2004 Annual Report

(osi)™ pharmaceuticals

Tarceva was approved for the treatment of advanced non-small cell lung cancer patients after the failure of at least one prior chemotherapy on November 18, 2004.

(osi)™ pharmaceuticals

Dear Shareholders

It is with great enthusiasm that we report to you our progress during 2004, without doubt the most remarkable year in the Company's history to date. At the heart of a year of transformation was the successful demonstration that our flagship product Tarceva™ improved the survival of patients in large, randomized Phase III clinical trials for advanced lung and pancreatic cancers, widely recognized as amongst the toughest cancers to treat. The results from the lung cancer trial led to the filing of our first New Drug Application (NDA) at the end of July and the drug's subsequent approval by the U.S. Food and Drug Administration (FDA) on November 18th – the fastest ever full approval by the FDA.

The Tarceva approval delivered on our long-standing commitment, to cancer patients and shareholders alike, that we would bring this innovative new medicine to market in a timely and comprehensive manner. The Tarceva success has also positioned our oncology organization at the very forefront of a paradigm-shifting change in the treatment of cancer patients – away from the aggressive and toxic chemotherapy agents that have been the mainstay of cancer treatment for decades and toward a new generation of more targeted agents many of which, like Tarceva, can be taken as a simple pill in the comfort of the patient's home.

Even beyond the Tarceva approval, 2004 has been a productive year. Our newly established commercial organization in oncology earned $34.5 million in sales commission revenues for Novantrone®, some 15% more than our assumptions entering the year. We were also able to both trigger our co-promote rights with Genentech, Inc. (our U.S. partner for Tarceva) and participate actively in the successful launch of Tarceva.

Beyond oncology, the cornerstone of our growing business, we have quietly set about constructing a second disease area franchise in diabetes with the investment of over $90MM in our UK-based subsidiary, Prosidion. The acquisition of the dipeptidyl-peptidase inhibitor PSN9301, and its associated intellectual property estate, from the German company Probiodrug AG over the summer gave our diabetes franchise a high-quality Phase II clinical development asset in what is clearly seen as one of the most topical areas of research and development in diabetes today.

The decision in the spring to call the remaining $160 million of 4% convertible senior subordinated notes issued in 2002 followed by the recently completed $445MM secondary offering – the largest public equity offering in the global biotech industry since 2000 – has improved our balance sheet to such a degree that we are able to move forward with over $650MM in cash and investments as we enter 2005.

Colin Goddard, Ph.D.,
Chief Executive Officer

Robert A. Ingram, Chairman of the Board

This year has indeed been a remarkable one for OSI. We have established ourselves amongst an elite group of biotech companies with proven capabilities from discovery through to commercialization. The Company is anchored by a strong financial foundation and is well positioned to capitalize on Tarceva, a solid oncology organization and an emerging diabetes franchise.

Tarceva – Delivering on Expectations

Last November's commercial launch of our flagship product, Tarceva, marks the Company's most significant milestone to date. Tarceva is a potent, selective and orally active inhibitor of HER1/EGFR, a receptor that is present, overexpressed or mutated in a wide variety of solid tumors including those of the lung, brain, liver, ovary, head and neck and pancreas. Tarceva was approved for use in the treatment of advanced non-small cell lung cancer (NSCLC) patients after failure of at least one prior chemotherapy regimen just three and a half months after OSI completed the filing of the NDA. We believe that the speed of the FDA's response and the strength of the label we obtained are testaments to the compound itself, to the quality of the NDA assembled by the OSI development and regulatory teams (who took the lead role in this application on behalf of our partners, Genentech and Roche) and to the professionals within the FDA, who have committed themselves to respond proactively on review of drugs that address major unmet clinical needs. Tarceva was launched less than three business days after approval.

At the core of the Tarceva clinical success are two well-designed and well-executed Phase III trials conducted by our colleagues at the National Cancer Institute of Canada's Clinical Trial Group in collaboration with our own development group. Top-line results for the first of these two trials were announced in April and showed that the study met its primary endpoint of improving overall survival and its key secondary endpoints of progression-free survival and objective tumor response in a 731-patient, randomized, double-blind, placebo-controlled trial which compared single-agent Tarceva to placebo in the treatment of patients with advanced NSCLC following the failure of first- or second-line chemotherapy. This study formed the basis of our recently approved NDA. In September, we announced the results of a second Phase III study, this time in patients with locally advanced or metastatic pancreatic cancer who had received no prior drug therapy. The study, comparing Tarceva in combination with gemcitabine with chemotherapy alone, surprised many observers by demonstrating a 23.5% improvement in overall survival and meeting its primary endpoint. The positive outcome of this trial was great news for pancreatic cancer patients and their families. Tarceva is only the second agent ever to show the ability to improve survival in this challenging disease setting. We hope to file a

Our mission remains the development of novel therapies that will shape the future of medicine and improve the lives of millions of patients worldwide.

supplemental NDA for Tarceva's use for this indication in the first half of 2005. Indeed, Tarceva is the only agent in the EGFR class and the first non-traditional chemotherapy agent to demonstrate an improvement in survival in either advanced NSCLC or pancreatic cancer.

Meanwhile, the recent failure of a competitor's molecule to match Tarceva's demonstrated ability to improve survival in NSCLC has further served to emphasize our long-held belief that Tarceva is a unique agent well positioned to emerge as the best-in-class EGFR inhibitor. It is now up to our tripartite alliance to continue to draw out the full potential of the product. Key components of this effort in 2005 will be the launching of the product in territories outside of the U.S. and the expansion of an ongoing development program for Tarceva. We are pleased that Roche, our partner for Tarceva outside of the United States, has made significant progress on the European front. Roche completed the submission of its filing to the European health authorities last August, and we anticipate a launch for Tarceva in major European markets during the second half of 2005.

Together with our partners, Genentech and Roche, we will pursue a comprehensive development program designed to demonstrate the effectiveness of Tarceva in earlier-stage lung cancer patients (in both front-line and adjuvant disease settings), broaden utility of Tarceva to additional disease settings (with the results in pancreatic cancer paving the way), and continue to explore paradigm-shifting combinations of all targeted therapies, such as Tarceva and Avastin®, for which we recently presented very intriguing preliminary data in lung and renal cell cancers.

Establishing a Premier Oncology Franchise

In March of 2003, we entered into an agreement with Serono S.A. to market and promote Novantrone for oncology use in the United States. This was a largely strategic move designed to allow the Company to transition itself into a commercial organization in preparation for the launch of Tarceva. Today we have an 80-person-plus core commercial organization including sales, marketing, medical affairs, and commercial planning functions. Notwithstanding the success of the commercial group in generating oncology sales for Novantrone that have exceeded our expectations, our foresight in building the group has allowed us to play an active role in launching Tarceva and positions us as a potential partner-of-choice for prospective alliances in the oncology arena as we move forward.

Our research and development efforts are increasingly focused on the development of next-generation targeted therapies designed to supplement and complement a portfolio built around Tarceva. OSI-930, a molecule designed as a co-inhibitor of the c-kit and VEGFR tyrosine kinase receptors, is scheduled to begin clinical trials in the first quarter of 2005 and OSI-817, a second development

Left to right: Kathy Galante, Director, Investor & Public Relations; Barbara A. Wood, Esq., Vice President, General Counsel and Secretary; Robert L. Van Nostrand, Vice President and Chief Financial Officer; Linda E. Amper, Ph.D., Vice President Business Administration & Human Resources.

candidate to arise from this program, is en route to begin clinical development toward the end of the year. We were disappointed, but not surprised, to report in June that Aptosyn®, an inducer of apoptosis (or programmed cell death) that we acquired with the SAANDs technology platform from Cell Pathways in 2003, did not meet its primary endpoint of improving overall survival when used in combination with Taxotere® in patients with advanced NSCLC. We continue to evaluate OSI-461, a more potent analog of Aptosyn, and we continue to believe that apoptosis is an important area of investigation in cancer research today. In fact, we have expanded our efforts in this area beyond the SAANDs technology platform. Our research programs have also established a network of alliances with outstanding research institutions (such as Cold Spring Harbor Laboratory, where we are using siRNA technology to identify and validate novel targets for cancer drug discovery) and other biotechnology companies (such as Structural Genomix, where we are employing crystallography techniques in structure-based design approaches to drug discovery).

Although we believe that the future of our oncology franchise, and of cancer treatment in general, will focus on these targeted therapies, chemotherapeutic agents continue to be an important part of cancer treatment today. In this respect, we are continuing the development of our differentiated cytotoxic drug candidate, OSI-7904L. This candidate is a liposomal formulation of a thymidylate synthase inhibitor and is designed to compete with the most prominent agent in this class, 5-fluorouracil (5-FU). Our goal is to mimic with a single, short-term infusion of our liposomal agent, the sustained exposure achieved with long-term infusions of 5-FU. OSI-7904L is being evaluated in a development program that includes Phase II trials in gastric and biliary tract cancers and early combination studies with cisplatin and oxaliplatin.

Building a Second Disease Area Franchise: Prosidion

We believe we have established the foundation from which to build a major biotechnology organization. However, we are convinced that achieving this goal will require us to build expertise and strength in more than one therapeutic area. As a result, Prosidion was established as a subsidiary of OSI in the United Kingdom in January of 2003 in order to provide a dynamic and independent

vehicle to pursue research in the diabetes and obesity areas. While early partnering opportunities were explored, the dramatic progress of the group over the last 18 months coupled with the success of Tarceva and our financing efforts has allowed us to continue to nurture this valuable asset within the OSI framework.

Since early 2003 we have injected some $90MM of funding into the subsidiary, reached agreements with Tanabe Seiyaku Co., Ltd. (our former partner in funded diabetes research) and Lundbeck A/S that give us freedom-to-operate in our fields of interest in diabetes and obesity, and hired Dr. Anker Lundemose, an executive with extensive experience in the diabetes arena, who, as Chief Executive Officer of Prosidion, has assembled an outstanding management team at our Oxford, UK facility.

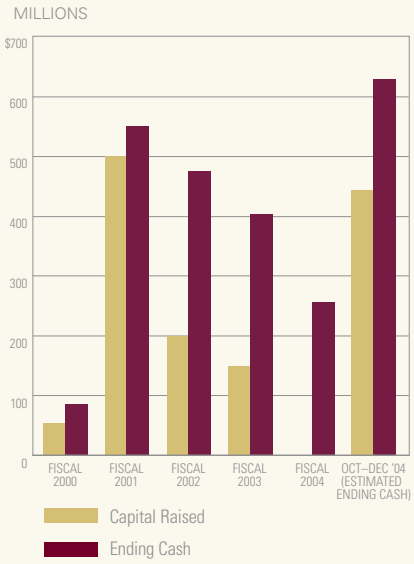
Our internal research efforts have led to the development of two lead candidate programs that target the activation of glucokinase and the inhibition of glycogen phosphorylase. We expect to begin clinical programs in both these areas during 2005. Finally, the acquisition of the dipeptidyl peptidase IV inhibitor, PSN9301, and a strong intellectual property estate from Probiodrug AG this summer has positioned Prosidion with an anchoring clinical program in one of the most attractive target areas in diabetes research and development today. Although we will likely need a major pharmaceutical industry partner to effectively commercialize these assets if they are successfully developed, we believe that, with over 90 million type II diabetics worldwide and a growing obesity problem in the western world, this investment represents a logical second disease area for our Company, which could realize significant value into the future.

Bringing it all Together: A Strong Financial Base and Striking the Right Balance

The success of Tarceva has given us the opportunity to establish a major biotechnology organization capable of delivering sustainable growth and value creation for our shareholders. In order to do this we will need to balance the goal of taking the business profitable around the anticipated commercial success of Tarceva with the continued investments in both our internal R&D and corporate development activities that will be necessary for us to fully capitalize on the business opportunity that is before us.

Maintaining a strong balance sheet and control of our core operating expenses are key financial requirements for our success. To this end, we took the difficult but necessary step of closing our oncology research efforts in the UK and consolidating them into our U.S.-based research operations in 2004. This has allowed us to continue our investments in Prosidion and expand our investments in translational research and commercial operations while maintaining

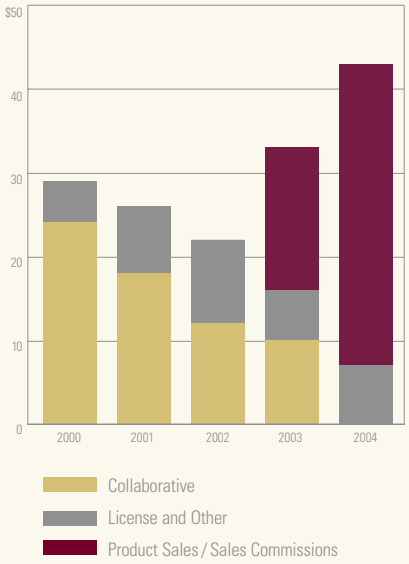
Maintaining a Strong Balance Sheet for Future Growth



Since 2000, OSI has raised over $1.2 billion in working capital and has established a strong financial foundation from which to build the business. The Company's business model combines the internal discovery and development of quality products with a corporate development strategy designed to supplement and complement our internal portfolio with licensing, acquisition and partnering activities. We believe the maintenance of a strong balance sheet is essential to the effective execution of this strategy.

Transitioning to a Product Driven Business

REVENUES (MILLIONS)



In four years, OSI has transformed itself from a research boutique offering quality discovery research services, and dependent on collaborative research funding from major pharmaceutical houses, into a fully-integrated research, development and commercial business focused on the discovery, development and commercialization of innovative products that extend life and improve the quality of life for cancer and diabetes patients around the world. The Company is well positioned for an exciting future as a leading biotechnology company with three marketed oncology products generating commercial revenues, including Tarceva, which was launched in November 2004.

a firm commitment to our stated goal of taking the company profitable within three years of Tarceva launch. With this level of investment in our ongoing business (we spent approximately $225MM on our core operations in 2004), we envision a robust OSI as we turn profitable – with a flagship product in Tarceva that continues to grow, a strong supplementary portfolio in our oncology business and the emerging commercial potential of a vibrant diabetes business. To ensure a strong capital base from which to build this organization we completed, in November, the largest secondary financing in the biotech sector since 2000 with a placement of 6,000,000 shares of our common stock (and a further 900,000 shares of common stock following the full exercise by the underwriters of their over-allotment option) at $64.50 per share. The Company ended the year with over $650 million in cash and investments.

Our Commitment to an Exciting Future

There can be no doubt that this has been a banner year for OSI – clearly our best ever. We now have an opportunity to continue to build upon this base and take advantage of the success of Tarceva.

In closing, we also acknowledge that, in addition to the researchers and medical professionals who have contributed to the clinical success of Tarceva, none of our achievements would have been possible without the selfless contributions of the patients and their families who have participated, and continue to participate, in the many clinical trials we conduct each year aimed at improving the health of cancer and diabetes patients around the world.

Our mission remains the development of novel therapies that will shape the future of medicine and improve the lives of millions of patients worldwide and we are firmly committed to the belief that we can combine our mission with the goal of creating a commercially successful organization capable of creating sustainable growth and value for our patients, our stakeholders and our shareholders alike.

As we continue to develop our programs in oncology, diabetes and obesity, we will not lose sight of the fact that the partnership and commitment of our shareholders have been, and will continue to be, key to our success.

We would like to thank all of you who have supported OSI through your work, dedication and investment of time and money and we hope you will continue with us on our journey.

Colin Goddard, Ph.D.
Chief Executive Officer

Robert A. Ingram
Chairman of the Board

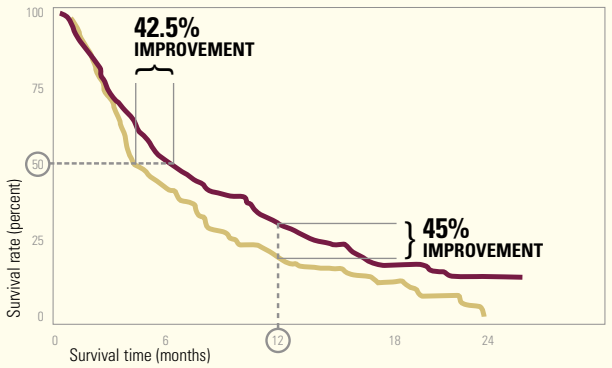
Tarceva
A promise delivered

(osi)™ oncology

Tarceva™
erlotinib

Tarceva is a once-a-day oral therapy available in three doses, shown here at actual size.

Tarceva prolongs median survival time by 42.5% and increases 1-year survival by 45%



Tarceva (N=488)
Median OS 6.7 months

Placebo (N=243)
Median OS 4.7 months

Hazard ratio 0.73
(*P*<0.001)

Hazard ratio of 0.73 indicates a 27% reduction in risk of death for patients who received Tarceva

Targeting Cancer Pathways

Targeted therapies have the potential to change cancer from an acute and often fatal disease to a chronic, manageable illness. These therapies are designed to disrupt the "cellular pathways," or the flow, from the outside of the cell to the inside, of biological signals that cancer cells use to grow, divide, repair themselves and communicate. Targeted therapies are often more focused on the particular biology of the cancer cell. This results in patients experiencing fewer of the toxic side effects of traditional cytotoxic drugs, which usually harm normal tissues.

Tarceva – A Paradigm-Shifting Therapy for Cancer Patients Today

Tarceva is a small molecule inhibitor of the epidermal growth factor receptor, or HER1/EGFR. Tarceva is designed as an oral once-a-day therapy to inhibit the tyrosine kinase activity of the HER1 signaling pathway inside the cell, which blocks tumor cell growth. We are developing and commercializing Tarceva in a global alliance with Genentech and Roche.

In November of 2004, the U.S. Food and Drug Administration (FDA) approved Tarceva for use as a monotherapy in the treatment of advanced non-small cell lung cancer (NSCLC) patients who have failed at least one prior chemotherapy regimen. OSI and its partner Genentech initiated the launch of Tarceva less than three business days after its approval, making Tarceva available to lung cancer patients immediately. By year end, Tarceva had captured over 60% of all new prescriptions for EGFR targeted drugs in lung cancer.

The Tarceva approval was based on results from the BR.21 study that were presented in full at the 2004 meeting of the American Society of Clinical Oncology (ASCO) meeting in June. These results showed that the study met its primary endpoint of improving overall survival and its key secondary endpoints of progression-free survival and objective tumor response in a 731-patient, randomized, double-blind, placebo-controlled trial which compared single-agent Tarceva to placebo in the treatment of patients with advanced NSCLC following the failure of first- or second-line chemotherapy. Tarceva improved overall

By year end Tarceva had captured over 60% of all new prescriptions for EGFR targeted drugs in lung cancer.

Left to right: Gabriel Leung, Executive Vice President and President, Oncology Business; Neil Gibson, Ph.D., Vice President, Research; Nicole Onetto, M.D., Executive Vice President and Chief Medical Officer; Robert L. Simon, Vice President, Global Regulatory Affairs and CMC.

survival in the study, with a hazard ratio of 0.73 (hazard ratio (HR) is a measure of the risk of death and a hazard ratio of less than one indicates a survival benefit) and also demonstrated a survival benefit in essentially all subsets of patients examined, including males and females, patients with adenocarcinoma and squamous cell histology, patients with good as well as impaired performance status, and both smokers and non-smokers. Median and one-year survival of the overall population in the BR.21 study was improved by 42.5 percent (6.7 versus 4.7 months) and 45 percent (31.2 versus 21.5 percent) respectively, and patients were treated with Tarceva for an average of just over four months in the study (23% of patients were on therapy for more than 6 months). Certain subsets of patients, including never smokers and patients who had tumors determined to be EGFR-positive, were seen to have a large survival benefit in response to treatment with Tarceva. The subgroup of patients who never smoked had a substantial survival benefit with a hazard ratio of 0.42. The subgroup of smokers also had a survival benefit (HR = 0.87) despite the fact that this group was also seen to have a 24 percent higher rate of Tarceva clearance (higher clearance rates lead to lower levels of exposure to a drug).

Although patients with tumors determined to be EGFR-negative did not appear to have a survival benefit the statistical variation on this small subset of patients was large and a survival benefit in this group cannot be ruled out. However, we believe that, in practice, an appreciable majority of patients with relapsed NSCLC presenting for therapy will have tumors of unknown EGFR status. Indeed, this represented the largest EGFR status subgroup in the BR.21 study and this group of "EGFR-Unknown" patients had a robust survival benefit (HR = 0.76). No EGFR diagnostic test is validated or approved for use in

Tarceva improves overall survival in front-line pancreatic cancer patients by 23.5%.

	TARCEVA PLUS GEMCITABINE	PLACEBO PLUS GEMCITABINE	HAZARD RATIO	P-VALUE
Survival	MEDIAN 6.4 mo	MEDIAN 5.9 mo	0.81	0.025
1-year Survival	24%	17%		
Progression-Free Survival	MEDIAN 3.7 mo	MEDIAN 3.5 mo	0.76	0.003

lung cancer and the FDA has not required EGFR testing prior to the initiation of therapy with Tarceva.

In the pivotal study, the principal side effects associated with Tarceva were rash (in 75% of patients, with approximately 9% of patients exhibiting grade 3/4 rash) and a generally mild-moderate diarrhea (in 54% of patients, with approximately 6% of patients exhibiting grade 3/4 diarrhea).

In September of 2004, OSI announced the positive results of a second Phase III study which evaluated Tarceva in pancreatic cancer, comparing Tarceva in combination with gemcitabine versus chemotherapy alone in patients with locally advanced or metastatic pancreatic cancer who had not received any prior drug therapy. The study met its primary endpoint of improving survival, demonstrating a statistically significant (23.5%) improvement in overall survival for patients receiving Tarceva plus gemcitabine when compared to patients receiving gemcitabine plus placebo (HR = 0.81).

Each of the pivotal trials (BR.21 and the pancreatic Phase III program) were sponsored by OSI and conducted by the National Cancer Institute of Canada Clinical Trials Group at Queen's University in collaboration with our development group.

The ability of Tarceva to show a survival benefit in two cancers that are widely recognized among the most difficult to treat suggests that Tarceva has broad therapeutic potential in the treatment of cancer and is clearly distinguished as a highly competitive agent within its class. In addition, Tarceva has demonstrated indications of activity in head and neck, ovarian, liver and brain cancers. Currently there are over 110 ongoing clinical studies, including a Phase IV development program to seek expanded use of Tarceva to earlier-stage lung cancer patients (where the compound has already shown indications of activity), additional disease settings, and to develop all targeted therapy combinations as a truly paradigm-shifting approach to cancer therapy. Studies of Tarceva used in combination with Avastin in renal cell carcinoma have demonstrated an encouraging initial response rate in the early stages of an ongoing study, and a similar study is under way in NSCLC.

We and our partners are confident that Tarceva will emerge as the leader in its class with the ability to provide a meaningful difference to the lives of cancer patients around the world.

We now have an 80-person-plus core commercial organization including sales, marketing, medical affairs and commercial planning.

Novantrone® mitoxantrone for injection concentrate

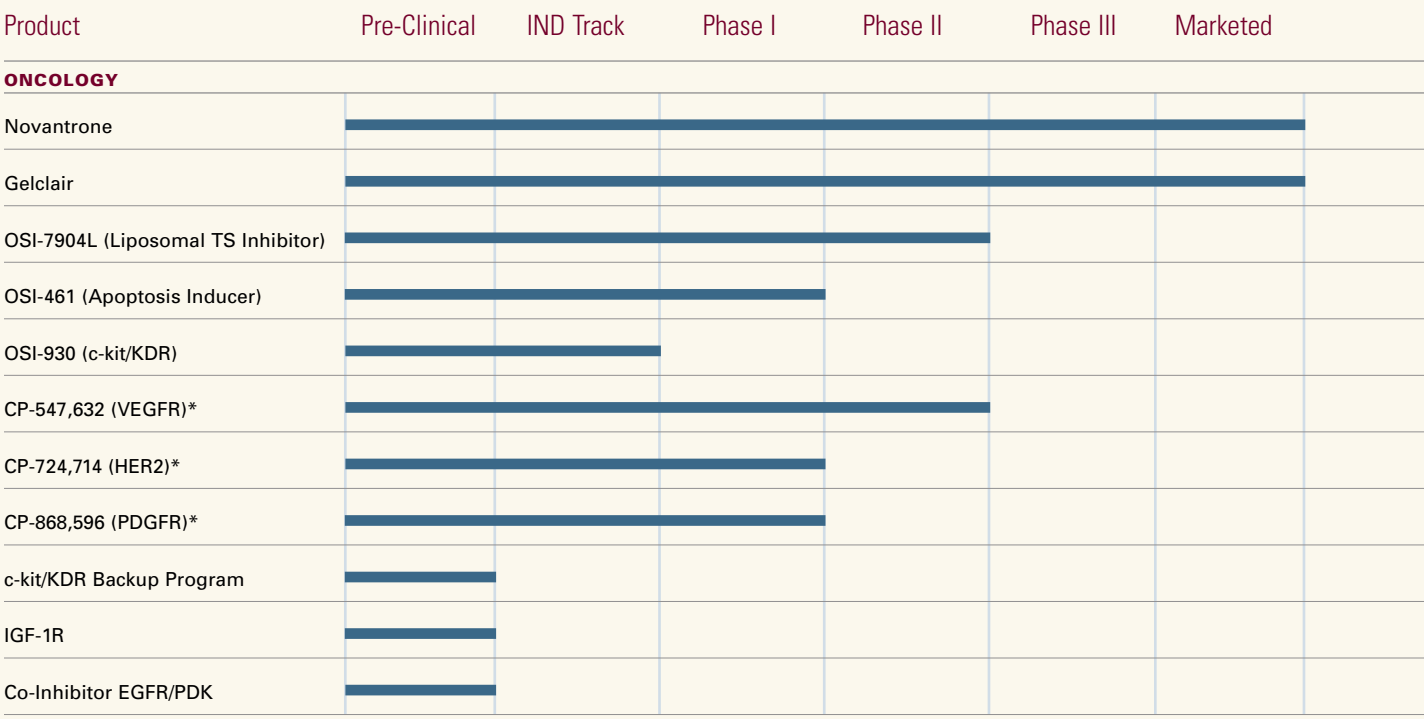
Novantrone is a synthetic antineoplastic anthracenedione used intravenously as an anti-cancer agent. The FDA approved the product in 1987 for acute nonlymphocytic leukemia (ANLL) and in 1996 for the relief of pain associated with hormone-refractory prostate cancer (HRPC). It was also registered for multiple sclerosis (MS) indications in October 2000 and is approved for use in the treatment of Non-Hodgkin's Lymphoma in markets outside the U.S. In March 2003, OSI entered into an agreement with Serono to market and promote Novantrone in the oncology marketplace in the United States.

While the transaction was executed largely as a strategy to allow us to establish our commercial organization in preparation for the launch of Tarceva, we are proud to participate in marketing a quality anti-cancer drug like Novantrone to the oncology community. We now have an 80-person-plus core commercial organization including sales, marketing, medical affairs and commercial planning. We are also happy to report that we exceeded our revenue goals for Novantrone by 15% generating $34.5 million in sales commission revenues during fiscal year 2004. Our sales force will continue to actively promote Novantrone through its patent expiration date of April 2006.

GELCLAIR® BIOADHERENT ORAL GEL

Nearly 15% of all cancer patients who receive chemotherapy and more than 90% of all patients receiving a combination of chemotherapy and radiation therapy experience oral mucositis, a painful and often debilitating side effect. Pain associated with oral mucositis can be so severe that patients have difficulty eating and drinking. In 2003, through the acquisition of Cell Pathways, we acquired the North American rights to Gelclair, a bioadherent oral gel that provides rapid and durable relief of pain by adhering to the mucosal surface of the mouth, forming a protective barrier over the mouth and throat and thus shielding and soothing the exposed and sensitized nerves. Although, as a device, Gelclair is not a major product commercially, we will continue to offer this valuable treatment option to cancer patients and their healthcare providers, who are dealing with this painful side-effect of chemo- and radiotherapy.

Delivering an oncology business beyond Tarceva



*Products discovered in OSI/Pfizer alliance being developed by Pfizer. OSI will receive royalties on net sales.

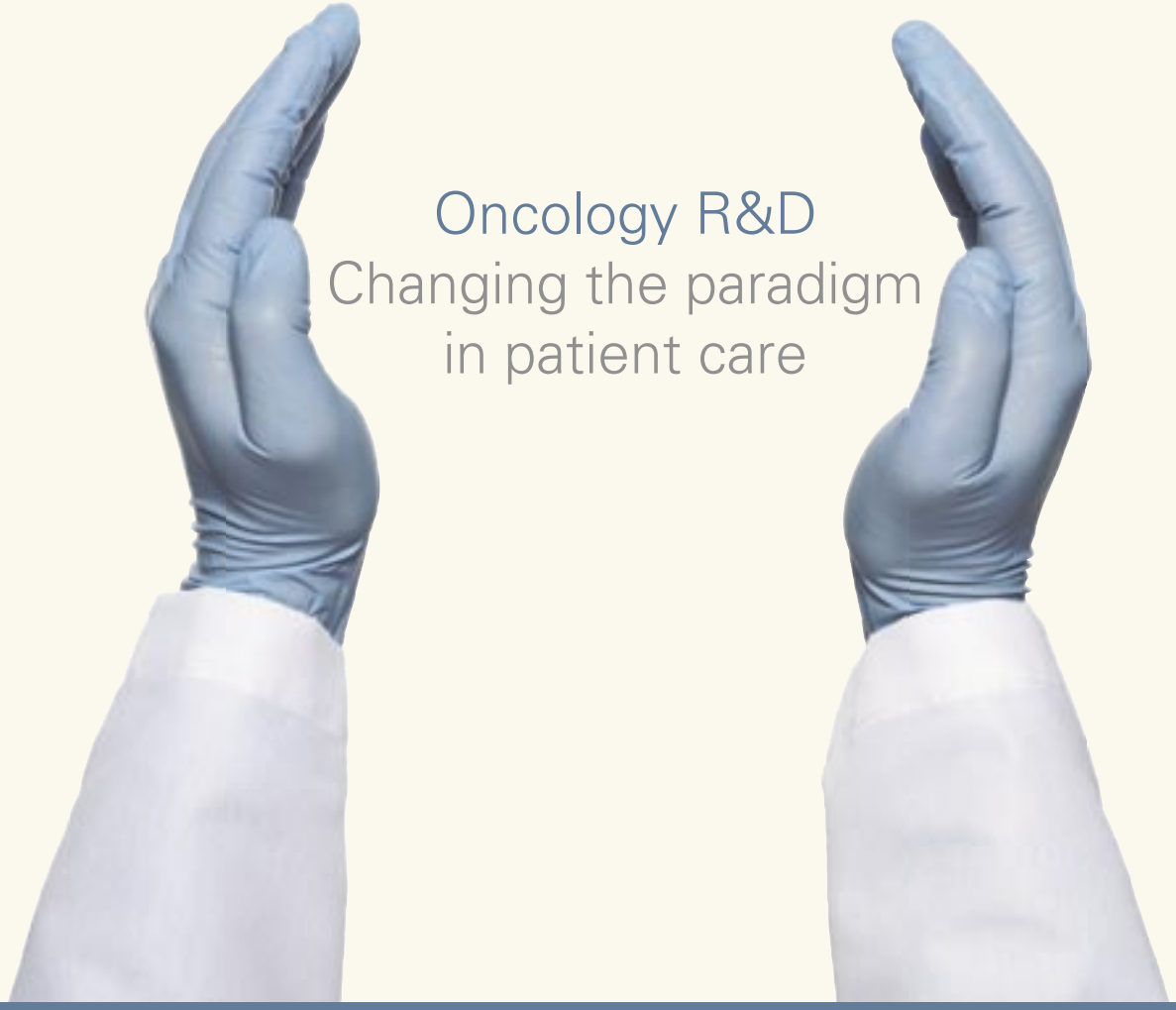
Beyond Tarceva – A Franchise Delivered

The successful FDA approval and subsequent launch of Tarceva has established a substantial corporate presence for OSI in the oncology arena. Our strategy over the last several years has been focused on assembling all of the pieces of a puzzle that adds up to a first-rate oncology organization built around Tarceva.

We believe that we have achieved this goal and that only minimal infrastructural investments will be required for the continued growth of our oncology business. We believe it is essential that we continue to aggressively manage our pipeline and to explore licensing and acquisition initiatives designed to add oncology products and clinical candidates to our pipeline in order to further strengthen our growing position in oncology.

We believe that in order to function as a successful oncology franchise in the 21st century, we should focus on developing targeted therapies as viable, next-generation options for patients who suffer from cancer.

Additionally, we consider the expansion into a second disease area to be an important part of our strategy for long-term value creation. We have therefore established Prosidion as a subsidiary of OSI with the mission of establishing a portfolio of innovative diabetes and obesity products that will make a meaningful impact on these growing healthcare threats.



Oncology R&D
Changing the paradigm in patient care

(OSI)™ oncology

Oncology Research & Development at OSI

An important part of our mission at OSI is to improve upon the available treatment options for patients suffering from cancer. The success of Tarceva positions us at the forefront of a paradigm-shifting movement toward more targeted and better-tolerated therapies. While we do not discount the importance of traditional chemotherapy in the treatment of cancer patients today, our ongoing R&D efforts are predominantly focused on developing a portfolio of novel molecular targeted therapies built around Tarceva.

Targeting Cancer Cell Growth and Apoptosis

Our growing understanding of the genetic aberrations associated with various cancers has allowed us to develop agents that directly target these abnormalities and thus treat their consequences. As these new targeted therapies emerge from clinical testing, they are likely to be used independently or in combination with other targeted agents and they may also be used in combination with traditional cytotoxic chemotherapy agents.

We have made significant strides this year in the advancement of OSI-930, a co-inhibitor of the receptor-tyrosine kinases c-kit and vascular endothelial growth factor receptor (VEGFR). c-kit is an important growth regulator implicated in many tumors and VEGFR is one of the most important genes in the regulation of blood vessel growth (or angiogenesis). As tumors grow they need a network of blood vessels to ensure a supply of nutrients. OSI-930 is designed to target both proliferative and angiogenic signaling in selected tumors. We have filed an IND for OSI-930 and anticipate beginning a clinical program in

An important part of our mission at OSI is to improve upon the available treatment options for patients suffering from cancer.

the first half of 2005. OSI-817 is a second development candidate to arise from our c-kit/VEGFR program and this molecule could enter clinical development by year end.

In addition to Tarceva, three other molecules targeting receptor tyrosine kinases are currently in clinical trials resulting from our historical relationship with Pfizer in cancer drug discovery. CP-547,632, a potent and selective inhibitor of VEGFR, has been advanced to Phase II studies in ovarian cancer patients with minimal disease and in NSCLC. Phase I trials also continue for CP-868,596, a platelet-derived growth factor receptor of PDGF receptor inhibitor and for CP-724,714, an oral HER2 receptor inhibitor. If Pfizer is successful in commercializing these products, we will receive royalties based upon their sales.

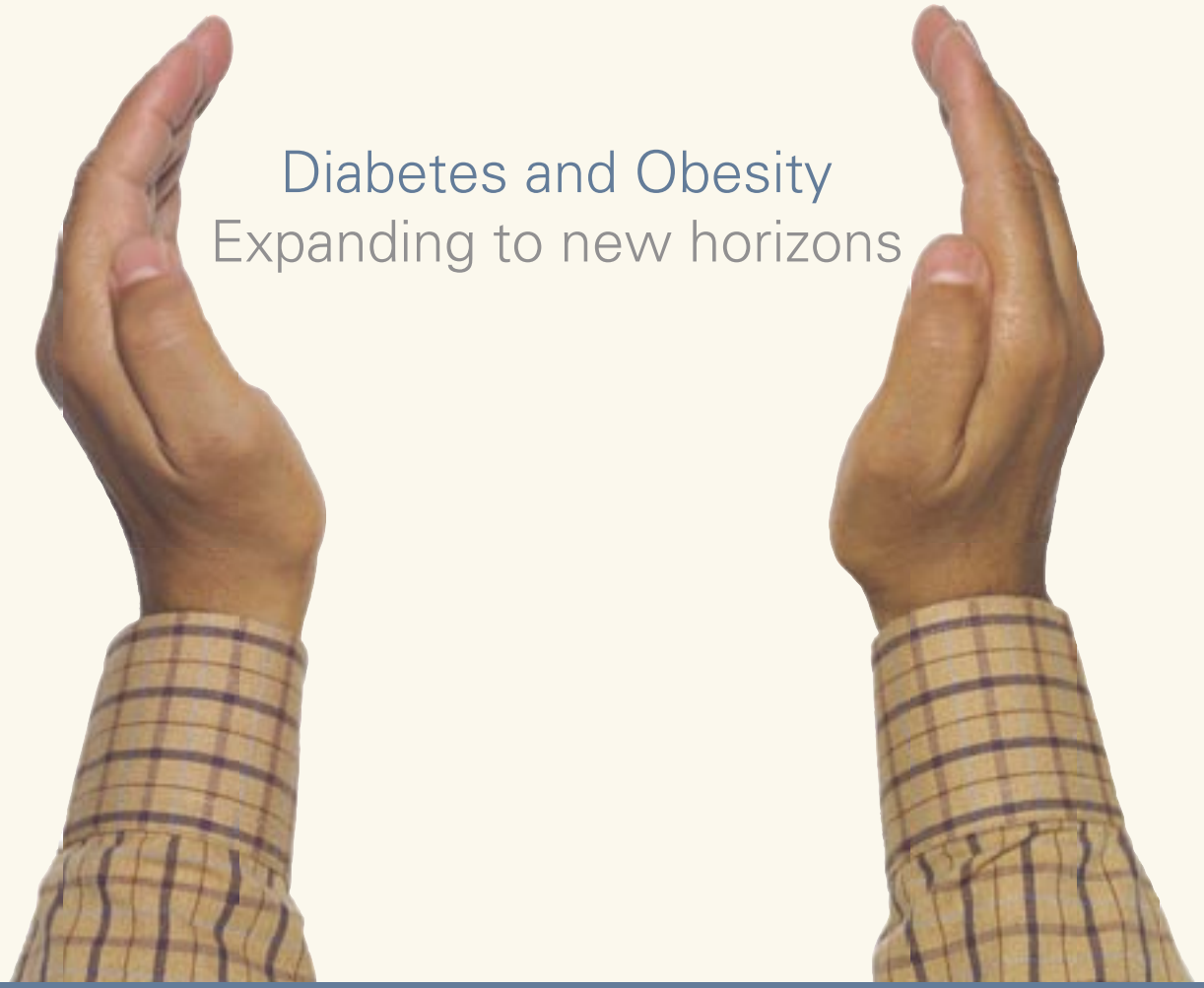
We are also targeting apoptosis, or programmed cell death. Cancer cells often possess genetic aberrations that allow them to avoid the normally tightly regulated process of cell death. Our apoptosis program utilizes apoptosis inducers to restore and enhance programmed cell death in cancer cells that no longer respond to this tightly regulated process. The Cell Pathways acquisition in 2003 gave us access to a technology platform in apoptosis called SAANDs (Selective Apoptotic Anti-Neoplastic Drugs). In June 2004, we were disappointed but not surprised to announce that our Phase III study evaluating Aptosyn in combination with Taxotere in advanced non-small cell lung cancer did not meet its primary endpoint of improving overall survival. We had concerns about the potency of Aptosyn and are continuing to evaluate OSI-461, a more potent follow-on candidate. We have also expanded

our apoptosis program beyond the SAANDs technology platform and are targeting a number of crucial genes in the apoptosis arena including IGF-1R.

Beyond our targeted therapy programs, we are continuing the clinical development of OSI-7904L, a liposomal formulation of a potent thymidylate synthase (TS) inhibitor that we are developing as a differentiated competitor in this class of cytotoxic drugs.

The activity of 5-FU, the lead agent in the class, is improved by continuous, long-term infusion of the product. We are trying to mimic this effect with a single, short-term infusion of a liposomal formulation of our TS inhibitor. Last May, we announced that we had initiated a randomized open-label Phase II study of OSI-7904L versus 5-FU as first-line treatment in patients with advanced or metastatic gallbladder or biliary tract cancers. This multi-center study is designed to evaluate the efficacy and safety of OSI-7904L in parallel with that of 5-FU. Our overall program for OSI-7904L also includes an ongoing Phase II clinical study of the product candidate in chemotherapy-naïve gastric and gastro-esophageal junction cancer patients and two ongoing Phase I studies evaluating the use of OSI-7904L in combination with the chemotherapy agents cisplatin and oxaliplatin.

Diabetes and Obesity
Expanding to new horizons



Prosidion

A strong second disease area is an important part of a long-term strategy to sustain value creation for our shareholders.

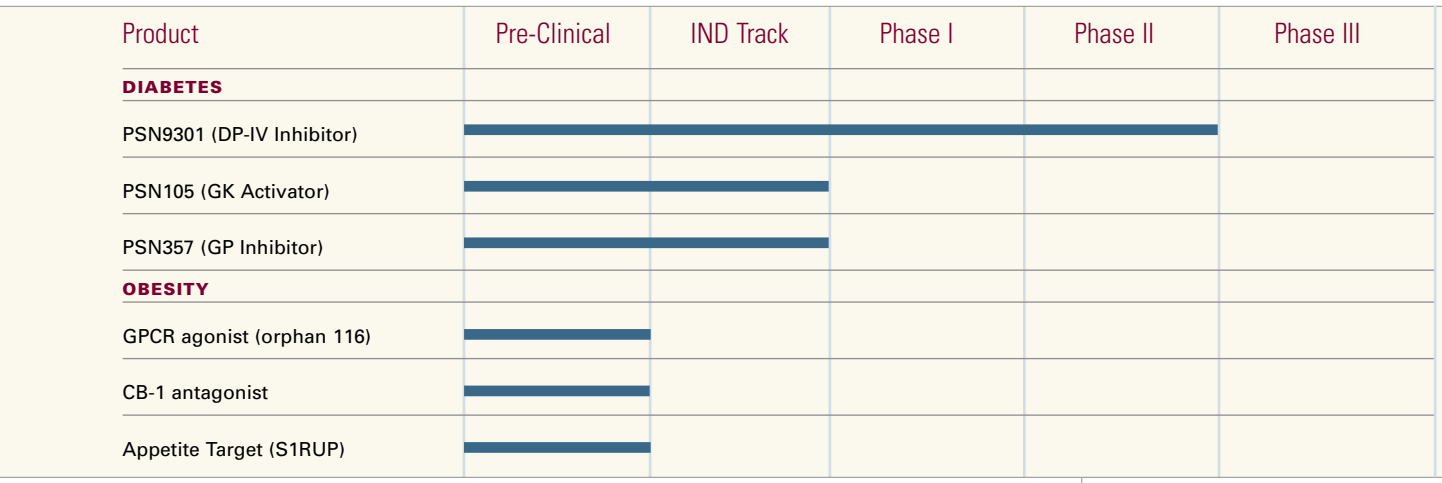
Prosidion Management Team, left to right: Jim McCormack, Ph.D., D.Sc., VP, Research & CSO; John Harvey, Finance Director; Mikael Thomsen, M.Sc., Ph.D., VP, Development; Anker Lundemose, M.D., Ph.D., D.Sc., CEO; Konrad Glund, Ph.D., D.Sc., VP, Corporate Development; Sian Bishop, General Counsel, VP Legal, IP and Facilities.

Diabetes and Obesity

Diabetes and obesity currently threaten the health, well-being and economic welfare of virtually every developed country in the world. Worldwide, more than 150 million people currently live with diabetes. In the United States, diabetes is the fifth leading cause of death by disease and contributes to higher rates of morbidity including heart disease, blindness and kidney failure. Obesity has risen at an epidemic rate during the past 20 years with an estimated 300 million obese adults worldwide and another 18 million children classified as obese. Obesity is a risk factor in many serious conditions, and is the major risk factor contributing to type II diabetes, with approximately 80% of cases directly related to obesity.

Over the last two years we have invested approximately $90MM in our UK-based diabetes and obesity subsidiary, Prosidion. (OSI owns approximately 97% of the shares of the subsidiary). Dr. Anker Lundemose, CEO of Prosidion, has spent his career in both the pharmaceutical and biotech industries working in this area and he has assembled a talented and experienced leadership team based in our Oxford, UK facility. Prosidion is committed to the discovery and early development of novel, next-generation small molecule compounds to treat type II diabetes and obesity.

Prosidion has a strong and diverse early pipeline of projects and development candidates in diabetes and obesity. Over the last year lead candidates have been advanced from two discovery projects focused on the development of small molecules designed to target glucokinase activation and glycogen phosphorylase inhibition. Two of these candidates (PSN105 and PSN357) are expected to enter clinical trials in the first half of 2005.



In June of 2004, we announced that Prosidion had successfully acquired a Dipeptidyl Peptidase IV (DP-IV) platform, which included a Phase II development candidate, P93/01, from the German company, Probiodrug. Dipeptidyl Peptidase IV cleaves and inactivates Glucagon-like Peptide-1 (GLP-1), an important mediator of blood glucose levels. Inhibition of DP-IV leads to increased GLP-1 activity and the development of inhibitors of DP-IV has become a very competitive arena for major pharmaceutical companies active in diabetes. P93/01, re-named PSN9301, is an orally active, competitive inhibitor of DP-IV and has been shown to lower glucose in type II diabetics in clinical trials, and will enter further evaluation in Phase II trials scheduled for early 2005. Prosidion also acquired a valuable intellectual property estate in the DP-IV area that has been licensed on a non-exclusive basis to several competitors in the field, including Merck and Novartis. Prosidion will receive milestones and royalties on the successful development and commercialization of DP-IV targeted drugs by these licensees.

While it is likely that Prosidion will seek a major pharmaceutical company as a commercialization partner for any diabetes drug that successfully emerges from its efforts in this area, we believe that the combination of expertise recruited into Prosidion and the subsidiary's access to our full R&D support infrastructure, has resulted in a highly focused and dynamic research and development effort that will ultimately result in valuable new products in the treatment of diabetes and obesity and return considerable value to our shareholders.

(OSI)™ pharmaceuticals

2004 Form 10-K

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 September 30, 2004 or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 0-15190

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

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

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

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

Title of each class	Name of each exchange on which registered
None	**None**

Securities Registered Pursuant to Section 12(g) of the Act:
Common Stock, par value $.01 per share, and
Series SRPA Junior Participating Preferred Stock Purchase Rights
(Title of Class)

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 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. ☐

As of March 31, 2004 the aggregate market value of the Registrant's voting stock held by non-affiliates was $1,140,265,997. 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 March 31, 2004 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.

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). ☑ Yes ☐ No

As of December 1, 2004, there were 50,634,509 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 2005 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K.

On the following pages, we have reproduced the first nine items of our annual report on Form 10-K filed with Securities and Exchange Commission on December 14, 2004, as amended on January 18, 2005. 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 Exchange Commission, and amendments thereto may be obtained without charge by writing to: OSI Pharmaceuticals, Inc., Barbara A. Wood, Corporate Secretary, 58 South Service Road, Suite 110, Melville, New York 11747.

PART I

ITEM 1. BUSINESS

We are a leading biotechnology company primarily focused on the discovery, development and commercialization of high quality oncology products that both extend life and improve the quality-of-life for cancer patients worldwide. Our flagship product, Tarceva™, is an oral, once-a-day, small molecule inhibitor of the epidermal growth factor receptor, or HER1/EGFR. Tarceva™ is the first EGFR inhibitor, and the first non-chemotherapy agent, to demonstrate a survival benefit in advanced non-small cell lung cancer, or NSCLC, and also in pancreatic cancer, two forms of cancer widely recognized as amongst the toughest treatment challenges facing oncologists. On November 18, 2004, after a review lasting only three and a half months, the U.S. Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for monotherapy Tarceva™ use in the treatment of all NSCLC patients who have failed at least one prior chemotherapy regimen. We launched Tarceva™ on November 22, 2004, the second business day after approval. We intend to file a supplemental NDA, or sNDA, for the treatment of front-line pancreatic cancer patients (in combination with gemcitabine) in 2005. In addition, our partner, Roche, has completed a regulatory filing under the centralized process in the European Union, or EU, for Tarceva™ in NSCLC. Beyond Tarceva™, we have a balanced pipeline of oncology drug candidates that includes signal transduction inhibitors, apoptosis inducers and a next-generation cytotoxic chemotherapy agent. We market and promote Novantrone® (mitoxantrone concentrate for injection) for approved oncology indications in the United States, and we market and distribute Gelclair®, a bioadherent oral gel for the relief of pain associated with oral mucositis, a frequent side-effect of chemotherapy, in North America. We also have a diabetes and obesity subsidiary, Prosidion Limited, which is based in the United Kingdom. Prosidion's lead clinical candidate, PSN9301, an inhibitor of dipeptidyl peptidase IV, or DP-IV, is in Phase II clinical trials for the treatment of type 2 diabetes. PSN9301 was acquired by Prosidion from Probiodrug AG in July 2004. Behind PSN9301, Prosidion has an emerging pipeline of diabetes and obesity drug candidates.

Our Strategy

Our strategy is to build upon Tarceva™'s significant market potential and to capitalize on the experienced management team and the comprehensive set of capabilities from discovery to commercialization that we have established over the last several years in order to create a premier biotechnology organization and drive value creation for our stockholders. To accomplish this, we intend to:

- maximize Tarceva™'s value by supporting an effective launch in the United States, a timely registration and effective launch in the EU and Japan, and an effective product growth strategy;
- establish our position as a premier oncology franchise by advancing our pipeline, reinforcing our commercial presence, validating our research capabilities and actively pursuing in-licensing and acquisition opportunities; and
- diversify our business through continued investment in Prosidion to grow a second business unit focused on diabetes and obesity in order to help drive long term growth.

Maximize Tarceva™'s value. Our immediate focus is on the timely registration and launch of Tarceva™ in the key global markets of the United States, the EU and Japan. Our primary indication is NSCLC after failure of at least one prior chemotherapy regimen; however, we intend to submit an sNDA to the FDA for the pancreatic cancer indication during 2005. On July 30, 2004, we filed our NDA for Tarceva™ as a monotherapy for the treatment of patients with advanced NSCLC for whom chemotherapy has failed. Tarceva™ was designated Fast Track status in September 2002 and, in June 2004, Tarceva™ was granted priority review status and Pilot 1 status which required the FDA to initiate a six-month review of each unit of the submission as it was received, or upon granting of Pilot 1 status, whichever was later. After a review lasting only three and a half months, the FDA approved Tarceva™ on November 18, 2004, at which time we and our partner, Genentech, Inc., announced pricing for the United States. Tarceva™ is the first EGFR inhibitor to receive full approval from the FDA. We launched Tarceva™ on November 22, 2004. We anticipate that Roche will launch Tarceva™ for NSCLC in the EU, assuming an approval by the European Agency for the Evaluation of Medicinal Products, or EMEA, in the second half of calendar 2005 and that Chugai Pharmaceutical Co., Ltd., Roche's subsidiary in Japan, will pursue a timely registration for NSCLC in Japan.

We have responsibility for manufacturing and supply of Tarceva™ in the United States, and we believe we have a supply chain in place with inventory on hand to support the launch of the product. While Genentech has primary responsibility for distribution and commercialization of Tarceva™ in the United States and Roche has responsibility for registration, manufacturing and commercialization outside of the United States, we are actively

engaged in supporting the activities of our partners in order to successfully launch Tarceva™. We are also co-promoting the product in the United States and field at least 25% of the combined U.S. sales force.

Our strategy to rapidly grow and expand Tarceva™ post-launch has three main themes:

- *Expand the use of Tarceva™ to earlier stage NSCLC patients, both in the front-line and adjuvant settings.* We believe that the survival data from our BR.21 study is similar to the survival data from the recent Phase III study comparing the cytotoxic chemotherapy agents, Taxotere® and Alimta®, and the side-effect profile for Tarceva™ is considerably more benign than these cytotoxic chemotherapy agents. The FDA has approved Tarceva™ for use in patients who have failed at least one prior regimen of chemotherapy, a second-line label comparable to these cytotoxic chemotherapy agents. To expand on this, we intend to move directly to registration-oriented studies in both the front-line and adjuvant settings. As part of our Phase IV agreement with the FDA, we will be conducting a front-line maintenance trial, which if positive, would lead to a front-line indication for Tarceva™.

- *Expand the use of Tarceva™ to other oncology disease settings.* Tarceva™ is designed to target the HER1/EGFR signaling pathway. The EGFR gene itself is known to be over-expressed, mutated or amplified in a significant portion of the approximately 1.3 million new cases of cancer diagnosed each year in the United States. The positive results from our pancreatic cancer Phase III trial are an endorsement of our belief that Tarceva™ will have broad utility in a wide variety of disease settings beyond NSCLC. To date, indications of anti-tumor activity have been documented in Phase II studies for monotherapy Tarceva™ in bronchioalveolar cell carcinoma, glioblastoma multiforme, head and neck cancer, hepatocellular carcinoma, breast cancer and ovarian cancer. We will continue programs to broaden the use of Tarceva™ to additional indications.

- *Develop all-targeted therapy combinations of Tarceva™ with other targeted agents, particularly the anti-angiogenic antibody Avastin®.* Targeted therapies like Tarceva™ and Avastin® are designed to deliver a treatment benefit without the significant toxicities evident with the use of cytotoxic chemotherapy agents. We believe that combinations of these novel targeted therapies have the potential to deliver enhanced efficacy without the severe cumulative toxicities associated with widely used combinations of cytotoxic chemotherapy. This program is already underway and has revealed promising indications of activity in single arm Phase II studies, using combinations of Tarceva™ and Avastin® in renal cell carcinoma and in NSCLC patients with adenocarcinoma. We will also explore combinations of Tarceva™ with other oral targeted therapies that offer patients the important benefits of ease-of-use and convenience in addition to the potential for enhanced efficacy with more benign side-effects.

To pursue these strategic themes, we will continue to execute, together with our alliance partners, Genentech and Roche, a development program comprised of both registration oriented and publication studies designed to expand the indications and market potential for Tarceva™.

Establish our position as a premier oncology franchise. Over the past several years we have assembled through acquisitions and internal investment the necessary components of a high quality oncology franchise operating from drug discovery through commercialization. A key goal for us is to raise awareness of the value of our franchise by advancing our pipeline, validating our research and exploiting our broad capabilities to effectively pursue in-licensing, acquisition and partnering opportunities. We have a diverse pipeline of oncology drug candidates which includes signal transduction inhibitors, apoptosis inducers and a next-generation cytotoxic agent. We plan to add to our pipeline both from our internal research efforts and through third-party transactions, such as partnering, in-licensing and product acquisitions. We intend to continue to focus our research efforts on two main areas of cancer drug discovery, namely the discovery of modulators of signal transduction pathways that either (i) drive cancer cell proliferation or (ii) prevent apoptosis in cancer cells. In order to effectively manage the risks inherent in biotechnology research and development and to complement our internal research efforts, we believe that we must continue to aggressively manage our pipeline and actively explore in-licensing and acquisition initiatives. We expect these activities to add to our pipeline of oncology products and clinical candidates and strengthen our growing presence in oncology.

We believe that we are also well positioned to enhance our commercial presence by competing for co-promotion and product acquisition opportunities. Our marketed products, Novantrone® and Gelclair®, have allowed us to establish a core commercialization group, which includes approximately 50 sales representatives and managers. We believe that our commercial group and research and development capabilities make us a highly attractive partner in oncology.

Diversify our business through continued investment in Prosidion. We believe that expansion into a second disease area is an important part of our strategy for long term value creation, and will ultimately be important in establishing ourselves as a premier biotechnology organization. We, therefore, consider it important that we continue to invest in our diabetes and obesity subsidiary, Prosidion, based in Oxford, United Kingdom. To this end, we announced in July 2004 the acquisition by Prosidion of the type 2 diabetes clinical candidate, PSN9301, currently in Phase II clinical trials, and its associated intellectual property estate from Probiodrug AG. PSN9301 is an oral, small molecule inhibitor of DP-IV, which is recognized as an important target in diabetes. In addition to composition of matter claims for PSN9301, the acquired intellectual property estate includes issued U.S. method-of-use claims, covering the inhibition of DP-IV as a target in diabetes that have been non-exclusively licensed to Novartis Pharma AG and Merck & Co. Inc., among others, for milestones and royalties. Prosidion also anticipates initiating clinical trials for two diabetes candidates, PSN105, a glucokinase activator, and PSN357, a glycogen phosphorylase inhibitor, in the first half of calendar 2005.

We believe that we have the integrated capabilities and the strength and depth of management to accomplish our goal of establishing ourselves as a premier biotechnology company. In the past several years, we have demonstrated a proven capability to execute complex, large scale development and registration programs, manage intricate partnerships, execute transactions, integrate acquisitions, and build new capabilities, such as our commercial group, in a manner that positions us well for future growth.

Tarceva™

Tarceva™ was discovered jointly by us and Pfizer Inc. in the course of a long-standing discovery collaboration between us and Pfizer that terminated in 2001. We gained full development and marketing rights to Tarceva™ in June 2000, when the U.S. Federal Trade Commission, or FTC, ordered Pfizer to divest its rights to Tarceva™ to us as a result of an antitrust finding upon the FTC's review of Pfizer's merger with the Warner-Lambert Company.

Tarceva™ is an oral, once-a-day, small molecule drug designed to inhibit the receptor tyrosine kinase activity of the product of the HER1/EGFR gene. HER1/EGFR is a key component of the HER signaling pathway, which plays a role in the regulation of growth in many normal cells. EGFR inhibitors were designed to arrest the growth of tumors (cytostasis); however, under certain circumstances EGFR inhibition can lead to apoptosis which in turn would result in tumor shrinkage. The HER1/EGFR gene is over-expressed, mutated or amplified in approximately 40% to 60% of all cancers and contributes to the abnormal growth signaling in these cancer cells. A frequently occurring mutation of the HER1/EGFR gene called EGFRVIII is also found in many tumors, including glioblastoma multiforme and NSCLC, and recently publications in scientific literature have associated tumor response in lung cancer patients treated with EGFR inhibitors with additional newly identified mutations. There is a strong scientific rationale and a substantial potential market for EGFR inhibitors. We believe that Tarceva™ is likely to have utility in many oncology disease settings. However, the initial focus of the program has been on NSCLC and pancreatic cancer since effective treatment of both of these forms of cancer remains a major unmet need. According to the American Cancer Society, lung cancer is the leading cause of cancer-related deaths in the United States each year with an estimated 160,000 deaths in 2004. Patients with NSCLC account for approximately 80% of these deaths. The American Cancer Society also estimates that 31,000 cancer patients in the United States will die from pancreatic cancer in 2004.

In order to help us accomplish the goals of a registration program focused on NSCLC and pancreatic cancer and to ensure the optimal competitive positioning of Tarceva™, we entered into a co-development and commercialization alliance with Genentech and Roche in January 2001. Since the inception of our alliance, we have implemented a global development strategy for Tarceva™ with our partners. This strategy was a broad-based approach that implemented simultaneous clinical programs designed to result in a registration with the FDA. This plan included a single agent Phase III trial for second and third-line NSCLC patients as well as combination trials with existing cytotoxic chemotherapy regimens for front-line use in pancreatic cancer and NSCLC. Currently, there are approximately 100 investigator-sponsored studies and National Cancer Institute/Cancer Therapy Evaluation Program Studies ongoing or planned in the Tarceva™ program. These studies are exploring monotherapy and combination uses of Tarceva™ in various tumor types, with a variety of treatment modalities, such as radiation, and in the adjuvant setting.

Clinical Data

NSCLC

In April 2004, we announced that Tarceva™ met all its key predetermined study endpoints (including overall survival, progression-free survival, and objective tumor response) in a 731-patient randomized, double-blind placebo controlled Phase III trial, known as the BR.21 study. Tarceva™ also delayed the deterioration of selected lung cancer symptoms in the BR.21 study. The trial compared Tarceva™ to placebo in the treatment of patients with advanced NSCLC who had previously received one or two prior chemotherapy regimens. Patients were randomized to the Tarceva™ or placebo arm in a 2:1 ratio, respectively. Approximately 50% of the patients in the study had failed one prior regimen of chemotherapy and the other half had failed at least two prior regimens. In addition, a large proportion of the patients entered the study with poor performance status (25% with performance status 2 and 9% with performance status 3). This international study was conducted by the National Cancer Institute of Canada's Clinical Trial Group in collaboration with our own clinical development team.

Patients receiving Tarceva™ had a median survival of 6.7 months versus 4.7 months for patients receiving placebo, a 42% improvement. A hazard ratio of 0.73 and a p-value of <0.001 were determined for comparisons of overall survival, indicating a highly statistically significant treatment benefit. In addition, 31.2% of patients receiving Tarceva™ in the study were alive at one year versus 21.5% in the placebo arm, a 45% improvement. The results of the study also revealed a treatment benefit in virtually all subsets of patients examined. A treatment effect (hazard ratio of <1) was seen in males, smokers and patients with squamous cell carcinoma histology (subsets that, consistent with previous studies with EGFR inhibitors, had a relatively low rate of tumor response in our study), as well as in females, non-smokers and patients with adenocarcinoma histology (subsets with higher rates of tumor response). Recent publications have shown an association between tumor response and a group of newly identified EGFR mutations which are clustered in patients who are non-smokers or have tumors with adenocarcinoma histology. The BR.21 study results clearly show that tumor response is not always a good surrogate for survival benefit and that the improvement in overall survival seen in our BR.21 study cannot be explained by the reported incidence (10%) of these mutations. The patient population was also unusual in that patients with ECOG performance status 3 were included in the study.

In the course of following up on the collection of tumor samples from the BR.21 study, we have been able to determine, to date, the EGFR status of 325 of the 731 patients in the study. We have determined that 71% of the patients for whom we have results were found to express EGFR. This group had a hazard ratio of 0.7 in exploratory analysis. In addition, EGFR negative subsets had hazard ratios numerically less than one although the confidence intervals are too wide to draw any definitive conclusions. Moreover, the package insert for Tarceva™ does not contain any restriction related to EGFR status nor does it require any sort of testing for EGFR status. More importantly, even after considerable effort we were only able to obtain a sample analysis on 44% of the patients in the study. We believe this to be representative of clinical practice, where most patients who will present for Tarceva™ treatment will likely have no available biopsy sample and therefore a tumor of unknown status. In the BR.21 study this group of patients, of unknown status, had a survival benefit with a hazard ratio of 0.77.

Summary Data for the Tarceva™ Phase III Study in Second and Third-Line NSCLC

	Tarceva™ N = 488	Placebo N = 243	Hazard Ratio(1)	P-Value(2)
Median Survival/Hazard Ratio	6.7 months	4.7 months	0.73(3)	<0.001(3)
One-Year Survival Rate	31.2%	21.5%	—	—
Median Progression — Free Survival/ Hazard Ratio	2.2 months	1.8 months	0.59(3)	<0.001(3)
Objective Tumor Response Rate(4)	9%	<1%	—	—

Note: The data is based on our statistical analysis of data from the BR.21 study.

(1) Hazard ratio is a statistical measure of the difference in overall survival between the study drug group and the control group. A hazard ratio of less than 1 indicates a reduction in the risk of death; for example, a hazard ratio of 0.73 represents a 27% reduction in the risk of death and a 37% improvement in overall survival.

(2) P-value is a statistical measure of significance. A p-value of <0.05 indicates a statistically significant difference.

(3) Data is adjusted for stratification factors prior to randomization.

(4) Objective tumor response rate represents the sum of the percentage of patients who exhibited a PR or a CR.

In the BR.21 study, the average (or mean) duration of Tarceva™ therapy was slightly more than four months.

The safety profile observed in the BR.21 study was relatively benign compared to cytotoxic chemotherapy and was consistent with that seen in prior Tarceva™ studies with 75% of patients receiving Tarceva™ exhibiting rash versus 17% in the placebo group and 54% of patients receiving Tarceva™ experiencing diarrhea versus 18% for placebo. Most of these events were mild to moderate. In this large placebo controlled study, severe pulmonary events, including potential cases of interstitial lung disease, were rare and generally equally distributed between the Tarceva™ and placebo arms. We believe this combination of survival benefit with a relatively benign side-effect profile positions Tarceva™ as an important treatment option for oncologists treating advanced lung cancer patients who have failed front-line chemotherapy.

Pancreatic Cancer

In September 2004, we announced that Tarceva™ also met its primary endpoint of improving overall survival in a 569-patient randomized, double-blind placebo controlled Phase III trial in front-line pancreatic cancer patients with locally advanced or metastatic disease. This study was also conducted by the National Cancer Institute of Canada's Clinical Trial Group in collaboration with our own clinical development team. The trial compared a combination of Tarceva™ and the chemotherapy agent gemcitabine (the only recently approved agent for the treatment of pancreatic cancer) with gemcitabine plus placebo. The data demonstrates a 23.5% improvement in overall survival (a hazard ratio of 0.81 and a p-value of 0.025) for the Tarceva™ arm compared to the placebo arm. Median and projected one-year survival in the Tarceva™ plus gemcitabine arm were 6.4 months and 24%, respectively, compared to 5.9 months and 17%, respectively, in the gemcitabine plus placebo arm. A statistically significant improvement in progression-free survival was also observed. A preliminary analysis of the safety data did not reveal any unexpected safety signals beyond that seen in the prior use of Tarceva™ in both monotherapy and combination settings. As expected, rash and diarrhea were the principal Tarceva™-related side effects in the study. The results were noteworthy in that Tarceva™ was used at a lower dose (100 mg) for the majority of patients randomized in the study (521 patients were randomized to 100 mg per day of Tarceva™ or placebo and 48 patients were randomized to 150 mg per day of Tarceva™ or placebo) and Tarceva™ was used in combination with a chemotherapy agent. We believe that the data demonstrates that Tarceva™ is likely to have broad utility beyond the initial lung cancer indication and will also have profound implications for our understanding of this new class of drugs.

Other Data

Earlier Phase I and Phase II trials of Tarceva™ in NSCLC, head and neck cancer and ovarian cancer demonstrated that the drug possessed activity as a single agent and was relatively well-tolerated with manageable side-effects, principally, a reversible rash and generally mild diarrhea. Indications of anti-tumor activity have been documented in Phase II studies for monotherapy Tarceva™ in bronchioalveolar cell carcinoma, glioblastoma multiforme, breast cancer and hepatocellular carcinoma. Our Phase III clinical trial program also included two front-line Phase III combination trials in NSCLC that had been initiated for business reasons in order for us to be competitive with a similar clinical trial program with a competitor's EGFR product, Iressa®, in this setting. On October 1, 2003, we announced that the two front-line Phase III studies of Tarceva™ plus standard chemotherapy in metastatic NSCLC did not meet their primary endpoints of improving overall survival. These results were widely anticipated based on the competitor's previously announced failure of Iressa® in this front-line setting in August 2002. The failure of these combination trials of Tarceva™ with chemotherapy in NSCLC are such that Tarceva™ treatment in combination with platinum-based chemotherapy regimens is not indicated for front-line NSCLC.

Competitive Positioning

The market for NSCLC therapeutics is competitive with multiple treatment options available in the market today. These therapeutic options include cytotoxic chemotherapy agents, targeted therapeutics and radiation and surgery. These available options are often ineffective or have severe side-effects. For example, front-line combination cytotoxic chemotherapy treatment of NSCLC only provides a median survival of approximately ten months and is accompanied by severe side-effects. Patients subsequently also may be treated with cytotoxic chemotherapy agents, such as Taxotere® or Alimta®, in the second-line setting. While these agents have previously shown similar survival results to Tarceva™, they exhibit a more severe side-effect profile than those seen in the Tarceva™ trial. Furthermore, only approximately 46,000 people a year suffering from NSCLC receive second and/or third-line treatments, usually with limited success, while many other patients either decline treatment or have treatment

withheld due to the side-effects of cytotoxic chemotherapy or a perception that further treatment would be of limited benefit.

The table below summarizes the results announced within the last 18 months of three large, randomized, placebo controlled Phase III trials in advanced NSCLC, consisting of our BR.21 study, a study comparing Taxotere® to Alimta®, and our study comparing Taxotere® plus Aptosyn® to Taxotere® plus placebo. The table is presented for comparative purposes only and does not purport to represent all existing second and third-line NSCLC trials after failure of initial therapy.

	Tarceva™ vs. Best Supportive Care (BSC) (731 patients)		Taxotere® vs. Alimta® (51 patients)		Taxotere® Plus Aptosyn® vs. Taxotere® (610 patients)(1)	
STUDY	**Tarceva™ (N=488)**	**BSC (N=243)**	**Taxotere® (N=288)**	**Alimta® (N=283)**	**Taxotere® Plus Aptosyn® (N=304)**	**Taxotere® (N=306)**
Performance Status:						
0-1	65%	68%	88%	89%	87%	87%
2	26%	23%	12%	11%	11%	10%
3	9%	9%	0%	0%	0%	0%
Missing	0%	0%	0%	0%	2%	3%
Prior Regimens:						
1	50%	50%	100%	100%	74%	75%
> or = to 2	50%	50%	0%	0%	23%	22%
Response Rate (Complete Response & Partial Response)	8.9%	<1%	8.8%	9.1%	9.2%	7.2%
Survival:						
1 year Survival	31.2%	21.5%	29.7%	29.7%	30.7%	29.5%
Median Survival (Months)	6.7(2)	4.7	7.9	8.3	6.9	6.9

(1) OSI data from our Phase III study for Aptosyn® unblinded on June 11, 2004.

(2) Tarceva™ Median Survival in performance status 0-1: 8.2 months

Although Tarceva™ has not been tested in a direct head-to-head study with either Taxotere® or Alimta®, the table shows that Tarceva™ produced similar survival data to Taxotere® and Alimta® in this comparison of contemporary studies. This was despite the fact that Tarceva™ was tested in a more advanced patient population, both in terms of number of prior regimens and overall performance status, which makes the ability to show a survival benefit in absolute terms more challenging. Tarceva™ demonstrated statistically significant delays in the time-to-symptom deterioration of the key lung cancer symptoms of cough, dyspnea and pain in the BR.21 study, as well as avoiding the severe drug related toxicities associated with chemotherapy, such as neutropenia, thrombocytopenia, neurotoxicity and alopecia. We therefore believe that Tarceva™ will provide oncologists with an attractive option in the treatment of NSCLC patients who have failed at least one prior chemotherapy regimen.

Patients may also be treated with another EGFR inhibitor, Iressa®, which was recently approved for the third-line setting based on response rate data only. Iressa® has yet to demonstrate a survival benefit. Recent scientific publications have also identified a subset of NSCLC patients, predominantly females with tumors that typically have adenocarcinoma histology, who possess mutations in their EGFR gene. This subset of patients has now been shown to be responsive to treatment with EGFR targeted agents like Tarceva™ and Iressa®. Data suggests that patients with lung tumors possessing these mutations may constitute the majority of patients seen to have a tumor response when treated with these agents and some investigators have hypothesized that the clinical benefits observed for EGFR inhibitors may be restricted to patients whose tumors have these EGFR mutations. However, our BR.21 study clearly shows that tumor response is not always a good surrogate for survival benefit and that the improvement in overall survival cannot be explained by the reported incidence (approximately 10%) of these mutations. For example, patients treated with Tarceva™ in our BR.21 study who had tumors with squamous cell carcinoma histology had only a 3.8% tumor response rate but a 49% improvement in survival (hazard ratio 0.67) whereas patients in the study with tumors of adenocarcinoma histology had a similar improvement in survival of 41% (hazard ratio 0.71) but a 13.9% response rate. Based on this data, we and others believe that patients that express non-mutant forms of EGFR will also benefit from EGFR treatment at higher doses of drug even if this is not manifested by high response rates. The pancreatic cancer trial supports this belief in that a survival benefit was seen in the study despite the fact that there was no difference in the percentage of patients

achieving a partial response between the Tarceva™ plus gemcitabine arm and the gemcitabine plus placebo arm and that publications in the scientific literature indicate that the mutations may be largely confined to lung cancer. Based on published studies, Tarceva™ at 150mg/day produces greater drug exposure in patients' blood than 700mg/day of Iressa®, which is approved for use only at 250mg/day. We believe that dose and drug exposure will be important components to the activity of EGFR targeted agents for this larger second group of patients and that the ability to safely dose these agents at higher dose levels will be critical to their effective use for these patients. Tarceva™ is currently the only EGFR inhibitor to have demonstrated a survival benefit in NSCLC patients at a dose accompanied by a relatively mild side-effect profile.

Antibody products are also under development which target the EGFR pathway and have demonstrated improved anti-cancer activity when used in conjunction with existing treatment and chemotherapy regimens. One of these, Erbitux™, has been approved for advanced colorectal cancer in the United States and is marketed by Bristol-Myers Squibb Company, or BMS, and ImClone Systems Incorporated for this indication. Erbitux™ also recently demonstrated a survival benefit in combination with radiotherapy in a Phase III study in the treatment of squamous cell carcinoma of the head and neck. However, to date clinical studies in lung cancer have yet to demonstrate robust activity for Erbitux™ and it is significantly more expensive than the small molecule inhibitors. Furthermore, we believe these antibodies may be less likely than the tyrosine kinase inhibitors to effectively inhibit mutated forms of HER1/EGFR. Antibody products also require mandatory EGFR testing and also require delivery via intravenous infusion and are relatively difficult and expensive to produce. In contrast to these agents, we believe that small molecule inhibitors of the tyrosine kinase activity, such as Tarceva™, should be effective against either mutant or non-mutuant forms of HER1/EGFR, are convenient once-a-day oral therapies and are relatively easy and inexpensive to manufacture.

Registration Strategy

Tarceva™ was granted a Fast Track designation from the FDA in September 2002 for the second and third-line NSCLC indication. In January 2004, we initiated the rolling submission of our NDA with the FDA for the use of Tarceva™ in this indication. Following the release of the positive results of the BR.21 study, the FDA informed us that Tarceva™ had been granted a priority review designation and also Pilot 1 status, a new FDA initiative aimed at reducing drug approval times for agents with Fast Track status. Tarceva™ is among the first group of drugs to be accepted into the new Pilot program. The Pilot 1 program introduces a six-month review period for each submitted reviewable unit of the rolling NDA. Unlike the Fast Track designation which does not require the FDA to begin review of the sections at the time they are submitted, the Pilot 1 program requires the FDA to complete its review of each section within six months following the submission of such section, or from the date of granting of Pilot 1 status, whichever is later. On November 18, 2004 after a review lasting only three and a half months we received FDA full approval for monotherapy Tarceva™use in the treatment of NSCLC patients who have failed at least one prior chemotherapy regimen. Tarceva™ is the first EGFR inhibitor to receive full approval from the FDA. In conjunction with the approval, we have agreed with the FDA to conduct the following post-marketing clinical studies: (i) a double-blind randomized Phase III study to evaluate the efficacy of Tarceva™ or placebo following four cycles of chemotherapy in patients with advanced, recurrent or metastatic NSCLC who have not experienced disease progression or unacceptable toxicity during chemotherapy and (ii) a randomized Phase III study to evaluate the efficacy of Tarceva™ or chemotherapy (Alimta® or Taxotere®) following four cycles of chemotherapy in advanced, recurrent metastatic NSCLC who have experienced disease progression or unacceptable toxicity during chemotherapy. We launched Tarceva™ on November 22, 2004, two business days following approval, shortly prior to which we and our partner, Genentech, announced pricing for the United States. The NDA was prepared in the International Committee of Harmonization-approved common technical dossier format which can facilitate registration in the EU and Japan. Roche filed the EU application under the centralized process for the NSCLC indication in the third quarter of calendar 2004 and we anticipate that Roche will launch Tarceva™ in the NSCLC indication in the EU, assuming an approval by the EMEA, in the second half of calendar 2005 and that Chugai, Roche's subsidiary in Japan, will pursue a timely registration in Japan. We plan to discuss the submission of an sNDA for the pancreatic cancer indication with the FDA and other regulatory agencies in the near future.

Other Marketed Products

Novantrone®. We market and promote Novantrone® for approved oncology indications in the United States and receive commissions from Serono, S.A. on net oncology sales in this market. Novantrone® is an anthracenedione used as an intravenous chemotherapy agent. Novantrone® is approved by the FDA for the treatment of acute non-lymphocytic leukemia, or ANLL, which includes myelogenous, promyelocytic, monocytic and erythroid acute leukemias, and the relief of pain associated with advanced hormone refractory prostate cancer, or HRPC. Novan-

trone® is also used extensively by oncologists for the treatment of non-Hodgkin's lymphoma which is not an approved indication in the United States. The drug is also approved for certain advanced forms of multiple sclerosis, a key strategic area for Serono. The drug was licensed by Serono from Amgen, Inc., and we signed a co-promotion agreement with Serono to market the drug for its cancer indications in March 2003. Serono is continuing to market Novantrone® for the multiple sclerosis indication and records all U.S. sales in all indications. The patent for Novantrone® expires in April 2006.

Gelclair®. We market and distribute Gelclair® in the oncology setting in the United States. Gelclair® was cleared for sale as a device by the FDA in 2002. Gelclair® is a bioadherent oral gel that provides relief for pain associated with oral lesions, including oral mucositis, a debilitating side-effect often seen in cancer patients undergoing radiation treatment or chemotherapy. An estimated 320,000 cancer patients undergoing chemotherapy or radiotherapy develop oral mucositis every year.

On October 15, 2004, we announced that it would be necessary to record an impairment charge related to the intangible asset for exclusive distribution rights to Gelclair®. In performing our recoverability test, we determined that the total of the expected future undiscounted cash flows directly related to the Gelclair® asset was less than the carrying value of the Gelclair® asset. As a result, we determined that an impairment charge of approximately $24.6 million, which represented the full unamortized balance of the Gelclair® intangible asset, was necessary and will be recorded during the quarter ended September 30, 2004.

The impairment charge is non-cash and will not result in future cash expenditures. The impairment charge resulted from both the recent discontinuance of discussions with a replacement dental partner and slower than originally expected sales growth in the oncology marketplace following the re-launch of the product in October 2003. In addition to the impairment charge related to the Gelclair® intangible asset, we also recorded a provision for excess inventory of $8.6 million related to inventory on-hand as well as additional purchase commitments with Helsinn Healthcare S.A. This excess inventory relates to the substantial inventory obtained upon acquisition of Cell Pathways and the required purchase commitments that we assumed in the acquisition and the current low demand for the product. In late October 2004, we exercised our right to terminate the agreement with Helsinn. Under the terms of the agreement, Helsinn has the option to purchase any and all of our inventory at cost plus 5%. If Helsinn does not elect to purchase our inventory, we are permitted to continue to sell such inventory. We are currently negotiating a new agreement with Helsinn.

Commercial Operations

We have established a core commercial group of approximately 80 people, which includes approximately 50 sales representatives and managers covering the major territories in the United States. All of our sales representatives have considerable experience in the pharmaceutical industry, and most have ample experience with oncology products. We intend to market all future products directly in the United States but we may partner with other pharmaceutical companies to support our products in territories outside of the United States.

Consolidation of Our Oncology Operations

On August 5, 2004, we announced to our employees a plan to consolidate our U.K. based oncology research and development activities into our New York locations by November 30, 2004. This decision was based on the need to prioritize the expansion of our commercial operation infrastructure and increase our level of investment in both translational research and our diabetes and obesity subsidiary, Prosidion.

This consolidation has primarily affected our Oxford facility where the consolidation has resulted in the reduction of our work force by 82 employees. Following the consolidation, the only operations remaining at the Oxford facility are those related to our international clinical trials group and Prosidion.

Our Approach to Cancer Therapy

Cancer remains a major healthcare concern with approximately 1.3 million Americans diagnosed with various solid tumors, lymphomas and leukemias every year. In total, it is estimated that the overall direct medical costs for cancer in the United States for 2002 were in excess of $60 billion. The worldwide total cancer market has been estimated to be $14 to $15 billion and is expected to grow as new products, which offer safer and more effective treatment options, based upon an improved understanding of the genetic basis of human cancer, begin to enter the market. Traditionally, development of anti-cancer drugs has resulted in products which generally kill rapidly dividing cells. Although these products, called cytotoxic drugs, are effective in killing rapidly dividing cancer cells,

they usually interfere directly and non-selectively with normal processes in the cell associated with DNA replication and cell division. Since these cell division processes occur routinely in healthy tissues, the cytotoxic drugs are limited in their utility by their serious side-effects, such as disruption of the blood, immune and gastrointestinal systems.

Our approach to cancer therapy includes three diversified areas in an attempt to improve the available drug treatment options for cancer patients: signal transduction inhibitors that target either aberrant cancer cell growth or the induction of apoptosis in cancer cells that no longer respond to these tightly regulated processes, and next-generation cytotoxics. The aberrant cancer cell growth and apoptosis inducer programs are targeted therapy approaches focused on the exploitation of our rapidly growing understanding of the genetic basis for cancer in order to develop drugs that directly target the genetic abnormalities present in human cancers or treat their consequences. These areas are the focus of our pre-clinical research efforts. As these new targeted therapies emerge in clinical testing, they may be used independently, in combination with other targeted drugs or in combination with cytotoxic chemotherapy drugs, in an attempt to maximize the anti-cancer benefit by using so-called drug cocktails.

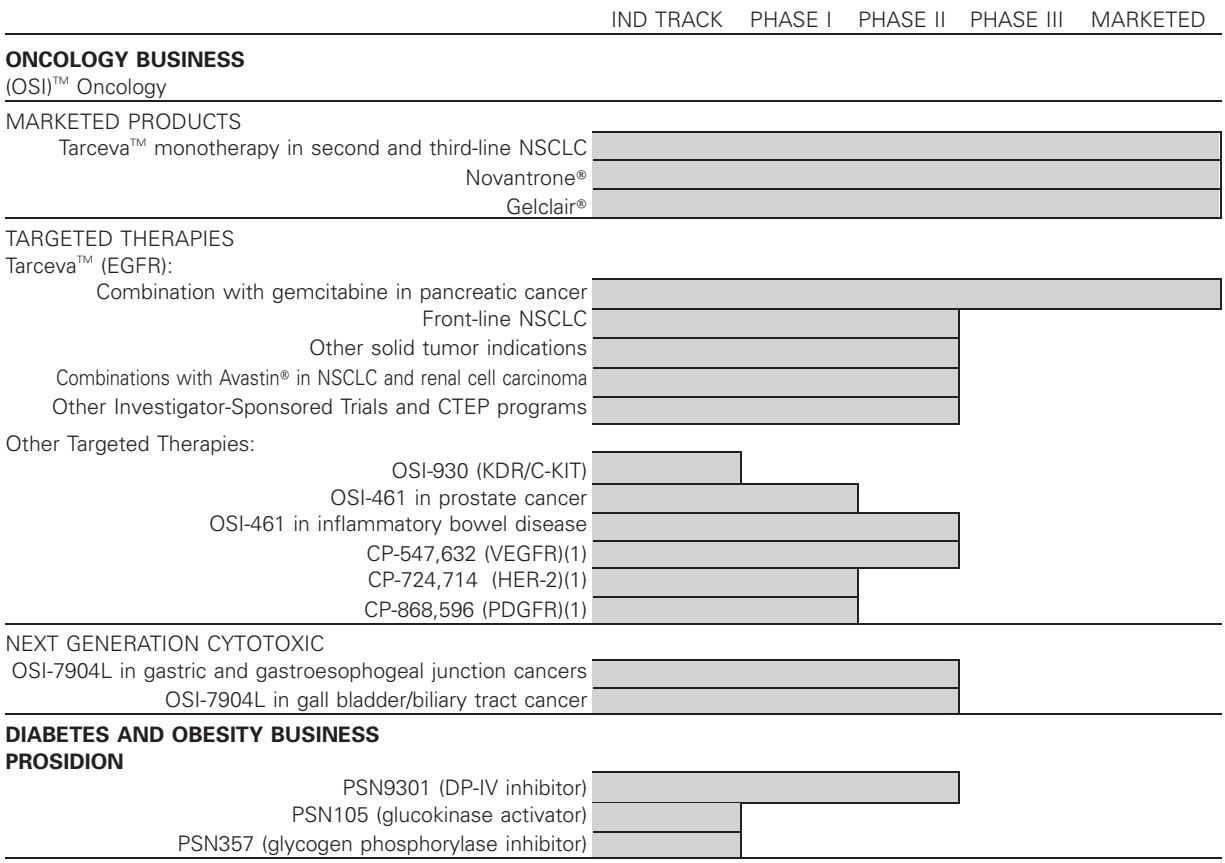
We have also previously acquired drug candidates in the cytotoxic area where we believe these new cytotoxic agents represent improvements in activity or technological innovations over existing drugs. OSI-7904L is a liposomal formulation of a thymidylate synthase inhibitor, or TSI, a known class of cytotoxic agents. Liposomal formulations are technological innovations that are designed either to improve targeting of the cytotoxic agent to the tumor or to change the exposure profile of the drug molecule, thus improving the therapeutic index, the drug benefits versus its toxic side-effects.

Our drug discovery efforts in targeted therapies were conducted in partnership with Pfizer from 1986 to 2001. Tarceva™ was jointly discovered as part of this alliance. Pfizer is continuing to develop three other clinical stage targeted therapies from this alliance, the funded discovery phase of which concluded in April 2001. If Pfizer is successful in commercializing any of these drug candidates, we will receive a royalty from Pfizer on the sales of these drugs. If Pfizer chooses to discontinue development of any of these drug candidates, we will have the right to pursue development of them.

Our Research and Development Programs

Research and Development Pipeline

The chart below summarizes our marketed products and the status of our research and development pipeline, including Tarceva™.



Note: Bars indicate the current stage of development of each program.

(1) Being developed by Pfizer for which we are entitled to royalties if commercialized and to which we have development rights if Pfizer chooses to halt development for any reason.

Proprietary Clinical and Pre-Clinical Development Programs

OSI-7904L. OSI-7904L is a liposomal formulation of the TSI, which was licensed from GlaxoSmithKline plc and acquired by us as part of the acquisition of Gilead Sciences, Inc.'s oncology business in 2001. TSIs are a class of cytotoxic chemotherapy agents. The leading TSI used today is 5-FU, a generically available TSI which is extensively used in many tumor types, notably colorectal cancer. Clinical studies with 5-FU have shown that long, continuous infusions of the drug have shown better activity than more typical intravenous bolus infusion regimens. The goal of our OSI-7904L program is to mimic this effect with a single short infusion of the liposomal formulation of our TSI molecule. OSI-7904L was formulated in liposomes with a goal of extending its pharmacokinetic, or drug exposure, half-life and improving its therapeutic index. We are developing OSI-7904L primarily for gastrointestinal tract cancers. OSI-7904L demonstrated promising activity in pre-clinical testing for the potential treatment of various solid tumors. Data from the Phase I study indicated that the liposomal formulation has extended the drug exposure profile of the free drug in patients' blood. Our Phase II single-agent study of OSI-7904L for gastric and gastroesophageal junction cancer in patients who have received no prior chemotherapy has moved forward to its second stage. The study, having met the initial requirement of achieving at least three objective responses in the first 18 evaluable patients has completed accrual of 53 patients in Europe and the United States. The primary endpoint of this trial is response rate. This open-label, non-randomized study was initiated in October 2003. We also broadened the OSI-7904L development program by initiating an additional randomized Phase II study versus

5-FU infusion in gall bladder/biliary and two additional studies evaluating the use of OSI-7904L in combination with the chemotherapy agents cisplatin and oxaliplatin commonly used in the treatment of gastrointestinal malignancies. Milestone and royalty payments are due to GlaxoSmithKline upon successful development of this product.

OSI-930. OSI-930 is a tyrosine kinase inhibitor that acts as a potent co-inhibitor of the receptor tyrosine kinases c-kit and VEGFR, and is designed to target both cancer cell proliferation and blood vessel growth (angiogenesis) in selected tumors. It is the first de novo development candidate to emerge from our discovery research operation since we realigned the focus of our core business towards oncology research in the fall of 2002. We have continued to advance OSI-930 through pre-clinical development and anticipate initiating a clinical program in the first half of calendar 2005. The mutated Kit receptor is directly involved in tumor progression in the majority of gastrointestinal stromal tumors and certain leukemias, and over-expressed normal Kit is thought to play a role in small cell lung cancer. The inhibition of the tyrosine kinase activity of Kit is expected to result in reduced cancer cell proliferation and increased cellular apoptosis in tumor types driven by Kit, thus resulting in inhibition of tumor growth. In addition to inhibiting Kit activity, OSI-930 is also capable of inhibiting the receptor tyrosine kinase called KDR. KDR, or vascular endothelial growth factor receptor-2, or VEGFR-2, is present on endothelial cells and is the key mediator of blood vessel growth in response to the angiogenic growth factor VEGF. The pathway is believed to be the single most important mechanism for recruitment of new blood vessels in nearly all solid tumors; hence, inhibition of this pathway should impact the growth and metastases of a wide range of angiogenesis-dependent malignancies. While the combination of Kit and KDR inhibition would be expected to offer the greatest therapeutic benefit to patients bearing Kit expressing solid tumors, the KDR component is considered an attractive target for all solid tumors. At this year's National Cancer Institute/European Organization for Research and Treatment of Cancer/American Association of Cancer Research meeting we presented data showing that OSI-930 was able to inhibit the growth of human tumor xenografts. We believe that OSI-930 may represent a less promiscuous split kinase inhibitor when compared to other known inhibitors of Kit/KDR driven tumors and other promiscuous kinase inhibitors in development (such as Pfizer's SU11248).

SAANDs Platform. The SAANDs platform that we acquired from Cell Pathways, Inc. in June 2003 consisted of two clinical candidates, Aptosyn® and OSI-461, designed to induce apoptosis through the sustained activation of protein kinase G, and associated intellectual property. Aptosyn®, the prototype product was originally developed by Cell Pathways to treat familial adenomatous polyposis. Following rejection of an NDA by the FDA in September 2000, Cell Pathways initiated a large scale Phase III program comparing a combination of Aptosyn® and Taxotere® versus Taxotere® and placebo in second-line NSCLC. The 610-patient trial was based primarily on promising pre-clinical data in orthotopic rat models, and on June 11, 2004, we announced that this Phase III trial failed to meet its primary endpoint of improving patient survival. Survival in the Taxotere® plus Aptosyn® arm (median survival = 6.9 months; one-year survival rate = 30.7%) was essentially indistinguishable from survival in the Taxotere® plus placebo arm (median survival = 6.9 months; one-year survival rate = 29.5%). Since our acquisition of Cell Pathways in June 2003, we had anticipated a negative outcome for this trial due to the absence of clinical data for the compound in advanced NSCLC. To date there have been some indications of activity for Aptosyn® in pre-cancerous settings; however, we do not believe Aptosyn® will have utility in advanced cancers and have halted development of the agent as an anti-cancer drug. Like Aptosyn®, OSI-461 is an inhibitor of cGMP phosphodiesterases which leads to sustained activation of the intracellular signaling protein, protein kinase G, and subsequent stimulation of apoptosis through the c-jun kinase pathway. OSI-461 also has effects on tubulin and microtubular biology in cells which is a known mechanism of action for other anti-cancer agents. OSI-461 is more potent than Aptosyn® in in-vitro assays but has proven to be difficult to dose to therapeutic levels in animal models. Following the completion of the acquisition of Cell Pathways in June 2003, we completed a detailed review of the OSI-461 program and concluded that further dose optimization studies would be required before committing to a full Phase II program. In February 2004, we expanded an ongoing Phase I dose escalating and pharmacokinetic trial of OSI-461 in patients with advanced solid tumors. This study has been amended to allow us to explore the possibility that administering OSI-461 with food may increase drug exposure levels achievable in humans following oral dosing of OSI-461. Data from this study is expected in the first quarter of calendar 2005. In July 2002, Cell Pathways also commenced a Phase II trial of OSI-461 in the non-cancerous area of inflammatory bowel disease at doses we consider to be sub-optimal. We recently received inconclusive results from this study which we need to further analyze in order to determine how best to proceed with this compound in this indication.

Oncology Discovery Research

In fiscal 2003, we refocused our pre-clinical research efforts into two areas in which we believe we can build a competitive presence in cancer drug discovery. These areas relate to the discovery of targeted therapies focused on two core biological processes important in both normal and cancer cell regulation, namely signal transduction

pathways that either (i) drive cancer cell proliferation or (ii) prevent apoptosis in cancer cells. The dysfunctional regulation of these two processes is a key element in the progression of normal cells to the cancerous state. Within these areas, we have focused our efforts on three key signaling axes described by the central signal transduction gene products that make up these pathways. These pathways are thought to be critical in driving either cancer cell proliferation or in protecting cancer cells from undergoing apoptosis.

More advanced discovery projects include co-inhibitors of PDK and EGFR and those targeting IGF-1R inhibitors. Recent studies have indicated that NSCLC patients who respond to EGFR inhibitors show both loss of EGFR phosphorylation as well as loss of protein kinase B, or PKB, phosphorylation. PKB, also known as AKT, is another important regulatory protein on the EGFR signaling axis. In contrast, NSCLC patients who are not responsive to EGFR inhibitors, show a loss of EGFR phosphorylation, but do not show the same degree of reduction in PKB phosphorylation to that observed in the responding patients. This data suggests that the PKB/AKT pathway is activated in an EGFR independent fashion in the non-responding NSCLC patients. Similar data has been observed in NSCLC cell lines as well as in other tumor types. We believe the PKB activation is dependent upon phosphorylation by phosphoinositide-dependent kinase-1, or PDK-1. PDK-1 is a serine/threonine kinase ubiquitously expressed in human tissues. We have postulated that a dual PDK-1/EGFR inhibitor would be expected to have a broader range of antitumor activity in NSCLC patients when compared with a selective EGFR inhibitor, such as Tarceva™, and have an ongoing drug discovery project designed to identify a dual inhibitor of PDK-1 and EGFR.

IGF-1R is a receptor tyrosine kinase that stimulates proliferation, enables oncogenic transformation, and suppresses apoptosis. It is an excellent strategic fit within our core strategy. Inhibitors of IGF-1R are expected to have broad utility in oncology since the over-expression of IGF-IR and/or its ligands (IGF-I and IGF-II) or the down-regulation of ligand binding proteins, or IGFBP, occurs in numerous human malignancies including lung, colon, breast, prostate, brain and skin cancers. Correlations with increased risk and poor prognosis have been established. In addition, signaling through the IGF system has also been implicated in protecting tumor cells from apoptosis induced by a number of anti-cancer treatments such as EGFR inhibitors (e.g., Tarceva™, the anti-HER2/erbB2 antibody Herceptin®) and cytotoxic agents. To be competitive in the IGF-1R space, we have initiated a research collaboration that uses structure based design as an enabling technology to identify proprietary IGF-1R inhibitors for us. The collaboration has significantly improved our understanding of the structure activity relationship within our lead chemical series and we anticipate identifying a development candidate in the first quarter of calendar 2005. We believe that an IGF-1R inhibitor should be useful both as a single agent, and in the potentiation of other molecularly targeted therapeutic agents and cytotoxic agents.

Our approach to discovering drugs is focused on the discovery and development of small molecule pharmaceutical products that, typically, would be taken either orally by a patient as a pill, capsule or suspension or intravenously as is common for many cancer products. Our drug discovery platform constitutes an integrated set of technologies and capabilities covering every major aspect of pre-clinical research and pre-clinical and clinical development. We have built a fully-integrated drug discovery platform in order to accelerate the process of identifying and optimizing high-quality, small molecule drug candidates. Our core technologies and capabilities include (i) signal transduction, protein kinases, gene transcription and other assay systems, (ii) automated high throughput screening, (iii) an extensive library of proprietary small molecule compounds, (iv) medicinal and automated combinatorial chemistry, (v) in vivo pharmacology, pharmacokinetics and pharmaceutical development capabilities and (vi) core clinical project management and regulatory affairs units. We currently employ approximately 117 scientists in our pre-clinical research activities.

In order to be competitive in the oncology drug discovery field we have endeavored to build a network of alliances designed to fill gaps in our expertise as well as enhance our existing understanding of the drug discovery process. This is based upon a philosophy that we should access complementary technology and expertise on the outside where and when this is appropriate. We have made external investments in three key areas: (i) target identification and validation, (ii) lead optimization, and (iii) surrogate biomarkers translational research.

Target Identification and Validation

Early in fiscal 2003 we established a research collaboration with Cold Spring Harbor Laboratory to utilize RNA interference to identify and validate new drug targets. Cold Spring Harbor Laboratory has a patent application covering the use of viral delivery of RNA hairpins into cells. An extensive gene library has been generated with the expectation that the size of this library will cover the entire genome. The entire gene library will be screened against genetically defined cancer cell lines and will identify those specific gene products that may modulate apoptosis and/or drive tumor cell proliferation. Additional research within OSI will help define potential drug targets.

We also initiated a research collaboration with EiRX Therapeutics plc of Cork, Ireland in June 2003. Using appropriate growth factors and reagents, EiRX is able to manipulate and test the apoptosis process in primary cells associated with normal and disease conditions. EiRX has been able to demonstrate that several of the genes they have identified are present in cancer cells, and are functional in blocking cell death. We entered into our agreement with EiRX to evaluate a set of 12 genes, whose use as cancer targets is covered within a filed patent application. We have selected four new targets for entry into our drug discovery efforts.

Lead Optimization

We have approached lead optimization in two ways. First, we have enhanced the quality of our chemical library through two major deals in the last year. We have acquired 130,000 new compounds from Array BioPharma, Inc. which are of high purity, are well characterized and are considered highly ''drug-like.'' Second, we became a subscriber to a library of structures available from Albany Molecular Research, Inc. representing a variety of chemical building blocks. These transactions have improved the diversity of our chemical library and, as a result, we are confident that our high throughput screening efforts are more likely to identify promising drug-like leads for our ongoing project teams.

We have also enhanced our capabilities in lead optimization through investments in structure based drug design. We have an ongoing alliance with Structural Genomix, Inc., or SGX, in which SGX will provide and will continue to provide crystal structures of up to 12 of our drug targets over a collaboration period ending February 1, 2005, unless extended. SGX has received milestone payments for successfully co-crystallizing target with inhibitor. To date, we have made significant progress in a number of our projects and we view this collaboration as being a successful entry for OSI into the field of structure based drug design.

Surrogate Biomarkers and Translational Research

The optimal clinical development of novel targeted therapies requires assays and reagents (surrogate markers) that are capable of identifying whether a specific patient tumor will respond to the therapy under investigation. Going forward, we intend to invest in this area in order to:

- identify surrogate biomarkers that predict cellular sensitivity and tumor response to OSI compounds of interest; and
- determine the pathways that are influenced/impacted through RNA interference of select OSI drug targets.

To ensure that our lead compounds are active against the target of interest, they are profiled in pharmacodynamic assays. This allows us to develop surrogate biomarkers of drug activity in vivo and will enable and support our future clinical development. This process ensures that our lead compounds have retained their anticipated mechanism of action in vivo.

Translational research is designed to bridge our research knowledge base into the clinic and the marketplace. The current emphasis of our translational research programs is on Tarceva™ and a series of collaborations and studies are ongoing (including, for example, our Phase II dose-to-rash study in NSCLC) designed to improve our understanding of how best to use Tarceva™ clinically.

Oncology Drug Development

After identifying a suitable drug candidate, a molecule is advanced toward clinical trials and enters the investigational new drug, or IND, track phase, in which toxicological, scale-up synthesis and clinical development strategy are addressed. The IND track phase typically takes up to one year. An IND application is reviewed by the FDA or its foreign equivalent prior to the commencement of clinical studies. A drug is typically first assessed for its safety and pharmacokinetic properties. After these Phase I trials, drugs are tested for preliminary efficacy in Phase II trials to demonstrate initial activity and confirm safety in humans prior to the initiation of extensive Phase III trials designed to collect the safety and efficacy data necessary to support a filing of an NDA with the FDA or similar marketing application authorization overseas. We currently employ over 101 physicians, scientists and clinical operations specialists who are responsible for generating pre-clinical data required for IND submission and managing clinical trials and the associated regulatory affairs effort to support submissions and interactions with the FDA and other regulatory agencies around the world.

The entire drug discovery and development process typically takes over a decade and is subject to significant risk and attrition. A significant majority of drug candidates which enter clinical trials fail to result in a successful

product. We have, therefore, adopted a research strategy that manages a portfolio of product opportunities, adding, through in-licensing, lead compounds at various stages of the process in order to help mitigate the risks inherent in these efforts.

Manufacturing and Supply

We currently rely on third-party manufacturers to manufacture all of our marketed products and late stage product candidates. 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. We entered into a Manufacturing and Supply Agreement with Genentech, effective as of June 4, 2004, to define each party's rights and responsibilities in connection with such supply. Under our collaboration agreement with Roche, Roche has elected to take responsibility for the supply of tablets for sales outside of the United States.

Erlotinib is manufactured in a three-step process with high yield. Sumitomo Chemical Co., Ltd. (formerly known as Sumika Fine Chemicals Co. Ltd.) and Dinamite Dipharma S.p.A are our manufacturers of erlotinib used for commercial supplies. Both of these manufacturers have manufactured API for Tarceva™ clinical trials. We contracted with Schwarz Pharma AG to manufacture Tarceva™ tablets and placebo product for clinical supplies and are engaging Schwarz to manufacture Tarceva™ tablets for commercial supplies. We are also evaluating the capability of another manufacturer to serve as an alternative (i.e., back-up) provider of Tarceva™ tablets. Clinical supplies of Tarceva™ tablets are currently stored, labeled, packaged and distributed by Cardinal Health Clinical Services, and we are engaging Cardinal Health Packaging Services for labeling and secondary packaging services for commercial supplies of Tarceva™ tablets before their subsequent distribution to Genentech or a storage facility designated by Genentech. We expect to enter into long term supply agreements with our API and tablet manufacturers. All manufacturers of erlotinib and Tarceva™ tablets are required to comply with current good manufacturing practices. We have produced sufficient quantities of Tarceva™ tablets to conduct our ongoing clinical trials, and we believe we have a supply chain in place with inventory on hand to support launch.

In connection with our acquisition of Cell Pathways in June 2003, we acquired the exclusive marketing and distribution rights to Gelclair® in North America. The manufacturing rights and obligations are held by Helsinn.

In connection with our purchase of certain oncology assets from Gilead in December 2001, we entered into a manufacturing agreement covering products acquired from Gilead. During the one-year transition period, Gilead manufactured and supplied us with the API for preparation of OSI-7904L drug product. We have transitioned the manufacture of the API to new manufacturers. Gilead will produce for us liposomal formulations of OSI-7904L at its manufacturing facility in San Dimas, California to support our ongoing clinical trial activities.

Prosidion

In 2002, we made the decision to focus our initial research and development efforts into the oncology area and to either shut down or divest research programs in other areas with the exception of our research assets in the diabetes and obesity arena. These programs were transferred to a newly created U.K. based subsidiary, Prosidion, in January 2003. Prosidion is registered in England and Wales under registered number 4600121 and is a majority-owned subsidiary.

As part of the formation of Prosidion, we transferred and/or licensed our diabetes assets to Prosidion and we also transferred our employees who were focusing on diabetes research. In 2003, we hired Anker Lundemose, M.D., Ph.D. as Chief Executive Officer of Prosidion, established a separate board of directors and committed approximately $10 million in funding to support Prosidion's operations. In August 2003, Prosidion completed a transaction with H. Lundbeck A/S's subsidiary, Synaptic Pharmaceutical Corporation, to license co-exclusive rights to a novel G-protein coupled receptor, or GPCR, target for the treatment of diabetes and obesity. In March 2004, Prosidion signed an agreement with Tanabe Seiyaku Co., Ltd. in order to obtain U.S. and European rights to the OSI/Tanabe joint technology in glucokinase activators and to gain freedom to operate in all other areas previously covered by the OSI/Tanabe alliance. Both Tanabe and Synaptic are minority shareholders of Prosidion as a result of these transactions.

On July 26, 2004, Prosidion acquired a platform of DP-IV technology from Probiodrug for approximately $35 million in cash plus future milestones. The milestone payments are payable upon the successful development of PSN9301, the lead DP-IV inhibitor acquired from Probiodrug, which is in Phase II clinical trials for the treatment of type 2 diabetes. These milestone payments are payable in January 2007 and/or January 2010, or on such earlier dates upon which the criteria are met unless the development of PSN9301 is terminated prior to such dates due to

safety, efficacy or regulatory issues in which event the obligation to make the milestone payments will lapse. Probiodrug, based in Halle (Saale), Germany, had pioneered much of the research and development that has led to the characterization of DP-IV as one of the most important targets in diabetes drug development today. Included in the assets acquired by Prosidion is a portfolio of medical use patents around the target. This portfolio includes issued and pending patents with claims covering DP-IV as a target for anti-diabetic therapy and licensed rights to patent applications claiming combinations of DP-IV inhibitors with other oral anti-diabetes drugs such as Metformin™. Merck, Novartis and Ferring B.V. are all non-exclusive licensees to the estate. Future potential milestones and royalties arising from this intellectual property have been transferred to Prosidion. Prosidion also entered into a research agreement with Probiodrug under which Prosidion will provide funding of certain research aimed at discovering backup compounds to PSN9301 and discovering the potential therapeutic use of the related target glucose-dependent insulinotropic peptide receptor in metabolic diseases.

DP-IV cleaves and inactivates GLP-1, an important mediator of blood glucose levels. Inhibition of DP-IV leads to prolonged GLP-1 activity and inhibitors of DP-IV have demonstrated significant effects on mean blood glucose and post-prandial blood glucose and HbA(1C) levels, a reference marker widely used in the monitoring of diabetes patients, in pre-clinical and clinical trials. The field is competitive with the Novartis DP-IV inhibitor, LAF237, currently in Phase III trials and compounds from Merck and BMS are entering Phase III trials. PSN9301 is an orally active, competitive inhibitor of DP-IV that is designed as a shorter acting inhibitor. PSN9301 has been shown to lower glucose in type 2 diabetics in early clinical trials.

In addition to PSN9301, Prosidion has two molecules in the late stages of pre-clinical development which are scheduled to enter clinical trials in the first half of calendar 2005. PSN105 is an oral, small molecule activator of glucokinase and PSN357 is an oral, small molecule inhibitor of glycogen phosphorylase. Both glucokinase and glycogen phosphorylase are targets for therapeutic intervention in diabetes. The molecules have demonstrated efficacy in animal models and successfully completed acute toxicological profiling.

In April 2004, we announced that our board of directors approved an investment of up to an additional $40 million in Prosidion. The first installment of $10 million was invested at a cost of $10 per share. In order to finance the Probiodrug transaction and fund the current ongoing research and development efforts at Prosidion, we increased our investment commitment in Prosidion. Following the closing of the Probiodrug acquisition and our increased investment in Prosidion to finance the transaction, our ownership of Prosidion increased to approximately 97%.

Roche and Genentech Alliance

On January 8, 2001, we entered into an alliance with Genentech and Roche for the global co-development and commercialization of Tarceva™. We received upfront fees of $25 million related to this alliance, and Genentech and Roche each purchased $35 million of our common stock at $75.66 per share. We are also entitled to up to $92 million upon the achievement of certain milestones under the terms of the alliance a portion of which have been received. 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 on an equal basis; to share information generated under a global development plan; to facilitate attainment of necessary regulatory approval of Tarceva™ for commercial marketing and sale in the world; and to work together on such matters as the parties agree from time to time during the development of Tarceva™. We, as well as Genentech and Roche, may conduct clinical and pre-clinical activities for additional indications for Tarceva™ not called for under the global development plan, subject to certain conditions. The Tripartite Agreement will terminate when either the OSI/Genentech collaboration agreement or the OSI/Roche agreement terminates.

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 agree with Genentech as to who will own and be responsible for the filing of drug approval applications with the FDA other than the first NDA, which we own and filed, and the first supplemental NDA, which we have the option to own and be responsible for filing. 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 were defined in an amendment to the agreement effective as of June 4, 2004. Pursuant to this amendment, we co-promote Tarceva™ using a sales force that is equal to or greater than 25% of the combined OSI/Genentech sales force. We will 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 will recognize all U.S. sales of Tarceva™. We will recognize revenues from our alliance with Genentech, which will consist of our share of the pretax profits (loss) generated from the sales of Tarceva™ in the United States. We also will recognize manufacturing revenue from the sale of inventory to Genentech for commercial sales of Tarceva™ in the United States, partial reimbursement from Genentech of our Tarceva™ -related commercial expenses. We will receive royalties on sales of Tarceva™ outside of the United States by Roche and up to $92 million in non-refundable milestone payments from Genentech and Roche, upon the achievement of certain milestones relating to regulatory submissions and approval, certain of which have already been received.

The OSI/Genentech collaboration agreement continues until the date on which neither we nor Genentech are entitled to receive a share of the operating profits or losses on any products resulting from the collaboration, that is, until the date that we and Genentech mutually agree to terminate the collaboration or until either party exercises its early termination rights. The OSI/Genentech collaboration agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. The provisions of the amendment allowing us to co-promote are also subject to termination by Genentech upon a material breach by us of the amendment which remains uncured or upon a pattern of nonmaterial breaches which remains uncured. In addition, since January 8, 2003, Genentech has had 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 product development of Tarceva™ and is responsible for future marketing and commercialization of Tarceva™ outside of the United States in certain territories as defined in the agreement. The grant is a royalty-bearing, non-transferable (except under certain circumstances), non-sublicensable (except under certain circumstances), sole and exclusive license to use, sell, offer for sale and import products resulting from the development of Tarceva™ worldwide, other than the territories covered by the OSI/Genentech collaboration agreement. In addition, Roche has the right, which it has exercised, to manufacture commercial supplies of Tarceva™ for its territory, subject to certain exceptions. Roche will pay us certain milestone payments and royalty payments on sales of products resulting from the collaboration. We have primary responsibility for patent filings for the base patents protecting Tarceva™ and, in addition, we have the right, but not the obligation, to institute, prosecute and control patent infringement claims relating to the base patents. The OSI/Roche agreement continues until the date on which we are no longer entitled to receive a royalty on products resulting from the development of Tarceva™, that is, until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva™ or, in countries where there is no valid patent covering Tarceva™, on the tenth anniversary of the first commercial sale of Tarceva™ in that country, or until either party exercises early termination rights. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, since July 31, 2003, Roche has had the right to terminate the agreement on a country-by-country basis with six months' prior written

notice. Since such time, we also have had the right to terminate the agreement on a county-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

Pfizer Collaborative Cancer Programs

Pfizer is continuing to develop three drug candidates which arose from our collaborative drug discovery program in targeted therapies for cancer, all of which are in clinical trials. These programs are focused on developing drugs which are orally available, potent inhibitors of key protein tyrosine kinase receptors involved in signal transduction and angiogenesis. Angiogenesis is the process of blood vessel growth and is induced by solid tumors which require nutrients that enable growth. We believe that the ability to safely and effectively inhibit this process represents an intriguing opportunity in cancer drug development. Under our alliance with Pfizer, we discovered two compounds in this area. CP-547,632 targets VEGFR and is in Phase II and Phase I trials, and CP-868,596 targets PDGFR and is in Phase I trials. An additional candidate from the Pfizer program, CP-724,714, is a potent and selective small molecule inhibitor of the HER2/erbB2 receptor tyrosine kinase, and is in Phase I clinical trials. Overexpression of HER2/erbB2 oncogenes has been demonstrated to correlate with aggressive cancer growth particularly in metastatic breast cancer. Approximately 25% to 30% of all women with metastatic breast cancer overexpress HER2/erbB2.

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. 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.

Patents issued in the United States, Europe, Japan, and 20 other countries cover composition of matter for erlotinib (the API for Tarceva™), processes for its preparation, and pharmaceutical compositions containing erlotinib. These patents expire in 2015. Patent applications are being pursued, seeking protection in and outside the United States, for polymorphic, anhydrous, hydrate, and certain salt forms of erlotinib, as well as for processes and important intermediate chemicals in the manufacture of erlotinib. The polymorphic patent, when it issues, should provide patent exclusivity for erlotinib through 2020. Further, patent protection for methods of use of Tarceva™ are being sought.

Patents directed to the OSI-7904L compound have issued in the United States, Japan, and Europe. Patent protection is also being sought, with a composition of matter and method-of-use patent issuing earlier this year in the United States, for liposomal formulations of OSI-7904L. From our acquisition of Cell Pathways, we have a patent estate to methods of identifying compounds that participate in a specific apoptotic pathway. Aptosyn® and OSI-461 are each covered by U.S. and foreign patents to methods of treatment using the compounds. We have rights to a U.S. patent covering a method-of-use of Novantrone® for solid tumors, expiring April 11, 2006. A patent application has been allowed in the United States covering the composition of Gelclair®.

We have assembled a strong gene transcription patent portfolio and have a non-exclusive out-licensing program for our gene transcription patent estate. Currently, we have licensed this technology to Aurora Biosciences Corporation (assigned to Vertex Pharmaceuticals Incorporated), Pharmacia Corporation, R.W. Johnson Pharmaceutical Research Institute, Wyeth, BASF Corporation and Merck. We also have non-exclusive licenses from Cadus Corporation (seven U.S. patents and additional U.S. and foreign applications) and Wyeth (four U.S. patents and additional foreign applications) 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.

Prosidion has acquired rights to U.S. patents and foreign patents and patent applications covering methods of treatment of diabetes through the administration of a DP-IV inhibitor, as well as patents and patent applications covering composition of matter for specific small molecule DP-IV inhibitors including the clinical candidate PSN9301, which is in Phase II clinical trials, as part of its asset acquisition from Probiodrug. Merck and Novartis, among others, have taken licenses to some of these method-of-use patents and patent applications, from which Prosidion may accrue certain milestone payments and royalties. One of these patents has been challenged in

Europe and, in May 2004, in a ruling by the European Patent Office in Munich, one of the DP-IV method-of-use patents was revoked. Prosidion has appealed this decision.

Our Competition

The pharmaceutical and biotechnology industries are intensely competitive. We face, and will continue to face, intense competition from organizations such as large pharmaceutical companies, biotechnology companies and academic and research institutions. We face significant competition from fully-integrated pharmaceutical companies, as well as numerous smaller companies, which possess extensive drug discovery programs in oncology and diabetes, are pursuing the same or similar technologies as those that comprise our technology platforms and are pursuing pharmaceutical products or therapies that are directly competitive with ours, including developing novel small molecule pharmaceuticals. Most of the major pharmaceutical organizations competing with us have greater capital resources and larger overall research and development staff and facilities than we do in drug research and development, regulatory affairs and pharmaceutical product manufacturing and marketing.

With respect to our cancer drug discovery and development programs, other companies have potential drugs in clinical trials to treat diseases in the same areas for which we are seeking to discover and develop drug candidates. These competing drug candidates may be further advanced in clinical development than our potential products within our small molecule programs, and may result in effective, commercially successful products. At least three competitors, AstraZeneca plc, BMS/ImClone/Merck KGaA and Amgen/Abgenix, Inc., also have substantial clinical development programs for the same target as our flagship product, Tarceva™. AstraZeneca has received approval for its anti-EGFR, small molecule drug in the United States (accelerated approval, contingent studies required by FDA), Switzerland, Japan and other territories. However, AstraZeneca's drug has not yet demonstrated a survival benefit. AstraZeneca has recently announced that the survival data from their ongoing Iressa® study will be available by the end of the year. BMS/ImClone/Merck KGaA's anti-EGFR antibody, Erbitux™, has been approved (as single agent or in combination with irinotecan) in the United States and in the EU and Switzerland for the treatment of metastatic colon carcinoma in patients who are refractory or have developed intolerance to irinotecan based chemotherapy. In addition to agents that target EGFR, Taxotere® and Alimta® are chemotherapy agents that are approved for use in second-line NSCLC. Taxotere® and Alimta® are manufactured and distributed by Aventis and Eli Lilly and Company, respectively.

With the acquisition of the co-promotion rights for Novantrone® in the oncology arena in the United States and the marketing and distribution rights for Gelclair® in North America, we are facing competition in their respective areas of use. Novantrone® is mainly used for the treatment of pain associated with advanced HRPC, ANLL and non-Hodgkin's lymphoma, which is not an approved indication in the United States. A key competitor in HRPC is Taxotere®, which the FDA approved for use in combination with prednisone in May 2004 for HRPC based on a survival benefit for Taxotere®-based regimens compared to the better tolerated Novantrone® plus prednisone. In ANLL, Novantrone® competes against a variety of generic products including idarubicin and daunorubicin. In non-Hodgkin's lymphoma, the reference standard is the CHOP regimen consisting of four generic agents: cyclophosphamide, doxorubicin, vincristine and prednisone. In addition, Rituxan®, marketed by Genentech/IDEC Pharmaceuticals, Inc., is used extensively in non-Hodgkin's lymphoma both as a single-agent and in combination with CHOP or other chemotherapies including Novantrone®.

Gelclair® is a bioadherent oral gel for the relief of pain associated with oral mucositis. Key competitors include a myriad of products often blended in the dispensing pharmacy, none of which have been specifically approved for this indication, such as Xylocaine®, Benadryl® Elixir®, Carafate®, Orabase®, and over-the-counter and prescription analgesics.

OSI-7904L, our next-generation cytotoxic drug candidate, is designed to improve upon products of similar mechanism already in the market and available generically. We must therefore clearly differentiate the activity or safety of our molecule if we are to successfully register this drug and compete in the marketplace. OSI-7904L, which is currently in Phase II trials, is a TSI designed to compete with generic 5-FU, as well as Xeloda® by Roche, an oral TSI.

Companies with related research and development activities also present significant competition for us. Research efforts with respect to gene sequencing and mapping are identifying new and possibly superior target genes than our target genes. In addition, alternative drug discovery strategies, such as monoclonal antibodies, may prove more effective than those pursued by us. Furthermore, competitors may have access to more diverse compounds than we do for testing by virtue of larger compound libraries.

With respect to Prosidion's drug discovery and development programs for diabetes and obesity, other companies have potential drugs in clinical trials to treat diseases in the same areas for which we are seeking to discover and develop drug candidates. These competing drug candidates may be further advanced in clinical development than our potential products within our small molecule programs, and may result in effective, commercially successful products. At least three competitors, Merck, Novartis and BMS, have advanced clinical development programs directly competitive with Prosidion's lead clinical candidate, PSN9301, an inhibitor of DP-IV for treating diabetes which is in Phase II clinical trials. DP-IV inhibitors are designed to prevent cleaving and inactivation of GLP-1, an important mediator of blood glucose levels. There are no DP-IV inhibitors that are currently marketed, although Amylin Pharmaceuticals, Inc. has filed an application with the FDA to market a GLP-1 product, Exenatide™, for the treatment of diabetes. Prosidion must therefore clearly distinguish the profile of PSN9301 if we are to successfully register this product and compete in the marketplace. Prosidion's other clinical candidates for diabetes, a glucokinase activator, PSN105, and a glycogen phosphorylase inhibitor, PSN357, are currently in late pre-clinical development and anticipated to enter clinical development in the first half of calendar 2005. At least two competitors, Roche and Pfizer, have, at various times, announced similar research and development activities.

We believe that our ability to compete successfully will be based upon, among other things, our ability to create and maintain scientifically advanced technology, attract and retain scientific and clinical personnel possessing a broad range of expertise, obtain patent protection or otherwise develop and protect proprietary products or processes, compete for premium in-licensing products, conduct clinical trials, obtain required government approvals on a timely basis and commercialize our products on a profitable basis.

Government Regulation

We and our collaborative partners are subject to, and any potential products discovered and developed by us must comply with, comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, and local entities regulate, among other things, the pre-clinical and clinical testing, safety, effectiveness, approval, manufacture, quality, labeling, distribution, marketing, export, storage, record keeping, advertising and promotion of pharmaceutical and diagnostic products.

The FDA Process

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

- pre-clinical laboratory and animal tests;
- submission to the FDA of an IND application, 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 and effective for its intended uses.

Pre-clinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies, to assess the potential safety and efficacy of the product. Certain pre-clinical tests must comply with FDA regulations regarding current good laboratory practices. The results of the pre-clinical tests are submitted to the FDA as part of an IND, to support human clinical trials and are reviewed by the FDA, with patient safety as the primary objective, prior to the IND commencement of human clinical trials.

Clinical trials are conducted according to protocols that detail matters such as a description of the condition to be treated, the objectives of the study, a description of the patient population eligible for the study and the parameters to be used to monitor safety and efficacy. Each protocol must be submitted to the FDA as part of the IND. Protocols must be conducted in accordance with FDA regulations concerning good clinical practices to ensure the quality and integrity of clinical trial results and data. Failure to adhere to good clinical practices and the protocols may result in FDA rejection of clinical trial results and data, and may delay or prevent the FDA from approving the drug for commercial use.

Clinical trials are typically conducted in three sequential Phases, which may overlap. During Phase I, when the drug is initially given to human subjects, the product is tested for safety, dosage tolerance, absorption, distribution, metabolism and excretion. Phase I studies are often conducted with healthy volunteers depending on the drug being tested; however, in oncology, Phase I trials are more often conducted in cancer patients. Phase II involves studies in a limited patient population, typically patients with the conditions needing treatment, to:

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

Pivotal or Phase III adequate and well-controlled trials are undertaken in order to evaluate efficacy and safety in a comprehensive fashion within an expanded patient population for the purpose of registering the new drug. The FDA may suspend or terminate clinical trials at any point in this process if it concludes that patients are being exposed to an unacceptable health risk or if they decide it is unethical to continue the study. Results of pre-clinical and clinical trials must be summarized in comprehensive reports for the FDA. In addition, the results of Phase III studies are often subject to vigorous statistical analysis. This data may be presented in accordance with the guidelines for the International Committee of Harmonization that can facilitate registration in the United States, the EU and Japan.

FDA approval of our own and our collaborators' products is required before the products may be commercialized in the United States. FDA approval of an NDA will be based, among other factors, on the comprehensive reporting of clinical data, risk/benefit analysis, animal studies and manufacturing processes and facilities. The process of obtaining NDA approvals from the FDA can be costly and time consuming and may be affected by unanticipated delays.

There is an NDA review process referred to as the Fast Track program which is designed to expedite the approval of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Applicants that meet the relevant acceptance criteria may receive Fast Track designation. The benefits of a Fast Track designation include the ability to schedule meetings to seek FDA input into development plans, the option of submitting an NDA in sections on a rolling basis rather than submitting all components simultaneously, and the option of requesting evaluation of studies using surrogate endpoints (accelerated approval). Tarceva™ was granted a Fast Track designation for the advanced NSCLC indication.

In addition, the FDA has recently instituted a new trial program, the Pilot 1 program, which provides for the review of a limited number of pre-submitted portions, or reviewable units, of an applicant's marketing application before submitting the complete application. The Pilot 1 program only applies to certain new drug or biological products that have received Fast Track designation, have been the subject of an end-of-Phase II and/or a pre-NDA meeting, and have demonstrated significant promise as a therapeutic advance in clinical trials. As part of the Pilot 1 program, the FDA agrees to complete reviews of an applicant's reviewable units within six months of the date of the submission of such reviewable unit or from granting of Pilot 1 status, whichever is later, and to provide early feedback in the form of information requests and discipline review letters. Tarceva™ was granted Pilot 1 status and is one of the first drugs to be entered into the program.

Among the conditions for NDA approval is the requirement that the prospective manufacturer's procedures conform to current good manufacturing practices, 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. Domestic manufacturing establishments are subject to periodic inspections by the FDA in order to assess, among other things, compliance with current good manufacturing practices. To supply products for use in the United States, foreign manufacturing establishments also must comply with current good manufacturing practices and are subject to periodic inspection by the FDA or by regulatory authorities in certain countries under reciprocal agreements with the FDA.

An sNDA is a submission to an existing NDA that provides for changes to the NDA and therefore requires FDA approval. Changes to the NDA that require FDA approval are the subject of either the active ingredients, the drug product and/or the labeling. A supplement is required to fully describe the change. There are two types of sNDAs depending on the content and extent of the change. These two types are (i) supplements requiring FDA approval before the change is made and (ii) supplements for changes that may be made before FDA approval. Supplements to the labeling that change the Indication Section require prior FDA approval before the change can be made to the labeling, e.g. a new indication.

Both before and after market approval is obtained, a product, its manufacturer and the holder of the NDA for the product are subject to comprehensive regulatory oversight. 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 of an approved product from the market and the imposition of criminal penalties against the manufacturer and NDA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product, manufacturer or NDA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Other Regulatory Processes

In addition to regulations enforced by the FDA, we must also comply with regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. For example, sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, the privacy provisions of the Health Insurance Portability and Accountability Act, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug Improvement and Modernization Act of 2003. If products are made available to authorized users of the Federal Supply Schedule of the General Services administration, additional laws and requirements may apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. In addition, our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds the handling and disposal of which are governed by various state and federal regulations.

In addition to regulations in the United States, we are subject to various foreign regulations governing clinical trials and the commercial sales and distribution of our products, including Tarceva™. We must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement and the regulatory approval process all vary greatly from country to country. Additionally, the time it takes to complete the approval process in foreign countries may be longer or shorter than that required for FDA approval. Foreign regulatory approvals of our products are necessary whether or not we obtain FDA approval for such products. Finally, before a new drug may be exported from the United States, it must either be approved for marketing in the United States or meet the requirements of exportation of an unapproved drug under Section 802 of the Export Reform and Enhancement Act or comply with FDA regulations pertaining to INDs.

Under European Union regulatory systems, we are permitted to submit marketing authorizations under either a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all member states of the European Union. The decentralized procedure provides for mutual recognition of national approval decisions by permitting the holder of a national marketing authorization to submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

Our Employees

We believe that our success is largely dependant upon our ability to attract and retain qualified personnel in the scientific and technical fields. As of December 1, 2004, we, including Prosidion, have 452 employees worldwide, 363 of whom are in the United States. Of the 452 employees, 154 are primarily involved in research activities, 105 are primarily involved in development and manufacturing activities, 81 are primarily involved in sales and marketing, with the remainder engaged in executive and administrative capacities. Although we believe that we are appropriately sized to focus on our mission, we intend to add personnel with specialized expertise, as needed.

We believe that we have been successful to date in attracting skilled and experienced scientific and business professionals. We consider our employee relations to be good. However, competition for personnel is intense and we cannot assure that we will continue to be able to attract and retain personnel of high caliber.

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. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, 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.

CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

(Cautionary Statement under the Private Securities Litigation Reform Act of 1995, as amended)

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.

We have incurred losses since our inception, and we expect to incur losses over the next several years, which may cause the value of our common stock to decrease.

We have had net operating losses since our inception in 1983. We expect to continue to incur operating losses over the next several years as a result of our expenses for the continued development of Tarceva™ and our other clinical products and research programs and the expansion of our commercial operations. We cannot predict when our business will become profitable. We do not expect to achieve profitability for at least three years following the launch of Tarceva™.

At September 30, 2004, our accumulated deficit was $766.0 million. Our net losses were $260.4 million, $181.4 million and $218.5 million for fiscal years 2004, 2003 and 2002, respectively. Our net loss for fiscal 2004 included an in-process research and development charge of $32.8 million related to the acquisition of certain assets from Probiodrug AG in July 2004 and a charge of $24.6 million related to an impairment of an intangible asset. Our net loss for fiscal 2003 included an in-process research and development charge of $31.5 million related to the acquisition of Cell Pathways, Inc. in June 2003. Our net loss for fiscal 2002 included an in-process research and development charge of $130.2 million related to the acquisition of certain assets from Gilead Sciences, Inc. in December 2001.

We, together with our alliance partners Genentech, Inc. and Roche, may not be able to market or generate sales of Tarceva™ to the extent anticipated.

Our ability to successfully penetrate the market and generate sales of Tarceva™ may be limited by a number of factors, including the following:

- Certain of our competitors in the HER1/EGFR field, namely AstraZeneca plc and Bristol-Myers Squibb Company/ImClone Systems Incorporated, have already received regulatory approvals for and have begun marketing similar products in the United States, the EU, Japan and other territories, which may result in greater physician awareness of their products as compared to Tarceva™.

- Information from our competitors or the academic community indicating that current products or new products are more effective than Tarceva™ could, if and when it is generated, impede our market penetration or decrease our existing market share.

- Physicians may be reluctant to switch from existing treatment methods, including traditional chemotherapy agents, to Tarceva™.

- The price for Tarceva™, which is set by Genentech in the United States after consultation with us and will be set by Roche outside of the United States, as well as pricing decisions by our competitors, may have an effect on our Tarceva™-derived revenues.

- Our Tarceva™-derived revenues may diminish if third-party payors, including private health coverage insurers and health maintenance organizations, do not provide adequate coverage or reimbursement for Tarceva™.

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

All of our potential products must undergo extensive regulatory approval processes in the United States and other countries. These regulatory processes, which include pre-clinical testing and clinical trials of each compound to establish safety and efficacy, can take many years and require the expenditure of substantial resources. The FDA and the other regulatory agencies in additional markets which are material to us and our collaborative partners, including the European Agency for the Evaluation of Medicinal Products, or EMEA, 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 for the NSCLC indication, there can be no guarantee of subsequent approvals either for Tarceva™ in other territories (including the EU) 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 that could negatively affect the profitability of a drug.

Furthermore, once a drug is approved, the drug can only be marketed for the indications and claims approved by the FDA. If we fail to comply with the FDA regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained, the FDA, or the Office of the Inspector General of the U.S. Department of Health and Human Services, or state Attorneys General could bring an enforcement action against us that would inhibit our marketing capabilities as well as result in significant penalties. 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.

We are responsible for the supply of Tarceva™ in the United States. Since we have no commercial manufacturing facilities, we are dependent on two suppliers for the active pharmaceutical ingredient, or API, for Tarceva™ and a single supplier for the tableting of Tarceva™ in the United States.

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 the API, erlotinib, for Tarceva™. We also currently rely on a single manufacturer to formulate the Tarceva™ tablets. We are presently seeking another manufacturer to serve as an alternative (i.e. back-up) provider of Tarceva™ tablets. If our relationships with any of these manufacturers terminate or if they are unable to meet their obligations, we will 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, could negatively impact our Tarceva™-derived revenues.

Furthermore, the manufacturing of our products is, and will continue to be, subject to current good manufacturing practices regulations prescribed by the FDA or other standards prescribed by the appropriate regulatory agency in the country of use. If our manufacturers, including the current manufacturers of erlotinib and Tarceva™ tablets, do not comply with all applicable regulatory standards, they may not be permitted to manufacture Tarceva™ or any other product for commercial sale. If this occurs, we might not be able to identify another third-party manufacturer on terms acceptable to us or in a timely manner, or such other third-party manufacturer may not receive FDA approval in a timely manner or at all. Any of the foregoing could cause delays in the availability of our products, including erlotinib and/or Tarceva™ tablets, which would negatively impact our revenues. If we fail to meet our manufacturing obligations, our partner, Genentech, also has the right to take over supply of Tarceva™ in the United States.

If we do not maintain our co-development and marketing alliance with Genentech and Roche for Tarceva™, the marketing and sale of Tarceva™ may be compromised or delayed.

Tarceva™ is being developed and commercialized in an alliance under co-development and marketing agreements with Genentech and Roche. The development program is managed by us, Genentech and Roche under a global development committee. Under the alliance, Genentech leads the marketing efforts in the United States and Roche will market the drug in the rest of the world. Recently, we signed an amendment to our collaboration agreement with Genentech to provide us with the right to co-promote Tarceva™ in the United States and 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 continues until the date on which neither we nor Genentech is 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. Since January 8, 2003, Genentech has had the right to terminate the OSI/Genentech collaboration agreement with six months' prior written notice. The provisions of the amendment allowing us to co-promote are also subject to termination by Genentech upon a material breach of the amendment by us which remains uncured or upon a pattern of nonmaterial breaches which remains 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, since July 31, 2003, Roche has had the right to terminate the agreement on a country-by-country basis with six months' prior written notice. Since July 31, 2003, we also have had the right to terminate the agreement on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

If we do not maintain a successful collaborative partnership with Genentech and Roche for the co-development and commercialization of Tarceva™, we may be forced to focus our efforts internally to commercialize Tarceva™. This would require greater financial resources and would result in us incurring greater expenses and may cause a delay in market penetration while we continue to build our own commercial operation or seek alternative collaborative partners.

If any of our current or future marketed products, including Novantrone® or Tarceva™, were to become the subject of problems related to their efficacy, safety, or otherwise, or if new, more effective treatments were to be introduced, our revenues from such marketed products could decrease.

If Novantrone® or Tarceva™ or any of our other current or future marketed products become the subject of problems, including those related to, among others:

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

our revenues from such marketed products could decrease. For example, efficacy or safety concerns may arise, whether or not justified, that could lead to the recall or withdrawal of such marketed products. In the event of a recall or withdrawal of a product such as Novantrone® or Tarceva™, our revenues would significantly decline.

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

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

The Medicare Prescription Drug Improvement and Modernization Act of 2003 materially changes the Medicare reimbursement guidelines for intravenous and oral oncology products. Such changes may negatively impact our revenues for Novantrone®.

After a Congressional debate regarding the formula by which Medicare reimbursement for intravenous oncology products is rendered to oncologists, the levels of reimbursement to oncologists for intravenous oncology products like Novantrone® were lowered, effective January 2004. Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare benefits will be primarily provided through private entities that will attempt to negotiate price concessions from pharmaceutical manufacturers, which may increase pressure to lower prescription drug prices. The Act also includes other cost containment measures for Medicare in the event Medicare cost increases exceed a certain level, which may also impose limitations on prescription drug prices. These changes in Medicare reimbursement could have a negative impact on our revenues derived from sales of Novantrone®.

If Serono S.A. does not fulfill its obligations for manufacturing and supplying Novantrone®, we may not be able to continue the marketing and distribution of the product which could cause our revenues to decrease.

Serono is responsible for the manufacture and supply of Novantrone®. Under our agreement with Serono, we do not have the obligation nor the right to manufacture Novantrone®. These obligations and rights are held solely by Serono. If Serono is delayed in or restricted from supplying the product, we would be directly affected in that any such delay or restriction would impede us from selling the product. Without the sales of Novantrone®, our revenues would decrease.

One aspect of our business strategy depends on our ability to identify and acquire product candidates and marketed products, which if not met, may prevent us from achieving expected future performance.

As part of our business strategy, we plan to identify and acquire product candidates and approved products for markets that we can reach through our commercial operations. We may not be able to acquire rights to additional products or product candidates on acceptable terms, if at all. If we fail to obtain, develop and successfully commercialize such additional product candidates and approved products, we may not achieve expectations of our future performance.

Although we have potential products that appear to be promising at early stages of development and in clinical trials, none of our potential products may reach the commercial market for a number of reasons.

Successful research and development of pharmaceutical products is high risk. Most products and development candidates fail to reach the market. Our success depends on the discovery of new drugs that we can commercialize. It is possible that our potential oncology products and diabetes and obesity products 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. We may find that certain products cannot be manufactured on a commercial scale basis 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 have a number of product candidates in various stages of development and do not expect them to be commercially available for a number of years, if at all. Our candidates that are in clinical

trials will still require significant research and development and regulatory approvals before we or our collaborative partners will be able to market them.

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 similar products and technologies that we are pursuing and 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. For example, changes in our understanding of the appropriate population of patients who should be treated with a targeted therapy like Tarceva™ may limit the drug's market potential if it is subsequently demonstrated that only certain subsets of patients should be treated with the targeted therapy.

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

In the course of product development, we engage CROs to conduct and manage clinical studies and to assist us in guiding our products through the FDA review and approval process. For example, we collaborated with the National Cancer Institute of Canada's Clinical Trial Group based at Queens University, Ontario, in connection with our Tarceva™ Phase III trials. Because we have engaged and intend to continue to engage CROs to help us obtain market approval for our drug candidates, many important aspects of this process have been and will be out of our direct control. If the CROs fail to perform their obligations under our agreements with them or fail to perform clinical trials in a satisfactory manner, we may face delays in completing our clinical trials, as well as commercialization of one or more drug candidates. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our clinical trials and the market approval of drug candidates.

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 testing, 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. A number of patients who participate in trials are already critically 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.

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

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

If we cannot successfully protect, exploit or enforce our intellectual property rights, our ability to develop and commercialize our products will be severely limited.

We hold numerous U.S. and foreign patents and have many pending applications for additional patents. We intend to continue to seek patent protection for or maintain as trade secrets all of the commercially promising product candidates that we have discovered, developed or acquired. Our success depends, in part, on our ability and our collaborative partners' ability to obtain and maintain patent protection for new product candidates, maintain trade secret protection and operate without infringing the 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 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. We can never be certain that we were first to develop the technology or that we were the first to file a patent application for the particular technology because most U.S. patent applications are confidential until a patent publishes or issues, and publications in the scientific or patent literature lag behind actual discoveries. If our pending patent applications are not approved for any reason or if we are unable to receive patent protection for additional proprietary technologies that we develop, the degree of future protection for our proprietary rights will remain uncertain. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents.

If other companies claim that we infringe on their intellectual property rights, we may be subject to costly and time-consuming litigation and delays in product introduction.

Our processes and potential products may conflict with patents that have been or may be granted to competitors, academic institutions or others. As the biotechnology and pharmaceutical industries expand and more patents are filed and issued, the risk increases that our product candidates may give rise to a declaration of interference by the U.S. Patent and Trademark Office, to administrative proceedings in foreign patent offices or 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 testing, manufacturing or marketing our products. If any of these actions were successful, 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. Any litigation, regardless of the outcome, could be extremely costly to us.

Our ability to raise capital in the future may be limited, which could adversely impact our growth.

Changes in our operating plans, increased expenses or other events described in this ''Risk Factors'' section may require us to seek additional debt or equity financing. Such financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could negatively impact our growth, financial condition and results of operations. Additional financing would most likely be dilutive to the holders of our common stock, and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

We have outstanding options, convertible debt, contingent value rights and warrants, the exercise, conversion or exchange of which could dilute stockholder value and cause our stock price to decline.

We grant stock options to our employees and other individuals as part of our overall compensation plan which, upon vesting, are exercisable for common stock. In addition, we have issued convertible debt which may be converted into common stock as well as contingent value rights which, upon the occurrence of certain events, may be exchanged for common stock. We are not able to estimate when, if ever, the stock options or convertible debt will be exercised or converted into common stock or when, if ever, shares will be issued in connection with the contingent value rights, but any such conversion or issuance would almost certainly dilute stockholder value.

Further, if some or all of such shares are registered and sold into the public market over a short time period, the price of our stock is likely to decline, as the market may not be able to absorb those shares at the prevailing market prices.

Our outstanding indebtedness increased substantially with the issuance of convertible senior subordinated notes in September 2003, or the 2023 Notes, and we may not be able to make the required payments on these notes when due and therefore may face liquidity problems.

As a result of the issuance of our 2023 Notes, our long-term debt represented by these notes was $150.0 million as of September 30, 2004. Our 2023 Notes significantly increased our interest expense and related debt service costs. Interest on these notes accrues at the rate of 3.25% per annum. This amounts to interest payments of $2.4 million due and payable on the 2023 Notes semi-annually on March 8 and September 8 of each year on the outstanding amount of the notes. Total interest payments of $92.6 million are scheduled to be paid between March 8, 2005 and September 8, 2023 on the 2023 Notes.

This long-term debt may:

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

We currently are not generating sufficient net cash flow to satisfy the annual debt service payments on the notes. If we are unable to satisfy our debt service requirements, we will default on our 2023 Notes, and we would face liquidity problems as a result.

If the market price of our common stock, similar to other biotechnology companies, remains highly volatile, then our stockholders may not be able to sell their stock when desired or at desirable prices.

When the stock prices of companies in the Nasdaq Biotechnology Index fall, our stock price will most likely fall as well. The stock price of biotechnology and pharmaceutical companies, including our stock price, has been volatile and may remain volatile for the foreseeable future. From October 1, 2001 through September 30, 2002, the range of our stock price was between $50.94 and $11.50, and the range of the Nasdaq Biotechnology Index was between 978.42 and 397.36. From October 1, 2002 through September 30, 2003, the range of our stock price was between $38.34 and $12.84, and the range of the Nasdaq Biotechnology Index was between 801.40 and 442.09. From October 1, 2003 through September 30, 2004, the range of our stock price was between $98.70 and $24.47, and the range of the Nasdaq Biotechnology Index was between 851.44 and 622.01. The following factors, among others, some of which are beyond our control, may also cause our stock price to decline:

- fluctuations in operating results;
- announcements of technological innovations or new therapeutic products by others;
- negative or neutral clinical trial results;
- developments concerning strategic alliance agreements;
- unanticipated clinical efficacy or safety results from our competitors' products;
- changes in government regulation, including pricing controls;
- delays with the FDA in the approval process for clinical candidates;
- developments in patent or other proprietary rights;
- public concern as to the safety of our products;
- future sales of substantial amounts of our common stock by existing stockholders; and
- comments by securities analysts and general market conditions.

In addition, historically, our stock price has been affected by technological, clinical and regulatory developments in the HER1/EGFR field, including developments with respect to the products of our main competitors in the field. It is possible that future developments concerning our competitors' products as well as further research and clinical results of targeted therapies in general and the HER1/EGFR field in particular could have an impact on our stock price due to Tarceva™'s classification as a targeted therapy in the HER1/EGFR field.

If our stock price falls, our stockholders may not be able to sell their stock when desired or at desirable prices.

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 by our stockholders to acquire additional shares of our common stock, and, in certain cases, the stock of the potential acquiror, at a bargain purchase 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. 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;
- 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 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 2. PROPERTIES

We currently lease three facilities in New York, one located at 58 South Service Road, Melville, New York, consisting of approximately 27,000 square feet, one located at One Bioscience Park Drive, Farmingdale, New York, consisting of approximately 53,000 square feet, and one located at 106 Charles Lindbergh Boulevard, Uniondale, New York, consisting of approximately 30,000 square feet. The Melville facility houses our principal executive, commercial, finance, legal and administrative offices. The Farmingdale facility houses our U.S. drug discovery and pre-clinical laboratories. In August 2003, we consolidated our employees from the Uniondale facility into the Farmingdale facility. We are currently in the process of attempting to either assign or sublease our rights under the lease agreement for the Uniondale facility.

We currently lease three facilities in Boulder, Colorado, one located at 2860 Wilderness Place, consisting of approximately 60,000 square feet, one located at 2900 Center Green Court South, consisting of approximately 10,000 square feet, and one located at 2970 Wilderness Place, consisting of approximately 26,000 square feet. The Boulder facilities house our clinical research, regulatory affairs and drug development personnel. The lease for the facility at 2900 Center Green Court South, expires in February 2005 and we do not expect to renew the lease.

In June 2003, in connection with our acquisition of Cell Pathways, Inc., we acquired a lease to a facility in Horsham, Pennsylvania, consisting of approximately 40,000 square feet. In May 2004, we subleased our rights under the lease agreement for this facility.

Our wholly-owned subsidiary, OSI Pharmaceuticals (UK) Limited, currently leases two facilities, one located at Windrush Court, Watlington Road, Oxford, England, consisting of approximately 88,000 square feet, and another located at Isis House, Watlington Road, Oxford, England, consisting of approximately 34,000 square feet. In August 2004, we announced a plan to consolidate our U.K. based oncology research and development activities into our New York locations. Following the consolidation, the only operations remaining at the Oxford facilities are those related to our international clinical trials group and our diabetes and obesity subsidiary, Prosidion Limited. We expect to vacate the facility at Isis House by January 2005 and attempt to assign or sublease our rights under the related lease agreement.

ITEM 3. LEGAL PROCEEDINGS

There are no material legal proceedings pending against us.

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 2004.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

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 October 1, 2002 through September 30, 2004 as reported on the NASDAQ National Market:

2004 FISCAL YEAR	HIGH	LOW
First Quarter	$34.19	$24.47
Second Quarter	43.26	29.41
Third Quarter	98.70	33.94
Fourth Quarter	70.41	50.71

2003 FISCAL YEAR	HIGH	LOW
First Quarter	$22.74	$14.04
Second Quarter	17.39	12.84
Third Quarter	37.30	13.05
Fourth Quarter	38.34	29.15

Holders and Dividends

As of December 1, 2004, there were approximately 3,641 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 September 30, 2004		
Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders(a)	4,353,868	$35.34	1,857,141(d)
Equity compensation plans not approved by security holders(b)	534,006(c)	$47.03	—
Total	4,887,874	$36.61	1,857,141

(a) Consists of five plans: 1989 Incentive and Non-Qualified Stock Option Plan, 1993 Incentive and Non-Qualified Stock Option Plan, 1997 Incentive and Non-Qualified Stock Option Plan, 1999 Incentive and Non-Qualified Stock Option Plan and the Amended and Restated Stock Incentive Plan.

(b) 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 represents the fair value of our stock at the date granted. The options vest one-third in a year from the date of grant and monthly thereafter for twenty-four months.

In connection with the acquisition of Cadus Corporation, 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 represents 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.

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

(d) Includes 776,428 shares reserved for issuance under the 1993 Employee Stock Purchase Plan, the 1995 Employee Stock Purchase Plan, the stock purchase plan for employees of OSI-UK and the Stock Purchase Plan for Non-Employee Directors (see notes 11(d) and 11(e) to the accompanying consolidated financial statements).

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

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth our selected consolidated financial data as of and for each of the years in the five-year period ended September 30, 2004. The information below should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this report.

	YEARS ENDED SEPTEMBER 30, (In thousands, except per share data)				
	2004(a)	2003(b)	2002(c)	2001(d)	2000(e)
Consolidated Statement of Operations Data:					
Revenues	$ 42,800	$ 32,369	$ 21,816	$ 26,022	$ 28,652
Expenses:					
Cost of product sales	8,985	157	—	—	—
Research and development	110,398	102,642	102,202	56,038	39,622
Acquired in-process research and development	32,785	31,451	130,200	—	—
Selling, general and Administrative	98,909	70,532	28,146	16,033	11,773
Impairment of intangible asset	24,599	—	—	—	—
Amortization of intangibles	18,606	9,300	1,255	742	870
Loss from operations	(251,482)	$(181,713)	$(239,987)	$(46,791)	$(23,613)
Other income (expense) — net	(8,889)	356	7,904	25,661	3,519
Gain on sale of diagnostic business	—	—	1,000	—	3,746
Gain on early retirement of convertible senior subordinated notes — net	—	—	12,604	—	—
Loss before cumulative effect of accounting change	$(260,371)	$(181,357)	$(218,479)	$(21,130)	$(16,348)
Cumulative effect of the change in accounting for the recognition of upfront fees	—	—	—	(2,625)	—
Net loss	$(260,371)	$(181,357)	$(218,479)	$(23,755)	$(16,348)
Basic and diluted net loss per common share:					
Loss before cumulative effect of change in accounting policy	$ (6.50)	$ (4.87)	$ (6.07)	$ (0.62)	$ (0.67)
Cumulative effect of change in accounting policy	—	—	—	$ (0.08)	—
Net loss	$ (6.50)	$ (4.87)	$ (6.07)	$ (0.70)	$ (0.67)
Weighted average number of shares of common stock outstanding	40,083	37,249	35,978	33,852	24,531

	AS OF SEPTEMBER 30, (In thousands)				
	2004(a)	2003(b)	2002(c)	2001(d)	2000(e)
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investment securities (unrestricted and restricted)	$257,229	$404,147	$476,277	$551,479	$85,065
Receivables	12,112	11,654	6,981	6,633	1,049
Working capital	228,223	379,598	445,596	533,761	80,467
Total assets	388,029	591,502	579,044	591,689	99,776
Long-term liabilities	186,574	338,592	169,774	14,387	3,082
Stockholders' equity	154,233	218,057	379,108	549,831	89,882

(a) The fiscal 2004 consolidated financial statements include the acquisition of certain assets from Probiodrug AG for approximately $36.4 million in cash; the impairment of the Gelclair® intangible asset of $24.6 million; the conversion of $160.0 million aggregate principle amount of convertible senior subordinated notes into 3.2 million shares of our common stock; the charge of $8.6 million relating to excess Gelclair® inventory; and the recognition of $3.0 million of Tarceva™-related milestone revenues. (See notes 1(b), 1(l),3(a),5(a), 8, and 10(b) to the accompanying consolidated financial statements.)

(b) The fiscal 2003 consolidated financial statements include the acquisition of the marketing and promotion rights to Novantrone® for approved oncology indications in the United States for approximately $45.0 million in cash; the acquisition of Cell Pathways, Inc. for approximately $55.0 million in common stock, contingent value rights and cash; the issuance of $150.0 million of convertible senior subordinated notes for net proceeds of approximately $145.1 million and the purchase of 503,800 shares of our common stock for $19.0 million. (See notes 2, 3(b) and 10(a) to the accompanying consolidated financial statements.)

(c) The fiscal 2002 consolidated financial statements include the acquisition of certain assets from Gilead Sciences, Inc. for approximately $175.7 million in cash and common stock; the receipt of $4.5 million from the phase-down of our collaboration with Anaderm Research Corporation, of which $1.8 million was recognized as revenue in accordance with SAB No. 101; the issuance of $200.0 million of convertible senior subordinated notes for net proceeds of approximately $192.9 million; and the early retirement of $40.0 million aggregate principal amount of convertible senior subordinated notes resulting in a net gain of approximately $12.6 million. (See notes 3(c), 5(b) and 10(b) to the accompanying consolidated financial statements.)

(d) The fiscal 2001 consolidated financial statements include a cumulative effect of the change in accounting principle of $2.6 million relating to the adoption of SAB No. 101; the acquisition of certain assets from British Biotech plc for $13.9 million; $25 million in upfront fees received upon the execution of collaboration agreements with Genentech, Inc. and Roche; net proceeds of approximately $404 million from a public offering of common stock in November 2000; the sale of newly-issued shares of common stock to Genentech and Roche for an aggregate purchase price of $35 million each; and a charge to operations of $5.1 million for the estimated cost of closing our Birmingham, England and Tarrytown, New York facilities. (See notes 5(a), 17(d) and 17(e) to the accompanying consolidated financial statements.)

(e) The fiscal 2000 consolidated financial statements include a $3.5 million technology access fee received upon the execution of a collaborative research and license agreement with Tanabe Seiyaku Co., Ltd.; non-cash compensation charges of approximately $6.8 million and deferred compensation of approximately $8.8 million associated with options issued to an employee and consultants; net proceeds of approximately $53 million from a private placement of common stock; a $3.7 million gain resulting from the sale of our diagnostics business, including the assets of our wholly-owned subsidiary, OSDI, Inc., to Bayer Corporation; and a charge to operations of $700,000 representing the cost of a license to use and practice certain of Cadus Corporation's technology and patents.

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

Overview

We are a leading biotechnology company primarily focused on the discovery, development and commercialization of high quality oncology products that both extend life and improve the quality-of-life for cancer patients worldwide. Our flagship product, Tarceva™ (erlotinib), is an oral, once-a-day, small molecule inhibitor of the epidermal growth factor receptor, or HER1/EGFR. Tarceva™ is the first EGFR inhibitor, and the first non-chemotherapy agent, to demonstrate a survival benefit in advanced non-small cell lung cancer, or NSCLC, and also in pancreatic cancer, two forms of cancer widely recognized as amongst the toughest treatment challenges facing oncologists. On November 18, 2004, after a review lasting only three and a half months, the U.S. Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for monotherapy Tarceva™ use in the treatment of all NSCLC patients who have failed prior chemotherapy. We, along with our partner Genentech, Inc. launched Tarceva™ on November 22, 2004, two business days following approval, shortly prior to which we and Genentech announced pricing for the drug in the United States. We intend to file a supplemental NDA, or sNDA, for the treatment of front-line pancreatic cancer patients (in combination with gemcitabine) in fiscal 2005. In addition, our partner, Roche, has completed a regulatory filing under the centralized process in the European Union, or EU, for Tarceva™ in NSCLC. We anticipate that Roche will gain approval for the drug in the second half of calendar 2005. Beyond Tarceva™, we have a balanced pipeline of oncology drug candidates that includes signal transduction inhibitors, apoptosis (also know as programmed cell death) inducers and a next-generation cytotoxic chemotherapy agent. We have established a core commercial organization, which includes approximately 50 sales representatives and managers covering the major territories in the United States. We market and promote Novantrone® (mitoxantrone concentrate for injection) for approved oncology indications in the United States, and we market and distribute Gelclair® in North America, a bioadherent oral gel for the relief of pain associated with oral mucositis, a frequent side-effect of chemotherapy. We also have a diabetes and obesity subsidiary, Prosidion Limited, which is based in the United Kingdom. Prosidion's lead clinical candidate, PSN9301, an inhibitor of dipeptidyl peptidase IV, or DP-IV, is in Phase II clinical trials for the treatment of type 2 diabetes. PSN9301 was acquired by Prosidion from Probiodrug AG, a German company, in a transaction which closed in July 2004. Behind PSN9301, Prosidion has an emerging pipeline of diabetes and obesity drug candidates.

Our objective going forward is to build upon Tarceva™'s significant market potential and to capitalize on the experienced management team and the comprehensive set of capabilities from discovery to commercialization that we have established over the last several years in order to create a premier biotechnology organization and drive value creation for our stockholders. To accomplish this, we intend to:

- maximize Tarceva™'s value by supporting an effective launch in the United States, a timely registration and effective launch in the EU and Japan and an effective product growth strategy;
- establish our position as a premier oncology franchise by advancing our pipeline, reinforcing our commercial presence, validating our research capabilities and actively pursuing in-licensing and acquisition opportunities; and
- diversify our business through continued investment in Prosidion to grow a second business unit focused on diabetes and obesity in order to help drive long-term growth.

Significant Events

Tarceva™

On November 18, 2004, we announced that the FDA approved our NDA for monotherapy Tarceva™ use in the treatment of all NSCLC patients who have failed at least one prior chemotherapy regimen. Tarceva™ met its primary endpoint of improving overall survival and its key secondary endpoints of progression-free survival and objective tumor response rate in a 731-patient randomized, double-blinded placebo controlled Phase III trial, or the BR.21 study. The study compared Tarceva™ to placebo in the treatment of patients with advanced NSCLC following the failure of first or second-line chemotherapy. The data demonstrates a 42% improvement in median survival and a 45% improvement in the one-year survival rate relative to placebo. The results revealed a survival benefit in essentially all subsets of patients examined, including males, smokers and patients with squamous cell carcinoma histology (subsets that, consistent with previous studies with EGFR inhibitors, had a relatively low rate of tumor response in our study), as well as females, non-smokers and patients with adenocarcinoma (subsets with higher rates of tumor response). We believe that these results are particularly noteworthy in that they demonstrate

a meaningful, broad-based clinical benefit in a very advanced population of lung cancer patients and that these results form the basis for our recent approval.

The safety profile observed in the BR.21 study was relatively benign compared to cytotoxic chemotherapy and was consistent with that seen in prior Tarceva™ studies with 75% of patients receiving Tarceva™ exhibiting rash versus 17% in the placebo group and 54% of patients receiving Tarceva™ experiencing diarrhea versus 18% for placebo. In this large placebo controlled study, severe pulmonary events, including potential cases of interstitial lung disease, were infrequent and generally equally distributed between the Tarceva™ and placebo arms. We believe that this combination of survival benefit with a relatively benign side-effect profile positions Tarceva™ as a potentially important treatment option for oncologists treating advanced NSCLC patients who have failed front-line chemotherapy.

In September 2004, we announced that Tarceva™ also met its primary endpoint of improving overall survival in a 569-patient randomized, double-blind placebo controlled Phase III trial in front-line pancreatic cancer patients with locally advanced or metastatic disease. The trial compared a combination of Tarceva™ and the chemotherapy agent gemcitabine with gemcitabine plus placebo. The data demonstrates a 23.5% improvement in overall survival (a hazard ratio of 0.81 and p-value of 0.025) for the Tarceva™ arm compared to the placebo arm. The results were noteworthy in that Tarceva™ was used at a lower dose (100mg) than was used in our BR.21 study for the majority of patients treated in the study and Tarceva™ was used in combination with a chemotherapy agent. We believe that the data demonstrates that Tarceva™ is likely to have broad utility beyond the initial lung cancer indication.

In connection with the further development and commercialization of Tarceva™, we recently entered into agreements with Genentech with respect to promotion, marketing and manufacturing responsibilities for Tarceva™ in the U.S. market. Genentech will have the lead responsibility for the marketing and promotion of Tarceva™ in the United States. However, we will co-promote the product in the field by providing at least 25% of the combined U.S. sales force. We also have responsibility for the manufacturing and supply of Tarceva™ in the United States, and we believe we have a supply chain in place with inventory on hand to support launch of the product. We, along with our supply chain of third-party providers, have sufficient inventory for the launch of the product. Tarceva™ is priced to wholesalers at $2,026 per 30-day supply of the 150mg tablets, and is also available in 100mg and 25mg tablet strengths. With the Iressa® price increase effective November 18, 2004 Tarceva™ is priced at less than a 20% premium to the competitor's product.

The successful execution of a strategy to expand Tarceva™ indications and grow the product post-launch is our clear priority. We intend to broaden the use of Tarceva™ to earlier stage lung cancer patients, both in the first-line and adjuvant settings. The first part of this strategy has been initiated with an ongoing randomized Phase II trial evaluating monotherapy Tarceva™ against chemotherapy in patients who have received no prior chemotherapy and have poor performance status.

Public Offering

On November 12, 2004, subsequent to the end of fiscal 2004, we concluded a public offering of 6.0 million shares of common stock at a price of $64.50 per share. Gross proceeds totaled $387.0 million with net proceeds of approximately $365.0 million after all related fees. In addition, on November 17, 2004, underwriters associated with this offering exercised their over-allotment option to purchase an additional 900,000 shares of our common stock at a price of $64.50 per share. Gross proceeds from the exercise of the over-allotment option totaled $58.1 million with net proceeds of approximately $54.9 million. We believe that the proceeds from this offering together with existing cash resources and projected cashflows from Tarceva™ will be sufficient to execute our strategy going forward.

Redemption of 4% Convertible Senior Subordinated Notes

On June 18, 2004, we exercised the redemption option for our 4% senior convertible subordinated notes due 2009 that we issued in February 2002 and called for the full redemption of the outstanding $160.0 million of the notes. As expected, all of the noteholders converted their notes into shares of our common stock prior to the redemption date of July 19, 2004. As a result of these conversions, in July 2004, we reduced our long-term debt by $160.0 million and issued 3.2 million shares of our common stock. We also paid the remaining portion of the guaranteed interest of $6.4 million to the noteholders. (See note 10(b) to the accompanying consolidated financial statements.)

Impairment of Intangible Asset

In October 2004, we announced that it will be necessary to record an impairment charge as of September 30, 2004 related to our intangible asset for the exclusive distribution rights to the marketed product, Gelclair®, in North America. We determined that an impairment charge of approximately $24.6 million, which represented the full unamortized balance of the Gelclair® intangible asset, was necessary as of September 30, 2004. The impairment charge resulted from both the recent discontinuance of discussions with a replacement dental partner and slower than originally expected sales growth in the oncology marketplace following the re-launch of the product in October 2003.

Prosidion's Asset Acquisition

We consider expansion into a second disease area to be an important part of our strategy for long-term value creation. To this end, on July 26, 2004, Prosidion acquired from Probiodrug, its Type 2 diabetes Phase II clinical candidate, PSN9301 (formerly P93/01), and its associated intellectual property estate. PSN9301 is an oral, small molecule inhibitor of DP-IV, which is recognized as an important target in diabetes. In addition to composition of matter claims for PSN9301, the acquired intellectual property estate includes issued U.S. method-of-use claims that have been non-exclusively licensed to Novartis Pharma AG and Merck & Co., Inc., among others, for milestones and royalties. Prosidion also anticipates initiating clinical trials for two diabetes candidates, PSN105 (a glucokinase activator) and PSN357 (a glycogen phosphorylase inhibitor), in the first half of calendar 2005. (See note 3(a) to the accompanying consolidated financial statements.)

Consolidation of Our Oncology Operations

On August 5, 2004, we announced to our employees a plan to consolidate our U.K. based oncology research and development activities into our New York locations by November 30, 2004. This decision was based on the need to prioritize the expansion of our commercial operation infrastructure and increase our level of investment in both translational research and our diabetes and obesity subsidiary, Prosidion. This consolidation primarily affects our Oxford facility where the consolidation has resulted in the layoff of 82 employees. Upon the consolidation, the only operations remaining at the Oxford facility are those related to our international clinical trials group and Prosidion. As a result of this decision, we recorded a charge of $5.7 million during the fourth quarter of fiscal 2004 related to termination benefits and the acceleration of depreciation on certain leasehold improvements at the Oxford facility. (See note 17(b) to the accompanying consolidated financial statements.)

Aptosyn®

On June 11, 2004, we announced that, as we had expected, the Phase III study of Aptosyn® (exislund) in combination with Taxotere® (docetaxal) did not meet its primary endpoint of improving overall survival in patients with advanced NSCLC. The trial also did not meet its secondary endpoints of improvement in one-year survival, progression-free survival and response rate. Survival in the Aptosyn® plus Taxotere® arm of the study was essentially indistinguishable from the Taxotere® plus placebo arm. Although the further development of Aptosyn® is unlikely, we believe that the more potent follow-on molecule, OSI-461, warrants continued development. We acquired both Aptosyn® and OSI-461 in June 2003 as part of the acquisition of Cell Pathways, Inc.

Provision for Excess Gelclair® Inventory

During fiscal 2004, we recorded total charges of $8.6 million relating to obsolete Gelclair® inventory that we deemed in excess of forecasted demand. This excess inventory relates to the substantial inventory obtained from the Cell Pathways acquisition, the required purchase commitments that we assumed in the Cell Pathways acquisition and the current low demand for the product. We purchased an additional $2.0 million of inventory during the fourth quarter of fiscal 2004 based upon the required purchase commitments. We are required to purchase another $1.0 million of inventory by December 31, 2004 and will be required to purchase an additional $5.0 million in 2005. As of September 30, 2004, we have accrued a charge of $4.9 million related to the remaining 2004 and 2005 purchase commitments that we have determined to be in excess of forecasted demand. In addition, we recorded a charge of $3.7 million for excess inventory on hand during fiscal 2004. In late October 2004, we exercised our right to terminate our agreement with Helsinn Healthcare S.A., the supplier of the product. Under the terms of the agreement, Helsinn has the option to purchase any and all of our inventory at cost plus 5% and if Helsinn does not elect to purchase our inventory, we are permitted to continue to sell such inventory. We are currently negotiating a new agreement with Helsinn.

Financial Expectations For Fiscal 2005

In terms of fiscal 2005 guidance, we are not currently providing Tarceva™ specific revenue guidance as per our agreement with Genentech. Tarceva™ was launched in late November and therefore we will only have ten months of sales for our fiscal 2005. In order to maximize Tarceva™'s value with an effective launch and product growth strategy in the United States, we, along with our partner, Genentech, expect to incur significant costs related to the launch of Tarceva™. As a result of the significant investment required with a product launch, we believe that our share of the co-promotion split from the sale of Tarceva™ in the United States may not be profitable in the near term.

We currently estimate that our total fiscal 2005 sales commissions and Gelclair® product sales will be between $33 million and $35 million. In terms of operating expenses, we expect our selling, general and administrative expenses to decrease and be in the range of $80 million to $90 million, primarily due to our share of the fiscal 2005 commercial costs associated with Tarceva™ that are expected to be offset against Tarceva™-derived revenue in the co-promotion split. We expect to maintain our current level of R&D between $110 million to $120 million. We expect that amortization expense will decrease to approximately $15.0 million as a result of the impairment of the Gelclair® asset in the fourth quarter of fiscal 2004. We expect total operating expenses to be approximately $220 million in fiscal 2005. Further we expect interest expense to decrease to approximately $5.0 million as a result of the conversion in July 2004 of the 4% senior subordinated convertible notes.

Actual results could differ materially and will depend on, among other things, the continuing growth of our currently marketed products; developments with competitive products; the timing and scope of regulatory approvals and the success of our new product launches; foreign exchange rates; possible regulatory actions; and the impact of state, federal, and foreign government pricing and reimbursement measures. This guidance excludes material unusual items and in-process research and development charges that we may report. We currently expect to record a charge in either the first or second quarter of fiscal 2005 for rental obligations relating to the portion of our U.K. facilities that we will vacate as a result of our decision to consolidate our U.K. based oncology research and development activities into our New York facilities. We are currently not aware of any other material unusual charges that will occur in fiscal 2005. Except for our ongoing obligations to disclose material information under the federal securities laws, we undertake no duty to update these forward-looking statements.

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

Sales commissions from Novantrone® on net oncology sales are recognized in the period the sales occur based on the estimated split between oncology sales and multiple sclerosis sales, as determined on a quarterly basis by an external third party. The split between oncology and multiple sclerosis sales is subject to further adjustment based on the parties final review in the subsequent quarter. Based on past experience, we do not believe these adjustments, if any, will be significant to the consolidated financial statements.

Given the limited sales history of Gelclair®, we at this time defer the recognition of revenue on product shipments of Gelclair® to wholesale customers until such time as the product is sold from the wholesale customer to the retail and non-retail outlets. For each reporting period, we monitor shipments from wholesale customers to pharmacies and hospitals' and wholesale customers' reorder history based on data from an external third party.

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 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 00-21, ''Revenue Arrangements with Multiple Deliverables'' for multiple element revenue arrangements entered into or materially amended after June 30, 2003. Our most significant application of these policies, to date, is the $25.0 million in upfront fees received from Genentech and Roche in January 2001, which were originally being recognized evenly over the expected three-year term of our required research and development efforts under the terms of the agreement. A change in the expected term impacts the period over which the remaining deferred revenue is recognized. In the fourth quarter of fiscal 2002, the expected term was changed from three years to four years to reflect the revised estimated timing of our research and development commitment for Tarceva™ under the alliance. The revision was a result of a review of the research data available, developments in the HER1/EGFR targeted therapy market and the involved parties' revised projections for the clinical development plan. Further, as a result of the amendment to the OSI/Genentech agreement in June 2004, the remaining unearned upfront fee from Genentech of approximately $1.8 million will be recognized in accordance with EITF 00-21, as discussed below. As the Roche agreement was not modified or amended subsequent to its original execution, the unearned upfront fee from Roche continues to be recognized over the revised term and will be fully recognized as of December 31, 2004.

In connection with our collaboration with Genentech, Genentech will recognize all U.S. sales of Tarceva™. We will recognize revenues and losses from our alliance with Genentech, which will consist of our share of the pretax profits (loss) generated from the sales of Tarceva™ in the United States. We also will recognize manufacturing revenue from the sale of inventory to Genentech for commercial sales of Tarceva™ in the United States and partial reimbursement from Genentech of our Tarceva™-related commercial expenses. We will receive royalties on sales of Tarceva™ outside of the United States by Roche and up to $92 million in non-refundable milestone payments from Genentech and Roche upon the achievement of certain milestones relating to regulatory submissions and approval, of which $10 million has been received. In the fourth quarter of fiscal 2004, we recognized $3.0 million in milestone revenues from our partner Roche based upon the EMEA's notice of acceptance for filing and review of our NDA for the use of Tarceva™ as a monotherapy for the treatment of patients with advanced NSCLC patients who have failed at least one chemotherapy regimen. Milestone payments from Roche are accounted for such that revenue related to each payment be recognized over the entire contract performance period, but not prior to the removal of the contingencies for each milestone. Once a contingency is removed and the customer is obligated to make a payment, the costs of the effort that has been incurred to date is divided by the total expected research and development costs and revenue is recognized for that milestone to the extent of the ratio of performance to date, less revenue previously recognized.

In the fourth quarter of fiscal 2004, we also received a $7.0 million milestone payment from Genentech based upon the FDA's notice of acceptance for filing and review of our NDA for the use of Tarceva™ as a monotherapy for the treatment of NSCLC patients who have failed at least one chemotherapy regimen. As a result of the amendment to the OSI/Genentech agreement in June 2004, we were required to account for the Genentech milestone received and the remaining unearned upfront fee of approximately $1.8 million, in accordance with EITF 00-21. Milestones received from Genentech and the remaining unearned upfront fee will be recognized over the term of the Manufacturing and Supply Agreement between Genentech and us. This accounting resulted from the inability to determine the fair value of the undelivered items in the arrangement as required by EITF 00-21. As a result, the milestones are attributed to the last item delivered under the Manufacturing and Supply Agreement. We will recognize such deferred revenue over the term of the Manufacturing and Supply Agreement based on the lesser of the ratio of units sold by Genentech to total expected units or the cumulative straight-line basis. This estimate of expected unit sales will be adjusted periodically and whenever events or changes in circumstances indicate that there could be a significant change in such estimate.

Inventory

Our current inventory consists solely of Gelclair® inventory and is stated at the lower of cost or market value, and our inventory costs are determined by the first-in, first-out method. We analyze our inventory levels quarterly and write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements. Expired inventory is disposed of and the related costs are written off. Provisions for excess or expired inventory are primarily based on our estimates of forecasted sales levels. During the quarter ended March 31, 2004, we recorded a provision of $2.0 million for obsolete inventory that we considered to be in excess of forecasted future demand based on the expiration date of the product on hand. During the fourth quarter of fiscal 2004, we recorded an additional provision of $6.6 million in relation to inventory on-hand and 2004 and 2005 purchase commitments with Helsinn that we deemed in excess of forecasted demand, based on the expiration date of the product. This additional provision related to $1.7 million of inventory on hand and $4.9 million of purchase commitments. This excess inventory relates to the inventory

obtained from Cell Pathways and the required purchase commitments that we assumed in the Cell Pathways acquisition and the current low demand for the product. If actual market conditions are less favorable than those projected by us, additional inventory write-downs may be required.

To date, all costs associated with the manufacturing of Tarceva™ have been included in research and development expenses when incurred. Effective November 18, 2004, the date on which we received approval from the FDA for Tarceva™, we began to capitalize in inventory the cost of manufacturing Tarceva™ for commercial sale and will expense such cost as cost of goods sold at the time of sale. However, as we sell existing inventory that was previously expensed, we will reflect product sales with no corresponding cost of goods sold for a period of time. Although it is currently impossible to project demand for Tarceva™ due to lack of historical experience, we believe we have sufficient inventory to supply our partner, Genentech, with the product for a significant period. As we began to package our bulk inventory, we capitalized the cost of packaging and labeling such inventory. Therefore, we anticipate that our cost of sales of Tarceva™ to our partner, Genentech, will fluctuate in fiscal 2005 from quarter to quarter.

Accruals for Clinical Research Organization and Clinical Site Costs

We make estimates of costs incurred to date but not yet invoiced in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period.

Goodwill and Other Long-Lived Assets

SFAS No. 142, ''Goodwill and Other Intangible Assets,'' requires that goodwill and certain other intangibles with indefinite useful lives are not amortized into results of operations but instead are reviewed for impairment at least annually and written down, and charged to results of operations in periods in which the recorded value of goodwill and certain other intangibles is more than their implied fair value. We completed our annual impairment review of goodwill during the first quarter of fiscal 2004 and determined that no impairment charge was required.

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

Our judgments regarding the existence of impairment indicators are based on historical and projected future operating results, changes in the manner of our use of the acquired assets or our overall business strategy, and market and economic trends. Our two most significant intangible assets are our rights to Novantrone® and Gelclair®, and therefore, we continually monitor sales activity and market and regulatory conditions for these products for the existence of any impairment indicators. In October 2004, we determined that it was necessary to record an impairment charge as of September 30, 2004 related to our intangible asset for exclusive distribution rights to the marketed product, Gelclair®, in North America. The impairment charge resulted from both the recent discontinuance of discussions with a replacement dental partner and slower than originally expected sales growth in the oncology marketplace following the re-launch of the product in October 2003. In accordance with SFAS No. 144, these events indicated that the carrying value of the Gelclair® intangible should be tested for recoverability. The revised forecast indicated a period of continuing losses associated with the sales and distribution of Gelclair®. In performing such recoverability test we determined that the total of the expected future undiscounted cash flows directly related to the Gelclair® asset was less than the carrying value of the Gelclair® asset. As a result, an impairment charge was required. The amount of the impairment charge represents the difference between the fair value of the intangible asset and its associated carrying value. We calculated the fair value of the intangible asset using discounted cash flows. The discounted cash flows calculation was made utilizing various assumptions and estimates regarding future revenues and expenses, cash flow and discount rates. Based on these calculations, we determined that an impairment charge of $24.6 million, which represented the full unamortized balance of the Gelclair® intangible asset, was necessary as of September 30, 2004. 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.

Comparison of Fiscal 2004 and Fiscal 2003

Results of Operations

Our fiscal 2004 net loss of $260.4 million increased $79.0 million compared to our fiscal 2003 net loss of $181.4 million. The fiscal 2004 net loss included an in-process R&D charge of $32.8 million in connection with the acquisition of certain assets of Probiodrug by Prosidion, a charge of $24.6 million related to the impairment of the Gelclair® intangible asset and a charge of $8.6 million for excess inventory. The fiscal 2003 net loss included an in-process R&D charge of $31.5 million in connection with the acquisition of Cell Pathways.

Revenues

	Year Ended September 30, (In thousands)		
	2004	2003	$ Change
Sales commissions and product sales	$35,525	$16,726	$18,799
License, milestone and other revenues	7,275	6,088	1,187
Collaborative revenues	—	9,555	(9,555)
Total revenues	$42,800	$32,369	$10,431

Revenues for fiscal 2004 were primarily comprised of sales commissions as compared to sales commissions and collaborative revenues for fiscal 2003. This shift reflects our transition from a business centered on funded collaborative programs to one of generating our own product revenues in conjunction with the launch of Tarceva™.

Sales Commissions and Product Sales

We began recording Novantrone® sales commissions upon the execution of our Co-Promotion Agreement with an affiliate of Serono, S.A. in March 2003. Sales commissions for fiscal 2004 of $34.3 million were $18.0 million higher than the fiscal 2003 sales commissions of $16.3 million. The increase was primarily due to a full 12 months of sales commissions in fiscal 2004 compared to six and a half months of sales commissions in fiscal 2003. The increase was also due in part to net oncology sales exceeding a contractual threshold limit in both the first and fourth quarters of fiscal 2004, thus resulting in higher effective commissions. The commission rate will revert back to the base commission rate effective with the new calendar year.

We began recording Gelclair® product sales upon the close of our acquisition of Cell Pathways in June 2003. Net product sales for fiscal 2004 were $1.2 million compared to $437,000 for fiscal 2003. The increase was due to a full 12 months of sales in fiscal 2004 compared to three and a half months of sales in fiscal 2003. We previously had a marketing agreement with John O. Butler Company, under which Butler marketed Gelclair® to the dental market. In April 2004, we agreed with Butler to terminate this agreement. In late October 2004, we exercised our right to terminate our distribution agreement with Helsinn upon 90 days notice. Under the terms of the agreement, Helsinn has the option to purchase any and all of our inventory at cost plus 5% following termination and if Helsinn does not elect to purchase our inventory, we are permitted to continue to sell such inventory. We are currently negotiating a new agreement with Helsinn.

License, Milestone and Other Revenues

License revenues consist principally of the recognition of the $25.0 million upfront fees from Genentech and Roche over the expected term of the collaboration. We recognized $4.0 million and $5.0 million in license revenue in fiscal 2004 and 2003, respectively, relating to these upfront fees. License fees in fiscal 2003 also included recognition of the remaining $875,000 of the $3.5 million upfront fee received from Tanabe Seiyaku Co., Ltd. relating to the research collaboration that expired on October 1, 2003.

In the fourth quarter of fiscal 2004, we recognized $3.0 million in milestone revenues from our partner Roche based upon the EMEA's notice of acceptance for filing and review of our NDA for the use of Tarceva™ as a monotherapy for the treatment of patients with advanced NSCLC patients who have failed at least one chemotherapy regimen. Milestone payments from Roche are accounted for such that revenue related to each payment be recognized over the entire contract performance period, but not prior to the removal of the contingencies for each milestone. Once a contingency is removed and the customer is obligated to make a payment, the costs of the effort that has been incurred to date is divided by the total expected research and development costs and revenue

is recognized for that milestone to the extent of the ratio of performance to date, less revenue previously recognized.

In the fourth quarter of fiscal 2004, we also received a $7.0 million milestone payment from Genentech based upon the FDA's notice of acceptance for filing and review of our NDA for the use of Tarceva™ as a monotherapy for the treatment of NSCLC patients who have failed at least one chemotherapy regimen. As a result of the amendment to the OSI/Genentech agreement in June 2004, we were required to account for the Genentech milestone received and the remaining unearned upfront fee of approximately $1.8 million, in accordance with EITF 00-21, Revenue Arrangements with Multiple Deliverables. Milestones received from Genentech and the remaining unearned upfront fee will be recognized over the term of the Manufacturing and Supply Agreement between Genentech and us. This accounting resulted from the inability to determine the fair value of the undelivered items in the arrangement as required by EITF 00-21. As a result, the milestones are attributed to the last item delivered under the Manufacturing and Supply Agreement. We will recognize such deferred revenue over the term of the Manufacturing and Supply Agreement based on the lesser of the ratio of units sold by Genentech to total expected units or the cumulative straight-line basis. This estimate of expected unit sales will be adjusted periodically and whenever events or changes in circumstances indicate that there could be a significant change in such estimate. Additional milestone payments will be paid by Genentech and Roche upon registration of Tarceva™ in the United States and the European Union, respectively, and upon successful filing and registration of Tarceva™ in Japan. Further milestones are also due upon the successful filing and approval of Tarceva™ in a second oncology indication and upon the approval of the first two adjuvant oncology indications in the United States, European Union and Japan.

Collaborative Revenues

Collaborative program revenues represent funding arrangements for research and development in the field of biotechnology and are recognized when earned in accordance with the terms of the contracts and the related development activities undertaken. There were no collaborative program revenues in fiscal 2004 due to the completion of our remaining collaborations with Anaderm Research Corporation in March 2003 and Tanabe in October 2003.

Expenses

	Year Ended September 30, (In thousands)		
	2004	2003	$ Change
Cost of product sales	$ 8,985	$ 157	$ 8,828
Research and development	110,398	102,642	7,756
Acquired in-process R&D	32,785	31,451	1,334
Selling, general and administrative	98,909	70,532	28,377
Impairment of intangible asset	24,599	—	24,599
Amortization of intangibles	18,606	9,300	9,306
	$294,282	$214,082	$80,200

Cost of Product Sales

Cost of product sales relate to sales of Gelclair® and also includes a provision for obsolete inventory of $8.6 million. During the fourth quarter of fiscal 2004, we purchased $2.0 million of Gelclair® inventory based upon the purchase commitments for Gelclair® under our agreement with Helsinn that we assumed in the Cell Pathways acquisition. We are obligated to purchase an additional $1.0 million of inventory by December 31, 2004 and an additional $5.0 million in 2005. During the second quarter of fiscal 2004, we recorded a provision of $2.0 million for obsolete inventory that we considered to be in excess of forecasted future demand based on the expiration date of the product on hand. During the fourth quarter of fiscal 2004, we recorded an additional provision of $6.6 million in relation to inventory on-hand and 2004 and 2005 purchase commitments with Helsinn that we deemed in forecasted demand, based on the expiration date of the product. This additional provision related to $1.7 million of inventory on hand and $4.9 million of purchase commitments. This excess inventory relates to the inventory obtained from the Cell Pathways acquisition and the required purchase commitments that we assumed in the Cell Pathways acquisition and the current low demand for the product. Excluding the provision for obsolete inventory,

cost of product sales were $420,000 and $157,000 in fiscal 2004 and 2003, respectively, or approximately one-third of product sales.

Research & Development

On November 18, 2004, our flagship product, Tarceva™, was approved by the FDA as a monotherapy for the treatment of all NSCLC patients who have failed at least one prior chemotherapy regimen and has successfully completed a Phase III trial for pancreatic cancer. Tarceva™ is also the subject of an extensive collaborative clinical program encompassing over 100 additional clinical trials. We also have additional drug candidates in various stages of clinical development. OSI-930 is a tyrosine kinase inhibitor that acts as a potent co-inhibitor of the receptor tyrosine kinases c-kit and VEGFR, and is designed to target both cancer cell proliferation and blood vessel growth (angiogenesis) in selected tumors. OSI-930 is currently in pre-clinical development and we anticipate initiating a clinical program in the first half of calendar 2005. OSI-7904L is a liposomal formulation of TSI, which was licensed from GlaxoSmithKline plc and acquired by us as part of the acquisition of Gilead's Sciences, Inc.'s oncology business. We are developing OSI-7904L primarily for gastrointestinal tract cancers. The SAANDs platform that we acquired from Cell Pathways in June 2003 consisted of two clinical candidates, Aptosyn® and OSI-461. The Phase III study of Aptosyn® (exislund) in combination with Taxotere®, did not meet its primary endpoint of improving overall survival in patients with advanced NSCLC. The trial also did not meet its secondary endpoints of improvement in one-year survival, progression-free survival and response rate. Although we have halted the further development of Aptosyn®, we believe that the more potent follow-on molecule, OSI-461, warrants continued development. In February 2004, we expanded an ongoing Phase I dose escalating and pharmacokinetic trial of OSI-461 in patients with advanced solid tumors. In July 2002, Cell Pathways commenced a Phase II trial of OSI-461 in the non-cancerous area of inflammatory bowel disease at doses we consider to be sub-optimal. We recently received inconclusive results from this study, which we need to further analyze in order to determine how best to proceed with this compound in this indication. The lead clinical candidate of our diabetes and obesity subsidiary, Prosidion is PSN9301, an inhibitor of DP-IV, which is in Phase II clinical trials for the treatment of type 2 diabetes. PSN9301 was acquired by Prosidion from Probiodrug in a transaction which closed in July 2004. Behind PSN9301, Prosidion has an emerging pipeline of diabetes and obesity drug candidates. Three other oncology candidates (CP-547,632, CP-724,714 and CP-868,596) for which we are entitled to royalties, are gene-targeted therapies currently being developed by Pfizer Inc. and require no further research and development investment by us.

We consider the active management and development of our clinical pipeline crucial to the long-term approval process. We manage our overall research, development and in-licensing efforts in a manner designed to generate a constant flow of clinical candidates into development to offset both the advancement of products to the market and the anticipated attrition rate of drug candidates that fail in clinical trials or are terminated for business reasons. The table below summarizes the typical duration of each phase of clinical development and the typical cumulative probabilities of success for approval of drug candidates entering clinical development. The numbers are based upon industry survey data for small molecule drugs:

Development Phase	Estimated Completion Time	Estimated Cumulative Probability of Success
Phase I	1-2 Years	20%
Phase II	1-2 Years	30%
Phase III	2-3 Years	65%
Registration	6-15 months	85%

The Tufts Center for the Study of Drug Development estimates that the average cost to develop a new prescription drug is $802 million. The actual probability of success for each drug candidate and clinical program will be impacted by a variety of factors, including the quality of the molecule, the validity of the target and disease indication, early clinical data, investment in the program, competition and commercial viability. Because we manage our pipeline in a dynamic manner, it is difficult to give accurate guidance on the anticipated proportion of our research and development investments assigned to any one program prior to the Phase III stage of development, or to the future cash inflows from these programs. For fiscal 2004, we invested a total of $52.4 million in research and $58.0 million in pre-clinical and clinical development. For fiscal 2003, we invested a total of $46.5 million in research and $56.1 million in pre-clinical and clinical development. We consider this level of investment suitable to sustain one major late stage clinical program and two to four earlier stage clinical programs at any time and we manage our overall research and development investments toward this level of activity.

The marginal increase in the research and development expense for fiscal 2004 was primarily due to costs associated with the clinical development of our pipeline, including increases in OSI-7904L, OSI-930, OSI-461 and Aptosyn® of $12.1 million, as well as an increased investment in Prosidion of $5.6 million. Prosidion's research and development expenses for fiscal 2004 were $12.7 million compared to expenses of $7.1 million in fiscal 2003. Included in Prosidion's research and development expenses in fiscal 2004 is a $2.0 million termination fee (paid in cash and Prosidion stock) to Tanabe relating to a termination agreement with Tanabe, whereby Prosidion obtained the rights to certain patents developed under the collaboration. Tanabe retained the rights to develop and commercialize, in certain Asian territories, compounds covered by such patents. Prosidion is also required to make payments to Tanabe upon the achievement of certain milestones. Also included in research and development expense for fiscal 2004 is $3.0 million relating to termination benefits paid to employees and $1.7 million relating to the acceleration of certain leasehold improvements, in connection with our decision to consolidate our U.K.-based oncology research and development activities into our New York locations. These increases to research and development expense in fiscal 2004 were offset by a decrease in the development expense of Tarceva™ of $8.2 million due to the completion of the Phase III trials in NSCLC and pancreatic cancer, as well as decreased investment in the OSI-211 and OSI-7836 programs of approximately $6.1 million. In fiscal 2004, we decided to halt the further development of OSI-211, since we were unable to differentiate the program from a current competitor's product, and OSI-7836, since we were unable to overcome certain toxicity issues.

The significant perceived market potential for Tarceva™ resulted in the OSI/Genentech/Roche alliance committing to a large and comprehensive global development plan for the candidate. The global development plan has included major Phase III clinical trials in lung and pancreatic cancers and a large number of earlier stage trials in a variety of disease settings. The alliance partners have initially committed to invest a combined $300 million in the global development plan to be shared equally by the three parties. We have made additional research and development investments outside of the global development plan with the consent of the other parties. As of September 30, 2004, we have invested in excess of $100 million in the development of Tarceva™ since the return of the full rights to the product from Pfizer in June 2000, representing our share of the costs incurred to date in the tripartite global development plan and additional investments outside the plan. Our research and development expenses for Tarceva™ incurred for fiscal 2004 were $27.7 million compared to $35.9 million for fiscal 2003. To date we have spent approximately 90% of our commitment under the plan; we expect to continue our investment in Tarceva™, along with our partners, to support its continued development and commercial growth beyond the original commitment.

Acquired In-Process Research and Development

In connection with the acquisition of certain assets from Probiodrug by Prosidion in July 2004, we recorded an in-process R&D charge of $32.8 million in fiscal 2004, representing the estimated fair value of the acquired in-process technology that had not yet reached technological feasibility and had no alternative future use (see note 3(a) to the accompanying consolidated financial statements). The in-process R&D charge was assigned to the development project, PSN9301, an oral, small molecule inhibitor of DP-IV, which is recognized as an important target in diabetes.

In connection with the acquisition of Cell Pathways in June 2003, we recorded an in-process R&D charge of $31.5 million during fiscal 2003, representing the estimated fair value of the acquired in-process technology that had not yet reached technological feasibility and had no alternative future use (see note 3(b) to the accompanying consolidated financial statements). The in-process R&D charge was assigned to the two development projects and related technology platform and patent estate, Aptosyn® ($3.7 million) and OSI-461 ($27.8 million) based on their value on the date of the acquisition.

Selling, General and Administrative

The increase in selling, general and administrative expenses of $28.4 million during fiscal 2004 reflects increased investment in our commercial infrastructure as we prepared for the launch of our flagship product, Tarceva™, as well as our continued investment in supporting our other commercial and pipeline programs. For fiscal 2004, our commercial operation expenses increased approximately $17.9 million compared to fiscal 2003. The most significant component of our investment has been commercialization and marketing costs relating to Tarceva™ which are shared with Genentech in accordance with the terms of our collaboration. The increase in commercial cost was also due to additional management and personnel relating to the establishment of commercial operations to support Tarceva™, Gelclair® and Novantrone®, as well as an additional two quarters of maintenance fees paid to Serono relating to Novantrone®. Also included in selling, general and administrative expenses for fiscal 2004 were exit costs of $4.8 million relating to remaining rental obligations for our Horsham, Pennsylvania and Uniondale,

New York facilities, termination benefits relating to the consolidation of our U.K.-based oncology research and development activities and the acceleration of depreciation of certain equipment and leasehold improvements at our Oxford and Uniondale facilities. Included in selling, general and administrative expenses for fiscal 2003 were fees paid to Serono for transition services provided by them after our acquisition of the Novatrone® rights, fees paid to Celgene Corporation in connection with our recovery of the full rights to market and distribute Gelclair™ in North America, and subcontracting expenses related to our transitional arrangement with a contract sales organization as we were building our commercial infrastructure. Our sales and marketing infrastructure is currently comprised of approximately 80 sales, marketing, medical affairs, commercial planning and support personnel, which includes approximately 50 sales representative and managers covering the major territories in the United States.

Impairment of Intangible Asset

In connection with our acquisition of Cell Pathways, we assumed the exclusive rights to market and distribute Gelclair® in North America. We recorded an identifiable intangible asset of $29.0 million which was being amortized over eight and a half years, the remaining term of the agreement. We assess the potential impairment of our long-lived assets, under the provisions of SFAS No. 144. In performing such recoverability test we determined that the total of the expected future undiscounted cash flows directly related to the Gelclair® asset was less than the carrying value of the Gelclair® asset. As a result an impairment charge was required. The amount of the impairment charge represents the difference between the fair value of the intangible asset and its associated carrying value. We calculated the fair value of the intangible asset using discounted cash flows. The discounted cash flows calculation was made utilizing various assumptions and estimates regarding future revenues and expenses, cash flow and discount rates. Based on these calculations, we determined that an impairment charge of $24.6 million, which represented the full unamortized balance of the Gelclair® intangible asset, was necessary as of September 30, 2004. The impairment charge is non-cash and will not result in future cash expenditures. The impairment charge resulted from both the recent discontinuance of discussions with a replacement dental partner, and slower than originally expected sales growth in the oncology marketplace following the re-launch of the product in October 2003.

Amortization of Intangibles

The increase of $9.3 million is primarily related to amortization expense related to our rights to Novantrone® acquired in March 2003 and to Gelclair® acquired in June 2003. As noted above, in the fourth quarter of fiscal 2004, we recorded an impairment charge for the remaining carrying value of the Gelclair® rights as of September 30, 2004. As a result of the impairment charge, amortization expense will decrease to approximately $15.0 million in fiscal 2005.

Other Income and Expense

	Year Ended September 30, (In thousands)		
	2004	2003	$ Change
Investment income — net	$ 5,259	$ 7,808	$(2,549)
Interest expense	(13,436)	(6,715)	(6,721)
Other expenses — net	(712)	(737)	25
Total other income (expenses)	$ (8,889)	$ 356	$(9,245)

The decrease in investment income in fiscal 2004 was primarily due to a decrease in the funds available for investment and a decrease in the average rate of return on our investments during the respective years. The increase in interest expense resulted from interest on the $150.0 million of 3.25% convertible senior subordinated notes that we issued in September 2003, as well as the guaranteed interest on the 4% convertible senior subordinated notes that were converted into common stock in July 2004. Under the terms of the 4% convertible senior subordinated notes, the note holders were guaranteed the payment of interest for the first three years through February 1, 2005. The note holders became fully entitled to the remainder of this guaranteed interest on June 18, 2004, the date we called the notes for redemption. As a result of the conversions, we issued 3.2 million shares of our common stock in July 2004 and paid the remaining portion of the guaranteed interest of $6.4 million. This resulted in an additional interest charge of $2.1 million in fiscal 2004 representing the portion of the guaranteed interest from October 1, 2004 to February 1, 2005. We expect interest expense to decrease to

approximately $5.0 million in fiscal 2005, as a result of the conversion of the 4% convertible senior subordinated notes. Included in other expenses-net for fiscal 2004 and 2003, were amortization of debt issuance costs of $1.7 million and $834,000, respectively, related to the convertible senior subordinated notes. The increase in the amortization of debt issuance costs related to the 3.25% convertible senior subordinated notes issued in September 2003. The debt issuance costs are being amortized over a period of five years, which represents the earliest date that we may redeem the notes. Upon the conversion of the 4% convertible senior subordinated notes, the unamortized balance of the debt issuance costs of $3.7 million was reclassified to additional paid in capital. Also included in other expenses-net for fiscal 2004 is minority interest in the net losses of Prosidion of $907,000. As of September 30, 2004, the minority interests represent approximately 3% ownership of Prosidion.

Comparison of Fiscal 2003 and Fiscal 2002

Results of Operations

Our fiscal 2003 net loss of $181.4 million decreased $37.1 million compared to our fiscal 2002 net loss of $218.5 million. The fiscal 2003 loss included an in-process R&D charge of $31.5 million in connection with the acquisition of Cell Pathways. The fiscal 2002 loss included an in-process R&D charge of $130.2 million in connection with the acquisition of Gilead's oncology assets.

Revenues

	Year Ended September 30, (In thousands)		
	2003	2002	$ Change
Sales commissions and product sales	$16,726	$ —	$16,726
License and other revenues	6,088	9,840	(3,752)
Collaborative revenues	9,555	11,976	(2,421)
Total revenues	$32,369	$21,816	$10,553

Sales Commissions and Product Sales

On March 11, 2003, we began recording Novantrone® sales commissions, upon the execution of our Co-Promotion Agreement with an affiliate of Serono. Total sales commissions for fiscal 2003 were $16.3 million. We launched our sales efforts for Novantrone® during the third quarter of fiscal 2003. We began recognizing Gelclair® product sales on June 12, 2003, upon the closing of our acquisition of Cell Pathways. Total product sales for the period June 12, 2003 to September 30, 2003 were $437,000. We launched our sales effort for this product in October 2003.

License and Other Revenues

The decrease in license and other revenues in fiscal 2003 was primarily due to the decrease in the amount of revenue recognized relating to the $25.0 million upfront fees received from Genentech and Roche in January 2001 (see note 5(a) to the accompanying consolidated financial statements). In accordance with the provisions of SAB No. 101, we were recognizing the $25.0 million received from Genentech and Roche evenly over the expected three-year development phase of our agreement. In the fourth quarter of fiscal 2002, we changed the expected term of the agreement from three years to four years to reflect the revised estimated timing of our research and development commitment for Tarceva™ under the alliance. The revision was a result of the review of the current research data available, current developments in the HER1/EGFR targeted therapy market and the involved parties' revised projections for the clinical development plan. In accordance with Accounting Principles Board Opinion No. 20, ''Accounting Changes,'' the remaining unearned revenue is being recognized prospectively over the revised term. As a result, we recorded revenues of $5.0 million during fiscal 2003 compared to revenues of $7.5 million during fiscal 2002. The decrease in fiscal 2003 was also due to a decrease in revenues of $923,000 related to certain administrative services provided to British Biotech plc and Gilead during the transition periods following the acquisitions of certain assets of each company in fiscal 2002.

Collaborative Revenues

The decrease in collaborative program revenues in fiscal 2003 was primarily due to the phase-down of our collaboration in cosmeceuticals with Anaderm. In July 2002, we entered into an agreement with Pfizer to accelerate the phase-down period of the collaboration with Anaderm so that it would terminate no later than April 23, 2003. In consideration for the work performed by us during the accelerated phase-down period, we received $4.5 million in September 2002 and $3.5 million in March 2003 upon the successful completion of the transition period. The $4.5 million was recognized as revenue ratably over the term of the transition period and the $3.5 million was recognized during the second quarter of fiscal 2003 upon the successful completion of the transition. The decrease for the year was also due to a decrease in activity related to our collaboration in diabetes with Tanabe, which expired in October 2003 and was not renewed. As a result of our strategic decision to divest all non-oncology research programs, as well as the completion of the Anaderm and Tanabe collaborations in fiscal 2003, we no longer expect collaborative revenue from research alliances going forward.

Expenses

	Year Ended September 30, (In thousands)		
	2003	2002	$ Change
Cost of product sales	$ 157	$ —	$ 157
Research and development	102,642	102,202	440
Acquired in-process R&D	31,451	130,200	(98,749)
Selling, general and administrative	70,532	28,146	42,386
Amortization of intangibles	9,300	1,255	8,045
	$214,082	$261,803	$(47,721)

Cost of Product Sales

Cost of product sales related to sales of Gelclair® for the period June 12, 2003 to September 30, 2003, were $157,000 or 36% of product sales. There were no costs of products sold prior to June 12, 2003 since we acquired the rights to Gelclair® on June 12, 2003 in connection with the Cell Pathways acquisition.

Research and Development

Research and development expenses marginally increased during fiscal 2003 due to costs associated with the clinical development of Tarceva™ and transition costs associated with the assimilation of Cell Pathways which were offset by a shift from non-oncology and collaborative programs to oncology programs. As of September 30, 2003, we invested in excess of $75 million, representing our share of the costs incurred to date in the tripartite global development plan and additional investments outside the plan. Our research and development expenses for Tarceva™ incurred for fiscal 2003 were $35.9 million as compared to $30.8 million for fiscal 2002. Also included in research and development expenses for fiscal 2003 was a severance charge of $694,000. This charge related to a reduction in our headcount in October 2002 as we refocused our business on oncology and away from services that we had historically provided to our former collaborative partners.

Acquired In-Process Research and Development

In connection with the acquisition of Cell Pathways, we recorded an in-process R&D charge of $31.5 million, representing the estimated fair value of the acquired in-process technology that had not yet reached technological feasibility and had no alternative future use (see note 3(b) to the accompanying consolidated financial statements). The in-process R&D charge was assigned to the two development projects and their related technology platform and patent estates for Aptosyn® ($3.7 million) and OSI-461 ($27.8 million), based on their value on the date of the acquisition. In determining the value of the in-process R&D, the assumed commercialization dates for these products ranged from 2005 to 2006. Significant assumptions and estimates used in the valuation of in-process R&D included: the stage of development for each of the two projects; future revenues; growth rates for each product; product sales cycles; the estimated life of a product's underlying technology; future operating expenses; probability adjustments to reflect the risk of developing the acquired technology into commercially viable products; and a discount rate of 25% to reflect present value.

In connection with the acquisition of certain assets from Gilead in December 2001, we recorded an in-process R&D charge of $130.2 million during fiscal 2002, representing the estimated fair value of the acquired in-process technology that had not yet reached technological feasibility and had no alternative future use (see note 3(c) to the accompanying consolidated financial statements). The in-process R&D was allocated to three oncology candidates acquired: OSI-7904L, OSI-211 and OSI-7836. The value of the acquired in-process R&D charges were determined by estimating the projected net cash flows related to products under development based upon the future revenues to be earned upon commercialization of such products.

Given the risks associated with the development of new drugs, the revenue and expense forecasts were probability-adjusted to reflect the risk of advancement through the approval process. The applied risk adjustments were based on each compound's stage of development at the time of assessment and the historical probability of successful advancement for compounds at that stage. These modeled cash flows were discounted back to their net present value. The projected net cash flows from such projects were based on management's estimates of revenues and operating profits related to such projects. The in-process R&D was valued based on the income approach that focuses on the income-producing capability of the assets. The underlying premise of this approach is that the value of an asset can be measured by the present worth of the net economic benefit (cash receipts less cash outlays) to be received over the life of the asset.

Selling, General and Administrative

Selling, general and administrative expenses increased in fiscal 2003 due to our significant investment in commercial operations during fiscal 2003. As a result of our acquisition of the Novantrone® and Gelclair® rights in fiscal 2003, as well as our preparation for the launch of Tarceva™, expenses related to commercial operations increased approximately $38.6 million. This was due to (i) additional management and personnel relating to the establishment of commercial operations to support Gelclair® and Novantrone®; (ii) subcontracting expenses relating to our short-term transitional arrangement with a contract sales organization comprising a core of sales representatives as we built our commercial operations; (iii) increased commercialization and marketing costs relating to Tarceva™ which were shared with Genentech in accordance with the terms of our collaboration with Genentech; (iv) expenses for maintenance fees and transition support services provided by Serono relating to Novantrone® sales in oncology indications; and (v) expenses associated with the full recovery of rights to market and distribute Gelclair® from Celgene, as well as transition support services provided by Celgene. Included in selling, general and administrative expenses for fiscal 2003 was a severance charge of $249,000 relating to a reduction in our headcount in October 2002.

Amortization of Intangibles

The increase in amortization in fiscal 2003 was primarily due to $8.1 million in amortization expense related to the exclusive rights to market and promote the drug Novantrone® for approved oncology indications in the United States. Also included in amortization for fiscal 2003 was $984,000 in amortization expense related to the exclusive rights to market and distribute Gelclair® in North America. Offsetting these increases was a $1.0 million decrease in amortization expense from fiscal 2002 attributable to the full adoption of SFAS No. 142 on October 1, 2002, whereby we ceased amortizing the assembled workforce acquired from British Biotech and reclassified the balance of $2.1 million to goodwill.

Other Income and Expense

	Year Ended September 30, (In thousands)		
	2003	2002	$ Change
Investment income — net	$ 7,808	$14,729	$ (6,921)
Interest expense	(6,715)	(5,235)	(1,480)
Other expenses — net	(737)	(1,590)	853
Gain on early retirement of notes	—	12,604	(12,604)
Gain on sale of diagnostics business	—	1,000	(1,000)
Total other income (expenses)	$ 356	$21,508	$(21,152)

The decrease to investment income-net in fiscal 2003 was primarily attributable to a decrease in the average rate of return on our investments and to less funds available for investment during the period. The increase in

interest expense was primarily due to the interest expense incurred on the convertible senior subordinated notes. In February 2002, we issued $200.0 million aggregate principal amount of convertible senior subordinated notes, which bore interest at 4% per annum, payable semi-annually, and were to mature in February 2009. In August and September 2002, we retired a total of $40.0 million in principal amount of these notes. In July 2004, all of the outstanding notes were converted into common stock. In September 2003, we issued $150.0 million aggregate principal amount of convertible senior subordinated notes, which bear interest at 3.25% per annum, are payable semi-annually, and mature in September 2023. The decrease in other expense-net was primarily due to the amortization of debt issuance costs of $834,000, offset by realized gains from the sale of investments of $347,000 in fiscal 2003 compared to amortization of debt issuance costs of $642,000 and a charge of $500,000 related to the writedown of our investment in a privately-held healthcare information company (see note 4(b) to the accompanying consolidated financial statements) in fiscal 2002. With respect to the early retirement of the 4% convertible senior subordinated notes in August and September 2002, we recognized a net gain of $12.6 million in fiscal 2002 representing the difference between the purchase price of $26.2 million and the aggregate principal of $40.0 million and related accrued interest less the writedown of $1.3 million of related debt issuance costs (see note 10(b) to the accompanying consolidated financial statements). Also in fiscal 2002, we recognized a $1.0 million contingent payment received from The Bayer Corporation in December 2001, in connection with the sale of the diagnostic business in November 1999.

Liquidity and Capital Resources

General

At September 30, 2004, working capital, representing primarily cash, cash equivalents, and restricted and unrestricted short-term investments, aggregated $228.2 million compared to $379.6 million at September 30, 2003. This decrease of $151.4 million was primarily due to net cash used in operating activities of $144.9 million and the acquisition of certain assets from Probiodrug of $36.4 million, offset by proceeds from the exercise of options of $38.7 million.

We expect to incur continued losses over the three years following the launch of Tarceva™ as we continue our investment in the commercialization and development of Tarceva™ and other product candidates in our pipeline as well as our research programs and our commercial operations. While we have established a goal of achieving profitability and positive cash flow within 3 years of our launch of Tarceva™, the time required to reach profitability is uncertain. As we continue to pursue strategic in-licensing and acquisition opportunities that would bring additional products and clinical development candidates to our cancer pipeline, we will be required to use our available cash and/or equity securities. To achieve profitability, we, alone or with others, must successfully develop and commercialize our technologies and products, conduct pre-clinical studies and clinical trials, secure required regulatory approvals and obtain adequate assistance to successfully manufacture, introduce and market such technologies and products.

In the past, we have funded our research, development, commercial and administrative support efforts through public and private sales of our securities, including debt and equity securities. On November 12, 2004, subsequent to the end of fiscal 2004, we concluded a public offering of 6.0 million shares of common stock at a price of $64.50 per share. Gross proceeds totaled $387.0 million with net proceeds of approximately $365.0 million after all related fees. In addition, on November 17, 2004, underwriters associated with this offering exercised their over-allotment option to purchase an additional 900,000 shares of our common stock at a price of $64.50 per share. Gross proceeds from the exercise of the over-allotment option totaled $58.1 million with net proceeds of approximately $54.9 million. We believe that the proceeds from this offering together with existing cash resources and projected cash flows from Tarceva™ will be sufficient to execute our strategy going forward as well as providing a solid financial base from which to fund our existing operations. In September 2003, we issued a total of $150.0 million aggregate principal amount of convertible senior subordinated notes due September 8, 2023, or the 2023 Notes, in a private placement for net proceeds of $144.8 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 related debt issuance costs of $5.3 million were deferred and are being amortized on a straight-line basis over a five-year term, which represents the earliest date that we may redeem the 2023 Notes. In connection with the issuance of the 2023 Notes, we used $19.0 million of the net proceeds for the purchase of 503,800 shares of our common stock. With respect to the 2023 Notes, we pledged $14.2 million of U.S. government securities with maturities at various dates through August 2006. Upon maturity, the proceeds of these restricted investment securities will be sufficient to pay the first six scheduled interest

payments on the notes when due. The aggregate fair value and amortized cost of the restricted investment securities at September 30, 2004 was $9.5 million. If all or any portion of the 2023 Notes have not been converted into common stock prior to their maturity date, we will be required to pay, in cash, the outstanding principal amounts of the notes plus any accrued and unpaid interest. This could have a significant impact on our liquidity depending on our cash position at time of maturity. If we do not have sufficient cash to repay the debt, we may need to borrow additional funds or sell additional equity in order to meet out debt obligations.

On February 1, 2002, we issued $200.0 million aggregate principal amount of convertible senior subordinated notes due February 1, 2009, or the 2009 Notes, in a private placement for net proceeds to us of approximately $192.9 million. The 2009 Notes were convertible into shares of our common stock at a conversion price of $50 per share, subject to normal and customary adjustments such as stock dividends. The 2009 Notes were redeemable, in whole or in part, at any time before February 1, 2005 if the closing price of our common stock exceeded 150% of the conversion price then in effect for a specified period of time, or the Provisional Redemption. The related debt issuance costs of $7.1 million were deferred and were being amortized on a straight-line basis over the seven-year term of the 2009 Notes. In August and September 2002, we retired a total of $40.0 million in principal amount of the 2009 Notes for an aggregate purchase price of $26.2 million, including accrued interest of $133,000. In June 2004, we exercised our Provisional Redemption option and called for the full redemption of the outstanding $160.0 million of the 2009 Notes. All of the holders of the 2009 Notes converted their notes into shares of our common stock prior to the redemption date of July 19, 2004. As a result of these conversions, we issued 3.2 million shares of our common stock and paid the remaining portion of the guaranteed interest of $6.4 million. Upon conversion, the $3.7 million unamortized balance of the debt issuance costs was reclassified to additional paid in capital.

Summary of Cash Flows

The following table summarizes our cash flows for fiscal years 2004, 2003 and 2002 (in thousands):

	2004	2003	2002
Cash used in:			
Operating activities	$(144,908)	$(147,784)	$ (92,569)
Investing activities	(11,987)	65,162	(152,518)
Financing activities	39,134	132,586	172,797
Net (decrease) increase in cash & cash equivalents	$(117,761)	$ 49,964	$ (72,290)

The fluctuations in cash used in operating activities are due to our increased investments in our commercial operations and research and development activities, as well as the timing of cash disbursements and receipts. Included in cash provided by (used in) investing activities are net payments for acquisitions in fiscal 2004, 2003 and 2002 of $36.4 million (Probiodrug), $46.0 million (Novantrone® rights) and $135.7 million (Gilead oncology assets), respectively. Included in cash provided by financing activities in fiscal 2004 is $39.3 million relating primarily to the exercise of stock options. Included in cash provided by financing activities in fiscal 2003 and 2002 are $131.0 million (net of purchase of treasury stock) and $173.9 million (net of retirements), relating to the issuance convertible senior subordinated notes, respectively.

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 September 30, 2004 and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	2005	2006	2007	2008	2009	2010 & Thereafter	Total
Contractual Obligations:							
Senior convertible debt(a)	$ 4,875	$ 4,875	$ 4,875	$ 4,875	$ 4,875	$218,250	$242,625
Operating leases	8,188	6,589	5,208	6,168	5,794	48,789	80,736
Purchase obligations(b)	19,767	17,500	1,000	—	—	—	38,267
Obligations related to exit activities(c)	4,078	—	—	—	—	—	4,078
Total contractual obligations	$36,908	$28,964	$11,083	$11,043	$10,669	$267,039	$365,706

(a) Includes interest payments at a rate of 3.25% per annum relating to our 2023 Notes.

(b) Purchase obligations include inventory commitments, commercial and research commitments and other significant purchase commitments.

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

Other significant commitments and contingencies include the following:

- We are committed to share equally with Genentech and Roche a combined $300 million in certain global development costs for Tarceva™. As of September 30, 2004, we have spent approximately 90% of our commitment under the agreement. We, along with our partners, expect to continue our investment in the further development of Tarceva™, beyond the originally committed $300 million. We are also 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 and development costs. However, we are in the process of determining, together with Genentech and Roche, a development plan for 2005 and, together with Genentech, a commercial plan for the United States for 2005. These costs will be shared by the parties pursuant to the terms of our agreement with our partners.
- 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 issued by a commercial bank totaling $3.0 million of which the full amounts were available on June 30, 2004. One is an irrevocable letter of credit related to our Oxford, England facility which expires and is renewed annually with a final expiration date of September 27, 2007. Another is an irrevocable letter of credit related to our Horsham, Pennsylvania facility, whose lease we assumed through the acquisition of Cell Pathways. The letter expires and is renewed annually with a final expiration date of September 22, 2008.
- We have a retirement plan which provides post-retirement medical and life insurance benefits to eligible employees, board members and qualified dependents. Eligibility is determined based on age and years of service. We have accrued postretirement benefit costs of $3.9 million at September 30, 2004.
- In connection with the acquisition of Cell Pathways, we provided additional consideration in the form of five-year contingent value rights through which each share of Cell Pathways' common stock will be eligible for an additional 0.04 share of OSI 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®.
- Under certain license and collaboration agreements with pharmaceutical companies and educational institutions, we are required to pay royalties and/or milestone payments upon the successful development and

commercialization of products. However, successful research and development of pharmaceutical products is high risk, and most products fail to reach the market. Therefore, at this time the amount and timing of the payments, if any, are not known.

- Under certain license and other agreements, we are required to pay license fees for the use of technologies and products in our research and development activities or milestone payments upon the achievement of certain predetermined conditions. These license fees are not deemed material to our consolidated financial statements and the amount and timing of the milestone payments, if any, are not known due to the uncertainty surrounding the successful research, development and commercialization of the products.

- We are negotiating the potential purchase of a 60,000 square foot building, for our Corporate Headquarters. We estimate the total cost of the building and required renovations, if acquired, to be approximately $14.0 million, which we would finance from our existing cash.

Accounting Pronouncements

In December 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Act introduced both a Medicare prescription drug benefit and a federal subsidy to sponsors of retiree health care plans that provide a benefit at least ''actuarially equivalent'' to the Medicare benefit. These provisions of the new law will affect accounting measurements. In May 2004, the FASB issued FASB Staff Position, or FSP, No. FAS 106-2, ''Accounting and Disclosure Requirements Related to the Improvement and Modernization Act of 2003.'' FSP No. FAS 106-2 provides guidance on the accounting for the effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, or the Act, for employers that sponsor post-retirement health care plans that provide prescription drug benefits. It requires those employers to provide certain disclosures regarding the effect of the Federal subsidy provided by the Act. The accumulated post-retirement benefits obligation or net post-retirement benefits cost in the consolidated financial statements or accompanying notes do not reflect the effects of the Act on our post-retirement benefit plan. We are in the process of determining the impact of the Act on the accumulated post-retirement benefits obligation and net post-retirement benefits cost.

Issued Exposure Draft

On March 31, 2004, the FASB issued a proposed Statement, ''Share-Based Payment,'' that addresses the accounting for share-based awards to employees, including employee-stock-purchase-plans, or ESPPs. The FASB formally proposed to require companies to recognize the fair value of stock options and other stock-based compensation to employees. The proposed statement would eliminate the ability to account for share-based compensation transactions using APB Opinion No. 25, ''Accounting for Stock Issued to Employees,'' and generally would require instead, that such transactions be accounted for using a fair-value-based method. The statement is expected to become effective for public companies during the second half of 2005. We currently account for our stock-based compensation plans in accordance with APB Opinion No. 25. Therefore, the eventual adoption of this proposed statement, if issued in final form by the FASB, will have a material effect on our consolidated financial statements.

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 1 ''Business — Cautionary Factors that May Affect Future Results.''

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

Our cash flow and earnings are subject to fluctuations due to changes in interest rates in our investment portfolio of debt securities, to the fair value of equity instruments held and to foreign currency exchange rates. We maintain an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale as defined by SFAS No. 115, ''Accounting for Certain Investments in Debt and Equity Securities,'' and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a component of accumulated other comprehensive income (loss) included in stockholders' equity. With respect to the convertible senior subordinated notes issued in September 2003 and February 2002, we pledged U.S. government securities, or Restricted Investment Securities, with maturities at various dates through August 2006 and November 2004, respectively. Upon conversion of the 2009 Notes into our common stock in July 2004, we were required to pay the remaining part of the guaranteed interest. Therefore, the restricted investment securities pledged in relation to these notes were liquidated. Upon maturity, the proceeds of the restricted investment securities will be sufficient to pay the first six scheduled interest payments of the 2023 Notes when due. We consider our restricted investment securities to be held-to-maturity as defined by SFAS No. 115. These securities are reported at their amortized cost, which includes the direct costs to acquire the securities, plus the amortization of any discount or premium, and accrued interest earned on the securities. We have not used or held derivative financial instruments in our investment portfolio.

At September 30, 2004, we maintained a portion of our cash and cash equivalents in financial instruments with original maturities of three months or less. We also maintained an investment portfolio principally comprised of government and government agency obligations and corporate obligations that are subject to interest rate risk and will decline in value if interest rates increase.

A hypothetical 10% change in interest rates during the periods would have resulted in a $526,000 change in our net loss for fiscal 2004.

In March 2004, we began to enter into forward exchange contracts to reduce foreign currency fluctuation risks relating to intercompany transactions for the funding of our research activities in the United Kingdom. We account for these derivative financial instruments in accordance with SFAS No. 133, ''Accounting for Derivative Instruments and Hedging Activities,'' which was amended by SFAS No. 137 and SFAS No. 138. Changes in the fair value of a derivative that is designated and documented as a cash flow hedge and is highly effective, are recorded in other comprehensive income until the underlying transaction affects earnings, and then are later reclassified to earnings. We formally assess, both at the inception and at each financial quarter thereafter, the effectiveness of the derivative instrument hedging the underlying forecasted cash flow transaction. Any ineffectiveness related to the derivative financial instruments' change in fair value will be recognized in the period in which the ineffectiveness was calculated. As of September 30, 2004, the notional and fair value of the foreign exchange contracts for British pounds was $1.6 million. The contracts will mature over the next two months.

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

Our long-term debt totaled $150.0 million at September 30, 2004 and was comprised of our 2023 Notes which bear interest at a fixed rate of 3.25%. In June 2004, we exercised our provisional redemption right and called for the full redemption of the outstanding $160.0 million of the 2009 Notes which we issued in February 2002. All of the holders of these notes converted their notes into shares of our common stock prior to the redemption date of July 19, 2004. As a result of these conversions, in July 2004, we issued 3.2 million shares of our common stock and paid the remaining portion of the guaranteed interest of $6.4 million.

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 convertible senior subordinated notes to common stock beneficial to the convertible senior subordinated notes holders. Conversion of the convertible senior subordinated notes would have a dilutive effect on any future earnings and book value per common share.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of OSI Pharmaceuticals, Inc. and subsidiaries (the ''Company'') as of September 30, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended September 30, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of OSI Pharmaceuticals, Inc. and subsidiaries as of September 30, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended September 30, 2004, in conformity with U.S. generally accepted accounting principles.

As discussed in note 1(b) to the consolidated financial statements, the Company adopted EITF 00-21 ''Revenue Arrangements with Multiple Deliverables'' in 2004.

As discussed in notes 1(j) and 8 to the consolidated financial statements, the Company fully adopted the provisions of Statement of Financial Accounting Standards (''SFAS'') No. 142, ''Goodwill and Other Intangible Assets'' in 2003.

As discussed in note 10 to the consolidated financial statements, the Company early adopted Statement of Financial Accounting Standards No. 145 ''Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections'' relating to the classification of the effect of early debt extinguishments in 2002.

/s/ KPMG LLP

Melville, New York
November 29, 2004

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
September 30, 2004 and 2003
(In thousands except per share data)

	September 30, 2004	September 30, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 84,598	$ 202,519
Investment securities	163,085	174,057
Restricted investment securities — short-term	4,835	12,758
Receivables, including amounts due from related parties of $1,283 and $74 at September 30, 2004 and 2003, respectively	10,771	10,121
Inventory — net	1,437	3,616
Interest receivable	1,341	1,533
Prepaid expenses and other current assets	9,378	9,847
Total current assets	275,445	414,451
Restricted investment securities — long-term	4,711	14,813
Property, equipment and leasehold improvements — net	35,356	44,977
Debt issuance costs — net	4,156	9,488
Goodwill	39,017	38,810
Other intangible assets — net	26,566	66,145
Other assets	2,778	2,818
	$ 388,029	$ 591,502
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including amounts due to related parties of $13,903 and $6,875 at September 30, 2004 and 2003, respectively	$ 46,140	$ 29,013
Unearned revenue — current; including amounts received in advance from related parties of $500 and $5,000 as of September 30, 2004 and 2003, respectively	1,074	5,779
Loans and capital leases payable — current	8	61
Total current liabilities	47,222	34,853
Other liabilities:		
Deferred rent expense — long term	1,873	2,179
Unearned revenue — long-term, representing amounts received in advance from related parties	8,750	1,250
Convertible senior subordinated notes and capital leases payable — long-term	150,000	310,008
Contingent value rights	22,047	22,047
Accrued postretirement benefit cost	3,904	3,108
Total liabilities	233,796	373,445
Stockholders' equity:		
Preferred stock, $.01 par value; 5,000 shares authorized; no shares issued at September 30, 2004 and 2003	—	—
Common stock, $.01 par value; 200,000 shares authorized, 45,030 and 40,298 shares issued at September 30, 2004 and 2003, respectively	450	403
Additional paid-in capital	943,994	747,737
Deferred compensation	(206)	(216)
Accumulated deficit	(765,951)	(505,580)
Accumulated other comprehensive income	1,397	1,164
	179,684	243,508
Less: treasury stock, at cost; 1,443 shares at September 30, 2004 and 2003	(25,451)	(25,451)
Total stockholders' equity	154,233	218,057
Commitments and Contingencies		
	$ 388,029	$ 591,502

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands except per share data)

	Years Ended September 30,		
	2004	2003	2002
Revenues:			
Sales commissions and product sales	$ 35,525	$ 16,726	$ —
License, milestone and other revenues, including $7,000, $5,000, and $7,500 from related parties in 2004, 2003 and 2002, respectively	7,275	6,088	9,840
Collaborative program revenues, including $6,187 and $7,824 from related parties in 2003 and 2002, respectively	—	9,555	11,976
	42,800	32,369	21,816
Expenses:			
Cost of products sales	8,985	157	—
Research and development	110,398	102,642	102,202
Acquired in-process research and development (note 3)	32,785	31,451	130,200
Selling, general and administrative	98,909	70,532	28,146
Impairment of intangible asset	24,599	—	—
Amortization of intangibles	18,606	9,300	1,255
	294,282	214,082	261,803
Loss from operations	(251,482)	(181,713)	(239,987)
Other income (expense):			
Investment income — net	5,259	7,808	14,729
Interest expense	(13,436)	(6,715)	(5,235)
Other expense — net	(712)	(737)	(1,590)
Gain on early retirement of convertible senior subordinated notes — net	—	—	12,604
Gain on sale of diagnostics business	—	—	1,000
Net loss	$(260,371)	$(181,357)	$(218,479)
Basic and diluted net loss per common share	$ (6.50)	$ (4.87)	$ (6.07)
Weighted average shares of common stock outstanding	40,083	37,249	35,978

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended September 30, 2004, 2003 and 2002
(In thousands)

	Common Stock		Additional Paid-in	Deferred	Accumulated	Accumulated Other Comprehensive	Treasury	Total Stockholders'
	Shares	Amount	Capital	Compensation	Deficit	Income (Loss)	Stock	Equity
Balance at September 30, 2001	35,901	$359	$664,095	$(3,922)	$(105,744)	$ 1,476	$ (6,433)	$ 549,831
Comprehensive income (loss):								
Net loss	—	—	—	—	(218,479)	—	—	(218,479)
Unrealized holding loss on investment securities, net of reclassification adjustment	—	—	—	—	—	(1,166)	—	(1,166)
Translation adjustment	—	—	—	—	—	695	—	695
Total comprehensive loss								(218,950)
Options exercised	432	4	5,676	—	—	—	—	5,680
Warrants exercised	11	—	375	—	—	—	—	375
Issuance of common stock for employee purchase plan and other	66	1	1,074	—	—	—	—	1,075
Change in deferred compensation	—	—	(349)	349	—	—	—	—
Amortization of deferred compensation	—	—	—	1,097	—	—	—	1,097
Reversal of deferred compensation	—	—	(2,427)	2,427	—	—	—	—
Issuance of common stock, in connection with acquisition of Gilead oncology assets	925	9	39,991	—	—	—	—	40,000
Balance at September 30, 2002	37,335	373	708,435	(49)	(324,223)	1,005	(6,433)	379,108
Comprehensive income (loss):								
Net loss	—	—	—	—	(181,357)	—	—	(181,357)
Unrealized holding loss on investment securities, net of reclassification adjustment	—	—	—	—	—	(991)	—	(991)
Translation adjustment	—	—	—	—	—	1,150	—	1,150
Total comprehensive loss	—	—	—	—	—	—	—	(181,198)
Options exercised	636	6	6,773	—	—	—	—	6,779
Warrants issued	—	—	146	—	—	—	—	146
Issuance of common stock for directors' annual retainer	31	—	487	(487)	—	—	—	—
Issuance of common stock for employee purchase plan and other	42	1	803	—	—	—	—	804
Issuance of common stock in connection with acquisition of Cell Pathways	2,246	23	31,223	—	—	—	—	31,246
Issuance of common stock to consultant	8	—	286	—	—	—	—	286
Registration costs in connection with acquisition of Cell Pathways	—	—	(416)	—	—	—	—	(416)
Amortization of deferred compensation	—	—	—	320	—	—	—	320
Purchase of treasury stock	—	—	—	—	—	—	(19,018)	(19,018)
Balance at September 30, 2003	40,298	403	747,737	(216)	(505,580)	1,164	(25,451)	218,057
Comprehensive income (loss):								
Net loss	—	—	—	—	(260,371)	—	—	(260,371)
Unrealized holding loss on investment securities, net of reclassification adjustment	—	—	—	—	—	(971)	—	(971)
Translation adjustment	—	—	—	—	—	1,204	—	1,204
Total comprehensive loss	—	—	—	—	—	—	—	(260,138)
Options exercised	1,493	15	38,673	—	—	—	—	38,688
Warrants exercised	6	—	—	—	—	—	—	—
Issuance of common stock for directors' annual retainer	11	—	474	(474)	—	—	—	—
Issuance of common stock for employee purchase plan and other	22	—	693	—	—	—	—	693
Issuance of common stock in connection with conversion of notes	3,200	32	159,968	—	—	—	—	160,000
Balance of unamortized debt issuance costs in connection with conversion of notes	—	—	(3,723)	—	—	—	—	(3,723)
Change in deferred compensation	—	—	(5)	5	—	—	—	—
Amortization of deferred compensation	—	—	—	479	—	—	—	479
Acceleration of director's options	—	—	177	—	—			177
Balance at September 30, 2004	45,030	$450	$943,994	$ (206)	$(765,951)	$ 1,397	$(25,451)	$ 154,233

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended September 30,		
	2004	2003	2002
Cash flow from operating activities:			
Net loss	$(260,371)	$(181,357)	$(218,479)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on early retirement of convertible senior subordinated notes — net	—	—	(12,604)
Gain on sale of diagnostic business	—	—	(1,000)
Loss (gain) on sale of investments	(41)	(347)	143
Loss on sale and disposals of equipment	2	86	359
Depreciation and amortization	34,914	21,434	11,102
Impairment of intangible asset	24,599	—	—
Provision for excess inventory	8,565	—	—
In-process research and development charge	32,785	31,451	130,200
Non-cash compensation charges	723	862	1,606
Other non-cash charges — net	493	—	678
Changes in assets and liabilities, net of the effects of acquisitions:			
Receivables	(459)	(4,634)	(520)
Inventory	(6,386)	(514)	—
Prepaid expenses and other current assets	594	(5,505)	(686)
Other assets	47	1,077	304
Accounts payable and accrued expenses	16,037	(2,034)	2,250
Unearned revenue	2,795	(8,941)	(6,312)
Accrued postretirement benefit cost	795	638	390
Net cash used in operating activities	(144,908)	(147,784)	(92,569)
Cash flows from investing activities:			
Payments for acquisitions, net of cash acquired	(36,393)	(193)	(135,742)
Payments for acquisition of Novantrone® marketing rights	—	(46,009)	—
Purchases of investments (restricted and unrestricted)	(250,714)	(412,944)	(400,951)
Maturities and sales of investments (restricted and unrestricted)	278,748	534,332	402,318
Net additions to property, equipment and leasehold improvements	(3,287)	(8,486)	(18,181)
Other	(341)	(1,538)	38
Net cash provided by (used in) investing activities	(11,987)	65,162	(152,518)
Cash flows from financing activities:			
Proceeds from the exercise of stock options, stock warrants, employee purchase plan, and other	39,315	7,327	6,247
Proceeds from the issuance of convertible senior subordinated notes	—	150,000	200,000
Payments for retirement of convertible senior subordinated notes	—	—	(26,098)
Debt issuance costs	(118)	(5,177)	(7,084)
Payments on loans and capital leases payable	(63)	(546)	(268)
Purchase of treasury stock	—	(19,018)	—
Net cash provided by financing activities	39,134	132,586	172,797
Net increase (decrease) in cash and cash equivalents	(117,761)	49,964	(72,290)
Effect of exchange rate changes on cash and cash equivalents	(160)	(23)	(282)
Cash and cash equivalents at beginning of year	202,519	152,578	225,150
Cash and cash equivalents at end of year	$ 84,598	$ 202,519	$ 152,578
Non-cash activities:			
Conversion of notes	$ 160,000	$ —	$ —
Reclassification of debt issuance costs in connection with notes	$ 3,723	$ —	$ —
Issuance of common stock to employees	$ 65	$ 92	$ 450
Issuance of common stock to directors	$ 475	$ 488	$ —
Issuance of Prosidion preferred stock to minority shareholders	$ 1,400	$ —	$ —
Issuance of common stock to consultant	$ —	$ 286	$ —
Acceleration of directors and employees' stock options	$ 177	$ 164	$ —
Issuance of common stock in satisfaction of deferred acquisition costs	$ —	$ —	$ 375
Issuance of common stock in connection with acquisition	$ —	$ 31,245	$ 40,000
Issuance of contingent value rights in connection with acquisition	$ —	$ 22,047	$ —
Assumption of warrants in connection with acquisition	$ —	$ 146	$ —
Cash paid for interest	$ 14,502	$ 6,418	$ 4,035

See accompanying notes to consolidated financial statements.

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

(1) Summary of Significant Accounting Policies

(a) Principles of Consolidation

Our consolidated financial statements include the accounts of OSI Pharmaceuticals, Inc., and our wholly-owned subsidiary, OSI Pharmaceuticals (UK) Limited, or OSI-UK and our majority-owned subsidiary, Prosidion Limited. During fiscal 2003, we created Prosidion, into which we transferred our diabetes and obesity research programs. As of September 30, 2004, we held an approximately 97% ownership interest in Prosidion. All intercompany balances and transactions have been eliminated in consolidation. We operate in one segment. We are primarily focused on the discovery, development and commercialization of high-quality oncology products that both extend life and improve the quality-of-life for cancer patients worldwide.

(b) Revenue Recognition

Sales Commissions and Product Sales
Sales commissions represent commissions earned on the sales of the drug, Novantrone® (mitoxantrone for injection concentrate), 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 Serono, S.A. (see note 2). Serono will continue to market Novantrone® in multiple sclerosis indications and will record 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 of Novantrone®, as determined by an external third party. The split between oncology and multiple sclerosis sales is subject to further adjustment based upon the parties' final review, in the subsequent quarter. Based on past experience, we do not believe these adjustments, if any, will be significant to the consolidated financial statements.

Product sales represent sales of Gelclair® Bioadherent Oral Gel in accordance with an exclusive distribution agreement with Helsinn Healthcare S.A., which allowed us to market and distribute Gelclair® in North America. Gelclair® was acquired as part of our acquisition of Cell Pathways, Inc. (see note 3(b)) and launched by us to the oncology market in the fourth quarter of calendar 2003. In late October 2004, we exercised our right to terminate the agreement with Helsinn. Under the terms of the agreement, Helsinn has the option to purchase any and all of our inventory at cost plus 5% and if Helsinn does not elect to purchase our inventory, we are permitted to continue to sell such inventory. We are currently negotiating a new agreement with Helsinn. In accordance with SFAS No. 48, ''Revenue Recognition When Right of Return Exists,'' given the limited sales history of Gelclair®, we at this time defer the recognition of revenue on product shipments of Gelclair® to wholesale customers until such time as the product is sold from the wholesale customer to the retail and non-retail outlets. For each reporting period, we monitor estimated shipments from wholesale customers to pharmacies and hospitals, and wholesale customer reorder history based on data from an external third party. The related cost of the product shipped to wholesale customers that has not been recognized as revenue has been reflected as inventory subject to return (see note 1(l)). The unearned revenue related to shipments of Gelclair® to wholesale customers was $574,000 and $779,000 as of September 30, 2004 and 2003, respectively, and is included in unearned revenue-current on the accompanying consolidated balance sheets.

Licenses, Milestones and Other Revenues
Our revenue recognition policies for all nonrefundable upfront license fees and milestone arrangements are in accordance with the guidance provided in the Securities and Exchange Commission's 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 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, Inc. and Roche in January 2001 which was originally being recognized on a straight-line basis over the expected three-year term of our required research and development efforts under the terms of a tripartite agreement with Genentech and Roche. In the fourth quarter of fiscal 2002, the expected term was changed to four

years to reflect our revised estimate of the term of the continued involvement in the research and development efforts under the agreement (see note 5(a)). In accordance with Accounting Principles Board Opinion No. 20, ''Accounting Changes,'' the remaining unearned revenue is being recognized prospectively over the revised term. Further, as a result of the amendment to the OSI/Genentech agreement in June 2004, the remaining unearned upfront fee from Genentech of approximately $1.8 million will be recognized in accordance with EITF 00-21, as discussed below. As the Roche agreement was not modified or amended subsequent to its original execution, the unearned upfront fee from Roche continues to be recognized over the revised term and will be fully recognized as of December 31, 2004.

In the fourth quarter of fiscal 2004 we recognized $3.0 million in milestone revenues from our partner Roche based upon the EMEA's notice of acceptance for filing and review of our NDA for the use of Tarceva™ as a monotherapy for the treatment of patients with advanced NSCLC who have failed at least one chemotherapy regimen. Milestone payments from Roche are accounted for such that revenue related to each payment be recognized over the entire contract performance period, but not prior to the removal of the contingencies for each milestone. Once a contingency is removed and the customer is obligated to make a payment, the costs of the effort that has been incurred to date is divided by the total expected research and development costs and revenue is recognized for that milestone to the extent of the ratio of performance to date, less revenue previously recognized.

In the fourth quarter of fiscal 2004, we also received a $7.0 million milestone payment from Genentech, Inc. based upon the FDA's notice of acceptance for filing and review of our NDA for the use of Tarceva™ as a monotherapy for the treatment of NSCLC patients who have failed at least one chemotherapy regimen. As a result of the amendment to the OSI/Genentech agreement in June 2004, we were required to account for the Genentech milestone received and the remaining unearned upfront fee of approximately $1.8 million, in accordance with EITF 00-21; Revenue Arrangements with Multiple Deliverables. Milestones received from Genentech and the remaining unearned upfront fee will be recognized over the term of the Manufacturing and Supply Agreement between Genentech and us. This accounting resulted from the inability to determine the fair value of the undelivered items in the arrangement as required by EITF 00-21. As a result, the milestones are attributed to the last item delivered under the Manufacturing and Supply Agreement. We will recognize such deferred revenue over the term of the Manufacturing and Supply Agreement based on the lesser of the ratio of units sold by Genentech to total expected units or the cumulative straight-line basis. This estimate of expected unit sales will be adjusted periodically and whenever events or changes in circumstances indicate that there could be a significant change in such estimate.

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

(c) Research and Development Costs

Research and development, or R&D, costs are charged to operations as incurred and include direct costs of R&D scientists and equipment, contracted costs, and an allocation of laboratory facility and other core scientific services. In fiscal years 2004, 2003 and 2002, R&D activities included $110.4 million, $99.8 million, and $95.1 million, respectively, of proprietary R&D. Proprietary R&D includes our proportionate share of development expenses related to the Tripartite Agreement with Genentech and Roche (see note 5(a)). The balance of R&D in fiscal years 2003 and 2002 represented expenses under our collaborative agreements.

(d) Acquired In-Process Research and Development

Costs to acquire in-process research and development projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are expensed as incurred (see note 3).

(e) Accounting for Stock-Based Compensation

We follow the provisions of SFAS No. 123, ''Accounting for Stock-Based Compensation.'' The provisions of SFAS No. 123 allow us to either expense the estimated fair value of stock options or to continue to follow the intrinsic value method set forth in Accounting Principles Board (''APB'') Opinion No. 25 ''Accounting for Stock Issued to Employees,'' but disclose the pro forma effect on net income (loss) had the fair value of the options been expensed. We have elected to continue to apply APB Opinion No. 25 in accounting for stock options issued to employees. In December 2002, the FASB issued SFAS No. 148, ''Accounting for Stock-Based Compensation — Transition and Disclosure.'' SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation as originally provided by SFAS No. 123. Additionally, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosure in both the annual and interim financial statements about the method of accounting for stock-based compensation and the effect of the method used on reported results.

Stock option grants are generally set at the closing price of our common stock on the date of grant and the related number of shares granted are fixed at that point in time. During fiscal 2004, Prosidion granted a fixed number of stock options to employees at a price equal to the estimated value of Prosidion common stock on the grant date. Therefore, under the principles of APB Opinion No. 25, we do not recognize compensation expense associated with the grant of stock options. Pro forma information regarding net loss and loss per share shown below was determined as if we had accounted for our employee stock options and shares sold under our stock purchase plan under the fair value method of SFAS No. 123.

The fair value of the options was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

	OSI Pharmaceuticals, Inc. Years Ended September 30,			Prosidion Limited Year Ended September 30,
	2004	2003	2002	2004
Risk-free interest rate	2.97%	1.76%	3.86%	4.75%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Volatility factors of expected market	78.91%	81.63%	77.19%	50.00%
Weighted-average expected life of option (years)	3.0	3.0	3.0	5.0
Weighted-average exercise price of stock option grants	$61.40	$28.10	$33.02	$ 9.36
Weighted-average fair value of stock option grants	$32.25	$14.82	$17.19	$ 4.58

For purposes of pro forma disclosures, the estimated fair value of the options is amortized over the options' vesting periods. Our pro forma information for fiscal 2004, 2003 and 2002 is as follows (in thousands, except per share information):

	Years Ended September 30,		
	2004	2003	2002
Net loss	$(260,371)	$(181,357)	$(218,479)
Add: stock-based compensation included in net loss	723	862	1,606
Compensation cost determined under fair value method	(25,854)	(20,690)	(18,711)
Pro forma net loss	$(285,502)	$(201,185)	$(235,584)
Basic and diluted loss per common share:			
Net loss — as reported	$ (6.50)	$ (4.87)	$ (6.07)
Net loss — pro forma	$ (7.12)	$ (5.40)	$ (6.55)

On March 31, 2004, the FASB issued a proposed Statement, ''Share-Based Payment,'' that addresses the accounting for share-based awards to employees, including employee-stock-purchase-plans, or ESPPs. The FASB formally proposed to require companies to recognize the fair value of stock options and other stock-based compensation to employees. The proposed statement would eliminate the ability to account for share-based compensation transactions using APB Opinion No. 25 and generally would require instead, that such transactions be accounted for using a fair-value-based method. The statement is expected to become effective for public companies during the second half of 2005. Therefore, the eventual adoption of this proposed statement, if issued in final form by the FASB, will have a material effect on our consolidated financial statements.

(f) Net Loss Per Share

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

Such common share equivalents (convertible senior subordinated notes, stock options and warrants) and contingent shares for fiscal 2004, 2003 and 2002 amounted to (in thousands):

	Years Ended September 30,		
	2004	2003	2002
Common share equivalents	7,152	5,016	4,895
Contingent shares	1,585	1,585	—

If fiscal 2004, 2003 and 2002 had resulted in net income and had the common share equivalents for our convertible senior subordinated notes due 2009 (3,200,000 shares) and our convertible senior subordinated notes due 2023 (2,998,800 shares) been dilutive, interest expense related to the notes would have been added back to net income to calculate diluted earnings per share. The related interest expense of these notes for fiscal 2004, 2003 and 2002 totaled $13.4 million, $6.7 million and $5.2 million, respectively. As discussed in note 10(b), the convertible senior subordinated notes due 2009 were fully converted into shares of our common stock in the fourth quarter of fiscal 2004.

(g) Comprehensive Income (Loss)

Comprehensive income includes foreign currency translation adjustments and unrealized gains or losses on our available-for-sale securities and derivative instruments.

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

	September 30,	
	2004	2003
Cumulative foreign currency translation adjustment	$2,034	$ 830
Unrealized gains (losses) on available-for-sale securities	(666)	334
Unrealized gains on derivative instruments	29	—
Accumulated other comprehensive income	$1,397	$1,164

(h) Cash and Cash Equivalents

We include as cash equivalents reverse repurchase agreements, treasury bills, commercial paper and time deposits with original maturities of three months or less. Such cash equivalents amounted to $34.7 million and $192.8 million as of September 30, 2004 and 2003, respectively.

(i) Investments

Investment securities at September 30, 2004 and 2003 consist of U.S. government securities, municipal obligations and debt and equity securities of financial institutions and corporations with strong credit ratings. We classify our investments as available-for-sale securities, as defined by SFAS No. 115, ''Accounting for Certain Investments in Debt and Equity Securities.'' These securities are recorded at their fair value. Unrealized holding gains and losses, net of the related tax effect, if any, on available-for-sale securities are excluded from earnings and are reported in accumulated other comprehensive income (loss), a separate component of stockholders' equity, until realized. The specific identification basis is utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities. A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary results in a reduction in carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Dividend and interest income are recognized when earned.

In September 2003, in connection with the issuance of 3.25% convertible senior subordinated notes (see note 10(a)), we pledged $14.2 million of U.S. government securities, or Restricted Investment Securities, with maturities at various dates through August 2006. In February 2002, in connection with the issuance of 4.00% convertible senior subordinated notes (see note 10(b)), we pledged $22.9 million of Restricted Investment Securities with maturities at various dates through November 2004. We consider our Restricted Investment Securities to be held-to-maturity, as defined by SFAS No. 115. These securities are reported at their amortized cost, which includes the direct costs to acquire the securities, plus the amortization of any discount or premium, and accrued interest earned on the securities. The balance of Restricted Investment Securities decreases as scheduled interest payments are made. The aggregate fair value and amortized cost of the Restricted Investment Securities at September 30, 2004 were $9.5 million, of which $4.8 million was classified as short-term and the balance of $4.7 million was classified as long-term. The aggregate fair value and amortized costs of the Restricted Investment Securities at September 30, 2003 were $27.8 million and $27.6 million, respectively, of which $12.8 million was classified as short-term and the balance of $14.8 million as long-term. As further discussed in note 10(b), all of the convertible senior subordinated notes issued in February 2002 were converted into our common stock in July 2004. In connection with the conversion, we paid the note holders the remaining portion of the guaranteed interest of $6.4 million.

With respect to our facility leases for Horsham, Pennsylvania and Oxford, England, we have outstanding letters of credit issued by a commercial bank. The irrevocable letter of credit for our Horsham, Pennsylvania facility expires annually with a final expiration date of September 22, 2008. This letter of credit is for $400,000, of which

the full amount was available at September 30, 2004. The irrevocable letter of credit for our Oxford, England facility expires annually with a final expiration date of September 27, 2007. This letter of credit is for $2.6 million, of which the full amount was available on September 30, 2004. The collateral for these letters of credit are maintained in a restricted investment account. Included in cash and cash equivalents and investments securities as of September 30, 2004 is $132,000 and $3.4 million, respectively, relating to restricted cash and investments to secure these letters of credit. Included in cash and cash equivalents and investment securities as of September 30, 2003 is $35,000 and $3.4 million, respectively, relating to restricted cash and investments to secure these letters of credit.

As further discussed in note 4(b), we received an equity interest in a research and development company in exchange for research services provided. We have recorded our investment in the company based on the cost of services rendered. We recognized our share of the operating losses of this company based on our percentage ownership interest under the equity method of accounting.

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

(j) Goodwill and Intangible Assets

We account for goodwill and other intangible assets in accordance with SFAS No. 141, ''Business Combinations'' and SFAS No. 142, ''Goodwill and Other Intangible Assets.'' 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 (see note 8).

As a result of our R&D programs, including programs funded pursuant to R&D funding agreements (see note 5), 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.

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

In accordance with SFAS No. 144, ''Accounting for the Impairment or Disposal of Long-Lived Assets,'' 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 as 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 the fourth quarter of fiscal 2004, we determined it was necessary to record an impairment charge as of September 30, 2004 related to our intangible asset for exclusive distribution rights to the marketed product, Gelclair® in North America (see note 8).

(l) Inventory

Inventory is comprised solely of Gelclair® and is stated at the lower of cost or market, as determined using the first-in, first-out method. During the second quarter of fiscal 2004, we recorded a provision of $2.0 million for

excess inventory that we considered to be in excess of forecasted future demand based on the expiration date of the product on hand. During the fourth quarter of fiscal 2004, we recorded an additional provision of $6.6 million in relation to inventory on-hand and 2004 and 2005 purchase commitments with Helsinn that we determined to be in excess of forecasted demand. This additional provision related to $1.7 million of inventory on-hand and $4.9 million of purchase commitments. The provision in connection with the purchase commitments is accrued in accounts payable and accrued expenses on the accompanying consolidated balance sheet. This excess inventory relates to the substantial inventory obtained from the Cell Pathways acquisition, the required purchase commitments that we assumed in the Cell Pathways acquisition and the current low demand for the product. In late October 2004, we exercised our right to terminate the agreement with Helsinn. Under the terms of the agreement, Helsinn has the option to purchase any and all of our inventory at cost plus 5% and if Helsinn does not elect to purchase our inventory, we are permitted to continue to sell such inventory. We are currently negotiating a new agreement with Helsinn. These inventory provisions are included in cost of product sales in the accompanying consolidated statement of operations for fiscal 2004. Inventory, net of the reserve for excess inventory, at September 30, 2004 and 2003, consisted of the following (in thousands):

	September 30,	
	2004	2003
Finished goods on hand — net	$1,263	$3,358
Inventory subject to return	174	258
	$1,437	$3,616

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

(m) Depreciation and Amortization

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

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

(n) Computer Software Costs

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

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

We record accruals for estimated clinical study costs. Clinical study costs represent costs incurred by clinical research organizations, or CROs, and clinical sites. These costs are recorded as a component of R&D expenses. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may or may not match the estimated costs for a given accounting period. Actual results could differ from those estimates under different assumptions. The accrued CRO and site costs as of September 30, 2004 and 2003 were $2.1 million and $5.0 million, respectively.

(p) Foreign Currency Translation

The assets and liabilities of our non-U.S. subsidiaries, OSI-UK and Prosidion, which operate in their local currency, are translated to U.S. dollars at exchange rates in effect at the balance sheet date with resulting translation

adjustments directly recorded as a separate component of accumulated other comprehensive income (loss). Income and expense accounts are translated at the average exchange rates during the year.

(q) Accounting for Derivatives

We enter into forward exchange contracts to reduce foreign currency fluctuation risks relating to intercompany transactions for the funding of our research activities in the United Kingdom. We account for these derivative financial instruments in accordance with SFAS No. 133, ''Accounting for Derivative Instruments and Hedging Activities,'' which was amended by SFAS No. 137 and SFAS No. 138. When entered into, we designate and document these derivative instruments as a cash flow hedge of a specific underlying exposure, as well as the risk management objectives and strategies for undertaking the hedge transactions. Changes in the fair value of a derivative that is designated and documented as a cash flow hedge and is highly effective are recorded in other comprehensive income until the underlying transaction affects earnings, and then are later reclassified to earnings. We formally assess, both at the inception and at each financial quarter thereafter, the effectiveness of the derivative instrument hedging the underlying forecasted cash flow transaction. Any ineffectiveness related to the derivative financial instruments' changes in fair value will be recognized in the period in which the ineffectiveness was calculated. As of September 30, 2004, the notional and fair value of the foreign exchange contracts for British pounds was approximately $1.6 million. The contracts will mature over the next two months. There were no foreign exchange contracts as of September 30, 2003.

(r) 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 bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

(s) Debt Issuance Costs

Costs incurred in issuing the 3.25% convertible senior subordinated notes are amortized using the straight-line method over a five year term, which represents the earliest date that we may redeem such notes. Costs incurred in issuing the 4.0% convertible senior subordinated notes were amortized using the straight-line method over a seven year term. Upon conversion of the 4.0% convertible senior subordinated notes, in July 2004, the remaining unamortized costs of $3.7 million were reclassified to additional paid in capital (see note 10(b)). The amortization of the debt issuance costs is included in other expense in the accompanying consolidated statements of operations.

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

(u) Reclassifications

We have made certain reclassifications to the prior period consolidated financial statements to conform them to current presentations.

(2) Co-Promotion Agreement

On March 11, 2003, we entered into a co-promotion agreement with Ares Trading, an affiliate of Serono, to market and promote Novantrone® for approved oncology indications in the United States through December 2017. In consideration for these exclusive rights, we paid $46.0 million in cash, including professional fees. The purchase price and related professional fees, net of related amortization, are included in other intangible assets-net in the accompanying consolidated balance sheets as of September 30, 2004 and 2003, and are being amortized on a straight-line basis through expiration of the Novantrone® patent in April 2006. In consideration for certain transition services required to be provided by Serono, we also paid a fee of $10.0 million, which was recognized over the four-month transition period from the effective date of the agreement and is included in selling, general and administrative expense in the accompanying consolidated statement of operations for fiscal 2003. Under the terms of the agreement, we are also required to pay quarterly maintenance fees until the later of the expiration of the last valid patent claim or the first generic date, as defined in the agreement. Such maintenance fees are expensed as incurred and included in selling, general and administrative expenses on the accompanying consolidated statements of operations for fiscal 2004 and 2003. We receive commissions on net sales of the product in the United States for oncology indications. Sales commissions totaled $34.3 million and $16.3 million for fiscal 2004 and 2003, respectively.

(3) Acquisitions

(a) Probiodrug Assets

On July 26, 2004, our subsidiary, Prosidion, which is focused on the discovery and development of diabetes and obesity therapeutics, completed the acquisition of certain assets of Probiodrug AG, pursuant to the terms of an asset purchase agreement dated June 17, 2004. Probiodrug is a development company engaged in the research and development of drug candidates for various targets and various indications, including metabolic diseases. The assets acquired included a platform of dipeptidyl peptidase IV (DP-IV) technology, which includes PSN9301 (formerly P93/01), a clinical candidate that is in Phase II clinical trials for the treatment of Type 2 diabetes and issued method-of-use claims that have been non-exclusively licensed to other companies for future milestones and royalties payments. Upon the closing of the acquisition, we paid $36.4 million in cash, including professional fees. The purchase price was allocated to the assets acquired based on the fair values as of the date of the acquisition. Of the $36.4 million purchase price, $32.8 million was assigned to the drug candidate in clinical development, PSN9301, and was expensed at the date of the acquisition and is included in acquired in-process research and development expenses in the accompanying consolidated statement of operations for fiscal 2004. The non-exclusive licenses issued to other companies as well as the patent estate were valued at $3.6 million and are included in other intangible assets-net on the accompanying consolidated balance sheet as of September 30, 2004, and are being amortized on a straight-line basis through the earliest expiration of the related patents in April 2017. We will also be required to pay additional contingent milestone payments upon the achievement of certain milestones related to the development of PSN9301.

The value assigned to the acquired in-process R&D was determined by identifying the acquired in-process research projects for which: (a) technological feasibility had not been established at the acquisition date, (b) there was no alternative future use, and (c) the fair value was estimable based on reasonable assumptions. The acquired in-process R&D was valued at $32.8 million and was assigned entirely to PSN9301. The value of the acquired in-process R&D and the other identifiable intangible assets was determined by estimating the projected net cash flows, based upon the future revenues to be earned upon commercialization. In determining the value of the in-process R&D, the assumed commercialization date for the product was 2010. Given the risks associated with the development of new drugs, the revenue and expense forecast was probability-adjusted to reflect the risk of advancement through the approval process. The risk adjustments applied were based on the compound's stage of development at the time of assessment and the historical probability of successful advancement for compounds at that stage. The modeled cash flow was discounted back to the net present value. The projected net cash flows from such project were based on management's estimates of revenues and operating profits related to such project. The value of the in-process R&D was based on the income approach that focuses on the income-producing capability of the asset. The underlying premise of this approach is that the value of an asset can be measured by the present worth of the net economic benefit (cash receipts less cash outlays) to be received over

the life of the asset. Significant assumptions and estimates used in the valuation of in-process R&D included: the stage of development for the project; future revenues; growth rates; product sales cycles; the estimated life of a product's underlying technology; future operating expenses; probability adjustments to reflect the risk of developing the acquired technology into commercially viable products; and a discount rate of 26% to reflect present value.

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

(b) Cell Pathways

On June 12, 2003, we completed our acquisition of Cell Pathways, pursuant to the terms of an Agreement and Plan of Merger dated February 7, 2003. The acquisition was structured as a merger of a wholly-owned subsidiary of OSI with and into Cell Pathways. The resulting subsidiary was merged with and into OSI on July 14, 2003.

The assets purchased and liabilities assumed by us included: (a) two drug candidates in clinical development, Aptosyn® (exisulind) and OSI-461 (formerly CP461), and the related technology platform and patent estate; (b) exclusive distribution rights to the marketed product, Gelclair®, in North America; (c) rights to Cell Pathways' leased facility in Horsham, Pennsylvania, as well as leasehold improvements and certain equipment; (d) inventory; and (e) certain other assets and liabilities. We entered into consulting agreements with former Cell Pathways employees and officers engaged to assist us with the transition. Certain of these agreements also provide for the forgiveness of certain loans to these former officers. As of September 30, 2003, the full amount of these loans were forgiven as a result of such officers' efforts with the transition.

Gelclair® is a bioadherent oral gel that provides relief for the treatment of pain associated with oral mucositis, a debilitating side effect often seen in patients undergoing chemotherapy or radiation treatment. As part of the Cell Pathways transaction, we assumed the rights and obligations under an exclusive distribution agreement with Helsinn that allowed us to market and distribute Gelclair® in North America (United States, Canada and Mexico) through January 2012. Cell Pathways previously had entered into a three-year agreement with Celgene Corporation for the promotion of Gelclair®, primarily in the U.S. oncology market. On June 12, 2003, we entered into an agreement with Celgene whereby we recovered full rights to market and distribute Gelclair®in the oncology setting in North America. Our payment to Celgene under this agreement for the full return of the rights was expensed in the fourth quarter of fiscal 2003, upon the return of certain sales and marketing data. We were also required to make a payment to Celgene on the first anniversary of the effective date provided the transition services, as defined in the agreement, had been provided to us. The transition services were expensed ratably over the transition period from July 2003 through December 2003, and the payment was made in June 2004. The agreement also provides for a milestone payment to Celgene upon the achievement of a specified amount of net sales of Gelclair®. We previously had a marketing agreement with John O. Butler Company, under which Butler marketed Gelclair® to the dental market. In April 2004, we agreed with Butler to terminate this agreement. In the fourth quarter of fiscal 2004, we recorded an impairment charge related to our intangible asset for the exclusive distribution rights to Gelclair® (see note 8). In late October 2004, we exercised our right to terminate the agreement with Helsinn. Under the terms of the agreement, Helsinn has the option to purchase any and all of our inventory at cost plus 5% and if Helsinn does not elect to purchase our inventory, we are permitted to continue to sell such inventory. We are currently negotiating a new agreement with Helsinn.

As consideration for the merger, each share of Cell Pathways common stock was exchanged for (i) 0.0567 shares of our common stock and (ii) a contingent value right to receive 0.04 shares of our common stock in the event a new drug application is accepted for filing with the U.S. Food and Drug Administration by June 12, 2008 for either of the two newly acquired clinical candidates, Aptosyn® or OSI-461. Based on the exchange ratio of 0.0567, approximately 2.2 million shares of our common stock were issued to Cell Pathways' stockholders in connection with the merger. The 2.2 million common shares were valued at $31.2 million which was based on the average five-day closing price of our common stock around the date of the announcement of the merger which occurred on February 10, 2003. Any outstanding options that were not exercised prior to the effective date of the

merger were, in accordance with their terms, terminated. We assumed approximately 44,000 outstanding and unexercised warrants to purchase shares of Cell Pathways common stock under the same terms and conditions as the original Cell Pathways' warrants except that the exercise price of the warrants and the number of shares of our common stock for which the warrants are exercisable were adjusted based on the exchange ratio described above.

The acquisition was accounted for under the purchase method of accounting. The results of operations of Cell Pathways have been included in the consolidated statements of operations commencing as of June 12, 2003. The purchase price was allocated to the acquired assets and assumed liabilities based on the fair values as of the date of the acquisition. The excess of the fair value of the net identifiable assets acquired over the purchase price paid represented negative goodwill of approximately $49.2 million. Since a portion of the negative goodwill was a result of not recognizing contingent consideration (i.e., the contingent value rights), the maximum value of the contingent value rights at the date of the acquisition was recorded as if it were a liability, thereby reducing the negative goodwill. The value of the contingent value rights of $22.0 million was based on the average five day closing price of our common stock around the date of the announcement of the merger which occurred on February 10, 2003. The remaining negative goodwill of $27.0 million was allocated proportionately to reduce the value of the non-current assets acquired and the in-process research and development which was charged to operations.

The purchase price was allocated as follows (in thousands):

Acquired in-process R&D	$ 31,451
Gelclair® rights	28,957
Inventory	3,102
Fixed assets	402
Cash	1,791
Prepaid expenses and other assets	1,420
Total assets and acquired in-process R&D	67,123
Less liabilities assumed	(12,118)
Common stock and contingent rights issued and cash paid	$ 55,005

The value assigned to the acquired in-process R&D was determined by identifying those acquired in-process research projects for which: (a) technological feasibility had not been established at the acquisition date, (b) there was no alternative future use, and (c) the fair value was estimable based on reasonable assumptions. The acquired in-process R&D was valued at $31.5 million after the allocation of the negative goodwill, expensed on the acquisition date, and included in the accompanying consolidated statements of operations for the year ended September 30, 2003. The portion of the purchase price assigned to the acquired in-process R&D was allocated to the following two clinical candidates: Aptosyn® ($3.7 million), which was at that time in a Phase III trial in combination with Taxotere® for the treatment of advanced non-small cell lung cancer, or NSCLC, and OSI-461 ($27.8 million).

The value of the acquired in-process R&D was determined by estimating the projected net cash flows related to products under development, based upon the future revenues to be earned upon commercialization of such products. In determining the value of the in-process R&D, the assumed commercialization dates for these products ranged from 2005 to 2006. Given the risks associated with the development of new drugs, the revenue and expense forecasts were probability-adjusted to reflect the risk of advancement through the approval process. The risk adjustments applied were based on each compound's stage of development at the time of assessment and the historical probability of successful advancement for compounds at that stage. These modeled cash flows were discounted back to their net present value. The projected net cash flows from such projects were based on management's estimates of revenues and operating profits related to such projects. The value of the in-process R&D was based on the income approach that focuses on the income-producing capability of the assets. The underlying premise of this approach is that the value of an asset can be measured by the present worth of the net

economic benefit (cash receipts less cash outlays) to be received over the life of the asset. Significant assumptions and estimates used in the valuation of in-process R&D included: the stage of development for each of the two projects; future revenues; growth rates for each product; product sales cycles; the estimated life of a product's underlying technology; future operating expenses; probability adjustments to reflect the risk of developing the acquired technology into commercially viable products; and a discount rate of 25% to reflect present value.

(c) Gilead's Oncology Assets

On December 21, 2001, we acquired certain assets from Gilead Sciences, Inc. pursuant to the terms of the Asset Purchase Agreement dated as of November 26, 2001. The assets purchased by us included: (a) a pipeline of three clinical oncology candidates, (b) certain related intellectual property, and (c) rights to Gilead's leased facilities located in Boulder, Colorado, as well as leasehold improvements and certain fixed assets. In connection with the acquisition, we retained 117 Gilead employees in clinical operations, regulatory affairs, toxicology and *in vivo* pharmacology. The results of operations of Gilead's oncology assets have been included in the consolidated statement of operations commencing as of the date of the closing. In consideration for the assets, we paid approximately $135.7 million, which includes professional fees and the assumption of certain liabilities, and issued 924,984 shares of common stock, valued at $40.0 million. The value of the 924,984 common shares issued was based on the average closing price of our stock for the five days around the date of closing. We would also be obligated to pay contingent consideration of up to an additional $30.0 million in either cash or a combination of cash and common stock, upon the achievement of certain milestones related to the development of OSI-211, the most advanced of Gilead's oncology product candidates acquired by us. Additionally, we assumed certain royalty and milestone obligations to third parties in connection with the oncology candidates, acquired as part of the acquisition.

The acquisition was accounted for under the purchase method of accounting. The purchase price was allocated to the acquired assets and liabilities assumed based on the fair values as of the date of the acquisition. The excess of the purchase price paid over the fair value of the net identifiable assets acquired representing goodwill was $35.7 million. During fiscal 2002, we recorded an increase of $800,000 to the goodwill for additional payments to Gilead for acquisition-related costs. The value assigned to the acquired in-process R&D was determined by identifying those acquired in-process research projects for which: (a) technological feasibility had not been established at the acquisition date, (b) there was no alternative future use, and (c) the fair value was estimable based on reasonable assumptions. The acquired in-process R&D was valued at $130.2 million and expensed at the acquisition date and is included in the accompanying consolidated statement of operations for fiscal 2002. The portion of the purchase price assigned to the acquired in-process R&D was allocated to the following three clinical oncology candidates: OSI-211, a liposomal lurtotecan ($19.9 million), OSI-7904L, a liposomal thymidylate ($13.4 million) and OSI-7836, a nucleoside analog ($96.9 million).

The purchase price was allocated as follows (in thousands):

In-process R&D acquired	$130,200
Fixed assets	10,529
Goodwill	36,528
Prepaid expenses and other assets	663
Total assets and in-process R&D acquired	177,920
Less liabilities assumed	(2,178)
Cash and common stock paid	$175,742

The value of the acquired in-process R&D was determined by estimating the projected net cash flows related to products under development, based upon the future revenues to be earned upon commercialization of such products. In determining the value of the in-process R&D, the assumed commercialization dates for these products ranged from 2004 to 2008. Given the risks associated with the development of new drugs, the revenue and expense forecasts were probability-adjusted to reflect the risk of advancement through the approval process.

The risk adjustments applied were based on each compound's stage of development at the time of assessment and the historical probability of successful advancement for compounds at that stage. These modeled cash flows were discounted back to their net present value. The projected net cash flows from such projects were based on management's estimates of revenues and operating profits related to such projects. The in-process R&D was valued based on the income approach that focuses on the income-producing capability of the assets. The underlying premise of this approach is that the value of an asset can be measured by the present worth of the net economic benefit (cash receipts less cash outlays) to be received over the life of the asset. Significant assumptions and estimates used in the valuation of in-process R&D included: the stage of development for each of the three projects; future revenues; growth rates for each product; product sales cycles; the estimated life of a product's underlying technology; future operating expenses; probability adjustments to reflect the risk of developing the acquired technology into commercially viable products; and a discount rate of 18% to reflect present value.

In connection with the acquisition, 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 represents the fair value of our stock at the date granted. The options vest one-third in a year from the date of grant and monthly thereafter for 24 months.

(d) Unaudited Pro Forma Financial Information

The following unaudited pro forma financial information presents a summary of our consolidated results of operations for fiscal 2003 and fiscal 2002, assuming (i) the Cell Pathways acquisition had taken place as of October 1, 2002 and October 1, 2001, respectively and (ii) the acquisition of certain assets from Gilead had taken place as of October 1, 2001 (in thousands, except per share information):

	Years Ended September 30,	
	2003	2002
Revenues	$ 33,751	$ 22,834
Loss before non-recurring charge related to the acquisitions	$(171,640)	$(124,513)
Basic and diluted loss per share before non-recurring charge related to the acquisitions	$ (4.42)	$ (3.24)

The unaudited pro forma financial information has been prepared for comparative purposes only. The pro forma information includes the historical unaudited results of Cell Pathways and certain assets from Gilead for the respective periods. The pro forma financial information includes adjustments to our historical results to reflect the issuance of approximately 2.2 million shares of common stock and excludes the charge of $31.5 million related to the acquired in-process R&D related to Cell Pathways and includes the issuance of approximately 925,000 shares of common stock and excludes the charge of $130.2 million related to the acquired in process R&D related to Gilead. The pro forma information does not purport to be indicative of operating results that would have been achieved had the acquisition taken place on the dates indicated or the results that may be obtained in the future.

(4) Investments

(a) Investment Securities

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

The following is a summary of available-for-sale securities as of September 30 (in thousands):

	Cost	Gross Unrealized Gains (Losses)	Fair Value
2004			
U.S. government securities	$135,695	$(542)	$135,153
Corporate and financial institutions debt and equity securities	28,053	(121)	27,932
Total	$163,748	$(663)	$163,085

	Cost	Gross Unrealized Gains	Fair Value
2003			
U.S. government securities	$144,026	$136	$144,162
Corporate and financial institutions debt and equity securities	29,690	205	29,895
Total	$173,716	$341	$174,057

Our investment securities include mutual funds with a cost basis and fair market value of $811,000 as of September 30, 2004 and a cost basis and fair market value of $1.6 million as of September 30, 2003. Net realized gains (losses) on sales of investments during fiscal 2004, 2003 and 2002 were $41,000, $347,000, and $(143,000), respectively.

Maturities of securities classified as available-for-sale, excluding mutual funds, were as follows at September 30, 2004 (in thousands):

	Cost	Fair Value
2005	$ 41,041	$ 40,872
2006	75,506	75,117
2007	44,946	44,875
2008	194	194
2009	—	—
2010 and thereafter	1,250	1,216
	$162,937	$162,274

(b) Other Investments

In July 1997, we, together with Cold Spring Harbor Laboratory and Roche, formed Helicon Therapeutics, Inc., a Delaware corporation. In exchange for approximately 30% of Helicon's outstanding capital stock, we contributed to Helicon molecular screening services which were completed in fiscal 1998 and a nonexclusive license with respect to certain screening technology. As of September 30, 2004, we owned approximately 4.17% of Helicon common stock. As of September 30, 2004 and 2003, our investment in Helicon was fully reserved.

We have an investment in a venture capital fund limited partnership that is focused on emerging companies that are developing therapeutics to treat cancer and other diseases. We account for our investment under the cost method of accounting. As of September 30, 2004 and 2003, our investment in the limited partnership was $1.3 million and $1.2 million, respectively, representing a 1.96% ownership interest, and is included in other assets in the accompanying consolidated balance sheets.

We had an investment in and a license and technology development agreement with a privately-owned healthcare information company that developed and provided web-based products and services for the clinical trial process, including facilitation of patient accrual. During fiscal 2002, we determined that there was an other than temporary decline in fair value for this investment and recorded a charge of $500,000 in other expense-net on the accompanying consolidated statement of operations for fiscal 2002, to fully reserve our investment. Such investment was written off in fiscal 2003. In addition, in fiscal 2002 we wrote-off a portion of the prepaid balance pertaining to the license agreement in order to reflect the remaining expected future benefit of this asset. The write-off resulted in a charge of $700,000, which is reflected in R&D in the accompanying consolidated statement of operations for fiscal 2002. The remaining portion of the prepaid balance was expensed in fiscal 2003.

(5) Product Development Contracts

(a) Roche and Genentech

On January 8, 2001, we entered into an alliance with Genentech and Roche for the global co-development and commercialization of Tarceva™. We received upfront fees of $25 million related to this alliance, and Genentech and Roche each purchased $35 million of our common stock at $75.66 per share. We are also entitled to up to $92 million upon the achievement of certain milestones under the terms of the alliance of which $10.0 million was received as of September 30, 2004. 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 on an equal basis; to share information generated under a global development plan; to facilitate attainment of necessary regulatory approval of Tarceva™ for commercial marketing and sale in the world; and to work together on such matters as the parties agree from time to time during the development of Tarceva™. We, as well as Genentech and Roche, may conduct clinical and pre-clinical activities for additional indications for Tarceva™ not called for under the global development plan, subject to certain conditions. The Tripartite Agreement will terminate when either the OSI/Genentech collaboration agreement or the OSI/Roche agreement terminates. Any reimbursement from or additional payments to Genentech or Roche for R&D costs under the cost sharing arrangement of the Tripartite Agreement are recorded as an increase or decrease to R&D expenses in the accompanying consolidated statements of operations.

Under the OSI/Genentech collaboration agreement, we agreed to collaborate in the product development of Tarceva™ with the goals of obtaining regulatory approval for commercial marketing and sale in the United States of products resulting from the collaboration, and, subsequently, supporting the commercialization of the product. Consistent with the development plan and with the approval of a joint steering committee, we agree with Genentech as to who will own and be responsible for the filing of drug approval applications with the FDA other than the first NDA, which we own and filed, and the first supplemental NDA, which we will own and for which we will be responsible for filing. 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 were defined in an amendment to the agreement effective as of June 4, 2004. Pursuant to this amendment, we will co-promote Tarceva™ using a sales force that will be equal to or greater than 25% of the combined OSI/Genentech sales force. We will 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 will recognize all U.S. sales of Tarceva™. We will recognize revenues and losses from our alliance with Genentech, which will consist of our 50% share of the pretax profits (loss) generated from the sales of Tarceva™ in the United States. We also will recognize manufacturing revenue from the sale of inventory to Genentech for commercial sales of Tarceva™ in the United States and partial reimbursement from Genentech of our Tarceva™-related commercial expenses. We will receive royalties on sales of Tarceva™ outside of the United States by Roche and up to an aggregate of $92 million in non-refundable milestone payments from Genentech and Roche upon the achievement of certain milestones relating to regulatory submissions and approval, certain of which have already been received.

The OSI/Genentech collaboration agreement continues until the date on which neither we nor Genentech are entitled to receive a share of the operating profits or losses on any products resulting from the collaboration, that is, until the date that we and Genentech mutually agree to terminate the collaboration or until either party exercises its early termination rights. The OSI/Genentech collaboration agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. The provisions of the amendment allowing us to co-promote are also subject to termination by Genentech upon a material breach by us of the amendment which remains uncured or upon a pattern of nonmaterial breaches which remains uncured. In addition, since January 8, 2003, Genentech has had 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 product development of Tarceva™ and is responsible for future marketing and commercialization of Tarceva™ outside of the United States in certain territories as defined in the agreement. The grant is a royalty-bearing, non-transferable (except under certain circumstances), non-sublicensable (except under certain circumstances), sole and exclusive license to use, sell, offer for sale and import products resulting from the development of Tarceva™ worldwide, other than the territories covered by the OSI/Genentech collaboration agreement. In addition, Roche has the right, which it has exercised, to manufacture commercial supplies of Tarceva™ for its territory, subject to certain exceptions. Roche will pay us certain milestone payments and royalty payments on sales of products resulting from the collaboration. We have primary responsibility for patent filings for the base patents protecting Tarceva™ and, in addition, we have the right, but not the obligation, to institute, prosecute and control patent infringement claims relating to the base patents. The OSI/Roche agreement continues until the date on which we are no longer entitled to receive a royalty on products resulting from the development of Tarceva™, that is, until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva™ or, in countries where there is no valid patent covering Tarceva™, on the tenth anniversary of the first commercial sale of Tarceva™ in that country, or until either party exercises early termination rights. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, since July 31, 2003, Roche has had the right to terminate the agreement on a country-by-country basis with six months' prior written notice. Since such time, we also have had the right to terminate the agreement on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

(b) Anaderm

On April 23, 1996, we formed Anaderm Research Corporation with Pfizer Inc. and New York University for the discovery and development of novel compounds to treat conditions such as baldness, wrinkles and pigmentation disorders. In April 1999, we amended a prior research agreement with Pfizer and Anaderm to expand our collaborative program. On September 23, 1999 we sold our interest in Anaderm to Pfizer. The amended research

agreement expired in April 2002, followed by a three-year phase-down period. Anaderm or Pfizer will pay royalties to us on the sales of products resulting from the collaboration. In July 2002, we announced our agreement with Anaderm to accelerate the conclusion of the phase-down period of this collaboration. We received an $8.0 million wind-down fee in consideration for transferring all research being performed by us to Anaderm. Of such amount, we received $4.5 million in September 2002 and received $3.5 million in March 2003 after completion of the transfer. The $4.5 million was recognized as revenue ratably over the expected term of the transition period and the $3.5 million was recognized upon the successful completion of the transition. For the years ended September 30, 2003 and 2002, we recognized $6.2 million and $1.8 million, respectively, of collaborative program revenues in the accompanying consolidated statement of operations relating to the phase-down.

(c) Tanabe

Effective as of October 1, 1999, we entered into the Collaborative Research and License Agreement with Tanabe Seiyaku Co. Ltd. focused on discovering and developing novel pharmaceutical products to treat diabetes. In April 2003, we assigned our rights and obligations under the collaborative agreement to Prosidion. The contract period under this agreement expired on October 1, 2003 and was not renewed. Tanabe had the responsibility for further development and marketing of any lead compound in exchange for milestone and royalty payments to us. In March 2004, Prosidion entered into a termination agreement with Tanabe, whereby Prosidion obtained the rights to certain patents developed under the collaboration, subject to Tanabe's rights to develop and commercialize, in certain Asian territories, certain compounds covered by such patents. In consideration of the termination, Prosidion paid Tanabe $1.0 million in cash and issued $1.0 million of Prosidion preferred stock. This expense of $2.0 million is included in R&D expenses on the accompanying statement of operations for fiscal 2004. Prosidion is also required to make certain payments to Tanabe upon the achievement of certain milestones.

(d) Vanderbilt

Effective as of April 28, 1998, we entered into a Collaborative Research, Option and Alliance Agreement with Vanderbilt University to conduct a collaborative research program and seek a corporate partner to fund a technology collaboration for the discovery and development of drugs to treat diabetes. Upon our collaboration with Tanabe and concurrently with the execution of the Tanabe agreement, we entered into an Amended and Restated Collaborative Research, License and Alliance Agreement with Vanderbilt and Tanabe with an effective date of August 31, 1999. In April 2003, we assigned our rights and obligation under the agreement of Prosidion. The term of the research program we conducted with Vanderbilt ended on the termination of the contract period under the Tanabe agreement which occurred on October 1, 2003.

We provided funding to Vanderbilt to conduct the OSI/Vanderbilt research program. A portion of this funding came from Tanabe's funding of the OSI/Tanabe research program. Prosidion will pay to Vanderbilt a percentage of the revenues it receives from Tanabe and any other third party which commercializes products resulting from the OSI/Tanabe research program based on the extent to which Vanderbilt technology and patents contributed to the product generating the revenue.

(e) Pfizer

In April 1986, we entered into a collaborative research agreement and a license agreement with Pfizer. We renewed the collaboration for additional five-year terms in 1991 and 1996, respectively. On April 1, 2001, the funded phase of the collaborative research agreement expired and was not renewed. Following the expiration of the collaborative research agreement, Pfizer is continuing to develop certain specified drug candidates which emanated from the collaborative research agreement and for which Pfizer will owe us a royalty if ultimately commercialized. We continue to have rights in joint technology developed during the collaboration.

In June 2000, we gained full development and marketing rights to Tarceva™ in order to allow Pfizer to meet certain requirements of the U.S. Federal Trade Commission, or FTC, arising from the FTC's review of Pfizer's merger with the Warner-Lambert Company. Under terms of the agreement with Pfizer, which became effective upon issuance and publication of the FTC's order on June 19, 2000, we received a royalty-free license to all rights for the further development and commercialization of Tarceva™. The terms of the agreement did not require us to

make any payments to Pfizer for the license. In January 2001, we entered into a co-development and marketing partnership with Genentech and Roche for Tarceva™ (see note 5(a)).

(f) Other

Under the terms of the aforementioned and other collaborative research agreements, with terms similar to the aforementioned agreements, certain collaborative partners will pay us royalties on net sales of products resulting from these research programs in addition to the research revenues described below. To date, we have not received any royalties pursuant to these agreements. We or our collaborative partners may terminate each of the collaborative research programs upon the occurrence of certain events.

We did not record any collaborative program revenues in fiscal 2004 due to the expiration of these collaborations. Total collaborative program revenues under our collaborative research agreements for fiscal 2003 and 2002 are as follows (in thousands):

	Years Ended September 30,	
	2003	2002
Related Parties:		
Anaderm	$6,187	$ 7,649
Other	—	175
Total related parties	6,187	7,824
Tanabe	3,368	4,077
Other	—	75
Total	$9,555	$11,976

(6) License Agreements

We have entered into various license agreements with third parties to grant the use of our proprietary assets. These licenses include the use of our patented gene transcription estate as well as the use of our DP-IV patent estate acquired from Probiodrug. Licensees may be obligated to pay us license fees, annual fees, and milestones and royalties based on the development and sale of products derived from the licensed patents. Generally, the duration of each license is to be coextensive with the life of the last to expire of the underlying patents.

(7) Property, Equipment and Leasehold Improvements

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

	Estimated Life (Years)	September 30,	
		2004	2003
Laboratory equipment	5-15	$29,329	$28,446
Office furniture & equipment and computer equipment	3-10	14,115	13,297
Capitalized software	3	3,863	3,410
Leasehold improvements	Life of lease	32,375	34,503
		79,682	79,656
Less: accumulated depreciation and amortization		44,326	34,679
Property, equipment and leasehold improvements — net		$35,356	$44,977

Depreciation expense relating to these assets for fiscal 2004, 2003 and 2002 was $14.3 million, $11.1 million and $8.7 million, respectively. We capitalized $3.9 million and $3.4 million of computer software costs as of September 30, 2004 and 2003, respectively, of which $2.9 million and $2.0 million was amortized as of September 30, 2004 and 2003, respectively.

(8) Goodwill and Other Intangible Assets

The carrying amount of goodwill was $39.0 million and $38.8 million as of September 30, 2004 and 2003, respectively. The balance as of September 30, 2004 includes a $206,000 effect from foreign currency exchange rate fluctuations during fiscal 2004. We completed our annual impairment review of goodwill during the first quarter of fiscal 2004 and determined that no impairment charge was required. Amortization expense relating to capitalized workforce for fiscal 2002 was $1.3 million.

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

	September 30,					
	2004			2003		
	Carrying Amount	Net Accumulated Amortization	Book Value	Carrying Amount	Net Accumulated Amortization	Book Value
Novantrone® rights	$46,009	$(23,004)	$23,005	$46,009	$(8,084)	$37,925
Gelclair® rights	—	—	—	28,957	(984)	27,973
Acquired patent estate	515	(7)	508	—	—	—
Acquired licenses issued to other companies	3,093	(40)	3,053	—	—	—
License to compound libraries	—	—	—	740	(493)	247
Total	$49,617	$(23,051)	$26,566	$75,706	$(9,561)	$66,145

We acquired the exclusive rights to market and promote Novantrone® for approved oncology indications in the United States from Serono in March 2003. These rights are being amortized over the life of the underlying patent. In connection with the acquisition of Cell Pathways, we assumed the exclusive rights to market and distribute Gelclair® in North America which Cell Pathways had acquired from Sinclair Pharma plc in January 2002 for a period of ten years. These rights were being amortized over eight and a half years, the remaining term of the agreement. SFAS No. 142 requires that intangible assets with determinable useful lives be amortized over their respective estimated useful lives and reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In the fourth quarter of fiscal 2004, it was determined that the carrying value of the Gelclair® rights exceeded the expected future undiscounted cash flows. The impairment charge resulted from both the recent discontinuance of discussions with a replacement dental partner, and slower than originally expected sales growth in the oncology marketplace following the re-launch of the product in October 2003. The discounted cash flows calculation was made utilizing various assumptions and estimates regarding future revenues and expenses, cash flow and discount rates. Based upon our analysis, we recognized an impairment loss for the remaining carrying value of the rights as of September 30, 2004. This impairment loss of $24.6 million is included as impairment of intangible asset expense in the accompanying consolidated statement of operations for fiscal 2004. In connection with Prosidion's acquisition of certain assets of Probiodrug, we recorded intangible assets for the acquired patent estate ($515,000) and two non-exclusive licenses issued to Merck & Co., Inc. and Novartis Pharma AG ($3.1 million). These intangible assets are being amortized over the shortest life of the patents in April 2017. In the first quarter of fiscal 2004, we made the decision not to renew our research agreement with British Biotech plc and as a result recorded an accelerated amortization relating to the license for compound libraries of $217,000 which is included in amortization expense in the accompanying consolidated statement of operations for fiscal 2004.

Amortization expense for these intangible assets for fiscal 2004, 2003 and 2002 was $18.6 million, $9.3 million, and $216,000, respectively. Amortization expense is estimated to be $15.2 million for fiscal 2005 and $8.4 million for fiscal 2006 and $283,000 for fiscal 2007 through 2010.

(9) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses at September 30, 2004 and 2003 are comprised of (in thousands):

	September 30, 2004	September 30, 2003
Accounts payable	$ 3,852	$ 4,106
Accrued payroll and employee benefits	3,502	2,054
Accrued incentive compensation	4,629	2,700
Accrued exit costs (see note 17)	6,963	—
Accrued interest	298	1,364
Accrued CRO and site costs	2,132	4,977
Accrued commercial and development costs due to related parties	13,411	6,353
Accrued inventory purchase commitments (see note 1(l))	4,868	—
Other accrued expenses	6,485	7,459
	$46,140	$29,013

(10) Convertible Senior Subordinated Notes

(a) 3.25% Convertible Senior Subordinated Notes

On September 8, 2003, we issued $135.0 million aggregate principal amount of convertible senior subordinated notes, or the 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 an additional net proceeds to us of $14.5 million. The 2023 Notes bear interest at 3.25% per annum, payable semi-annually, and mature on September 8, 2023. The 2023 Notes are convertible into shares of our common stock at a conversion price of $50.02 per share, subject to normal and customary adjustments such as stock dividends or other dilutive transactions. We may redeem the 2023 Notes, in whole or in part, for cash, at any time after September 8, 2008 for a price equal to 100% of the principal amount of the 2023 Notes to be redeemed, plus any accrued and unpaid interest. The holders of the 2023 Notes have the right to require us to purchase all of the 2023 Notes, or a portion thereof, on September 8, 2008, September 8, 2013 and September 8, 2018 for a price equal to 100% of the principal amount of the 2023 Notes plus any accrued and unpaid interest. Upon a change in control, as defined in the indenture governing the 2023 Notes, the holders of the 2023 Notes will have the right to require us to purchase all of the 2023 Notes, or a portion thereof, not previously called for redemption at a purchase price equal to 100% of the principal amount of the 2023 Notes purchased, plus accrued and unpaid interest. Upon the election, by the holders, of the right to require us to purchase the 2023 Notes or upon a change of control, we may elect to pay the purchase price in common stock instead of cash. The number of shares of common stock a holder will receive will equal the purchase price divided by 95% of the average of the closing prices of our common stock for the five-trading day period ending on the third business day prior to the purchase date. The related debt issuance costs of $5.3 million were deferred and are being amortized on a straight-line basis over a five-year term, which represents the earliest date that we may redeem the 2023 Notes. In connection with the issuance of the 2023 Notes, we used $19.0 million of the net proceeds for the purchase of 503,800 shares of our common stock (see note 11(h)). At September 30, 2004 and 2003, the fair value of the outstanding 2023 Notes, was approximately $223.5 million and $147.7 million, respectively, based on their quoted market value.

(b) 4.00% Convertible Senior Subordinated Notes

On February 1, 2002, we issued $200.0 million aggregate principal amount of convertible senior subordinated notes, or the 2009 Notes, in a private placement for net proceeds to us of $192.9 million. The 2009 Notes were convertible into shares of our common stock at a conversion price of $50 per share, subject to normal and customary adjustments such as stock dividends. The 2009 Notes were redeemable by us, in whole or in part, at any time before February 1, 2005 if the closing price of our common stock exceeded 150% of the conversion price then in effect for a specified period of time. The related debt issuance costs of $7.1 million were deferred and were being amortized on a straight-line basis over the seven-year term of the 2009 Notes. In August and September 2002, we retired a total of $40.0 million in principal amount of the 2009 Notes for an aggregate purchase price of $26.2 million, including accrued interest of $133,000. The difference between the purchase price and the principal amount of the 2009 Notes retired and accrued interest, resulted in a net gain on the early retirement of the 2009 Notes in the fourth quarter of fiscal 2002 of $12.6 million, including the write off of approximately $1.3 million of the related debt issuance costs. In June 2004, we called for the full redemption of the outstanding $160.0 million of the 2009 Notes. All of the holders of the 2009 Notes converted their notes into shares of our common stock prior to the redemption date of July 19, 2004. As a result of these conversions, we issued 3.2 million shares of our common stock and paid the remaining portion of the guaranteed interest of $6.4 million which is included in interest expense on the accompanying consolidated statement of operations for fiscal 2004. Under the terms of the 2009 Notes, the note holders were guaranteed the payment of interest for the first three years through February 1, 2005. Upon conversion of the 2009 Notes, the remaining balance of the unamortized debt issuance costs of $3.7 million was reclassified to additional paid in capital.

(11) Stockholders' Equity

(a) Stock Option Plans

We have established eight stock option plans for our employees, officers, directors and consultants, including the 2001 Incentive and Non-Qualified Stock Option Plan. The plans are administered by the Compensation Committee of the Board of Directors, which may grant either non-qualified or incentive stock options. The Committee determines the exercise price and vesting schedule at the time the option is granted. Options vest over various periods and expire no later than 10 years from date of grant. The total authorized shares under these plans is 12,565,249.

Our Board of Directors adopted the 2001 Incentive and Non-Qualified Stock Option Plan, or the 2001 Stock Option Plan, effective June 13, 2001, which was approved by the stockholders on March 13, 2002. Under the 2001 Stock Option Plan, we may grant incentive stock options and non-qualified stock options to purchase up to 4,000,000 shares. Participation in the plan is limited to our directors, officers, employees and consultants of our parent or subsidiaries. The 2001 Stock Option Plan also continues the automatic, formula-based grants of non-qualified stock options to directors who are not our employees. On December 11, 2002, our Board of Directors approved an amendment to the 2001 Stock Option Plan that only affected the automatic, formula-based grants of non-qualified stock options to directors who are not our employees. Under the amended formula, each individual who becomes a director on or after January 1, 2003 will receive an initial option to purchase 50,000 shares of common stock upon his or her election to the Board. Persons elected to the Board after June 13, 2001 but prior to January 1, 2003 were entitled to an initial grant of an option to purchase 30,000 shares of common stock upon their initial election. All persons elected to the Board after June 13, 2001 receive annual grants of options to purchase 7,500 shares upon reelection to the Board. Persons elected to the Board prior to June 13, 2001 will continue to be eligible, upon reelection to the Board, for annual grants of options to purchase shares of common stock in an amount which depends upon the number of years of service as a director (20,000 shares reducing to 7,500 shares). On March 17, 2004, at the 2004 Annual Meeting of Stockholders, our stockholders approved the Amended and Restated Stock Incentive Plan, which was adopted by the Board of Directors on January 23, 2004. This plan amends and restates the 2001 Stock Option Plan to permit, in addition to the grant of options, the grant of restricted stock awards, stock appreciation rights and stock bonus awards upon such terms and conditions as the Compensation Committee appointed by the Board of Directors shall determine.

The following table summarizes changes in the number of common shares subject to options in the eight stock option plans, options established for certain outside consultants, options granted to employees of OSI-UK, and options granted to outside directors during fiscal 2004, 2003 and 2002:

	Shares (In thousands)	Exercise Price		
		Low	High	Weighted Average
Balance at September 30, 2001 — Unexercised	3,758	$ 3.25	$60.06	$23.20
Granted	1,817	13.09	47.68	33.02
Exercised	(432)	3.25	23.25	13.16
Forfeited	(533)	3.50	60.06	41.73
Balance at September 30, 2002 — Unexercised	4,610	$ 3.25	$60.06	$26.00
Granted	1,665	15.02	37.16	28.10
Exercised	(642)	3.25	31.85	10.60
Forfeited	(341)	21.55	51.80	33.57
Balance at September 30, 2003 — Unexercised	5,292	$ 3.25	$60.06	$28.01
Granted	1,206	25.21	82.88	61.40
Exercised	(1,489)	3.25	60.06	26.21
Forfeited	(121)	13.09	67.63	36.97
Balance at September 30, 2004 — Unexercised	4,888	$ 3.63	$82.88	$36.61

At September 30, 2004, we have reserved 5.9 million shares of our authorized common stock for all shares issuable under options. At September 30, 2004, 2003 and 2002, the number of options exercisable were 2.6 million, 2.8 million, and 2.3 million, respectively.

Information regarding stock options outstanding as of September 30, 2004, is as follows:

	Options Outstanding			Options Exercisable	
Price Range	Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Shares (In thousands)	Weighted Average Exercise Price
$ 0.00 - $10.00	497	$ 6.66	2.9	497	$ 6.66
$10.01 - $20.00	295	16.04	7.8	183	16.02
$20.01 - $30.00	927	22.58	6.9	661	22.40
$30.01 - $40.00	1,346	32.57	8.7	464	32.06
$40.01 - $50.00	562	44.37	7.3	492	44.38
$50.01 - $60.00	287	52.74	6.9	225	51.80
$60.01 - $70.00	906	66.83	9.3	93	60.06
$70.01 - $80.00	13	79.13	9.7	—	—
$80.01 - $90.00	55	82.84	9.7	—	—
	4,888	$36.61	7.6	2,615	$28.68

(b) Shareholder Rights Plan

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

(c) Authorized Common and Preferred Stock

We have 200.0 million shares of authorized common stock, with a par value of $.01 per share, and 5.0 million shares of preferred stock with a par value of $.01 per share, with such designations, preferences, privileges, and restrictions as may be determined from time to time by our Board of Directors.

(d) Employee Stock Purchase Plan

We have an Employee Stock Purchase Plan under which eligible employees may contribute up to 10% of their base earnings toward the quarterly purchase of our common stock. The employee's purchase price is derived from a formula based on the fair market value of the common stock. No compensation expense is recorded in connection with the plan. During fiscal 2004, 2003 and 2002, approximately 16,000, 26,000, and 19,000 shares, respectively, were issued with approximately 136, 118, and 163 employees participating in the plan, respectively. At September 30, 2004, we had 566,000 shares of our authorized common stock reserved in connection with this plan.

We sponsor a stock purchase plan for employees of OSI-UK, our wholly-owned subsidiary. Under the terms of the plan, eligible employees may contribute between £5 and £250 of their base earnings, in 36 monthly installments towards the purchase of our common stock. The employee's purchase price is determined at the beginning of the 36-month period and compensation expense is recorded over the 36-month period. As a result of our decision in the fourth quarter of fiscal 2004 to consolidate all of our U.K.-based oncology research and development activities into our New York locations (see note 17(b)), we did not offer this plan to employees for fiscal 2004. During fiscal 2003, the maximum shares that may be issued under this plan was increased from 100,000 shares to 200,000 shares. As of September 30, 2004, there were 45 employees and 75 employees in the 2003 and 2002 stock purchase plans, respectively. At September 30, 2004, we had 152,000 shares of our common stock reserved in connection with this plan.

(e) Stock Purchase Plan for the Non-Employee Directors

Our Board of Directors approved the adoption of a stock purchase plan for non-employee directors on June 21, 1995 subject to the stockholders' approval. On March 25, 1996 at the 1996 Annual Meeting of Stockholders, the stockholders approved the Stock Purchase Plan for Non-Employee Directors, or the Directors' Stock Purchase Plan.

On December 11, 2002, our Board of Directors approved an amendment to the Directors' Stock Purchase Plan. Pursuant to the amended Directors' Stock Purchase Plan, fifty-percent of the annual retainer fee earned by each non-employee director will be paid to the director in the form of a restricted stock award. The restricted stock award will be made as of each annual stockholder meeting at which directors are elected beginning with the 2003 Annual Meeting of Stockholders which occurred on March 19, 2003. Annual restricted stock awards will vest in monthly installments over the one-year term for which the award is made. In the event a director's membership on the Board terminates prior to the end of such one-year term, any unvested portion of the director's restricted stock award will be forfeited. Shares of restricted stock awarded annually may not be sold or transferred by the director until the first anniversary of the date of grant of such award. Non-employee directors may elect to receive the remaining fifty-percent of the director's annual retainer in the form of shares of common stock under the Directors' Stock Purchase Plan as well. At September 30, 2004, we had 58,000 shares of our common stock reserved in connection with this plan.

(f) Issuance of Common Stock to Gilead

On December 21, 2001, in connection with the acquisition of certain oncology assets from Gilead, we issued approximately 925,000 shares of common stock valued at $40.0 million (see note 3(c)).

(g) Issuance of Common Stock to Cell Pathways

On June 12, 2003, in connection with the acquisition of Cell Pathways, we issued approximately 2.2 million shares of our common stock valued at $31.2 million (see note 3(b)).

(h) Convertible 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 2023 Notes, for additional net proceeds to us of $14.5 million. 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 (see note 10(a)). 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.

On February 1, 2002, we issued $200.0 million aggregate principal amount of 2009 Notes in a private placement. In August and September 2002, we retired a total of $40.0 million in principal amount of the 2009 Notes for an aggregate purchase price of approximately $26.2 million. The 2009 Notes were convertible into shares of our common stock at a conversion price of $50 per share, subject to normal and customary adjustments such as stock dividends or other dilutive transactions. In June 2004, we called for the full redemption of the outstanding $160.0 million of the 2009 Notes. All of the holders of the 2009 Notes converted their notes into shares of our common stock prior to the redemption date of July 19, 2004. As a result of these conversions, we issued 3.2 million shares of our common stock. Upon conversion of the 2009 Notes the remaining balance of the unamortized debt issuance costs of $3.7 million was reclassified to additional paid in capital (see note 10(b)).

(12) Income Taxes

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

The tax effect of temporary differences, net operating loss carry forwards and research and development tax credit carry forwards as of September 30 are as follows (in thousands):

	September 30, 2004	September 30, 2003
Deferred tax assets:		
Net operating loss carry forwards	$ 299,412	$ 213,358
Research and development tax credit carry forwards	12,125	12,610
Inventory reserve	3,486	—
Intangible assets	4,921	1,292
Unearned revenue	4,126	2,952
Purchased research and experimental expenditures	57,590	48,000
Capitalized research and experimental expenditures	14,586	16,764
Restructuring charge	1,358	—
Capitalized start-up costs	6,759	9,586
Other	12,492	9,396
	416,855	313,958
Valuation allowance	(415,355)	(300,159)
	1,500	13,799
Deferred tax liability:		
Gelclair® rights	—	(11,805)
UK accelerated depreciation allowance	(1,500)	(1,994)
	(1,500)	(13,799)
	$ —	$ —

As of September 30, 2004, we have available U.S. federal and foreign net operating loss carry forwards of approximately $696 million and $53 million, respectively which will expire in various years from 2005 to 2023 and may be subject to certain annual limitations. Our research and development tax credit carry forwards expire in various years from 2006 to 2024. Certain of our net operating loss carry forwards and research and development tax credits may be subject to significant limitations under Section 382 of the Internal Revenue Code.

Of the $415 million valuation allowance at September 30, 2004, $104 million relates to deductions for employee stock options for which the tax benefit will be credited to additional paid in capital if realized.

(13) Commitments and Contingencies

(a) Lease Commitments

We lease office, operating and laboratory space under various lease agreements. Rent expense was $8.8 million, $7.4 million, and $6.2 million for fiscal 2004, 2003 and 2002, respectively. Rent expense for fiscal 2004 includes the Oxford, England facility leases, the Boulder, Colorado facility leases (acquired in December 2001), the Farmingdale, New York facility lease, the Melville, New York facility lease (commenced in June 2001), the Uniondale, New York facility lease and the Horsham, Pennsylvania facility lease (acquired in June 2003). As further discussed in note 17, we accrued for the remaining net lease rental payments for the Horsham and Uniondale facilities in fiscal 2004 and the remaining net lease rental payments for the Birmingham, England facility in fiscal 2002.

The following is a schedule of future minimum rental payments for the next five fiscal years and thereafter required as of September 30, 2004, assuming expiration of the leases for the Uniondale facility in June 2006, the Boulder facilities in October 2006, the Horsham facility in June 2008, the Melville facility in December 2009, the

two Oxford facilities in August 2009 and March 2021, and the Farmingdale facility in May 2022. Also included in the amounts below are commitments for equipment under various operating leases (in thousands).

2005	$ 8,188
2006	6,589
2007	5,208
2008	6,168
2009	5,794
2010 and thereafter	48,789
	$80,736

Deferred rent expense reflected on the accompanying consolidated balance sheet reflects the expense recorded in excess of the required lease payments in connection with our facility leases.

(b) Contingencies

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

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

(c) Borrowings

As of September 30, 2004, we had a line of credit with a commercial bank in the amount of $10 million. This line expires annually on March 31st, and its current rate of interest is prime plus ¾. There were no amounts outstanding under the line of credit as of September 30, 2004 and 2003.

(14) Related Party Transactions

One member of our Board of Directors is a partner in a law firm which represents us on our patent and license matters. Fees paid to this firm in fiscal 2004, 2003 and 2002 were approximately $557,000, $579,000, and $504,000, respectively. One member of our Board of Directors is a controlling member of Mehta Partners LLC with which we had a strategic and financial services arrangement that expired in December 2002. In fiscal 2002, we paid Mehta Partners $175,000 for consulting services. In addition, we have compensated other directors for services performed pursuant to consultant arrangements. In fiscal 2004, 2003 and 2002, consulting fees in the amounts of $139,000, $150,000, and $153,000, respectively, were paid by us pursuant to these arrangements. One member of our Board of Directors was an officer of Cold Spring Harbor Laboratory through December 2003, which was a founder of Helicon. In fiscal 2003, we entered into a research agreement with Cold Spring Harbor Laboratory. One of our former executive officers was vice president of Helicon through November 2002 and vice president of Anaderm through November 2001. One member of our Board of Directors was the chief executive officer of Helicon through December 1999. We have a fully reserved investment in Helicon (note 4(b)). A director is on the faculty of Vanderbilt with which we had a collaborative research agreement through September 30, 2003, and also has a consulting agreement with our subsidiary, Prosidion, and is a shareholder of Prosidion. One member

of our Board of Directors is a non-executive director of Genentech and is an advisor to Roche, both entities with which we have collaboration agreements.

One of our officers and one of our vice presidents has outstanding loans with us aggregating $200,000 with a carrying amount of $164,000 as of September 30, 2004. We assumed these loans in connection with the acquisition of certain assets from Gilead on December 21, 2001.

(15) Employee Savings and Investment Plan

We sponsor an Employee Savings and Investment Plan under Section 401(k) of the Internal Revenue Code. The plan allows our U.S. employees to defer from 2% to 20% of their income on a pre-tax basis through contributions into designated investment funds. For each dollar the employee invests, up to 6% of his or her earnings, we will contribute an additional 50 cents into the funds. For fiscal 2004, 2003 and 2002, our expenses related to the plan were approximately $625,000, $543,000, and $502,000, respectively.

We also sponsor four pension plans covering the employees of OSI-UK and Prosidion. The Group Personal Pension Plan allows employees to contribute up to 31% (depending on their age) 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 will contribute from 4% to 9% depending on the employees' contributions. The British Biotech Pension Scheme covers employees retained from the acquisition of certain assets from British Biotech, as well as certain former employees of British Biotech hired by us subsequent to the acquisition. The plan allows the employees to defer up to 15% of their income on a pre-tax basis through contributions into designated pension funds. For each pound the employee invests, we will contribute up to 9% into the funds. We also sponsor a personal pension plan for one employee and a Flexible Executive Pension Plan covering two senior employees. The Flexible Executive Pension Plan allows the employees to defer up to 15% of their income on a pre-tax basis through contributions into designated pension funds. For each pound the employee invests, we will contribute up to 9% into the funds. For fiscal 2004, 2003, and 2002, our expenses related to the plans were $841,000, $714,000, and $602,000, respectively.

(16) Employee Postretirement Plan

On November 10, 1992, we adopted a plan which provides postretirement medical and life insurance benefits to eligible employees, board members and qualified dependents. Eligibility is determined based on age and service requirements. These benefits are subject to deductibles, co-payment provisions and other limitations. We follow SFAS No. 106, ''Employers' Accounting for Postretirement Benefits Other Than Pensions'' as amended by SFAS No. 132(R), ''Employers' Disclosures About Pensions and Other Postretirement Benefits,'' to account for and disclose the benefits to be provided by the plan. Under SFAS No. 106, the cost of postretirement medical and life insurance benefits is accrued over the active service periods of employees to the date they attain full eligibility for such benefits. In May 2004, the FASB issued FASB Staff Position, or FSP, No. FAS 106-2, ''Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003.'' FSP No. FAS 106-2 provides guidance on the accounting for the effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, or the Act, for employers that sponsor postretirement health care plans that provide prescription drug benefits. It requires those employers to provide certain disclosures regarding the effect of the federal subsidy provided by the Act. The accumulated postretirement benefits obligation or net postretirement benefits cost in the consolidated financial statements accompanying notes do not reflect the effects of the Act on our postretirement benefit plan. We are in the process of determining the impact of the Act on the accumulated postretirement benefits obligation and net postretirement benefits cost to be recorded.

Net postretirement benefit cost for fiscal 2004, 2003 and 2002 includes the following components (in thousands):

	2004	2003	2002
Service cost for benefits earned during the period	$572	$430	$255
Interest cost on accumulated postretirement benefit obligation	262	235	189
Amortization of initial benefits attributed to past service	6	6	6
Amortization of loss	39	29	—
Net postretirement benefit cost	$879	$700	$450

The accrued postretirement benefit cost at September 30, 2004 and 2003 was as follows (in thousands):

	2004	2003
Accumulated postretirement benefit obligation	$ 5,776	$ 4,425
Unrecognized cumulative net lost	(1,776)	(1,214)
Unrecognized transition obligation	(96)	(103)
Accrued postretirement benefit cost	$ 3,904	$ 3,108

The changes in the accumulated postretirement benefit obligation during fiscal 2004 and 2003 were as follows (in thousands):

	2004	2003
Balance at beginning of year	$4,425	$3,508
Benefit payments	(83)	(60)
Loss experience	600	312
Service cost	572	430
Interest cost	262	235
Balance at end of year	$5,776	$4,425

In fiscal 2004, the health care cost trend was increased to an initial level of 12% (from an initial level of 8% in fiscal 2003), decreasing to an ultimate rate of 5% by 2011 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 postretirement benefit obligation as of September 30, 2004 by $1.3 million and the fiscal 2005 net postretirement service and interest cost by $344,000. 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 postretirement benefit obligation as of September 30, 2004 by $1.0 million and the fiscal 2005 net postretirement service and interest cost by $252,000. Benefits paid during fiscal 2004, 2003 and 2002 were $83,000, $60,000 and $60,000, respectively.

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

	2004	2003	2002
Discount rate	5.75%	6.00%	6.75%
Expected long-term rate of return on plan assets	N/A	N/A	N/A

(17) Consolidation of Facilities

(a) Uniondale, New York

During the fourth quarter of fiscal 2003, we consolidated operations at our Uniondale, New York facility with our Farmingdale, New York facility. During the fourth quarter of 2004, we made the decision not to further utilize our Uniondale facility. As a result, we have accrued for costs relating to this exit activity. The estimated exit costs as of September 30, 2004 are $1.9 million, all of which are included in selling, general and administrative expenses in the accompanying consolidated statement of operations for fiscal 2004. These exit costs are comprised of the rental obligations for the remainder of the lease (through June 2006) of $994,000, offset by previously accrued rent expense of $180,000, the write down of equipment and leaseholds of $724,000, and costs to restore the facility to its original condition of $350,000.

(b) Oxford, England

During the fourth quarter of fiscal 2004, we announced the decision to consolidate all of our U.K.-based oncology research and development activities into our New York locations by approximately November 30, 2004. As of September 30, 2004, we estimate that the consolidation will result in a reduction in our U.K.-based oncology workforce by approximately 82 employees. The termination benefits provided to current employees is estimated at $3.7 million as of September 30, 2004, of which $3.0 million is included in research and development expenses and $767,000 is included in selling, general and administrative expenses in the accompanying consolidated statement of operations for fiscal 2004. Although our subsidiary, Prosidion, will continue operations at the Oxford facility, we will recognize a liability for rental obligations relating to the portion of the facilities vacated by our oncology operations, currently estimated to occur in either the first or second quarters of fiscal 2005. We did accelerate the useful lives of certain related leasehold improvements, which resulted in additional depreciation expense of $2.0 million, of which $1.7 million is included in research and development expenses and $277,000 is included in selling, general and administrative expenses in the accompanying consolidated statement of operations for fiscal 2004.

(c) Horsham, Pennsylvania

During the second quarter of fiscal 2004, we committed to and approved an exit plan for our Horsham, Pennsylvania facility which we acquired in connection with the acquisition of Cell Pathways in June 2003. We have recognized the rent obligations for the remainder of the lease (through June 2008), offset by the sublease rental income. This resulted in a charge of $1.8 million which has been included in selling, general and administrative expenses in the accompanying consolidated statement of operations for fiscal 2004. These exit costs are comprised of the net lease obligations of $2.1 million, offset by previously accrued rent expense of $338,000. In May 2004, we entered into a sublease agreement for the Horsham facility. We charge the rental payments less the sublease rental income received against the accrued liability. The consolidation activity for fiscal 2004 was as follows (in thousands):

	Lease Exit Costs
Provision recorded in fiscal 2004	$2,103
Cash paid less sublease income received	(295)
Balance at September 30, 2004	$1,808

(d) Birmingham

During the fourth quarter of fiscal 2001, we announced the decision to consolidate our Birmingham, England facility with the then newly acquired Oxford, England facility as a result of the acquisition of the British Biotech assets. The operations at the Birmingham facility ceased on March 31, 2002 and we completed closing down the facility in April 2003. Fifty research and administrative employees relocated to the Oxford facilities. Under the plan for consolidating this facility, we had anticipated that 28 research and administrative employees would not relocate

but would receive a severance package based on the number of years of service. As of the cessation of operations, 32 employees did not relocate and received the severance package.

The estimated cost of closing this facility as of September 30, 2001 was $4.3 million (R&D expense of $3.8 million and selling, general and administrative expenses of $511,000). The charge consisted of non-cancelable lease exit costs for the period April 2002 through February 2004 of $2.0 million, write down of equipment and leaseholds which were not being relocated of $2.1 million, and severance costs of $190,000. The consolidation activity for fiscal 2003 and 2002 was as follows (in thousands):

	Severance Costs	Lease Exit Costs	Writedown of Equipment and Leaseholds	Total
Balance at September 30, 2001	$ 190	$ 1,978	$ 2,116	$ 4,284
Cash paid/writedowns	(185)	(932)	(2,199)	(3,316)
Adjustments	—	473	—	473
Foreign currency translation adjustments	(5)	111	83	189
Balance at September 30, 2002	$ —	$ 1,630	$ —	$ 1,630
Cash paid/writedowns	—	(1,477)	—	(1,477)
Adjustments	—	(193)	—	(193)
Foreign currency translation adjustments	—	40	—	40
Balance at September 30, 2003	$ —	$ —	$ —	$ —

(e) Tarrytown

During the fourth quarter of fiscal 2001, we announced our strategic decision to close down our Tarrytown, New York facility and consolidate our operations into our Farmingdale, New York facility. The operations at the facility ceased on June 30, 2002 and we closed the facility in August 2002. The fungal extract libraries and certain furniture and equipment from the Tarrytown, New York facility were relocated to our other facilities. Twenty-eight research and administrative employees relocated to the Farmingdale and Uniondale facilities. Under the plan for consolidating this facility, we had anticipated that 28 research and administrative employees would not relocate and would receive a severance package, which included two weeks salary for each year of service. As of the closing of the facility, 35 employees did not relocate and received a severance package and two employees relocated to our Oxford, England facility. In August 2002, we entered into a Termination and Surrender Agreement with the landlord of the Tarrytown facility whereby we were released from our obligations under the lease. The consolidated activity for fiscal 2002 was as follows (in thousands):

	Severance Costs	Writedown of Equipment and Leaseholds	Total
Balance at September 30, 2001	$ 391	$ 384	$ 775
Cash paid/writedowns	(391)	(384)	(775)
Balance at September 30, 2003	$ —	$ —	$ —

(18) Quarterly Financial Data (unaudited)

The tables below summarize our unaudited quarterly operating results for fiscal 2004 and 2003.

	Three Months Ended (In thousands, except per share data)			
	December 31, 2003	March 31, 2004	June 30, 2004	September 30, 2004
Revenues	$ 11,391	$ 7,216	$ 11,166	$ 13,027
Net loss	$(40,133)	$(49,704)	$(47,345)	$(123,189)
Basic and diluted net loss per weighted average share of common stock outstanding:	$ (1.03)	$ (1.27)	$ (1.19)	$ (2.88)

	Three Months Ended (In thousands, except per share data)			
	December 31, 2002	March 31, 2003	June 30, 2003	September 30, 2003
Revenues	$ 4,472	$ 7,592	$ 8,022	$ 12,283
Net loss	$(30,100)	$(27,169)	$(75,118)	$(48,970)
Basic and diluted net loss per weighted average share of common stock outstanding:	$ (0.83)	$ (0.75)	$ (2.03)	$ (1.25)

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

(19) Subsequent Events

(a) Public Offering

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

(b) Tarceva™ Approval

On November 18, 2004, we announced that the FDA approved our NDA for monotherapy Tarceva™ use in the treatment of all NSCLC patients who have failed at least one prior chemotherapy regimen. Tarceva™ met its primary endpoint of improving overall survival and its key secondary endpoints of progression-free survival and objective tumor response rate in a 731-patient randomized, double-blinded placebo controlled Phase III trial, or the BR.21 study. We launched Tarceva™ on November 22, 2004, the second business day after approval.

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

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

CEO and CFO Certifications. Attached to this Annual Report 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 Chief Financial Officer, or CFO. This section of the Annual Report which you are currently reading 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 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 13(a)-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, despite the limitations noted below, our disclosure controls and procedures are effective to provide reasonable assurance 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 particularly during the period in which this Annual Report on Form 10-K was being prepared.

Limitations on the Effectiveness of Controls. Our management, including the CEO and CFO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. While we believe that our disclosure controls and procedures have been effective, in light of the foregoing we intend to continue to examine and refine our disclosure controls and procedures and to monitor ongoing developments in this area.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting (as defined in Rule 13(a)-15(f)) under the Exchange Act identified in connection with the evaluation of such internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not Applicable.

(osi)™ pharmaceuticals

Board of Directors

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

Colin Goddard, Ph.D.
Chief Executive Officer

Edwin A. Gee, Ph.D.
Chairman Emeritus
Former Chairman & CEO
International Paper, Inc.

Michael G. Atieh
Former Group President
Dendrite International

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

Daryl K. Granner, M.D.
Director, Vanderbilt Diabetes
Center; Professor, Molecular
Physiology and Biophysics,
Vanderbilt University

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

Viren Mehta
Mehta Partners LLC

Herbert Michael Pinedo, M.D., Ph.D.
Professor of Medical Oncology
Director of the VUMC Cancer
Center – Amsterdam

Sir Mark Richmond
Former Head of Research
and Special Assignments,
Glaxo Research & Development

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

Senior Executives

Colin Goddard, Ph.D.
Chief Executive Officer

Gabriel Leung
Executive Vice President and
President, Oncology Business

Nicole Onetto, M.D.
Executive Vice President and
Chief Medical Officer

Anker Lundemose, M.D., Ph.D.
Chief Executive Officer
Prosidion

Robert L. Van Nostrand
Vice President and
Chief Financial Officer

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

Robert L. Simon
Vice President, Global Regulatory
Affairs and CMC

Neil Gibson, Ph.D.
Vice President, Research

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Corporate Counsel

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

General Counsel

Mintz, Levin
666 Third Avenue
New York, NY 10017

Patent Counsel

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

Auditors

KPMG LLP
1305 Walt Whitman Road
Melville, NY 11747

Annual Meeting

The annual meeting of shareholders will be held on March 16, 2005 at 10:00am at OSI Pharmaceuticals, Inc. (Research Facility)
1 Bioscience Park Drive
Farmingdale, NY 11735

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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