain of our NOLs and R&D tax credit carry forwards may be subject to significant limitations under Section 382 of the Internal Revenue Code. As of December 31, 2008, we also had accumulated approximately \$97 million in other net deferred tax assets based on temporary differences between book and tax reporting.

As part of our evaluation of deferred tax assets, we recognized a tax benefit of approximately \$337 million at the end of the 2008 fourth quarter relating to the reduction of certain valuation allowances previously established in the United States. As our U.K. operations have not achieved profitability, we were unable to conclude that the utilization of our U.K. NOLs would be more likely than not and therefore, did not reduce any U.K.-based valuation allowances at December 31, 2008. Our evaluation encompassed (i) a review of our recent history of profitability in the United States for the past three years; (ii) a review of internal financial forecasts demonstrating our expected utilization of NOLs prior to expiration; and (iii) a reassessment of tax benefits recognition under FIN 48.

FIN 48 clarifies the criteria that must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN 48 provides a benefit recognition model with a two-step approach consisting of a “more-likely-than-not” recognition criteria, and a measurement attribute that measures a given tax position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. FIN 48 also requires the recognition of liabilities created by differences between tax positions taken on a tax return and amounts recognized in the financial statements. Our initial adoption of FIN 48, on January 1, 2007 did not result in us establishing liabilities for tax uncertainties because we had no unrecognized tax benefits at the time.

Our FIN 48 assessment in 2008, resulted in the reassessment and re-measurement of tax attributes resulting in the reversal of certain deferred tax assets relating to NOLs and R&D tax credit carry forwards of approximately \$25 million. Since we have not previously recognized these benefits, due to having recorded a full valuation allowance in prior periods, there was no financial impact from this reduction in deferred tax assets. As of December 31, 2008, we did not record any liabilities relating to tax uncertainties as we had not recognized any tax benefits associated with these NOLs and R&D tax credit carry forwards. In the event that we are able to utilize these tax attributes in the future, an assessment of the benefits would be performed at that time, in accordance with FIN 48, and we may be required to establish a liability for tax uncertainties.

The amount of our unrecognized tax benefits may increase or decrease in the future for various reasons, including adding or reducing amounts for current year tax positions, the expiration of statutes of limitation on open income tax returns, changes in our management’s judgment about the level of uncertainty, the status of tax examinations and legislative activity. We do not expect the unrecognized tax benefits to significantly decrease over the next twelve months.

As previously mentioned, approximately \$67 million of our deferred tax assets related to our U.S. NOLs consists of deductions for equity-based compensation for which the tax benefit will be credited to additional paid-in capital if and when realized. These assets relate to equity-based compensation deductions that were recognized on our U.S. income tax returns prior to the adoption of SFAS No. 123(R) on January 1, 2006. In addition, as of December 31, 2008, we have an additional \$10 million of SFAS No. 123(R) post-adoption benefits which relate to equity-based compensation deductions that have been, or will be recorded on our U.S. income tax returns for calendar years 2006 through 2008 for which no deferred tax asset has been recorded. The tax benefit for these post-adoption deductions will also be recorded to additional paid-in capital, if and when realized.

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The decrease in the valuation allowance of approximately \$465 million is principally attributable to the partial reversal of the valuation allowance based on our recent history of profitability in the United States for the past three years and a review of internal financial forecasts demonstrating our expected utilization of NOLs prior to expiration. Other changes in the valuation allowance include the re-measurement of our qualified R&D tax credit carry forwards, the reversal of other temporary differences, the impact of foreign currency translation adjustments, a change in the statutory tax rate in the U.K., and the reversal of certain deferred tax assets related to FIN 48 and equity-based compensation.

The valuation allowance as of December 31, 2008 consists principally of the NOLs and R&D tax credit carry forwards related to equity-based compensation incurred prior to our adoption of SFAS No. 123(R) and the U.K. NOLs. In the event that deferred taxes associated with approximately \$23 million of U.K. NOLs related to our Prosidion subsidiary were to be realized in the future, there could be an offsetting U.S. income tax because the Prosidion subsidiary is currently treated as a branch for U.S. income tax purposes.

(13) Convertible Senior Subordinated Notes

The following is a summary of the outstanding indebtedness under our convertible senior subordinated notes as of December 31, 2008 and 2007 (in thousands):

	December 31,	
	2008	2007
2038 Notes(a)	\$200,000	\$ —
2025 Notes(b)	115,000	115,000
2023 Notes(c)	99,950	150,000
Total	\$414,950	\$265,000

(a) 3.0% Convertible Senior Subordinated Notes

On January 9, 2008, we issued \$200.0 million aggregate principal amount of 2038 Notes in a private placement resulting in net proceeds to us of approximately \$193.0 million. We used a portion of the proceeds to repurchase of approximately 1.5 million shares of our common stock concurrently with the offering for an aggregate price of \$65.0 million. The 2038 Notes bear interest semi-annually in arrears through maturity at an annual rate of 3% and mature on January 15, 2038. We may redeem for cash, all or part of the 2038 Notes at any time on or after January 15, 2013, at a price equal to 100% of the principal amount of the 2038 Notes, plus accrued and unpaid interest. Holders of the 2038 Notes have the right to require us to purchase, for cash, all or any portion of their 2038 Notes on January 15, 2013, 2018, 2023, 2028 and 2033 at a price equal to 100% of the principal amount of the 2038 Notes to be purchased, plus accrued and unpaid interest.

The 2038 Notes will be convertible only under certain circumstances, as described below. If, at the time of conversion, the daily volume-weighted average price per share for a 20 trading day period, or VWAP, of our common stock is less than or equal to approximately \$73.82 per share, which is referred to as the base conversion price, the 2038 Notes will be convertible into 13.5463 shares of our common stock per \$1,000 principal amount of 2038 Notes, which is referred to as the base conversion rate, subject to adjustment upon the occurrence of certain events, as set forth in the indenture. If, at the time of conversion, the VWAP of the common stock exceeds the base conversion price of \$73.82 per share, the conversion rate will be determined pursuant to a formula resulting in the holders' receipt of up to a maximum of 20.9968 shares of our common stock per \$1,000 principal amount of 2038 Notes, subject to adjustment upon the occurrence of certain events. From and after January 15, 2013, the conversion rate for the 2038 Notes will be fixed.

The 2038 Notes are convertible until the close of business on the business day immediately preceding the maturity date, in multiples of \$1,000 in principal amount, at the option of the holder only under the following

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circumstances: (1) during any fiscal quarter beginning after March 31, 2008, and only during such fiscal quarter, if the closing sale price of our common stock for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the immediately preceding fiscal quarter is more than 130% of the base conversion price per share; (2) during the five business day period after any period of five consecutive trading days in which the trading price per \$1,000 principal amount of 2038 Notes for each trading day of that period was less than 97% of the product of the closing sale price of our common stock on such day and the applicable daily conversion rate for such day; (3) if we call the 2038 Notes for redemption, at any time prior to the close of business on the business day prior to the redemption date; (4) if specified distributions to holders of our common stock are made; (5) if a fundamental change occurs; or (6) beginning on December 15, 2037 and ending at the close of business on the business day immediately preceding the maturity date. 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.

A holder will receive in respect of each \$1,000 principal amount of the 2038 Notes converted, a number of shares of our common stock equal to the sum of the “daily share amounts” for each of the 20 consecutive trading days in the applicable conversion reference period. With respect to trading days prior to January 15, 2013, the daily share amount for a given trading day in the applicable conversion reference period is an amount equal to the fraction of (i) the VWAP for such trading day multiplied by the “applicable daily conversion rate,” divided by (ii) the VWAP on such trading day multiplied by 20. If the VWAP is less than or equal to the base conversion price, then the applicable daily conversion rate will be equal to the base conversion rate. If the VWAP is greater than the base conversion price, then the applicable daily conversion rate will be equal to the sum of the base conversion rate plus the product of: (i) 55% of the base conversion rate, multiplied by (ii) a fraction equal to the VWAP less the base conversion price, divided by the VWAP for the pertinent trading day. We will have the right to deliver cash in lieu of all or a portion of such shares, subject to certain limitations. If a fundamental change transaction occurs before January 15, 2013, and a holder elects to convert 2038 Notes in connection with the transaction, we may be required to pay a “make whole premium” by delivering additional shares of stock (or cash in lieu of such shares) based on an increase in the applicable base conversion rate for the 2038 Notes determined by the effective date of the fundamental change and the stock price paid per share in such transaction. Notwithstanding the foregoing, in no event will the conversion rate under the 2038 Notes exceed 22.3513 shares of our common stock per \$1,000 principal amount of the 2038 Notes, subject to certain proportional adjustments applicable to the base conversion rate.

The 2038 Notes are unsecured obligations and are subordinate to all of our existing and future senior indebtedness. The 2038 Notes rank equally with all of our existing and future senior subordinated indebtedness, and are effectively subordinated to all of our existing and future secured indebtedness to the extent of the security therefor.

As of January 1, 2009, the 2038 Notes were not eligible for conversion as our common stock did not close at or above \$73.82 per share for twenty trading days within the thirty trading day period ending on December 31, 2008.

(b) 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

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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 2025 Notes for redemption; or (v) any time on or after December 15, 2020. Upon conversion, we will have the right to deliver, in lieu of shares of common stock, cash or a combination of cash and shares of common stock.

At any time before the maturity date, we may irrevocably elect, in our sole discretion, to satisfy our conversion obligation in cash up to 100% of the principal amount of the notes converted, with any remaining amount to be satisfied in shares of our common stock. If certain fundamental changes occur before December 15, 2010, the conversion rate may increase, or under certain circumstances, we may elect to change our conversion obligations to provide for conversion of the notes into the acquiring company's common stock. We may redeem the 2025 Notes, in whole or in part, for cash, at any time on or after December 15, 2010 for a price equal to 100% of the principal amount of the 2025 Notes to be redeemed, plus any accrued and unpaid interest. The holders of the 2025 Notes have the right to require us to purchase, for cash, all of the 2025 Notes, or a portion thereof, on December 15, 2010, December 15, 2015, on December 15, 2020 and under certain other circumstances as set out in the indenture, for a price equal to 100% of the principal amount of the 2025 Notes plus any accrued and unpaid interest. The related debt issuance costs of \$3.9 million were deferred and are being amortized on a straight-line basis over a five-year term, which represents the earliest date that we may redeem the 2025 Notes.

Concurrent with the sale of the 2025 Notes, we used \$11.8 million of the net proceeds for the purchase of 500,000 shares of our common stock and we purchased a call spread overlay transaction from UBS, AG at a cost of \$12.2 million. The call spread is a European-type option with a lower strike price of \$29.425 and an upper strike price of \$40.00 and involves an aggregate of 3.4 million shares of our common stock and expires on December 15, 2010. The call spread overlay agreement has the effect of increasing the effective conversion price of the 2025 Notes from our perspective to \$40.00 per share on the intended sale of \$100.0 million (excluding the sale of \$15.0 million of 2025 Notes related to the exercise of the over-allotment). The agreement calls for settlement using net shares. Under the agreement, bankers associated with the debt offering will deliver to us the aggregate number of shares we are required to deliver to a holder of 2025 Notes that presents such notes for conversion. If the market price per share of our common stock is above \$40.00 per share, we will be required to deliver shares of our common stock representing the value in excess of the strike price. In accordance with EITF No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," and SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity," we recorded the purchase of the call spread overlay option agreement as a reduction in additional paid — in capital, and will not recognize subsequent changes in fair value of the agreement.

As of January 1, 2009, the 2025 Notes were not eligible for conversion as our common stock did not close at or above \$35.32 per share for twenty trading days within the thirty trading day period ending on December 31, 2008.

(c) 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. The holders of the Notes had the right to require us to purchase all of the 2023 Notes, or a

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portion thereof, on September 8, 2008. As discussed below, a significant portion of the holders did not exercise their right.

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, 2013 and September 8, 2018 for a price equal to 100% of the principal amount of the 2023 Notes plus any accrued and unpaid interest. If the holders of the 2023 Notes make this election, we can pay the purchase price in cash or by issuing our common stock. Upon a change in control, as defined in the indenture governing the 2023 Notes, the holders of the 2023 Notes will have the right to require us to purchase all of the 2023 Notes, or a portion thereof, not previously called for redemption at a purchase price equal to 100% of the principal amount of the 2023 Notes purchased, plus accrued and unpaid interest.

Upon the exercise by the holders of the right to require us to purchase the 2023 Notes or upon a change of control, we may elect to pay the purchase price in common stock instead of cash. The number of shares of common stock a holder will receive will equal the purchase price divided by 95% of the average of the closing prices of our common stock for the five-trading day period ending on the third business day prior to the purchase date.

The debt issuance costs of \$5.2 million related to the 2023 Notes were deferred and are being amortized on a straight-line basis over a five-year term, which represents the earliest date that we may redeem the 2023 Notes. In connection with the issuance of the 2023 Notes, we used \$19.0 million of the net proceeds for the purchase of 503,800 shares of our common stock. Since the beginning of the 2008 fiscal year, we have repurchased an aggregate of \$50.05 million of our 2023 Notes, reducing the outstanding balance of our 2023 Notes to \$99.95 million. The 2023 Notes had been classified as a short-term liability on the December 31, 2007 balance sheet since the holders had the right to require us to purchase all of the 2023 Notes, or a portion thereof, in September 2008. This purchase right expired on September 8, 2008. Prior to this expiration date, holders of an aggregate of \$50,000 principal amount of our 2023 Notes exercised their right to require us to repurchase their notes. The remaining holders of the 2023 Notes do not have the right to require us to purchase the 2023 Notes again until September 2013, except under certain other circumstances set forth in the indenture for the 2023 Notes. Therefore, we have reclassified the 2023 Notes as a long-term liability on the December 31, 2008 balance sheet. In connection with the repurchase of a portion of the 2023 Notes, during the year ended December 31, 2008, we recognized \$602,000 of costs relating to the premium paid over par for the 2023 Notes and the acceleration of unamortized issuance costs. The charge is included in other (expense) income-net in the accompanying statement of operations for the periods then ended.

(14) Employee Savings and Investment Plans

We sponsor an Employee Savings and Investment Plan under Section 401(k) of the Internal Revenue Code. The plan allows our U.S. employees to defer from 2% to 70% of their income on a pre-tax basis through contributions into designated investment funds provided the total contribution does not exceed the Internal Revenue Code's mandatory limits. We match each employee's contribution to the plan on a dollar-for-dollar basis up to 4% of such employee's salary, and then match 50% of such employee's contribution from 4% to 6% of his or her salary. Prior to January 1, 2007, we matched 50% of the employees contributions up to 6% of his or her earnings. During the years ended December 31, 2008, 2007 and 2006, our expenses related to the plan were \$2.0 million, \$2.0 million and \$1.4 million, respectively.

We also sponsor four pension plans covering the employees of OSI U.K. and Prosidion. The Group Personal Pension Plan allows employees to contribute a portion of their income on a post-tax basis into designated investment funds. The tax paid on the contribution is then recovered from the Inland Revenue. We generally contribute from 4% to 9% depending on the employees' contributions. The British Biotechnology Limited Pension Scheme covers employees retained from the acquisition of certain assets from British Biotechnology Limited, as well as certain former employees of British Biotechnology hired by us subsequent to the acquisition. The plan allows the employees to defer up to 15% of their income on a pre-tax basis through contributions into designated

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pension funds. For each period the employee invests, we will contribute up to 9% into the funds. For the year ended December 31, 2008, 2007 and 2006, our expenses related to the plans were \$754,000, \$704,000 and \$673,000, respectively.

In addition, effective July 2007, we adopted a nonqualified deferred compensation plan which permits certain employees to elect annually to defer a portion of their compensation, and as of December 31, 2008, we had recorded a \$682,000 liability related to this plan. The employees select among various investment alternatives, with the investments held in a separate trust.

(15) Employee Post-retirement Plan and Other

(a) Employee Post-retirement Plan

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

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

Net post-retirement benefit cost (excluding the \$4.3 million curtailment gain recognized in 2007) for the years ended December 31, 2008, 2007 and 2006 included the following components (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Service cost for benefits earned during the period	\$ —	\$337	\$1,054
Interest cost on accumulated post-retirement benefit obligation	176	252	409
Amortization of initial benefits attributed to past service	—	2	6
Amortization of loss	—	6	66
Net post-retirement benefit cost	<u>\$176</u>	<u>\$597</u>	<u>\$1,535</u>

The accrued post-retirement benefit cost at December 31, 2008 and 2007 totaled \$2.7 million and \$3.2 million, respectively.

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The changes in the accumulated post-retirement benefit obligation during years ended December 31, 2008 and 2007 were as follows (in thousands):

	<u>2008</u>	<u>2007</u>
Balance at beginning of year	\$3,163	\$ 8,070
Benefit payments	(182)	(118)
Loss experience	(506)	128
Service cost	—	337
Curtailment gain	—	(5,506)
Interest cost	<u>176</u>	<u>252</u>
Balance at end of year	<u>\$2,651</u>	<u>\$ 3,163</u>

For the year ended December 31, 2008, the health care cost trend assumption remained at an initial level of 9%, decreasing to an ultimate estimated rate of 5% by 2013 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, 2008 by \$271,000 and the fiscal 2008 net post-retirement service and interest cost by \$14,000. 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, 2008 by \$231,000 and the fiscal 2008 net post-retirement service and interest cost by \$12,000. Benefits paid in the years ended December 31, 2008, 2007 and 2006 were \$182,000, \$118,000 and \$134,000, respectively.

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

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Discount rate	5.25%	5.72%	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, 2008.

For the years ended 2009 through 2013, we anticipate paying benefits of \$146,000, \$161,000, \$178,000, \$180,000, and \$192,000, respectively. We anticipate paying aggregate benefits of \$878,000 for the years of 2014 through 2018.

(b) Sabbatical Leave Accrual

Effective January 1, 2007, we adopted EITF 06-02, "Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to SFAS No. 43." Sabbatical leave is generally defined as an employee's entitlement to paid time off after working for an entity for a specified period of time. The employee continues to be a compensated employee and is not required to perform any duties for the entity during the sabbatical leave. We provide a sabbatical leave of four weeks for employees who have achieved 15 years of service. Included in accrued post-retirement benefit costs and other as of December 31, 2008 and 2007 was \$468,000 and \$425,000, respectively, of accrued sabbatical leave.

(16) Stockholders' Equity

(a) Equity Plans

We have nine equity plans pursuant to which there are outstanding grants issued to our employees, officers, directors and consultants. Two of these plans still have shares available for future grant, the 1999 Incentive and Non-Qualified Stock Option Plan and the Amended and Restated Stock Incentive Plan. The plans are administered by the

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Compensation Committee of the Board of Directors, which may grant stock options and, in the case of the Amended and Restated Stock Incentive Plan, restricted stock, restricted stock units and deferred stock units. The Compensation Committee determines the terms of all equity grants under the plans. Our equity grants vest over various periods and expire no later than 10 years from date of grant. The total authorized shares under these plans are 21,388,777, of which 4,683,035 shares were available for future grant as of December 31, 2008.

On March 17, 2004, at our 2004 annual meeting of stockholders, our stockholders approved an amendment and restatement of the 2001 Stock Option Plan in the form of the Amended and Restated Stock Incentive Plan, or the Plan, which was adopted by the Board of Directors on January 23, 2004. On March 16, 2005, at our 2005 annual meeting of stockholders, our stockholders approved an amendment to the Plan to increase the number of equity awards issuable under the Plan from 4 million shares to 6.8 million shares. On June 13, 2007, our stockholders approved an amendment to the Plan to increase the number of equity awards issuable under the Plan from 6.8 million to 13.8 million. Participation in the Plan is limited to our directors, officers, employees and consultants of our parent or subsidiaries.

We have an employee stock purchase plan under which eligible employees may contribute up to 10% of their base earnings toward the quarterly purchase of our common stock. The employee's purchase price is derived from a formula based on the fair market value of the common stock. During the years ended December 31, 2008, 2007 and 2006, approximately 20,000, 24,000 and 38,000 shares, respectively, were issued with approximately 140, 150 and 214 employees participating in the plan, respectively. At December 31, 2008, we had 275,917 shares of our authorized common stock available for future grant in connection with these plans.

We sponsor a stock purchase plan for our U.K.-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 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 R&D activities into our New York locations, we did not offer this plan to U.K. 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 U.K. employees beginning in 2005 and continued to offer the plan in 2006, 2007 and 2008. 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 30 employees, 13 employees, and 47 employees that participated in the 2008, 2007 and 2006 plans, respectively. At December 31, 2008, we had 77,013 shares of our common stock available for future grant in connection with these plans.

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.

Compensation expense related to continuing operations for the years ended December 31, 2008, 2007 and 2006 were as follows (in thousands):

	Year Ended December 31,		
	2008	2007	2006
Cost of sales	\$ 620	\$ 338	\$ 251
Research and development expenses	7,373	4,683	2,973
Selling, general and administrative expenses	<u>12,789</u>	<u>10,406</u>	<u>9,957</u>
Stock-based compensation expense	<u>\$20,782</u>	<u>\$15,427</u>	<u>\$13,181</u>

Compensation expense related to discontinued operations for the year ended December 31, 2008 was \$(193,000), primarily related to forfeiture activity in 2008. Compensation expense related to discontinued

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operations for the year ended December 31, 2007 and 2006 was \$2.2 million and \$9.2 million, respectively. Compensation expense related to continuing operations attributable to net stock-based compensation for the years ended December 31, 2008, 2007, and 2006 was \$20.8 million, or \$0.31 diluted earnings per share, \$15.4 million, or \$0.25 diluted earnings per share and \$13.2 million, or \$0.23 diluted earnings per share, respectively. At December 31, 2008, the total remaining unrecognized compensation cost related to unvested stock-based payment awards was \$68.9 million. This cost is expected to be recognized over a weighted average period of approximately 2.77 years.

(b) Stock Options

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

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

	Year Ended December 31,		
	2008	2007	2006
Expected dividend yield	0%	0%	0%
Expected volatility	50.20%	46.40%	54.53%
Risk-free interest rate	2.32%	3.83%	4.53%
Expected term (years)	5.36	4.65	4.51
Per share weighted average fair value of stock options grants	\$15.81	\$19.26	\$16.21

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A summary of our stock option programs at December 31, 2008, 2007, 2006 and 2005 and changes during the year is presented below:

	<u>No. Shares (In thousands)</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value(1) (In millions)</u>	<u>Weighted Average Contractual Life Remaining in Years</u>
Outstanding at December 31, 2005	6,964	\$35.29		
Granted	777	\$32.87		
Exercised	(391)	\$20.22		
Forfeitures	(621)	\$31.15		
Expired	<u>(2)</u>	\$15.90		
Outstanding at December 31, 2006	<u>6,727</u>	\$36.01		
Granted	665	\$44.25		
Exercised	(1,042)	\$24.65		
Forfeitures	<u>(765)</u>	\$39.42		
Outstanding at December 31, 2007	5,585	\$38.69		
Granted	956	\$34.90		
Exercised	(569)	\$27.69		
Forfeitures	<u>(259)</u>	\$41.56		
Outstanding at December 31, 2008	<u>5,713</u>	\$39.07	\$28.4	4.62
Exercisable at December 31, 2008	<u>3,806</u>	\$40.61	\$19.3	4.39
Unvested at December 31, 2008	<u>1,907</u>	\$36.00	\$ 9.1	5.37

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

The total intrinsic value of stock options exercised during the years ended December 31, 2008, 2007 and 2006 was \$10.7 million, \$15.9 million, \$6.1 million, respectively.

Options granted prior to June 1, 2005 have exercise prices equal to the fair market value of the stock on the date of grant, a contractual term of 10 years and a vesting period of three years. Options granted subsequent to May 31, 2005 have exercise prices equal to the fair market value of the stock on the date of grant, a contractual term of seven years and a vesting period ranging from four to five years. For the years ended December 31, 2008 and 2007, the historical forfeiture rate was 9% and 21.84%, respectively, for non-executive employees and no forfeitures for executive employees was assumed for purposes of recognizing compensation expense based upon adjusted historical experience.

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

Our outstanding shares of restricted stock, restricted stock units, and deferred stock units generally vest annually over a four-year period depending on the award, are valued at the stock price on date of grant and are subject to certain additional terms and conditions, including but not limited to the continued service of the employee or director. An aggregate of 1,106,535 restricted shares and units were outstanding as of December 31, 2008, representing \$40.4 million of unrecognized compensation expense which is expected to be recognized over a weighted average period of 3.2 years. The aggregate intrinsic value was \$43.9 million as of December 31, 2008.

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The following is a summary of the status of our restricted stock, restricted stock units and deferred stock units for the years ended December 31, 2008, 2007 and 2006:

	<u>No. Shares (In thousands)</u>	<u>Weighted Average Grant Date Fair Value</u>
Outstanding at December 31, 2005	16	\$37.88
Granted	623	\$35.58
Vested	(4)	\$40.22
Forfeited	<u>(12)</u>	<u>\$31.29</u>
Outstanding at December 31, 2006	<u>623</u>	<u>\$35.69</u>
Granted	498	\$46.77
Vested	(127)	\$36.22
Forfeited	<u>(97)</u>	<u>\$35.59</u>
Outstanding at December 31, 2007	<u>897</u>	<u>\$41.90</u>
Granted	538	\$33.96
Vested	(276)	\$40.26
Forfeited	<u>(52)</u>	<u>\$43.12</u>
Outstanding at December 31, 2008	<u>1,107</u>	<u>\$38.46</u>

The total intrinsic value of restricted stock, restricted stock units and deferred stock units that vested during the years ended December 31, 2008, 2007 and 2006 was \$11.1 million, \$4.6 million and \$169,000, respectively.

(d) Shareholder Rights Plan

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

Upon the actual acquisition of 17.5% or more of our outstanding common stock by a person or group, the rights held by all holders other than the acquiring person or group will be modified automatically to be rights to purchase shares of common stock (instead of rights to purchase preferred stock) at 50% of the then-market value of such common stock. Furthermore, such rightholders will have the further right to purchase shares of common stock at the same discount if we merge with, or sell 50% or more of our assets or earning power to, the acquiring person or group or any person acting for or with the acquiring person or group. If the transaction takes the form of a merger of us into another corporation, these rightholders will have the right to acquire at the same percentage discount shares of common stock of the acquiring person or other ultimate parent of such merger party.

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

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(e) Authorized Common and Preferred Stock

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

(17) Commitments and Contingencies

(a) Lease Commitments

We lease office, operating and laboratory space under various lease agreements. Rent expense for continuing and discontinued operations was approximately \$6 million, \$6 million and \$10 million for the years ended December 31, 2008, 2007 and 2006, respectively. Rent expense for fiscal 2008 includes the Oxford, England facility leases, Boulder, Colorado facility leases, Cedar Knolls, the New Jersey facility lease and the Farmingdale, NY facility lease. As discussed in Note 11(b), we accrued the net remaining lease rental payments and refurbishment costs for a portion of the Oxford, England facility in fiscal 2005.

The following is a schedule of future minimum rental payments for the next five fiscal years and thereafter required as of December 31, 2008. In addition to the facilities noted above, the schedule includes subleased facilities in New York City and Lexington Massachusetts, exclusive of sub-rental income from these subleased facilities. Also included in the amounts below are commitments for equipment under various operating leases (in thousands).

2009	\$ 11,074
2010	10,792
2011	10,751
2012	10,181
2013	10,122
2014 and thereafter.....	<u>66,619</u>
	<u>\$119,539</u>

Rental obligations and deferred rent in the accompanying consolidated balance sheet reflects the rent expense recognized on a straight-line basis in excess of the required lease payments in connection with our facility leases and the present value of net operating lease payments for exited facilities. Included in rent and deferred rent as of December 31, 2008 is \$2.4 million related to deferred rental payments and \$4.5 million of accruals related to exited facilities and refurbishment costs.

(b) Contingencies

Under certain license and collaboration agreements with pharmaceutical companies and educational institutions, we are required to pay royalties, milestones and/or other fees 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 R&D by us may be infringing existing patents of such entities. These matters are reviewed by management, and if necessary, by our outside counsel. Where valid patents of other parties are found by us to be in place, management will consider entering into licensing arrangements with the universities and/or companies or modify the conduct of its research. Our future royalties, if any, may be 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.

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(18) Related Party Transactions

One member of our Board of Directors is a partner in a law firm which represents us on certain of our patent matters. Fees paid to this firm during the years ended December 31, 2008, 2007 and 2006 were approximately \$412,000, \$170,000 and \$115,000, respectively. In addition, we have compensated other directors for services performed pursuant to consultant arrangements. During the years ended December 31, 2008, 2007 and 2006, consulting fees in the amounts of \$257,000, \$75,000 and \$75,000, respectively, were paid to such directors pursuant to these arrangements.

(19) Acquisitions

(a) 7TM Pharma

In the fourth quarter of 2008, Prosidion acquired intellectual property and other assets from 7TM Pharma A/S for \$4.0 million. The \$4.0 million was recorded as an in-process R&D charge, since it was associated with the intellectual property which was deemed early stage with no alternative use.

(b) Acquisition of AdipoGenix Assets

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

(20) Eyetech Discontinued Operations

(a) Divestiture of Eye Disease Business

On November 6, 2006, we announced our intention to divest our eye disease business, a process which we completed in August 2008. Our eye disease business consisted principally of Macugen, a 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 finalized our exit plan during the first quarter of 2007 and began to actively market our eye disease business. In order to facilitate the divestiture of our eye disease business, on April 20, 2007, we terminated our existing collaboration agreement with Pfizer, Inc. Prior to the April 2007 amendment, we shared sales and marketing responsibility for sales of Macugen in the United States and reported product revenue on a gross basis for these sales. We determined that we qualified as a principal under the criteria set forth in EITF No. 99-19 based on our responsibilities under our original contracts with Pfizer, which included manufacture of product for sale in the United States, distribution, ownership of product inventory and credit risk from customers. After April 20, 2007, we no longer shared the gross profits of U.S. sales with Pfizer and no longer received royalties from Pfizer from rest of the world sales.

In July 2007, we entered into an agreement with Ophthotech Corporation to divest our anti-platelet derived growth factor, or PDGF, aptamer program for an upfront cash payment, shares of Ophthotech preferred stock and potential future milestones and royalties. Included in the loss from discontinued operations for the year ended December 31, 2007 was a gain of approximately \$6 million, recognized as a result of the agreement.

On August 1, 2008, we completed the sale of the remaining assets of our eye disease business to Eyetech, Inc., a newly formed corporation whose shareholders consisted primarily of members of the Macugen sales team. Under the terms of the transaction, the principal assets we transferred to Eyetech Inc. consisted of Macugen-related intellectual property and inventory, as well as \$5.8 million in working capital primarily in the form of Macugen trade receivables, in exchange for potential future milestone and royalty payments. Our consideration for the

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transaction also included payments in the event of any subsequent change-of-control affecting Eyetech Inc., as well as Eyetech Inc.'s agreement to assume certain obligations of (OSI) Eyetech. We also agreed to provide certain transition services to Eyetech Inc. for the period commencing with the closing through December 31, 2009. Michael G. Atieh, our former Executive Vice President, Chief Financial Officer and Treasurer, agreed to join Eyetech Inc. in a part-time executive chairman role upon his retirement from OSI. Mr. Atieh also holds stock in Eyetech Inc. that became voting and participating with respect to dividends and distribution following his retirement from our company.

(b) (OSI) Eyetech Milestone Revenue and Expense

In the second quarter of 2006, we received a \$35.0 million milestone payment from Pfizer upon the launch of Macugen in select European countries. In accordance with EITF 00-21, the milestone payment was recorded as unearned revenue and was being recognized as revenue on a straight-line basis over the expected term of our collaboration and license agreements with Pfizer, which approximates the expected level of performance under these agreements with Pfizer. In April 2007, we terminated our collaboration and license agreements with Pfizer and entered into an amended and restated license agreement. Under the terms of the amended and restated license agreement, Pfizer returned to us all rights to develop and commercialize Macugen in the United States, and we granted to Pfizer an exclusive right to develop and commercialize Macugen in the rest of the world. We also agreed with Pfizer to provide each other with certain transitional services related to Macugen. These ongoing obligations to Pfizer required us to amortize the \$35.0 million milestone payment over the term of the original agreement and include this unearned revenue in loss from discontinued operations. In connection with the sale of the remaining assets of our eye disease business to Eyetech Inc. on August 1, 2008, we assigned certain of our obligations under our amended and restated license agreement with Pfizer to Eyetech Inc. Accordingly, we believe that the earnings process with respect to the milestone payment is now complete. As a result, we have recognized \$27.9 million, the remaining unamortized balance of the \$35.0 million milestone payment from Pfizer, in net revenue from discontinued operations in 2008. We also recognized a \$2.0 million expense in the third quarter of 2008 related to a third-party milestone obligation for Macugen.

(c) (OSI) Eyetech Operating Results

As a result of our decision to divest the eye disease business, in accordance with the provision of SFAS No. 144, the results of operations of (OSI) Eyetech for the current and prior periods were reported as discontinued operations. In addition, assets and liabilities of (OSI) Eyetech were classified as assets and liabilities related to discontinued operations, including those held for sale. In the third and fourth quarters of 2007, we assessed the net realizable carrying amount or fair value of the assets held for sale and recognized impairment charges of \$5.6 million and \$5.1 million, respectively. Second quarter of 2008 results reflected an additional \$9.4 million impairment charge related to the adjustment of the assets held for sale down to their net realizable value. In the third quarter of 2008, as a result of our completion of the sale of the remaining assets of our eye disease business, we adjusted the remaining assets classified as held for sale to their final net realizable value, resulting in an additional charge of \$1.4 million. We also incurred expenses of \$3.3 million associated with the divestiture.

(d) Goodwill Impairment

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

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(e) Macugen Intangibles Impairment

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

Operating results of (OSI) Eyetech for the years ended December 31, 2008, 2007 and 2006 are summarized as follows (in thousands):

	Year Ended December 31,		
	2008	2007	2006
Net revenue	\$ 44,314	\$ 37,435	\$ 134,659
Gain on sale of PDGF aptamer research program	—	6,012	—
Loss on sale of eye disease business	(14,135)	—	—
Impairment loss	—	—	(505,985)
Operating income (loss)	18,267	(35,797)	(104,580)
Pretax income (loss)	3,582	(36,930)	(610,930)
Net income (loss) from discontinued operations	\$ 4,884	\$(36,288)	\$(610,930)

At December 31, 2008 and 2007, certain assets and liabilities related to the eye disease business were classified as assets or liabilities related to discontinued operations except for certain lease obligations that we continue to retain.

The summary of the assets and liabilities related to discontinued operations as of December 31, 2008 and 2007 is as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Assets:		
Accounts receivable	\$ 917	\$18,411
Prepaid expenses and other assets	—	470
Assets held for sale	—	6,561
Assets related to discontinued operations	<u>\$ 917</u>	<u>\$25,442</u>
Liabilities:		
Accounts payable and accrued expenses	\$1,522	\$13,382
Collaboration profit share	—	2,783
Unearned revenue	—	29,574
Liabilities related to discontinued operations	<u>\$1,522</u>	<u>\$45,739</u>

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(f) Variable Interest Entities

We have determined that, under FASB Interpretation No. 46(R), “Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51,” issued in January 2003, Eyetech Inc. qualifies as a variable interest entity, or VIE, but as we are not its primary beneficiary, consolidation is not required. FIN 46(R) requires an entity to be classified as a VIE where (i) the reporting company, or its related parties, participated significantly in the design of the entity, or where substantially all of the activities of the entity either involve or are conducted on behalf of the reporting company or its related parties and (ii) its equity investors do not have a controlling financial interest or where the entity is unable to finance its activities without additional financial support from other parties. Based on this test, Eyetech Inc. qualifies as a VIE due to its inability at the time of its acquisition of the remaining assets of our eye disease business to finance its activities without additional financial support from third parties, and due to the fact that Mr. Atieh, our former Executive Vice President, Chief Financial Officer and Treasurer, a stockholder in Eyetech Inc., participated in the design of the entity and agreed to serve as its part-time executive chairman following his retirement from OSI in January 2009.

FIN 46(R) further requires the consolidation of entities which are determined to be VIEs when the reporting company determines itself to be the primary beneficiary — in other words, the entity that will absorb a majority of the VIE’s expected losses or receive a majority of the VIE’s expected residual returns. We have determined that OSI is not the primary beneficiary of Eyetech Inc. as (i) OSI does not hold an equity position in Eyetech Inc., (ii) OSI’s ongoing interest in this entity is limited to OSI’s contingent right to receive future royalties and milestones and (iii) OSI does not have liability for the future losses.

(g) (OSI) Eyetech Divestiture — Severance Costs

As a result of our decision to exit our eye disease business in November 2006, we committed to a plan to re-scale the eye disease business. The plan included the consolidation of facilities as well as a reduction in the workforce for transitional employees throughout 2007 and 2008. The remaining liability is expected to be paid during 2009.

The activity for the years ended December 31, 2008 and 2007 was as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Opening liability	\$ 800	\$ 3,284
Accrual for severance, relocation and retention bonuses	1,376	5,206
Cash paid for severance	<u>(1,789)</u>	<u>(7,690)</u>
Ending liability	<u>\$ 387</u>	<u>\$ 800</u>

(21) Accounting Pronouncements

In May 2008, FASB issued FASB Staff Position, or FSP, No. APB 14-1, “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement).” This FSP clarifies that convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) are not addressed by paragraph 12 of APB Opinion No. 14, “Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants.” Additionally, this FSP specifies that issuers of such instruments should separately account for the liability and equity components in a manner that will reflect the entity’s nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. This FSP will be effective beginning with our financial statements issued for the first quarter of 2009. We are currently evaluating the impact this FSP will have on our financial position or results of operations and anticipate the adoption of this FSP will have a material impact on the carrying value and the interest expense associated with our 2025 Notes and 2038 Notes.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In April 2008, the FASB issued FSP No. FAS 142-3, "Determination of the Useful Life of Intangible Assets." FSP FAS 142-3 removes the requirement within SFAS No. 142 for an entity to consider, when determining the useful life of a recognized intangible asset, whether an intangible asset can be renewed without substantial cost or material modifications to the existing terms and conditions. FSP FAS 142-3 requires an entity to consider its own historical experience in developing renewal or extension assumptions. In the absence of entity specific experience, FSP FAS 142-3 requires an entity to consider assumptions that a marketplace participant would use about renewal or extension that are consistent with the highest and best use of the asset by a marketplace participant. FSP FAS 142-3 is effective prospectively for all intangible assets acquired after its effective date, for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, with additional disclosures required for all recognized intangible assets as of the effective date. We do not expect the adoption of FSP FAS 142-3 will have a material impact on our financial position, results of operations or cash flows.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities." SFAS No. 159 permits entities to choose to measure many financial instruments and certain items at fair value that are not currently required to be measured at fair value. Effective January 1, 2008, we elected to adopt the provisions of SFAS No. 159 for our fiscal year ending December 31, 2008. The adoption of SFAS No. 159 did not have a material impact on our financial position, results of operations or cash flows.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements," to clarify the definition of fair value, establish a framework for measuring fair value and expand the disclosures on fair value measurements. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. SFAS No. 157 also stipulates that, as a market-based measurement, fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability, and establishes a fair value hierarchy that distinguishes between: (a) market participant assumptions developed based on market data obtained from sources independent of the reporting entity, or observable inputs; and (b) the reporting entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances, or unobservable inputs. Except for the deferral for the implementation of SFAS No. 157 for specified other non-financial assets and liabilities, SFAS No. 157 is effective for our fiscal year ended December 31, 2008. The adoption of SFAS No. 157 did not have a material impact on our financial position, results of operations or cash flows.

In February 2008, the FASB issued FSP 157-2, "Effective Date of FASB Statement No. 157," which delays the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities. The delay is intended to allow FASB and constituents additional time to consider the effect of various implementation issues that have arisen, or that may arise, from the application of SFAS No. 157. For items within the scope of FSP 157-2, this FSP defers the effective date of SFAS No. 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. We currently do not believe that the adoption of the deferred portion of SFAS No. 157 will have a material impact on our financial condition, results of operations or cash flows.

On June 27, 2007, EITF Issue 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities," was issued. EITF Issue 07-03 provides that nonrefundable advance payments made for goods or services to be used in future R&D activities are deferred and capitalized until such time as the related goods or services are delivered or are performed, at which point the amounts will be recognized as an expense. EITF Issue 07-03 is effective for new contracts entered into after January 1, 2008. The adoption of EITF Issue 07-03 did not have a material impact on our financial position, results of operations or cash flows in 2008.

In November 2007, EITF Issue 07-01, "Accounting for Collaborative Arrangements," was issued. EITF Issue 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. EITF Issue 07-01 is effective for fiscal years beginning after December 15, 2008. We currently do not believe that this EITF will have a material impact on the results of our operations, financial position or cash flows.

In December 2007, the FASB issued SFAS No. 141R, "Business Combinations." SFAS No. 141R replaces SFAS No. 141 and establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS No. 141R also provides guidance on how the acquirer should recognize and measure the goodwill acquired in the business combination and determine what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141R is effective for us in our fiscal year beginning January 1, 2009. Most of the requirements of SFAS No. 141R are only to be applied prospectively to business combinations entered into on or after January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51." SFAS No. 160 states that accounting and reporting for minority interests will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS No. 160 also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 applies to all entities that prepare consolidated financial statements, except not-for-profit organizations, but will affect only those entities that have an outstanding noncontrolling interest in one or more subsidiaries or that deconsolidate a subsidiary. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. We currently do not believe that the adoption of SFAS No. 160 will have a material impact on the results of our operations, financial position or cash flows.

(22) Subsequent Event

On February 2, 2009, Genentech, informed us that a Genentech-conducted Phase III study, ATLAS, was stopped early on the recommendation of an independent data safety monitoring board. A pre-planned interim analysis showed that combining Tarceva and Avastin® (bevacizumab) significantly extended the time that patients with locally advanced, recurrent or metastatic non-small cell lung cancer lived without their disease advancing, as defined as progression-free survival, compared with Avastin plus placebo.

We are currently reviewing certification letters received in February 2009 from Teva Pharmaceuticals U.S.A., Inc. and Mylan Pharmaceuticals, Inc. alleging that the three patents listed in the FDA's Orange Book for Tarceva are invalid, unenforceable, or will not be infringed by generic versions of erlotinib for which these generic pharmaceutical companies have sought FDA approval to commercialize in the United States. We, together with Genentech, are currently reviewing these certifications, which are commonly referred to as Paragraph IV certifications, and expect to commence patent infringement lawsuits within the 45-day period triggered by our receipt of these certifications.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(23) Quarterly Financial Data (unaudited)

The tables below summarize our unaudited quarterly operating results for the years ended December 31, 2008 and 2007.

	Three Months Ended (In thousands, except per share data)			
	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008
Revenues from continuing operations	\$90,735	\$95,654	\$94,572	\$ 98,427
Net income from continuing operations	\$31,663	\$37,217	\$34,545	\$363,176
Net income	\$29,237	\$25,298	\$54,826	\$362,124
Basic earnings per share from continuing operations	\$ 0.55	\$ 0.65	\$ 0.60	\$ 6.30
Diluted earnings per share from continuing operations	\$ 0.52	\$ 0.61	\$ 0.56	\$ 5.50
Basic net income per share	\$ 0.51	\$ 0.44	\$ 0.95	\$ 6.29
Diluted net income per share	\$ 0.49	\$ 0.43	\$ 0.88	\$ 5.48

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

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

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

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

CEO/CFO CERTIFICATIONS

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

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

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

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

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

Under the supervision of and with the participation of our CEO and our CFO, our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework and criteria established in *Internal Control — Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management has concluded that, as of December 31, 2008, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by KPMG LLP, our independent registered public accounting firm, as stated in its report which is included in this Annual Report on Form 10-K.

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 2008 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**

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

We have audited OSI Pharmaceuticals, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). OSI Pharmaceuticals, Inc. and subsidiaries' management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, OSI Pharmaceuticals, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of OSI Pharmaceuticals, Inc. and subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2008, and our report dated February 27, 2009 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Melville, NY
February 27, 2009

ITEM 9B. OTHER INFORMATION

Not applicable.

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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 27, 2009

/s/ COLIN GODDARD, Ph.D.

Colin Goddard, Ph.D.
Chief Executive Officer

CERTIFICATION

I, Pierre Legault 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 27, 2009

/s/ PIERRE LEGAULT

Pierre Legault
Executive Vice President, Chief Financial Officer and
Treasurer (Principal Financial Officer)

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, 2008 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.

Date: February 27, 2009

/s/ COLIN GODDARD, Ph.D.

Colin Goddard, Ph.D.
Chief Executive Officer

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, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Pierre Legault, Executive Vice President, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 27, 2009

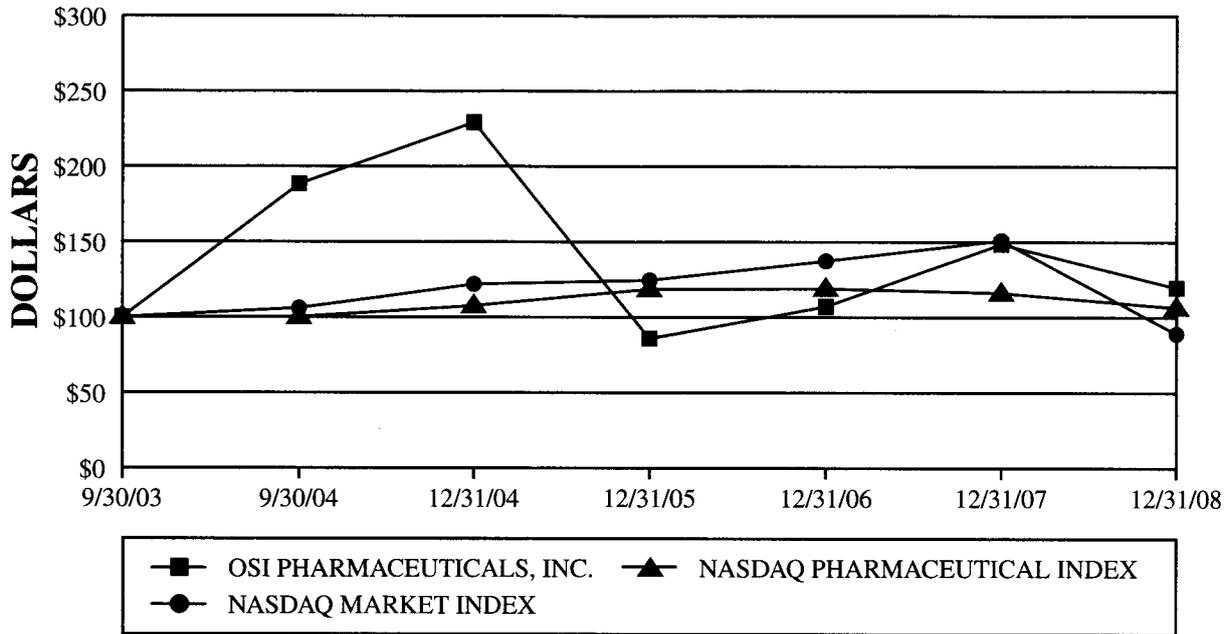
/s/ PIERRE LEGAULT

Pierre Legault
Executive Vice President, Chief Financial Officer and
Treasurer (Principal Financial Officer)

STOCK PRICE PERFORMANCE GRAPHS

The following graph presents the cumulative total return of our common stock with the cumulative total return of the Nasdaq Pharmaceutical Index and the Nasdaq Global Select Market Index ("Nasdaq Market Index") over a five-year period (including a three-month transition period ended December 31, 2004 due to the change in our fiscal year end from September 30 to December 31) based on an assumed investment of \$100 on October 1, 2003, in each case assuming reinvestment of all dividends. The companies comprising the Nasdaq Pharmaceutical Index are available upon written request to Investor Relations at OSI's executive offices.

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

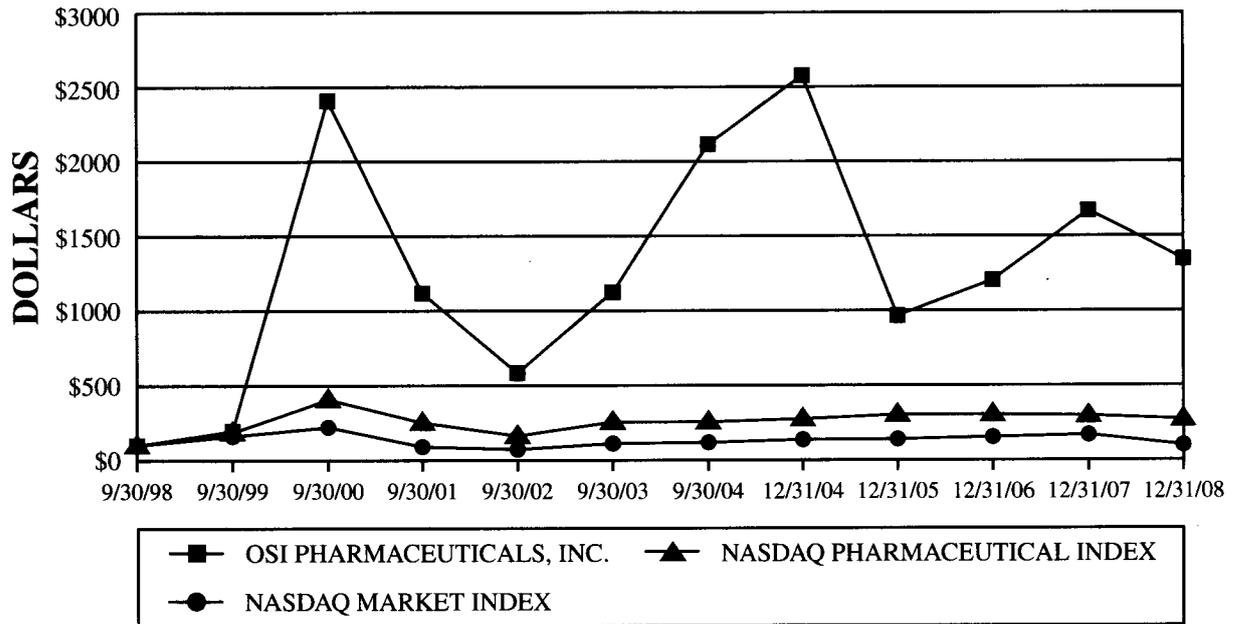


Company/Index/Market	As of						
	9/30/03	9/30/04	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08
OSI PHARMACEUTICALS, INC.	\$100.00	188.24	229.25	85.88	107.14	148.58	119.60
NASDAQ PHARMACEUTICAL INDEX	100.00	100.21	107.59	118.64	118.98	116.15	106.40
NASDAQ MARKET INDEX	100.00	106.02	121.88	124.56	137.35	150.98	89.10

STOCK PRICE PERFORMANCE GRAPHS — (Continued)

The following graph presents the cumulative total return of our common stock with the cumulative total return of the Nasdaq Pharmaceutical Index and the Nasdaq Market Index over a 10-year period (including a three-month transition period ended December 31, 2004 due to the change in our fiscal year end from September 30 to December 31) based on an assumed investment of \$100 on October 1, 1998, in each case assuming reinvestment of all dividends. The companies comprising the Nasdaq Pharmaceutical Index are available upon written request to Investor Relations at OSI's executive offices.

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



Company/Index/Market	As of											
	9/30/98	9/30/99	9/30/00	9/30/01	9/30/02	9/30/03	9/30/04	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08
OSI PHARMACEUTICALS, INC.	\$100.00	195.70	2408.56	1118.26	583.90	1123.42	2114.72	2575.44	964.80	1203.59	1669.13	1343.63
NASDAQ PHARMACEUTICAL INDEX	100.00	185.91	405.78	251.45	163.08	255.56	256.10	274.95	303.20	304.07	296.84	271.91
NASDAQ MARKET INDEX	100.00	161.77	221.30	90.67	72.95	111.80	118.53	136.26	139.26	153.55	168.80	99.61

BOARD OF DIRECTORS

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

Colin Goddard, Ph.D.
Chief Executive Officer

Santo J. Costa
Compensation Committee Chair
Retired Vice Chairman and President/COO
Quintiles Transnational Corp.

Joseph Klein, III
Managing Director
Gauss Capital Advisors, LLC

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

Viren Mehta
Mehta Partners, LLC

David W. Niemiec
Advisor
Saratoga Partners

Herbert Michael (Bob) Pinedo, M.D.,
Ph.D.
Professor-emeritus of Medical Oncology
at Vrije University Medical Center,
Amsterdam, the Netherlands
Visiting Professor at the Johns Hopkins
University, Baltimore, Maryland, USA
Visiting Professor at the Technical
University of Twente, the Netherlands

Katharine B. Stevenson
Audit Committee Chair

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

EXECUTIVE OFFICERS

Colin Goddard, Ph.D.
Chief Executive Officer

Pierre Legault
Executive Vice President,
Chief Financial Officer and
Treasurer

Gabriel Leung
Executive Vice President and
President, Oncology Business

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

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

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

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

CORPORATE HEADQUARTERS

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

OTHER COMPANY LOCATIONS

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

Oncology Development – Colorado
2860 Wilderness Place
Boulder, CO 80301

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

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

TRANSFER AGENT/REGISTRAR

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1500 Market Street
Philadelphia, PA 19102

Mintz, Levin
666 Third Avenue
New York, NY 10017

Cooper & Dunham LLP
30 Rockefeller Plaza
New York, NY 10112

AUDITORS

KPMG LLP
1305 Walt Whitman Road
Melville, NY 11747

ANNUAL MEETING

The annual meeting of shareholders
will be held on June 17, 2009 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:

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Melville, NY 11747
(631) 962-2000
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STOCK LISTING

Nasdaq: OSIP

(osi) pharmaceuticals

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