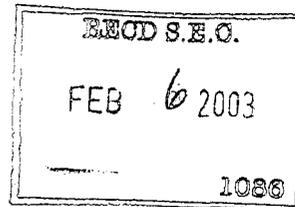




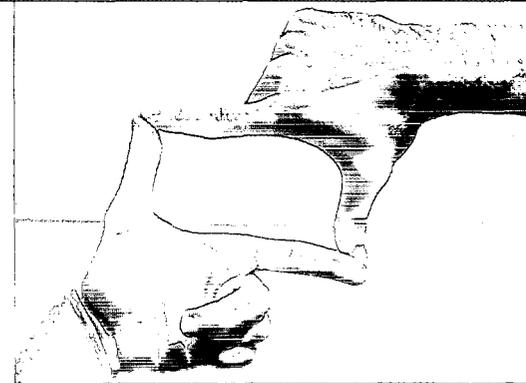
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We are focused on the discovery, development
and commercialization of high-quality oncology products
that will both extend life and improve the quality-of-life
for cancer patients around the world.

(OSI) pharmaceuticals

to our
shareholders

2002 HAS BEEN A YEAR marred by recession, corporate scandal and high-profile clinical disappointments for both biotechnology and pharmaceutical companies alike.

This has raised questions for some about the future prospects of the biotechnology sector and the integrity of leading U.S. corporations in general. For OSI, however, it's been a year of continued progress toward our goal of building a world-class oncology company. We are committed to building an organization of high quality and integrity focused on discovering, developing and commercializing innovative cancer products that both extend life and improve the quality-of-life for cancer patients around the world. We want to be an organization recognized for these attributes throughout the industry, and in 2002 we believe we made major strides toward achieving that goal.

In Tarceva™ we continue to believe that we have an outstanding drug candidate which is strongly positioned to emerge as a leader in the anti-HER1/EGFR field. Over the last several years we have been building our oncology franchise around Tarceva™. Most importantly, we have focused on ensuring that we provide all of the resources, experience and know-how to be confident that we have done all that we can do to allow for the successful development and registration of a product that has the potential to make a real difference in the lives of hundreds of thousands of cancer patients. To that end, we acquired and have successfully integrated both the oncology unit of Gilead Sciences, Inc. and the research operations of British Biotech plc which greatly enhanced our oncology pipeline and added strength to our research and development capabilities. With the Gilead acquisition, we added a proven world-class oncology drug development and regulatory affairs team which now leads our Tarceva™ development efforts. We also acquired three promising next-generation cytotoxic drug candidates in clinical development, balancing our pipeline of novel gene-targeted therapies.

Supporting our Tarceva™ development efforts are our co-development and marketing partners, Genentech, Inc. and Roche. By leveraging the development, regulatory and commercial expertise of these two leading oncology players, we further ensure a quality development program and remain confident of our ability to compete effectively in the marketplace. In the United States, OSI and Genentech employ an equal cost and profit sharing arrangement

for commercialization. Roche, our international partner, will commercialize Tarceva™ outside the United States and will pay us royalties on net sales.

We have also focused on expanding and strengthening the leadership of the company and have proactively improved our corporate governance procedures, including the formation of a disclosure control committee, the institution of outside director-only sessions at board meetings and the recruitment and appointment of a new non-executive chairman of the board. To this end, I am delighted to both introduce and welcome our new Chairman of the Board, Robert A. Ingram. Bob is currently Vice Chairman of Pharmaceuticals at GlaxoSmithKline and, prior to his recent retirement, was President and Chief Operating Officer of GSK's pharmaceutical operations. He is seen throughout the industry as a man of stature and integrity and, with a long and successful career on the commercial side of our business, will provide us with great wisdom and counsel as we move through the next exciting phase of our growth.

Transforming Our Vision Into Reality Tarceva™

Anchoring our oncology franchise is Tarceva™, a potent, selective and orally active inhibitor of HER1/EGFR, a receptor that is overexpressed or mutated in a wide variety of solid tumors including those of the lung and pancreas. Although some of our competitors have suffered disappointments with their EGFR development programs, we believe that the exciting potential of HER1/EGFR targeted therapies is firmly established within the oncology community. Although we have much to learn about the most effective way to use this approach in the fight against cancer, we remain confident that our broad-based registration strategy will ultimately be successful. Together with our partners, Genentech and Roche, we have carefully designed our clinical program to study Tarceva™ both in a monotherapy setting and in combination with standard cytotoxics. We are conducting four registration-oriented Phase III studies which are all large-scale, placebo-controlled and double-blinded with a primary endpoint of survival and secondary endpoints that include symptom relief and improvement in quality-of-life. Three of these studies are focused on our primary indication, non-small cell lung cancer (NSCLC) and the fourth on pancreatic cancer. 2003 will be a pivotal year for these studies with the possibility that top-line data for all four trials will be available by year end.

In May 2002, we received notice of Fast Track designation for Tarceva™ from the U.S. Food and Drug Administration for the treatment of chemotherapy-naïve (or front-line) stage III/IV NSCLC patients.

Genentech and Roche have completed patient enrollment for two large randomized Phase III trials in this indication, which compare Tarceva™ plus front-line chemotherapy to chemotherapy alone.

We also received notice of a second FDA Fast Track designation in September for Tarceva™ used as a monotherapy for the second/third-line treatment of patients with incurable stage III/IV NSCLC who failed standard therapy for advanced or metastatic disease. We are collaborating with the National Cancer Institute of Canada Clinical Trials Group to conduct an international, randomized and placebo-controlled Phase III trial in these patients that compares Tarceva™ as a single agent to best supportive care. In order to more clearly measure

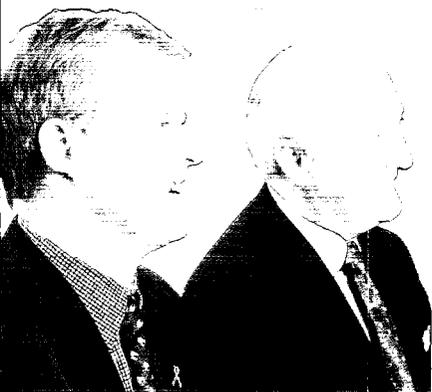
Other Activities

Establishing a Balanced Clinical Pipeline Behind Tarceva™

We now have a pipeline replete with product candidates that have the potential to improve the available treatment options for cancer patients—including targeted therapies and next-generation cytotoxics. To support this pipeline as well as expand and enrich it, we have developed cutting-edge capabilities in the form of a high-quality research and development infrastructure, coupled with a seasoned, multi-disciplined management team.

Next-Generation Cytotoxics

Cytotoxic therapies will, in our view, continue to play an important role in cancer treatment, offering the



left to right:

Colin Goddard, Ph.D.
Chief Executive Officer

Robert A. Ingram
Chairman of the Board

improvement in patient survival as well as other potential benefits of Tarceva™ as a monotherapy, we announced the expansion of this trial from the original enrollment target of 330 patients to approximately 700 patients. We expect to complete enrollment within the first two months of 2003.

We have provided updates to our Phase II NSCLC data at various clinical and scientific meetings during 2002, including the Annual Meeting of the American Society of Clinical Oncology (ASCO). These studies have continued to reinforce the basis for our Phase III program, revealing promising activity and survival data and a relatively benign side effect profile. An acneiform rash, which we now believe to be an important potential biomarker, and a mild diarrhea are the principal side effects, a considerable improvement in the often harsh toxicities of many cytotoxic therapy regimens. We observed a potentially important correlation between rash, as a potential biomarker of HER1/EGFR drug action, and improved patient survival. This analysis has further reinforced our belief, distinct from that of our major competitors, that aggressive dosing of Tarceva™ will be important to the potential success of our trials and for future clinical use.

potential of life-saving or palliative benefits in certain cancers. We are currently developing three compounds that are among the next generation of cytotoxic agents. The most advanced of these is OSI-211, a liposomal formulation of the topoisomerase-I inhibitor, lurtotecan, which is being developed for the treatment of ovarian cancer and small cell lung cancer (SCLC). Last October, we announced the initiation of two Phase II clinical trials for the treatment of relapsed ovarian cancer and relapsed SCLC. Results from these two studies will determine whether OSI-211 has the potential to provide an enhanced clinical benefit to patients with these diseases and will provide the basis for further development plans.

In November 2002, we presented data on both OSI-7904L and OSI-7836 at the EORTC-NCI-AACR 2002 symposium in Frankfurt, Germany. OSI-7904L is a liposomal formulation of a thymidylate synthase inhibitor, a well-established class of agents often used to treat metastatic colorectal and breast cancers. OSI-7836 is a member of the nucleoside class of cytotoxic drugs of which gemcitabine is the market leader. At least one of these drug candidates should enter Phase II clinical trials during 2003.

Other Targeted Therapies

Although the funded phase of our oncology drug discovery program with Pfizer Inc. has concluded, Pfizer has continued to develop drug candidates which originated from that collaboration. We will receive royalties from these products if and when they are ultimately commercialized. Two of these are the small molecule candidates, CP-724,714 and CP-547,632.

CP-724,714, a potent, selective and orally active inhibitor of HER2 (epidermal growth factor receptor 2), recently entered Phase I clinical trials to inhibit the growth of tumors dependent on the activity of the HER2 oncogene. Pfizer is also continuing Phase I trials with CP-547,632, a potent and selective oral inhibitor of vascular endothelial growth factor receptor (VEGFR). VEGFR is a tyrosine kinase receptor involved in promoting angiogenesis, an important mechanism in tumor growth.

In the Fall of 2002, we suspended clinical development of OSI-754, a farnesyl transferase inhibitor in Phase I clinical trials. Although we believe this compound represents a potential opportunity in the treatment of cancers containing the mutant *h-ras* oncogene, its limited commercial potential in the face of our more immediate needs with the Tarceva™ program led to this decision.

Business Activities

We remain committed to managing our business on a sound financial basis, balancing research and development investments in our future growth and success against our cash reserves and a strong belief that we should seek to take the business profitable within 18–24 months of a successful Tarceva™ launch. We closed our fiscal 2002 with approximately \$476 million in cash reserves and anticipate that we need to manage the business to an approximate cost base not exceeding \$145 million per year through the next several years in order to remain confident of our profitability goals, assuming the successful registration and launch of Tarceva™. This philosophy, and our continued efforts to focus on oncology, led us to announce a number of important business decisions during 2002.

In February 2002, in keeping with our desire to maintain a strong balance sheet, we issued \$200 million aggregate principal amount of Convertible Notes with interest payable at a rate of 4% per year. The Notes mature in 2009 and may be converted into OSI common stock at a conversion price of \$50 per share. In the fourth quarter of 2002, we took advantage of a market opportunity and repurchased \$40 million of these Notes in the open

market for a cost of approximately \$26 million, resulting in a net gain of \$12.6 million.

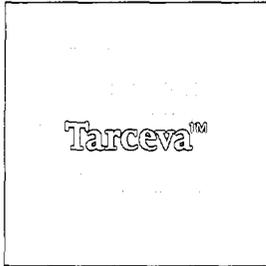
In October 2002, we announced a modest reduction in staff who had been predominantly dedicated to contract discovery research, and a commitment to divest the Company's remaining non-oncology assets. As part of this program, in July 2002 we decided to accelerate the wind-down period of our funded research alliance with Anadem Research Corp. We will still receive royalties on the sales of products that might arise from drug candidates identified as a result of this alliance.

We recently relocated our U.S. discovery research operations to a new 53,000 sq. ft. facility in Farmingdale, New York. The site is located on the grounds of State University of New York (SUNY) on land dedicated to the Broadhollow Bioscience Park, a New York State funded project to establish a biotechnology presence on Long Island. We serve as the anchor tenant in support of this initiative. We have also finished consolidating our United Kingdom operations into a state-of-the-art research facility in Oxford, UK which resulted from our acquisition of the pre-clinical research operations of British Biotech in September 2001. Approximately 50% of our pre-clinical discovery research is based on Long Island and the other 50% at the Oxford site.

In 2002, we believe we created the basis for a world-class oncology franchise and established an integrated, well-managed organization made up of more than 400 individuals with a diverse array of talent, experience and integrity which we believe will prove to be a winning combination as we move forward into 2003. The next year will be a pivotal one for our lead product, Tarceva™, a product that we believe will play an important role in opening up a new era of cancer treatment. We have built a strong and committed oncology organization behind Tarceva™. We hope that you, whether shareholder, employee, oncology professional or patient, share our belief that a focus on quality, thoroughness, honesty and commitment is the right way to build an organization capable of delivering long-term sustainable growth and value while making a major contribution to the treatment and management of cancer worldwide. I thank you all for your continued support and look forward to an exciting 2003.



Colin Goddard, Ph.D.
Chief Executive Officer



Tarceva™



Next-Generation
Targeted Therapy



Sarkis Torossian was diagnosed three years ago with lung cancer. Since that time he has undergone a number of different cancer treatments, including chemotherapy and radiation, but his cancer continued to worsen. Last year he was enrolled in a clinical trial of Tarceva™ and experienced the benefits of a shrinking tumor and relief of his symptoms.

Sarkis Torossian
Tarceva™ clinical trial patient

Advancing the Fight Against Cancer

The increase in our knowledge of cancer biology and cancer treatment over the last decade of the 20th century was dramatic, allowing us to enter the 21st century with renewed hope, improved understanding and a belief that we can now seriously contemplate the development of next-generation anti-cancer drugs that will make a real difference in the lives of cancer patients.

At OSI, we are proud to be a part of this revolution and to contribute to the progress in both our fundamental understanding of this disease and our efforts to treat it. To take full advantage of our growing insight, we have developed a two-pronged approach with the goal of improving available treatment options to both extend and increase the quality-of-life for cancer patients.

The first approach involves using our growing understanding of cancer's genetic basis to develop specific mechanism-based therapies that target both genetic abnormalities and normal processes that are important to tumor growth. The second approach focuses on the development of next-generation

cytotoxic drugs that represent improvements over the current cytotoxics. We believe that a successful oncology franchise should provide an array of treatment options for oncologists and the cancer patients they treat by developing both targeted therapies and next-generation cytotoxic therapies.

Targeted Therapies

Tarceva™—A Potential Cancer Blockbuster

Drugs that can target cancer cells with minimal side effects on the rest of the body have become an important part of the oncologist's arsenal. Indeed, the oncology community increasingly believes in selectively targeting genes important to the growth and survival of cancer with the expectation that we can manage cancer for the long term. At OSI, we have pioneered the development of anti-cancer drugs that target the multiple underlying mechanisms of cancer.

Some of these novel anti-cancer drugs are designed to target cancer-causing genes, or oncogenes. Oncogenes are growth-regulating genes that are either overexpressed or mutated in cancer cells. One of the most important of these oncogenes

Tarceva™ (erlotinib HCl) Phase III Trials

TRIAL	PATIENT POPULATION	NUMBER OF PATIENTS	ENROLLMENT STATUS
Tarceva™ single agent	second/third-line non-small cell lung cancer	700	enrollment complete by early 2003
carboplatin and paclitaxel +/- Tarceva™	first-line non-small cell lung cancer	1000	enrollment completed July 2002
gemcitabine and cisplatin +/- Tarceva™	first-line non-small cell lung cancer	1200	enrollment completed September 2002
gemcitabine +/- Tarceva™	first-line pancreatic cancer	450	enrollment complete by early 2003

These registration-oriented trials are randomized, placebo-controlled, double-blinded studies seeking a primary endpoint that demonstrates improvement in patient survival.

is the epidermal growth factor receptor HER1/EGFR. HER1/EGFR is mutated or overexpressed in a variety of the tumor types that impact a significant number of the approximately 1.3 million patients newly diagnosed with cancer in the U.S. each year.

We believe drugs that inhibit HER1/EGFR may have utility in treating a wide range of cancers. Our most advanced drug candidate, Tarceva™, is a small molecule, selective and orally active inhibitor of the HER1/EGFR tyrosine kinase activity, and is currently in Phase III clinical trials.

Tarceva™ is being developed as part of a global tripartite alliance with Genentech, Inc. and Roche. This global co-development and commercialization effort includes a broad-based Phase III clinical trial program that is oriented toward an effective registration with the U.S. Food and Drug Administration as well as other international regulatory agencies. The Phase III program is based on promising results seen in several completed Phase II clinical trials for Tarceva™. In these trials, Tarceva™ was used as a monotherapy in the treatment of refractory and advanced non-small cell lung cancer (NSCLC), head and neck cancer and ovarian cancer patients who had generally failed standard treatment regimens. Objective evidence of anti-tumor activity manifested itself as complete and partial responses and disease stabilization accompanied by encouraging survival data. The most common side effect observed in all trials was the development of an acneiform rash.

The Phase III Tarceva™ program includes one single-agent study (versus best supportive care) for the treatment of refractory NSCLC and three combination trials with existing chemotherapy regimens for front-line use in NSCLC and pancreatic cancer. All the trials are large, placebo-controlled,

Tarceva™ as a single agent on a 150mg oral daily dosing regimen elicits a reversible rash and predominantly mild diarrhea as the principal side effects. Clinical investigators have generally considered the rash, which is seen for all anti-HER1/EGFR drugs in development, to be the most common adverse event for this class of agents. We believe that rash may in fact serve as a biomarker of the effective delivery and potential activity of Tarceva™. This rationale is supported by our Phase II trials, where the survival of patients who developed rash during Tarceva™ treatment was longer than those who did not develop rash.

double-blinded studies designed to demonstrate survival and quality-of-life benefits for the patients.

Our highest clinical priority at this time is the management of the single-agent refractory NSCLC trial which is the primary registration study for Tarceva™. Currently this is the only single agent, controlled Phase III study of a HER1/EGFR targeted drug designed to detect a survival advantage.

The study of Tarceva™ for the treatment of pancreatic cancer remains an important secondary program for us. However, as part of our effort to focus resources on the refractory NSCLC study, we have reduced the total sample size of the international Phase III pancreatic study. This change in sample size will maintain the statistical power of the trial while allowing us to prioritize our resources into the NSCLC program. Specifically, the original 800-patient design will now enroll approximately 450 patients in a study that compares Tarceva™ in combination with gemcitabine to gemcitabine alone as a first-line treatment. Like



Tarceva™ (erlotinib HCl) Phase II Data

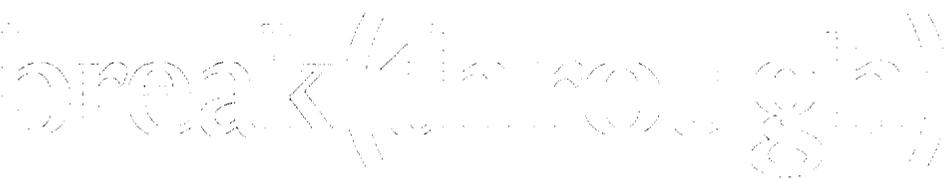
(Single-Agent Salvage Studies in Patients With Refractory or Advanced Cancer)

Principal Side Effects

	NON-SMALL CELL LUNG CANCER	HEAD & NECK CANCER	OVARIAN CANCER
Evaluable Patients	57	115	34
Complete Response (100% tumor reduction)	2	—	—
Partial Responses (greater than 50% but less than 100% tumor reduction)	5	5	2
Stable Disease (up to 50% tumor reduction or less than 25% tumor increase)	22	44	16
Overall Responders (complete response and partial response)	12.3%	4.3%	5.9%
Overall Responders and Stable Disease	51%	43%	53%
Median Survival	37 weeks	26 weeks	35 weeks
One-Year Survival	40%	21%	35%

ALL 3 STUDIES	
Rash and Related Disorders	79%
Diarrhea	45%

Data as of November 18, 2002



“Lung cancer remains one of the most devastating forms of cancer, with a five-year survival rate of less than 5% for patients with metastatic disease. A positive outcome for our Phase III trial could provide us with a valuable new agent to treat patients for whom chemotherapy has failed for this devastating disease.”

—Frances A. Shepherd, M.D.
 Scott Taylor Chair in Lung Cancer Research at the Princess Margaret Hospital. Professor of Medicine at the University of Toronto. Principal Investigator for Phase III Tarceva™ NSCLC Trial.

the refractory NSCLC trial, this trial is also being conducted in collaboration with the National Cancer Institute of Canada Clinical Trials Group.

We are also conducting several Phase Ib trials to study the effect of Tarceva™ with other chemotherapy drugs. Additional Phase II studies are being conducted both independently and in collaboration

TARCEVA™ AND HER1/EGFR

The epidermal growth factor receptor (HER1/EGFR) is part of a family of growth factor receptors (the HER family) responsible for regulating cell growth. HER1/EGFR has been shown to be either overexpressed or mutated in a variety of human tumors including those in the lung, pancreas, head and neck, brain and ovary. This overexpression or mutation leads to the abnormal stimulation of growth-factor pathways resulting in unregulated cell signaling. Tarceva™ is designed to specifically inhibit the signal transduction pathway by blocking the activity of the HER1/EGFR tyrosine kinase.

with the U.S. National Cancer Institute's Cancer Therapy Evaluation Program, or CTEP, in a wide variety of tumor types including bronchioalveolar carcinoma and glioblastoma multiforme.

Understanding the Nature of the Cancer Cell

At OSI, we are working to expand our knowledge of how a normal cell turns into a cancer cell. We now understand that this involves aberrations in the cell signaling pathways that control cell proliferation, apoptosis (programmed cell death), angiogenesis (the process of blood vessel growth), invasion and metastasis. We have therefore focused our targeted programs on these cellular processes.

Signal Transduction

Signal transduction is the complicated process by which signals, including growth stimulatory signals, are transmitted to the nucleus of a cell regulating the growth and activity of that cell. In the case of cancer, the normal patterns of signal transduction are disrupted. At OSI, we are focused on the

OSI Pharmaceuticals Oncology Pipeline

PRODUCT	TARGET	INDTRACK	PHASE I	PHASE II	PHASE III	ANTICIPATED LAUNCH
TARCEVA™ (erlotinib HCl)	HER1/EGFR	[Progress bar spanning Indtrack, Phase I, and Phase II]				2004
OSI-211	Liposomal Lurtotecan	[Progress bar spanning Indtrack and Phase I]				2006
OSI-7836	Gemzar® Analog	[Progress bar spanning Indtrack and Phase I]				2007
OSI-7904L	Liposomal TS Inhibitor	[Progress bar spanning Indtrack and Phase I]				2007
CP-547,632	VEGFR	[Progress bar spanning Indtrack and Phase I]				2006
CP-724,714	HER2-neu	[Progress bar spanning Indtrack and Phase I]				2007
CP-xxx	PDGFr	[Progress bar in Indtrack]				2007

development of agents that will ameliorate the resulting aberrant signaling. Tarceva™ is an example of a drug designed to inhibit aberrant HER1/EGFR signaling. HER2 (epidermal growth factor receptor 2) is an oncogene that, when functioning normally, regulates cell growth. However, overexpression of HER2 has been correlated with aggressive cancer growth, particularly in metastatic breast cancer. Approximately 25–30% of all women with metastatic breast cancer overexpress HER2.

As part of our long-standing discovery collaboration with Pfizer Inc., we co-discovered CP-724,714, a potent and selective oral inhibitor of HER2. Although the funded phase of our collaborative research with Pfizer has concluded, Pfizer has continued to develop drug candidates that originated from that collaboration. CP-724,714 is currently in Phase I clinical trials.

Angiogenesis

We believe the ability to safely and effectively inhibit the process of angiogenesis continues to represent one of the most intriguing opportunities in cancer research today. Angiogenesis is the process of

blood vessel growth and has been shown to play an important role in the development and spread of cancer. It has been firmly established that in order for a tumor to grow, it must develop its own blood supply. The induction of angiogenesis is mediated by the production of many growth factors including vascular endothelial growth factor (VEGF). This factor binds to the VEGF receptor (VEGFR), a key receptor tyrosine kinase involved in regulating blood vessel growth. CP-547,632, a potent and selective inhibitor of VEGFR, is presently in Phase I clinical trials. This agent was also discovered as part of our cancer discovery program with Pfizer, who is developing the product.

Apoptosis

At OSI, we are also studying apoptosis, or programmed cell death. Normal cells undergo tightly controlled or programmed death, which is often pathologically prevented in cancer cells. We are currently researching the mechanisms that underlie the ability of certain cells to avoid apoptosis and contribute to tumor growth by promoting cell survival.

R&D

Targeting the Genetic, Molecular and Cellular Basis of Cancer

Next-Generation Cytotoxics

Since their introduction in the 1950s, the development and use of cytotoxic drugs has helped to successfully treat many people with cancer. In fact, some cancers can now be cured routinely with chemotherapy and others can be controlled for long periods of time. These products are effective in killing rapidly dividing cancer cells, but because they usually interfere directly and non-selectively with normal processes in the cell, they are frequently associated with severe toxicities.

In addition to our targeted programs, we are also developing next-generation cytotoxics that are designed to improve the activity and reduce the undesired side effects associated with chemotherapy. We feel that our ability to develop both novel targeted drugs and next-generation therapies is a necessary approach to becoming a successful oncology franchise.

Our next-generation cytotoxic chemotherapy candidates are designed to improve upon currently marketed products that belong to the same class of drugs. As part of our acquisition of the Gilead oncology division in November of 2001, we acquired a portfolio of three promising next-generation cytotoxic agents. These include two compounds incorporating novel liposomal formulations — OSI-211, a topoisomerase I inhibitor, and OSI-7904L, a thymidylate synthase inhibitor. Non-liposomal formulations of these product classes are currently marketed for cancer indications. The third compound, OSI-7836, is being developed as an alternative to Gemzar® (gemcitabine) for multiple solid tumors.

OSI-211

OSI-211 is a proprietary liposomal formulation of the active topoisomerase I inhibitor lurtotecan. It is a

member of the camptothecin class of cytotoxics. Topoisomerase I is an enzyme critical to cellular replication. An example of a currently marketed non-liposomal topoisomerase inhibitor is Hycamtin® which is used to treat relapsed ovarian cancer and relapsed small cell lung cancer.

Initial Phase II studies of OSI-211 revealed comparable anti-tumor activity to Hycamtin® in ovarian cancer. However, in order to develop this agent we believe it is essential that we clearly differentiate it and we have therefore initiated a comparative Phase II trial versus Hycamtin® in refractory ovarian cancer and a Phase II trial in refractory small cell lung cancer.

OSI-7904L

OSI-7904L is a member of the class of drugs known as thymidylate synthase inhibitors (TSI), a well-established group of agents with a validated mechanism of action. The most frequently prescribed drug in the treatment of colorectal cancer is 5-Fluorouracil (5-FU), 5-FU, and more recently Xeloda®, are examples of TSIs that play a prominent role in the treatment of cancer. OSI-7904L is a liposomal formulation of a potent TSI (GW1843), which is designed to improve activity by maintaining active concentrations of drug in the tumor for extended periods of time. Phase I studies for this product are ongoing.

OSI-7836

OSI-7836 is a member of the nucleoside class of cytotoxic drugs of which gemcitabine is the market leader. We are developing OSI-7836 as an alternative to gemcitabine and the candidate has clearly demonstrated anti-tumor activity in a variety of solid tumor xenograft models. This product is currently in Phase I development.

re(search)



AT OSI, OUR EFFORTS HAVE FOCUSED

on applying the discovery technology platforms we have developed over the last decade to the cancer setting. With the Gilead oncology acquisition, we have added important *in vivo* pharmacology and toxicology capabilities, and the British Biotech acquisition significantly expanded our medicinal and process chemistry capabilities. Our research teams target the genetic, molecular and cellular basis of cancer. Both internally and through a range of collaborations with leading academic research institutions, we are working hard to translate basic research knowledge into effective treatments for cancer. Our drug discovery platforms constitute an integrated set of technologies and capabilities covering every major aspect of pre-clinical and clinical development.

This fully integrated drug discovery platform is built to advance the process of identifying and optimizing high-quality, small molecule drug candidates.

Our core discovery technologies and capabilities include:

- gene transcription, signal transduction, protein kinases and other assay systems
- automated high-throughput screening systems and automated lead compound profiling systems (assessing, for example, metabolism and pharmacokinetic characteristics)
- a library of over 350,000 proprietary small molecule compounds
- medicinal, computational, molecular modeling and automated combinatorial chemistry approaches
- *in vivo* pharmacology, pharmacokinetics and pharmaceutical development capabilities
- scale-up process chemistry and pilot-scale manufacturing and supply to support pre-clinical and early clinical development

With the successful integration of the Gilead and British Biotech acquisitions, we now possess an extensive pipeline of oncology product candidates, a strong core of discovery research and top-tier oncology clinical development and regulatory affairs capabilities that we feel differentiate our company and will provide us with the ability to excel in our goal of becoming a global leader in oncology.

management

Continuing a Tradition
of Responsibility
to our Shareholders



The OSI management team is seasoned, multidisciplined and dedicated to building a strong oncology organization.

left to right:

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

Robert L. Van Nostrand
*Vice President and
Chief Financial Officer*

Nicole Onetto, M.D.
Executive Vice President, Oncology

Barbara A. Wood, Esq.
General Counsel

WE ARE COMMITTED TO ASSEMBLING the right mix of talented scientists and clinical development specialists to allow us to succeed in our goal of becoming a premier oncology franchise. That commitment remains the driving force behind our endeavors in the fight against cancer today. Indeed, this strong sense of dedication is not just limited to the laboratory—but exists in every aspect of our work from the boardroom to the clinic. We believe the only way to deliver sustainable value to our shareholders and to cancer patients alike is to focus on building a high-quality organization with a strong corporate value set and high integrity. To ensure our continued sense of responsibility to our shareholders and compliance with securities regulations, we have added additional key pieces of corporate governance to our company policies.

Specifically, we have adopted several policies regarding disclosure and have established a process at the board level to provide continued adherence to both the letter and spirit of SEC and other governing regulations.

At OSI, we are proud to say that we manage our day-to-day affairs as conscientiously as our invaluable research endeavors. As a team of dedicated professionals we continue to strive for excellence.



left to right:
Oxford, UK
Boulder, CO
Farmingdale, NY

THE RAPID GROWTH OF THE COMPANY

during the past two years has established OSI as an international biotechnology company with facilities in New York, Colorado and the United Kingdom. In August 2002, we formally opened our newly built, state-of-the-art research facility in Farmingdale, New York. This site will serve as the Company's discovery research operations center with high-speed lead-seeking technologies, complemented by world-class biology and chemistry follow-up teams both here and in Oxford, U.K. Approximately 50% of our discovery research will be based in Farmingdale and the other 50% will be at the Oxford site. In addition to serving as home base for our U.K. research efforts, our state-of-the-art Oxford facility, comprising over 100,000 sq. ft., is equipped with a pilot manufacturing plant that has the capacity to scale up the production of small molecules for pre-clinical toxicology testing and early clinical trials.

Located in Boulder, Colorado is our world-class development capabilities group. This team is seasoned at every end of the continuum, with capabilities in toxicology, cell biology, cancer pharmacology, pharmacokinetics and regulatory affairs.

We now have a comprehensive array of proven talent and infrastructure that allows us to aggressively pursue new treatment options for patients suffering from cancer.

Going forward, we are on a journey to change the face of cancer treatment for the shared benefit of cancer patients around the world, our employees and our shareholders.

corporate

www.osip.com

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Viren Mehta
Mehta Partners LLC

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

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

SENIOR MANAGEMENT

Colin Goddard, Ph.D.
Chief Executive Officer

Nicole Onetto, M.D.
*Executive Vice President,
Oncology*

Robert L. Van Nostrand
*Vice President and
Chief Financial Officer*

Barbara A. Wood, Esq.
General Counsel

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

Neil Gibson, Ph.D.
Vice President, Research

Arthur M. Bruskin, Ph.D.
Vice President, Strategic Planning

Linda E. Amper, Ph.D.
*Vice President, Human Resources
and Administration*

Geoffrey Cooper, Ph.D.
*Vice President, Business
Development*

David Laskow-Pooley
General Manager, U.K.

Jim McCormack, Ph.D., D.Sc.
Vice President, U.K. Research

Pedro Santabárbara, M.D., Ph.D.
Vice President, Clinical Research

John A. Slack, Ph.D.
Vice President, Development

Raymond Bendele, D.V.M., Ph.D.
*Vice President, Pharmaceutical
Development*

CORPORATE HEADQUARTERS

OSI Pharmaceuticals, Inc.
58 South Service Road
Suite 110
Melville, NY 11747

OTHER COMPANY LOCATIONS

OSI Pharmaceuticals Ltd.
Watlington Road
Oxford, OX4 6LT
United Kingdom

OSI Pharmaceuticals (Boulder)
2860 Wilderness Place
Boulder, CO 80301

OSI Pharmaceuticals
(US Research)
1 Bioscience Park Drive
Farmingdale, NY 11735

TRANSFER AGENT & REGISTRAR

Bank of New York
101 Barclay Street
New York, NY 10286
(800) 524-4458
<http://stock.bankofny.com>

CORPORATE COUNSEL

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

GENERAL COUNSEL

Mintz, Levin
666 Third Avenue
New York, NY 10017

PATENT COUNSEL

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

AUDITORS

KPMG LLP
1305 Walt Whitman Road
Melville, NY 11747

ANNUAL MEETING

The annual meeting
of shareholders will be
held on March 19, 2003
at 10:00AM at
OSI Pharmaceuticals
(U.S. Research Facility)
1 Bioscience Park Drive
Farmingdale, NY 11735

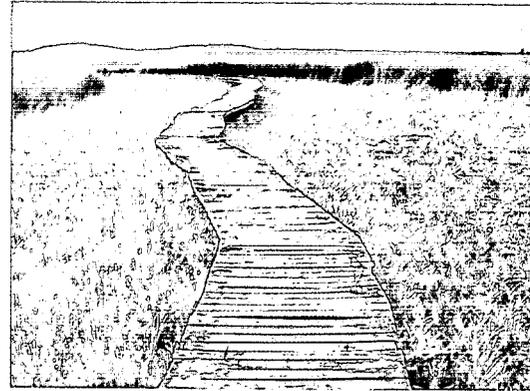
ANNUAL REPORT ON FORM 10-K

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

OSI Pharmaceuticals, Inc.
58 South Service Road
Suite 110
Melville, NY 11747
(631) 962-2000
www.osip.com

STOCK LISTING

Nasdaq: OSIP



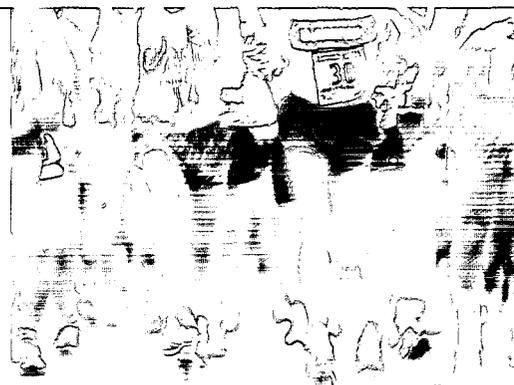
Roche pharmaceuticals

(osi) pharmaceuticals

58 South Service Road
Suite 110
Melville, NY 11747
631.962.2000 Telephone
631.752.3880 Fax
www.osip.com

(osi) pharmaceuticals

(share)holder



2002
Form 10-K



We are focused on the discovery, development and commercialization of high-quality oncology products that will both extend life and improve the quality-of-life for cancer patients around the world.

(OSI) pharmaceuticals

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, 2002 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

(State or other Jurisdiction of Incorporation or Organization)

13-3159796

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

58 South Service Road, Melville, N.Y.

(Address of Principal Executive Offices)

11747

(Zip Code)

Registrant's Telephone Number, including area code

(631) 962-2000

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

Title of each class

Name of each exchange on which registered

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 28, 2002, the aggregate market value of the Registrant's voting stock held by non-affiliates was \$1,057,560,516. 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 28, 2002 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 November 29, 2002, there were 36,418,319 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 2003 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K.

On the following pages, we have reproduced the first nine items of our annual report on Form 10-K filed with the Securities and Exchange Commission on December 12, 2002 and amended on January 23, 2003. The Form 10-K report 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, as filed with the Securities and Exchange Commission, and amendments thereto may be obtained without charge by writing to: OSI Pharmaceuticals, Inc., Robert L. Van Nostrand, Corporate Secretary, 58 South Service Road, Suite 110, Melville, New York 11747.

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PART I

ITEM 1. BUSINESS

We are a leading biotechnology company 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. We have established a balanced pipeline of oncology drug candidates that includes both next-generation cytotoxic chemotherapy agents and novel mechanism-based, gene-targeted therapies.

Our most advanced drug candidate, Tarceva™ (erlotinib HCl), is a small molecule inhibitor of the epidermal growth factor receptor, or HER1/EGFR. The protein product of the HER1/EGFR gene is a receptor tyrosine kinase that is over-expressed or mutated in many major solid tumors. We believe HER1/EGFR inhibitors represent an exciting new class of relatively safe and well tolerated anti-cancer agents that may have utility in treating a wide range of cancer patients. Tarceva™ is an oral once-a-day small molecule drug designed to specifically block the activity of the HER1/EGFR protein. Currently, Tarceva™ is being developed in an alliance with Genentech, Inc. and Roche. If the drug receives regulatory approval, Genentech will lead the marketing effort in the United States and Roche will market it in the rest of the world. We will receive milestone payments from both Genentech and Roche, an equal profit share from U.S. sales, and royalties on sales outside of the United States. Tarceva™ has demonstrated encouraging indications of anti-cancer activity in single-agent, open label Phase II trials in non-small cell lung cancer, head and neck cancer and ovarian cancer. Tarceva™ is currently in Phase III clinical trials for non-small cell lung cancer and pancreatic cancer.

Behind Tarceva™ we have five additional drug candidates in earlier stages of clinical development. Three of these (OSI-211, OSI-7904L and OSI-7836) are next generation cytotoxic chemotherapy agents and the other two (CP-547,632 and CP-724,714) are gene-targeted therapies currently being developed by Pfizer Inc. We own commercial rights to the first three and will receive royalty payments on the latter two if they are successfully commercialized.

Our next generation cytotoxic chemotherapy candidates are designed to improve upon currently marketed products in the same drug class. OSI-211 is a liposomal formulation of lurtotecan, a topoisomerase-1 inhibitor, that is being developed to compete with topotecan (Hycamptin®). OSI-7904L is a liposomal formulation of a thymidylate synthase inhibitor, GW1843, that is being developed as a potential competitor to 5-Fluorouracil (5-FU) and capecitabine (Xeloda®), and OSI-7836 is a nucleoside analog being developed to compete with gemcitabine (Gemzar®). OSI-211 is in Phase II clinical trials, and OSI-7904L and OSI-7836 are in Phase I clinical trials. Like Tarceva™, the two gene-targeted therapies are receptor tyrosine kinase inhibitors. CP-547,632 is a small molecule targeting the vascular endothelial growth factor receptor, or VEGFR, and CP-724,714 is a small molecule targeting HER2/erbB2. Both agents are currently in Phase I clinical trials.

In order to support our clinical pipeline, we have established (through acquisition and internal investment) a high quality oncology clinical development and regulatory affairs capability and a pilot scale chemical manufacturing and process chemistry group. Behind our clinical pipeline we have an extensive, fully integrated small molecule drug discovery organization designed to generate a pipeline of high quality oncology drug candidates to move into clinical development. This research operation has been built upon our historical strengths in high throughput screening, chemical libraries, medicinal and combinatorial chemistry, and automated drug profiling technology platforms.

Our Strategy

We believe that Tarceva™ has established a corporate presence for us in the oncology field. Our strategy over the last several years has been designed to capitalize upon this presence and to re-orient our business

towards becoming a world class oncology organization. To this end, we have raised capital, formed alliances and engaged in merger and acquisition activity with the strategic intent to:

- maximize our prospects for successful development and commercialization of Tarceva™;
- enhance our skill sets and improve the quality of our organization, allowing us to establish a comprehensive array of research, development and business skills necessary for our cancer mission;
- divest or exit from our current non-oncology research activities and alliances;
- engage in active in-licensing and partnering efforts to add to our cancer pipeline and complement our internal cancer research programs; and
- continue to invest in opportunities that will lead to successful growth while aggressively managing the risks inherent in our industry in order to sustain a strong balance sheet through to profitability.

As we move forward, we intend to follow through on the following core elements of our strategy:

Execution on Tarceva™. Together with our partners, Genentech and Roche, we have formulated a comprehensive, global development program for Tarceva™. Since the beginning of the alliance, we, with our partners, have collectively initiated numerous clinical trials, four of which are Phase III registration-oriented trials in lung and pancreatic cancers. This registration strategy focuses on the execution of adequate, controlled and well-designed studies to support a worldwide registration program. All four Phase III trials are designed as large-scale, placebo controlled, double-blinded trials with a primary endpoint of survival and several secondary endpoints which include, among others, symptom relief and quality of life. Should these studies prove successful, we have established a goal of achieving profitability within 18 to 24 months of market launch of Tarceva™.

Focus on Oncology. We intend to focus our business entirely on oncology and continue to build upon our extensive pipeline of oncology product candidates, our strong core of discovery research, and our top-tier oncology clinical development and regulatory affairs group. As our pipeline reaches the commercialization stage, we also intend to establish a full commercial operation, initially in the U.S. market. Although we intend to commercialize selected products independently, we will also continue to engage in marketing partnerships where we believe this will add value to our ability to effectively and competitively commercialize our products.

We also intend to complete the divestiture of all remaining non-oncology research programs. In July 2002, we agreed to accelerate the conclusion of the phase-down period of our funded research alliance with Anaderm Research Corporation, a wholly-owned subsidiary of Pfizer, focused on the development of novel treatments for skin and hair conditions. We expect the transfer of all research related to the collaboration to be completed by the beginning of 2003. We are in the process of divesting our diabetes program and certain of our adenosine receptor assets into an entity with the intent that this entity subsequently will be funded by third party investors and will be one in which we will maintain a minority interest. This planned divestiture coupled with steps we took in October 2002 to re-size and re-focus the skill sets of our organization will carry us into 2003 with approximately 425 research, development and business personnel focused entirely on oncology.

These steps will allow us to maintain the level of resource commitment we believe is required to achieve our primary goal of building a first-class oncology franchise with a pipeline of clinical and research opportunities anchored around Tarceva™.

Licensing and Acquiring Oncology Products and Clinical Candidates. In order to effectively manage the risks inherent in pharmaceutical research and development and to complement our internal research efforts, we believe it is essential that we continue 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. In December 2001, we acquired Gilead Sciences, Inc.'s entire pipeline of clinical candidates in oncology and certain related intellectual property, as well as Gilead's Boulder, Colorado operations, including clinical research, regulatory affairs and drug development personnel,

infrastructure, and facilities. This transaction accelerated our development and commercialization capabilities with the addition of an outstanding and complementary drug development and oncology group, and augmented our pipeline of gene-targeted small molecule therapeutics with several promising next-generation cytotoxic chemotherapy agents currently in clinical development. Under the terms of the transaction, we received exclusive worldwide development and commercialization rights to Gilead's three clinical development candidates in oncology. With a full array of cancer drug discovery and development capabilities and a strong balance sheet, we expect to be well positioned to compete for premier in-licensing and acquisition opportunities.

Our Research and Development Programs

Research and Development Pipeline

The following table summarizes the status of our more advanced oncology product candidates as of November 30, 2002 and identifies any related collaborator.

<u>Product/Indication</u>	<u>Status*</u>	<u>Drug Type</u>	<u>Collaborator(s)</u>
Tarceva™/Non Small Cell Lung Cancer	Phase III	Epidermal Growth	Genentech and Roche
Tarceva™/Pancreatic Cancer	Phase III	Factor Receptor Inhibitor	
Tarceva™/Ovarian, Head and Neck, Metastatic Breast and Glioblastoma Multiforme	Phase II	(HER1/EGFR)	
Tarceva™/various-exploratory	Phase I		
OSI-211/Ovarian Cancer	Phase II	Liposomal Topoisomerase-1	OSI-Owned
OSI-211/Small Cell Lung Cancer	Phase II	Inhibitor	
OSI-7904L/various-exploratory	Phase I	Liposomal Thymidylate Synthase Inhibitor	OSI-Owned
OSI-7836/various-exploratory	Phase I	Nucleoside Analog	OSI-Owned
CP-547,632/various-exploratory	Phase I	Vascular Endothelial Growth Factor Receptor (VEGFR) Inhibitor	Pfizer
CP-724,714/various-exploratory	Phase I	HER2/erbB2 Receptor Inhibitor	Pfizer

(*) Denotes clinical safety and efficacy tests as follows:

Phase I - Evaluation of safety in humans.

Phase II - Evaluation of safety, dosing, and initial efficacy in humans.

Phase III - Evaluation of safety and efficacy in humans.

OSI's Approach to Cancer Therapy

Cancer remains a major unmet 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 2001 were in excess of \$56 billion. The worldwide market for anti-cancer drugs is estimated to be \$14 billion in 2002 and is expected to grow as breakthrough 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 severely limited in their utility by their serious side effects, such as disruption of the blood, immune and gastrointestinal systems. These side effects limit the anti-tumor value of these cytotoxic drugs because they can be used only in sub-optimal dosing regimens.

We have taken two general approaches in an attempt to improve the available drug treatment options for cancer patients. The first approach involves the development of next-generation cytotoxic agents which present improvements in activity over existing drugs or technological innovations, such as liposomal formulations that are designed to improve targeting of the cytotoxic agent to the tumor, thus reducing the incidence of the harmful side effects usually associated with cytotoxic drugs. The second approach involves 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. 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. It is our belief that to be a successful oncology franchise, we should be developing both next-generation or improved cytotoxic drugs and targeted therapies in order to provide an array of effective treatment options for the cancer patient. Thus, while our drug discovery research efforts are focused on next-generation gene-targeted therapies, our acquisition of oncology assets from Gilead has complemented our research efforts with a portfolio of novel cytotoxic agents. These assets include OSI-211 and OSI-7904L, which are liposomal formulations of novel agents belonging to two classes of drug (topoisomerase 1 inhibitors and thymidylate synthase inhibitors, respectively), for which products are currently marketed. Our belief is that these liposomal formulations might allow us to achieve improved activity profiles over the existing marketed products. The third of our cytotoxic agents is OSI-7836, which, in pre-clinical testing, has clearly demonstrated anti-tumor activity in a variety of refractory solid tumor xenograft models and is being developed as an alternative to gemcitabine (Gemzar®), which is sold in the United States for the treatment of pancreatic cancer and non-small cell lung cancer.

Our drug discovery efforts in targeted therapies were for many years conducted in partnership with Pfizer. Tarceva™ was jointly discovered as part of this alliance. Pfizer is continuing to develop three other targeted therapies from this alliance (two of which are in clinical development), the funded discovery phase of which concluded in April 2001. These drugs represent the vanguard of a substantial research effort directed toward the discovery and development of these next generation targeted drugs. If Pfizer is successful in commercializing any of these drug candidates, we will receive a royalty from Pfizer on the sales of such drugs.

The novel, anti-cancer drugs resulting from our alliance with Pfizer, including Tarceva™, specifically target cancer-causing genes, or oncogenes, and processes required for tumor growth such as angiogenesis. Oncogenes are typically growth regulating genes that are either over-expressed or mutated in cancer cells in such a manner that they confer either a significant growth advantage on cancer cells in the body or interrupt the normal process of programmed cell death, or apoptosis, that contributes to the uncontrolled growth associated with cancer. One of the most important of these oncogenes is HER1 or EGFR. HER1/EGFR is part of a family of growth factor receptors (the HER family) that binds to natural protein signals like the epidermal growth factor, or EGF, and transforming growth factor- α , or TGF- α , sending growth signals, via the receptor's tyrosine kinase enzyme activity, to the nucleus of the cell controlling growth. In many solid tumors, HER1/EGFR is either over-expressed or mutated, leading to abnormal signaling which is linked to the development of a cancerous mass.

HER1/EGFR kinase is over-expressed in a wide range of solid tumors and a significant number of patients diagnosed with cancer each year in the United States have solid tumors that over-express HER1/EGFR. In addition, a frequently occurring mutation of the HER1/EGFR gene called EGFRvIII is found in many tumors. Thus, there is both an urgent medical need and a substantial potential market for effective anti-HER1/EGFR agents. Progress in the field has established HER1/EGFR as a validated target for cancer intervention and small molecule tyrosine kinase inhibitors as promising drug candidates in this area. Antibody products are also under development which target the EGF binding region of the receptor and have demonstrated indications of improved anti-cancer activity when used in conjunction with existing treatment and chemotherapy regimens. We believe these agents are unlikely to effectively inhibit mutated forms of HER1/EGFR. They also require delivery via intravenous infusion and are sometimes difficult and expensive to produce. In contrast to these agents, small molecule inhibitors of the tyrosine kinase activity, such as Tarceva™, should be effective against either mutant or over-expressed forms of HER1/EGFR, are convenient

once-a-day oral therapies, and are relatively easy and inexpensive to manufacture. In addition, Tarceva™ has demonstrated anti-tumor activity when used clinically as a single agent in Phase II clinical trials.

Tarceva™

From 1986-2001, the focus of our cancer collaboration with Pfizer was the discovery and development of novel classes of orally active, gene-targeted, small molecule anti-cancer drugs based on oncogenes and tumor suppressor genes and the fundamental mechanisms underlying tumor growth. Today these approaches remain at the core of our in-house discovery efforts. The most prominent and advanced of these programs targets HER1/EGFR. Tarceva™, a small molecule anti-cancer agent, is a potent, selective and orally active inhibitor of the receptor tyrosine kinase activity of HER1/EGFR. Tarceva™ has demonstrated anti-cancer activity in open-label Phase II trials and is now in Phase III trials for non-small cell lung cancer and pancreatic cancer. We gained full development and marketing rights to Tarceva™ in June 2000 when the U.S. Federal Trade Commission ordered Pfizer to divest it to us as a result of an anti-trust finding upon the FTC's review of Pfizer's merger with Warner-Lambert Company. In January 2001, we entered into an alliance with Genentech and Roche for the global co-development and commercialization of Tarceva™.

Clinical Data. Phase I and Phase II trials on Tarceva™ have demonstrated the drug to possess activity as a single agent and to be relatively safe and well-tolerated with manageable side effects, principally, reversible rash and a generally mild diarrhea. The dose limiting side effect in the Phase I trials was diarrhea, which was moderate to severe in three of nine patients in these particular studies involving very sick cancer patients at 200 mg per day. 150 mg per day was established as the maximum tolerated dose in this study. On a 150 mg oral daily dosing regimen, diarrhea is generally mild and is treated effectively (when necessary) with loperamide (over the counter Imodium®). Clinical investigators have generally considered the rash, which is common to all anti-HER1/EGFR drugs in development, to be the most common adverse event in the context of this anti-cancer therapy. Some success in treating rash has been observed with antibiotic creams as well as with a variety of other agents. However, we believe that the rash itself may serve to be a useful biomarker of the effective delivery and potential activity of Tarceva™. Indeed, in our Phase II trials the survival of patients who developed rash during Tarceva™ treatment was significantly higher than those who did not. A subset of patients in Phase I, Phase II and Phase III trials have now received daily doses of Tarceva™ for extended periods (one year or more) with generally well-managed side effect profiles.

We have now completed Phase II trials for Tarceva™ in non-small cell lung cancer, head and neck cancer and ovarian cancer. Patients in these trials had advanced or metastatic cancer and had generally failed standard treatment regimens. We believe these trials are encouraging because they demonstrate objective clinical responses and noteworthy survival data for patients treated with Tarceva™ as a single agent. The primary endpoint in these trials was response rate, with stable disease, survival, time to progression and quality-of-life being monitored as secondary endpoints. Updated analysis of data from these Phase II trials showed that rash and rash related disorders were seen in 162 patients, or 79%, of the patients. Mild to moderate rash was seen in 146 of these patients and 16 patients showed severe rash. Diarrhea was experienced by 93, or 45%, of the patients. For 86 patients, the diarrhea was mild to moderate, and seven patients had severe diarrhea.

Non-Small Cell Lung Cancer. This trial consisted of 57 non-small cell lung cancer, or NSCLC, patients having tumors that were confirmed to be HER1/EGFR positive and who had failed standard platinum-based chemotherapy. Patients received a daily dose of 150 mg of Tarceva™. The results from this trial showed that 51% of the patients had either a response or disease stabilization, 22 of whom demonstrated stable disease, five of whom had a partial response, and two of whom had a complete response. The median survival in this trial was 37 weeks. At 12 months, 40% of the patients were alive, 21% of the patients were alive at 18 months, and 16% of the patients are still alive, as of the last follow-up, over 18-24 months. In this trial, a strong correlation between rash and survival was observed. All seven responders experienced rash, 21 out of 22 patients (95%) with stable disease experienced rash while only 15 out of 28 patients (54%) with progressive disease experienced rash. The median survivals of patients who experienced no rash, grade 1 rash or grade 2/3 rash were 1.5, 8.5 and 19.6 months, respectively.

Head and Neck Cancer. This trial had 115 patients with advanced head and neck cancer receiving 150 mg of Tarceva™ per day. The results showed that 43% of the patients in the study had either a partial response or stable disease. Five patients had objective partial response while 44 patients demonstrated stable disease. The median survival in this study was 26 weeks with 21% of the patients surviving one year or longer.

Ovarian Cancer. The third Phase II trial was in advanced ovarian cancer and reported a response plus stable disease rate of 53% based on 34 evaluable patients. Two patients had a partial response, and 16 patients demonstrated stable disease. The median survival of these patients was 35 weeks with 35% of the patients surviving one year or longer.

Other Cancers. Genentech has completed an exploratory Phase II study in advanced metastatic breast cancer. Many of the patients in this study were resistant to Herceptin® which is another inhibitor of the HER family signaling pathway. Initial results from this study do not indicate broad-based activity for Tarceva™ in this patient population. We anticipate that results from this study will be presented in the near future.

The data from the NSCLC, head and neck cancer and ovarian cancer Phase II trials are summarized in the following table:

TARCEVA™ PHASE II DATA
(single-agent salvage studies in patients with refractory or advanced cancer)

	<u>Non-Small Cell Lung Cancer</u>	<u>Head & Neck Cancer</u>	<u>Ovarian Cancer</u>
Evaluable Patients	57	115	34
Complete Response (100% tumor reduction)	2	—	—
Partial Response (greater than 50% but less than 100% tumor reduction)	5	5	2
Stable Disease (up to 50% tumor reduction or less than 25% tumor increase)	22	44	16
Overall Responders (complete response and partial response)	12.3%	4.3%	5.9%
Overall Responders and Stable Disease	51%	43%	53%
Median Survival	37 weeks	26 weeks	35 weeks
One Year Survival	40%	21%	35%

Data as of November 18, 2002

SIDE EFFECTS
(all three studies)

Rash & Related Disorders	79%
Diarrhea	45%

Data as of November 18, 2002

Development. Since the inception of our alliance with Genentech and Roche in January 2001, we have implemented a global development strategy for Tarceva™ with our partners. This plan was designed to be a broad-based approach in implementing several Phase III trials to result in a registration with the U.S. Food and Drug Administration. These trials include a single agent trial for refractory NSCLC patients as well as combination trials with existing chemotherapy regimens for front-line use in pancreatic cancer and NSCLC. These trials are large, placebo-controlled, double-blind studies designed to demonstrate a survival and symptom improvement/quality-of-life benefit for Tarceva™ in either combination or single agent settings. We are also conducting several safety trials to review the effect of Tarceva™ in combination with other chemotherapy drugs, and additional Phase II studies are being conducted both independently and in collaboration with the U.S. National Cancer Institute's Cancer Therapy Evaluation Program, or CTEP, in a

wide array of tumor types including head and neck, ovarian and glioblastoma multiforme. Under the alliance, the following Phase III trials are being conducted, with the indicated enrollment goals:

- An approximately 700 patient Phase III trial in refractory NSCLC. In this trial, Tarceva™ is being used as a single agent to treat second/third line NSCLC versus best supportive care of patients as a control group. We have been given fast track status by the FDA for the indication covered by this trial, and patient enrollment is expected to be completed by early 2003.
- An approximately 1,000 patient Phase III front-line NSCLC trial comparing Tarceva™ used in combination with carboplatin (Paraplatin®) and paclitaxel (Taxol®), the standard of care in the United States, versus chemotherapy alone. This indication was given fast track status by the FDA and patient enrollment was completed in July 2002.
- An approximately 1,200 patient Phase III front-line NSCLC trial comparing Tarceva™ used in combination with gemcitabine (Gemzar®) and cisplatin (Platinol®), a commonly used treatment regimen in Europe, versus chemotherapy alone. Enrollment in this trial was completed in September 2002.
- A Phase III front-line pancreatic trial comparing Tarceva™ used in combination with gemcitabine (Gemzar®) versus chemotherapy alone. Patient enrollment is expected to be completed by spring 2003.

These Phase III trials are large scale, placebo controlled registration orientated trials. Improvement in patient survival is the primary endpoint in all of these studies with symptom improvement and quality-of-life as key secondary endpoints.

AstraZeneca PLC, a pharmaceutical company developing a direct competitor drug to Tarceva™, announced in August 2002 that its drug candidate, Iressa, showed no improvement in its front-line NSCLC trials when used in combination with chemotherapy against chemotherapy alone. These trials are similar to the Tarceva™ trials we are conducting in front-line NSCLC which assess Tarceva™ in combination with chemotherapy versus chemotherapy alone. AstraZeneca's announcement had a significant impact on our stock price. However, although both Tarceva™ and AstraZeneca's drug candidate belong to the same class of HER1/EGFR targeted therapies and a positive outcome for our Tarceva™ Phase III combination studies must therefore be considered higher risk, there are important differences between the two agents and the respective clinical programs including structure, formulation, pharmacokinetics, Phase III design, and dosing. The Phase III program for Tarceva™ is designed on the basis of our Phase II data which demonstrated encouraging indications of clinical activity in three separate single agent Phase II trials in refractory or advanced cancer patients with NSCLC, ovarian cancer or squamous cell carcinoma of the head and neck. Our two Phase III front-line studies in NSCLC are designed to assess the potential of survival benefit of Tarceva™ with standard chemotherapy. These trials contain noteworthy differences in study design as compared to those of AstraZeneca's trial design. The dose employed in our Phase III NSCLC program of 150 mg per day is the apparent maximum tolerated dose, or MTD, whereas the AstraZeneca trials were conducted at relatively lower doses for this agent versus the MTD determined for Iressa in earlier Phase I studies. The choice of the MTD as the dose for our Phase III studies is based on our belief that this dosing strategy may be clinically important in the use of this agent. In addition, and unlike AstraZeneca, we are conducting a Phase III study in refractory NSCLC investigating the potential survival benefit of single agent Tarceva™ at 150 mg per day. This is the most advanced single agent controlled Phase III study of an HER1/EGFR targeted agent designed to detect a survival advantage in refractory NSCLC. We believe this second/third line NSCLC trial is our highest priority and a key registration study for Tarceva™. We have, therefore, increased the patient size of this trial from 330 to approximately 700. We have also shifted emphasis from our pancreatic trial to our refractory NSCLC trial. In doing so, we intend to reduce the target patient enrollment in the pancreatic trial after consultation with the National Cancer Institute of Canada Clinical Trials Group with whom we are collaborating on this study. This reduction will not affect the endpoints but will extend the timeline for filing a new drug application, or NDA, for this indication. Initial results indicated that the combination of 100 mg per day of Tarceva™ with gemcitabine appeared to be the appropriate dose for this patient population.

During fiscal 2001, we agreed to collaborate with the U.S. National Cancer Institute in its CTEP program to conduct over 20 clinical trials with Tarceva™ in multiple tumor types, including epithelial malignancies of the gastrointestinal and genitourinary tracts, gynecological malignancies and brain tumors. The trials are being funded and managed by NCI, and we are providing Tarceva™ for these trials. These investigations generate useful clinical data in addition to maintaining awareness of Tarceva™ in the oncology community.

Other Proprietary Cancer Programs

OSI-211. OSI-211 is a proprietary liposomal formulation of the active topoisomerase-1 inhibitor lurtotecan, a drug candidate that was originally licensed by Gilead from GlaxoSmithKline and subsequently acquired by us from Gilead. It is a member of the camptothecin class of cytotoxics that act as topoisomerase-1 inhibitors. This class of drugs has established activity in cancers. Two members of this class of drugs that are currently marketed are irinotecan (Camptosar® by Pharmacia Corporation in the United States and by Aventis in Europe) which is indicated primarily for colorectal cancer, and topotecan (Hycamtin® by GlaxoSmithKline) which is used to treat relapsed ovarian cancer and relapsed small cell lung cancer. Lurtotecan had been active in Phase II clinical trials. The liposome formulation was designed to enhance efficacy and improve the drug's therapeutic index. OSI-211 has been demonstrated to be active in a d,1,2,3 schedule (intravenous doses of OSI-211 on three consecutive days) for the treatment of relapsed ovarian cancer. However, in order to develop this agent, we believe it is essential that we clearly differentiate it from topotecan in terms of activity, safety and convenience. We have, therefore, initiated a head-to-head Phase II trial versus topotecan in relapsed ovarian cancer and a Phase II trial in advanced small cell lung cancer using the d,1,2,3 schedule.

As part of the acquisition of the Gilead oncology assets, we have agreed to make a milestone payment to Gilead of \$20 million, payable in cash or shares of our common stock or a combination of cash and shares of our common stock, at our option, upon our commencement of Phase III clinical trials for OSI-211. We have also agreed to pay to Gilead \$10 million in cash upon our filing of an NDA with respect to OSI-211. Additional milestone payments are due to GlaxoSmithKline upon successful development of this product.

OSI-7904L. OSI-7904L is a member of the thymidylate synthase inhibitor, or TSI, class of cytotoxic chemotherapies. This drug candidate was also originally licensed by Gilead from GlaxoSmithKline and subsequently acquired by us from Gilead. Milestone and royalty payments are due to GlaxoSmithKline upon successful development of this product. It is formulated in liposomes with a goal of extending its pharmacokinetic (or drug exposure) profile and thereby improving its therapeutic ratio. It is in Phase I clinical trials, having demonstrated promising activity in pre-clinical testing for the potential treatment of various solid tumors. The leading TSI used today is 5-Fluorouracil, or 5-FU, a generically available TSI which is extensively used in many tumor types, notably colorectal cancer. A recently marketed entrant from this class is capecitabine (Xeloda® by Roche), which is indicated in second line treatment of metastatic breast cancer and colon cancer. We believe that there is a need for better therapies than 5-FU or Xeloda® in relapsed colorectal cancer and metastatic breast cancer. Initial data from the Phase I study has indicated that the liposomal formulation has extended the drug exposure profile in patients' blood.

OSI-7836. OSI-7836 was originally licensed by Gilead from the Southern Research Institute and subsequently acquired by us from Gilead. Milestone and royalty payments are due to Southern Research Institute upon successful development of this product. OSI-7836 is a member of the nucleoside class of cytotoxic drugs of which gemcitabine (Gemzar® marketed by Eli Lilly and Company) is the market leader. Gemzar® is approved in the United States for pancreatic cancer and non-small cell lung cancer. OSI-7836 is being developed as an alternative gemcitabine and has clearly demonstrated anti-tumor activity in a variety of refractory solid tumor xenograft models.

Pfizer Collaborative Cancer Programs

In April 1986, we entered into a collaborative research agreement and a license agreement with Pfizer which was focused on the discovery and development of cancer therapeutic products. On April 1, 2001, the

funded phase of the collaborative research agreement expired and was not renewed. We have three drug discovery programs in targeted therapies for cancer with Pfizer, two of which are in clinical trials and one is in advanced pre-clinical development. 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 one of the most intriguing opportunities 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 I trials. A second drug candidate in this area, CP-673,451, targets the platelet derived growth factor receptor, or PDGFR, and is in advanced pre-clinical development.

In September 2002, an additional candidate from the Pfizer program, CP-724,714, a potent, selective small molecule inhibitor of the HER2/erbB2 receptor tyrosine kinase, advanced to Phase I clinical trials. Overexpression of HER2/erbB2 oncogenes has been demonstrated to correlate with aggressive cancer growth, particularly in metastatic breast cancer. Approximately 25-30% of all women with metastatic breast cancer over express HER2/erbB2.

OSI-754. On November 21, 2001, Pfizer chose to discontinue development of OSI-754, a farnesyl transferase inhibitor that was undergoing Phase I trials, and returned to us full commercial rights pursuant to the terms of the original license agreement between the parties. In November 2002, we suspended Phase I clinical development of OSI-754, allowing prioritization of clinical development resources to the Tarceva™ program. We will continue to conduct further internal, pre-clinical experiments with OSI-754 in order to gain a better understanding of the possible interactions and synergies of this class with our other research compounds.

Continuous Enrichment of Our Product Pipeline

We intend, through a combination of in-house research and aggressive technology acquisition, candidate in-licensing and partnering efforts, to add to our oncology pipeline of drug candidates. Since drug development is by its nature a high-risk venture, a philosophy of combining internal research and business development activities is important to our ability to sustain a high quality pipeline of clinical candidates. With the acquisition of the Gilead oncology assets in December 2001, as well as assets acquired from British Biotech plc in September 2001, we now have the skill sets necessary to conduct the entire process of drug discovery and development from the inception of the drug discovery process through to registration. These skill sets also enable us to absorb external opportunities at any stage of the drug discovery or development process.

Licensing and Acquisitions

We have set ourselves a goal of continuing to enrich our pipeline beyond Tarceva™ by employing a strategy to identify and acquire products, clinical and pre-clinical development candidates and technology pertinent to our cancer mission. The acquisition of the oncology assets of Gilead is a successful example of this effort. This acquisition not only provided us with world class oncology development capabilities, but also three clinical stage drug candidates. The sourcing for these opportunities will range from academia to large pharmaceutical companies.

Internal Drug Discovery

The core of our company has historically been built around a base of high quality scientific research focused on gene targeted, small molecule drug discovery. We have focused our internal discovery organization on oncology while continuing to collaborate extensively with high quality academic and technical groups. We believe this scientific base coupled with a platform of discovery technologies and capabilities will provide a stream of high quality product opportunities for our future growth. The mission of our drug discovery research teams is to generate a flow of product candidates to create a valuable pipeline which will contribute significant revenues in the five-to ten-year time frame.

Our Drug Discovery and Development Capabilities

Background

Our approach is focused on the discovery and development of small molecule pharmaceutical products which, 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 and clinical development. The process begins with a lead seeking phase. In this phase, which generally takes one to two years, a combination of modern molecular biology, robotics and computational science is used to build assay or test systems in which large libraries of diverse small molecules are tested to determine if any of these molecules possess activity against a drug target. In order to enhance our capabilities in this area, we have recently entered into a research collaboration with Cold Spring Harbor Laboratories to rapidly identify and validate new targets for cancer drug discovery. This collaboration will focus on identifying specific targets that we consider to be important in the progression of a variety of cancer types, thus allowing us the opportunity to take advantage of the wealth of genetic information that is rapidly being generated within the field of oncology. Our goal is to identify and validate a number of targets that will be proprietary to us and which can enter our automated screening tests. After this initial testing, active compounds are tested in a variety of secondary assays designed to determine their potency and selectivity, and to obtain early information on their potential metabolism, toxicity and mechanism of action. Active compounds surviving this selection process are considered leads and progress into lead optimization.

During lead optimization, medicinal chemists synthesize new molecules and combinatorial libraries which are structurally related to the lead compound. These are tested extensively in order to produce a drug candidate which has greatly improved drug-like qualities, is active and well-tolerated in animal models and can be patented as a novel pharmaceutical. Having identified a suitable drug candidate, the molecule is advanced toward clinical trials and enters the IND-track phase, in which toxicological, scale-up synthesis and clinical trial design issues are addressed. This phase usually takes nine to 12 months.

Upon entering clinical trials (with an investigational new drug, or IND, approval from the FDA or its foreign equivalent), a drug is first assessed for its safety. After these Phase I trials, drugs are tested in efficacy, or Phase II, trials to demonstrate initial activity in humans prior to extensive Phase III trials designed to collect the data necessary to support an NDA filing with the FDA. The entire drug discovery and development process typically takes over a decade and is subject to significant risk and attrition. A significant number 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. We have integrated a platform of technologies designed to rapidly and cost-effectively enhance the overall process.

Our Technology Platform

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 discovery technologies and capabilities include (i) gene transcription, signal transduction, protein kinases and other assay systems, (ii) automated high throughput screening, (iii) a library of over 350,000 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.

Biology and Lead Seeking

We are able to conduct high throughput screening on a wide variety of assay platforms, including enzyme, immuno and receptor assays. We have developed proprietary hardware and software systems to automate the entire drug screening process, from the addition of the test substances to assay systems to the analysis of the data generated from the tests.

Part of our assay technology includes the use of genetically engineered human cells to identify compounds that affect transcription of target genes. These assay systems, which employ reporter gene technology, represent a broadly enabling technology that is the subject of an extensive patent estate which we have successfully licensed to third parties.

Access to large libraries of diverse, small molecule compounds is a key asset in our drug discovery efforts. Leads discovered from these libraries become the starting materials from which drugs are optimized. Our proprietary libraries include focused libraries of small molecule compounds derived from our high-speed combinatorial analoging, and libraries of diverse, high quality small molecule compounds that we have acquired.

Chemistry and Lead Optimization

The pharmaceutical properties of a lead compound generally must be optimized before clinical development of that compound begins. We have assembled a high quality medicinal chemistry team of combinatorial, computational and pharmaceutical development chemists, which are critical elements of the lead optimization process. A pilot manufacturing plant provides us the ability to rapidly scale up the production of small molecules for pre-clinical toxicology testing and early clinical trials and will further enable us to move competitively into clinical development. We also have a high quality group of professionals engaged in the *in vivo* testing of our lead compounds, including the use of so-called xenograft models. These models allow us to test potential anti-cancer drugs against human tumors grown in genetically modified mice.

Pre-Clinical Development

We have expertise in pharmacokinetics, toxicology, drug metabolism and pharmaceutical chemistry to support the development of pre-clinical drug candidates. In addition, we have expertise in the management and generation of good laboratory practices and accredited data, which are required for regulatory dossier submissions to agencies such as the FDA. We are, therefore, able to independently support the development of a drug candidate for clinical testing. We have invested significant resources in expanding this capability and in technological enhancements in this area.

Clinical Development

We have established an oncology development team with considerable expertise in clinical development, data management and analysis and regulatory approval. We also engage third-party clinical research organizations, or CROs, under the management and supervision of our clinical development team, to conduct large scale clinical studies. We have entered into agreements with CROs with expertise in oncology to monitor our ongoing clinical trials for Tarceva™. Our Tarceva™ development team works to integrate externally contracted clinical development support activities with contract research, manufacturing and inventory control organizations. Under our tripartite development agreement with Genentech and Roche, while the costs are shared equally, each party is responsible for managing certain trials. Genentech and Roche are each managing one of the Phase III trials in NSCLC testing Tarceva™ in combination with cytotoxic chemotherapy. We are managing the Tarceva™ Phase III trials in second/third line NSCLC and the combination chemotherapy trial in pancreatic cancer.

Manufacturing and Supply

We currently rely on third-party manufacturers to manufacture our late stage product candidates. Under our collaboration agreement with Genentech, we are responsible for the manufacture and supply of Tarceva™ for pre-clinical and clinical trials and to supply commercial quantities for sales within the United States. Under our collaboration agreement with Roche, Roche has elected to manufacture and supply Tarceva™ tablets for sale outside of the United States.

Erlotinib HCl (Tarceva™), a small molecule, is manufactured in a three-step process with high yield. We currently engage multiple third-party manufacturers to supply starting materials and active pharmaceutical ingredient, or API, used for the preparation of Tarceva™ tablets. We expect to enter into long-term

manufacturing and supply agreements with several of these manufacturers. In April 2001, we entered into a contract with a third party manufacturer to formulate erlotinib HCl into tablets. Additionally, we are in the process of identifying an additional source for the tablet manufacture. All manufacturers are required to comply with current Good Manufacturing Practices, or cGMP. We have sufficient quantities of Tarceva™ tablets to conduct our ongoing clinical trials. We currently use third parties to label, inventory and distribute the drug product. In addition, we are using third-party manufacturers in connection with the development of alternative formulations of drug product consisting of an IV formulation and an oral solution.

In connection with our acquisition of certain of the pre-clinical research operations of British Biotech in September 2001, we acquired a fully-integrated cGMP chemical pilot plant in Oxford, England. This plant is capable of producing clinical grade non-cytotoxic compounds on a scale sufficient to support our proprietary development activities generally through the completion of Phase II clinical trials. We plan to use this facility to manufacture products to support our current and future pre-clinical and clinical development programs.

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 a one-year transition period, Gilead has continued to manufacture and supply to us the API for preparation of OSI-7836 and OSI-7904L drug products. We are currently in the process of transitioning the manufacture of the API to new manufacturers as soon as practicable. Starting materials for OSI-7904L are manufactured by other third-party manufacturers. Starting materials for OSI-7836 are manufactured in our chemical pilot plant in our Oxford, England facility. The entire synthesis of OSI-211 API (including starting materials) is manufactured by a third party. Gilead will produce for us liposomal formulations of OSI-211 and OSI-7904L at its manufacturing facility in San Dimas, California to support our ongoing clinical trial activities and, upon FDA approval, commercial manufacturing needs for these two liposomal products. OSI-7836 drug product, which is a conventional IV formulation, will be prepared by a third party manufacturer that is yet to be determined.

Roche and Genentech Collaboration

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.

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™ products 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 agreement or the OSI/Roche agreement terminates.

Under the OSI/Genentech agreement, we agreed to collaborate in the product development of Tarceva™ with the goal of obtaining regulatory approval for commercial marketing and sale in the United States of products resulting from the collaboration. Consistent with the development plan and with the approval of a joint steering committee, we will 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 will own and be responsible for filing and the first supplemental NDA which we will 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 that may be enacted by mutual agreement at any time provided that we have established a commercial operation independent of Tarceva™. Genentech will pay us certain milestone payments and we will share equally in the operating profits or losses on products

resulting from the collaboration. Under the OSI/Genentech 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. The term of the OSI/Genentech 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. The OSI/Genentech agreement is subject to early termination in the event of certain defaults. The agreement is also subject to early termination under certain circumstances.

Under the OSI/Roche agreement, we granted to Roche a license under 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™ in the world, other than the territories covered by the OSI/Genentech 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 term of 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™. The OSI/Roche agreement is subject to early termination in the event of certain defaults. In addition, after two and one half years from the effective date, Roche may terminate the agreement on a country-by-country basis. We may also have the right to terminate the agreement on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

Other Collaborations

Anaderm Research Corporation

On April 23, 1996, we formed Anaderm with Pfizer 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 will receive an \$8 million wind-down fee in consideration for transferring all research being performed by us to Anaderm. The transfer is expected to be completed by the beginning of 2003.

Diabetes Collaborations

We have collaborations with Tanabe Seiyaku Co., Ltd and the Vanderbilt University Diabetes Center in the area of diabetes. As a result of our strategy to focus on oncology, we intend to divest our diabetes program into an externally funded entity in which we will maintain a minority equity interest by the end of the second quarter of fiscal 2003. We believe that our high quality discovery research programs in this area can be more effectively capitalized through an externally-funded entity. We expect that the Tanabe and Vanderbilt collaborations will be transferred along with the diabetes program. In addition to our alliances with Tanabe

and Vanderbilt, our discovery research program in diabetes includes six proprietary gene-targeted discovery programs in the lead seeking and lead optimization phases, primarily focused in the glucose regulation and obesity fields. We intend to also transfer to this new entity these programs and the existing diabetes teams comprising approximately 24 employees from our existing work force. If external funding for this entity does not materialize, we will consider other alternatives to discontinue the diabetes program, including the outlicensing of the diabetes assets and employee headcount reductions.

Our collaboration with Tanabe is focused on discovering and developing novel pharmaceutical products to treat diabetes. We are responsible for identification of targets, assay development, screening of compounds, identification of seed compounds, optimization of these seed compounds and identification of lead compounds meeting certain criteria specified in the agreement. Tanabe maintains responsibility for further development and marketing of a lead compound in exchange for milestone and royalty payments to us. The OSI/Vanderbilt research program, which commenced on April 28, 1998 and will end upon termination of the contract period under the Tanabe agreement unless mutually extended, is comprised of both research directed toward the targets identified, as well as those not identified, in the Tanabe agreement. Vanderbilt is assisting us in fulfilling our obligations under the OSI/Tanabe collaboration by providing access to Vanderbilt's drug discovery resources, including laboratories and assays. We provide funding to Vanderbilt to conduct the OSI/Vanderbilt research program. A portion of this funding comes from Tanabe's funding of the OSI/Tanabe research program. We will also pay to Vanderbilt a percentage of the revenues we receive 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.

Other Collaborative Research Programs

We have several other product candidates outside of cancer from our past collaborations which are being developed by our former partners. Should these candidates become commercialized drugs, we will receive royalties, and in one instance milestones, from sales of such products. These candidates are in various stages of early clinical and advanced pre-clinical development and include disease areas such as respiratory/asthma, heart disease and cosmeceuticals. The table below summarizes these agents.

<u>Product/Indication</u>	<u>Status *</u>	<u>Collaborator</u>	<u>OSI Interest</u>
AVE0309/Asthma	Phase I	Aventis Pharmaceuticals, Inc.	Royalty
OSIC-0961370/Congestive Heart Failure	IND-Track	Solvay Pharmaceuticals, Inc.	Milestones and Royalty
ADO1728/Cosmeceuticals	IND-Track	Pfizer/Anaderm	Royalty
AVE9488/Heart Disease	IND-Track	Aventis Pharmaceuticals, Inc.	Royalty

(*) Denotes clinical safety and efficacy tests as follows:

IND Track-Final stage of pre-clinical development which focuses on meeting formal FDA requirements for an IND. This phase typically takes nine months to one year to complete.

Phase I-Evaluation of safety in humans.

Our Intellectual Property

Patents and other proprietary rights are vital to our business. Our policy is to protect our intellectual property rights in technology developed by our scientific staff 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, the European Patent Office, Japan, and 20 other countries, cover composition of matter for the Tarceva™ compound itself, processes for its preparation, and pharmaceutical compositions containing Tarceva™. Patent applications are being pursued, seeking protection in and outside the United States, for polymorphic, anhydrous, hydrate, and certain salt forms of Tarceva™, as well as for processes and important intermediate chemicals in the manufacture of Tarceva™. Further, patent protection for methods of use of Tarceva™ are being sought.

As of September 30, 2002, we own 26 U.S. patents, 93 foreign patents, 32 pending applications for U.S. patents, two of which have been allowed, and 165 applications for foreign patents, two of which have been allowed. Moreover, we jointly own with Pfizer rights to numerous issued U.S. and foreign patents and pending U.S. and foreign patent applications and we jointly own, with North Carolina State University, two issued U.S. patent and certain U.S. and foreign pending patent applications. Further, other institutions have granted us exclusive rights under their U.S. and foreign patents and patent applications.

More specifically, we co-own with Pfizer about 600 U.S. and foreign patents and patent applications in about 50 patent families. The majority are patent applications that cover novel compounds discovered during our cancer collaboration with Pfizer. These include two families of patents covering composition of matter for Tarceva™. They also include several families covering farnesyl transferase inhibitors (e.g., OSI-754), an OSI program, and other development compounds being pursued by Pfizer (i.e., VEGFR, PDGFR and erbB2 inhibitors). Several of the compounds in which we have an interest in certain of our research programs are also generically covered by some of these patents.

We have assembled a strong gene transcription patent portfolio. We currently have 10 issued U.S. patents, one allowed European Patent Office patent, and two additional issued foreign patents in this patent estate. These include U.S. Patent Nos. 5,863,733, 5,665,543, 5,976,793 and 6,376,175, which cover the use of reporter genes in many cell-based transcription assays used for drug discovery; U.S. Patents Nos. 5,776,502 and 6,136,779, which cover methods of modulating gene transcription *in vivo* using low molecular weight compounds; U.S. Patent Nos. 5,580,722 and 5,846,720, which cover modulation of genes associated with cardiovascular disease, and U.S. Patent No. 6,165,712, which covers modulation of viral genes. We have additional patent applications pending, one of which has been allowed in the United States, that should further enhance our patent position in the area of gene transcription.

We have a non-exclusive out-licensing program for our gene transcription patent estate. Currently, we have licensed this technology to Aurora Biosciences Corporation, Pharmacia, the R.W. Johnson Pharmaceutical Research Institute, Wyeth Corporation, BASF and Merck & Co., Inc. Helicon Therapeutics, Inc. also has an exclusive license for a narrow use. Under these agreements, we receive reciprocal license rights to other technology or annual fees together with milestone and royalty payments with respect to small-molecule gene transcription modulators developed and marketed as pharmaceutical products. We are seeking to expand our transcriptional licensing program to include additional users of the screening aspects of this technology. Financial return from this patent estate could accrue from licensing revenues in the event a compound, whose use is covered by our claims to methods of modulating gene transcription *in vivo*, becomes an approved drug.

We have an exclusive license to patent applications filed by Southern Research Institute in the United States, European Patent Office, Japan, Canada, New Zealand and Australia to methods of use of OSI-7836 for the treatment of cancer, method of manufacture, and methods of inhibiting DNA synthesis. Patents directed to the OSI-211 and OSI-7904 compounds have issued in the United States, Japan, the European Patent Office, and, in the case of OSI-211, certain other countries. Patent protection is being sought for liposomal formulations of OSI-211 and OSI-7904.

We also have non-exclusive licenses from Cadus Pharmaceutical Corporation (to seven U.S. patents, and additional U.S. and foreign applications) and Wyeth (to four U.S. patents, and additional foreign applications) to a portfolio of patents and applications covering yeast cells engineered to express heterologous gene-protein coupled receptors, or GPCR, and G-protein polypeptides, methods of use thereof in screening assays, and DNAs encoding biologically active yeast-mammalian hybrid GPCRs.

Our Competition

The pharmaceutical and biotechnology industries are 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 industry participants which are pursuing the same or similar technologies as those that comprise our technology platform and are pursuing pharmaceutical products or therapies that are competitive with our potential products. Most of the major pharmaceutical organizations competing with us have greater capital resources, larger overall research and development staffs and facilities and greater experience in drug development, obtaining regulatory approval and pharmaceutical product manufacturing and marketing. Our major competitors include fully-integrated pharmaceutical companies that conduct extensive drug discovery efforts and are developing novel small molecule pharmaceuticals, as well as numerous smaller companies.

With respect to our small molecule drug discovery programs, other companies have potential drugs in clinical trials to treat disease 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 in our small molecule programs and may result in effective, commercially successful products. In the cancer field, our lead drug candidate, Tarceva™, is currently in Phase III trials. At least three competitors, AstraZeneca PLC, ImClone Systems Incorporated/Bristol Myers Squibb, and Abgenix, Inc./Amgen, Inc., also have substantial clinical development programs for this target. AstraZeneca has recently received approval for Iressa, its anti-EGFR drug, in Japan and has an NDA before the FDA.

We also face competition with respect to our next-generation cytotoxic drug candidates. The most advanced of these products, OSI-211, a topoisomerase-1 inhibitor, is currently in Phase II trials for refractory ovarian and small cell lung cancer. Hycamtin® is already marketed for this target by GlaxoSmithKline. The two other products, OSI-7836 and OSI-7904L, are both in Phase I trials. OSI-7836 is a nucleoside analog; Eli Lilly currently markets Gemzar® for this target. OSI-7904L is a thymidylate synthase inhibitor; this target faces generic competition, as well as competition from Xeloda® which is marketed by Roche.

Companies with related research and development activities also present significant competition for us. For example, 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 or through combinatorial chemistry skills or other means.

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.

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, labeling, marketing, export, storage, record keeping, advertising and promotion of pharmaceutical and diagnostic products.

The FDA Process

The process required by the FDA before pharmaceutical products 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;
- 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 investigational new drug application to support human clinical trials and are reviewed by the FDA, with patient safety as the primary objective, prior to the 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 investigational new drug application. 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. 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. 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 Europe 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 the NDA will be based, among other factors, on our 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.

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

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

For marketing of a drug outside the United States, we and our collaborators, and the drugs developed by us, if any, will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for drugs. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. 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.

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. Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated.

Our Employees

In October 2002, reflecting the refocusing of our business on oncology and away from the screening services that we had historically provided to our former collaborative partners, we reduced our headcount by 42 employees, most of whom had been involved in early research activities. Following this reduction, as of October 31, 2002, we employed 429 persons worldwide (277 in the United States), of whom 173 were primarily involved in research activities and 140 in development activities, with the remainder engaged in executive and administrative capacities. Although we believe that we are now more appropriately sized to focus on our mission in oncology, we intend to add personnel with specialized oncology 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. Further, we believe that our success is largely dependent upon our ability to attract and retain such qualified personnel.

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. 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.

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

Successful research and development of pharmaceutical products is high risk. Most projects 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 none of our potential oncology products, including Tarceva™, may ever reach the market for a number of reasons. They may be found ineffective or 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 oncology product candidates in early stages of development and we do not expect them to be commercially available for several years, if at all. All but six of our product candidates are in the pre-clinical development phase. The six 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 we have a setback in our Tarceva™ program, our stock price would almost certainly decline.

We are currently conducting four Phase III clinical trials for Tarceva™. If we do not receive any positive results from these trials, we would need to conduct additional clinical trials or abandon our Tarceva™ program. Since Tarceva™ is our most advanced product candidate, a setback of this nature would almost certainly cause a decline in our stock price. Recently, AstraZeneca announced unfavorable results from its clinical trials which were testing its drug candidate, Iressa, which is in the same class of targeted therapies as Tarceva™, in combination with traditional chemotherapy agents for the front line treatment of non small cell lung cancer. While there are important differences between Iressa and Tarceva™ and AstraZeneca's clinical program and our clinical program, including structure, formulation, pharmacokinetics and Phase III trial design and dosing, two of our four Phase III trials are designed to test Tarceva™ in combination with chemotherapy agents for NSCLC in studies similar to those of AstraZeneca. A positive outcome from these two trials must now be considered higher risk.

Set-backs on the part of our competitors who are developing drugs in the HER1/EGFR field which are similar to Tarceva™ could result in decreases in our stock price.

Our major competitors who are developing drugs in the HER1/EGFR field which are similar to our most advanced clinical candidate, Tarceva™, have suffered setbacks with respect to their drug candidates during the last 12 months which have impacted our stock price by raising concerns regarding the HER1/EGFR class of targeted therapies. Both AstraZeneca and ImClone, who are each developing drug candidates in the same

class of HER1/EGFR targeted therapies as Tarceva™, suffered setbacks in their programs during the last year. These setbacks have resulted in casting doubt amongst some investors on all drug candidates targeting the HER1/EGFR gene, including Tarceva™, which has led to declining stock prices for us and others developing drugs in this class. Additional set-backs on the part of our competitors could result in a further decrease in our stock price.

If we are unable to demonstrate acceptable safety and efficacy of Tarceva™ during clinical trials, we will not be able to obtain regulatory approval and thus will not be able to commercialize and generate revenues from Tarceva™.

We must continue to demonstrate, through pre-clinical testing and clinical trials, that Tarceva™ is safe and effective. The results from pre-clinical testing and early clinical trials may not be predictive of results obtained in subsequent clinical trials, and we cannot be sure that our clinical trials will demonstrate the safety and efficacy necessary to obtain regulatory approval for Tarceva™. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. In addition, certain clinical trials are conducted with patients having the most advanced stages of disease. During the course of treatment, these patients often die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested. These events can complicate our statistical analysis of clinical trial results and may lead to misinterpretation of clinical trial results.

Any significant delays in, or termination of, clinical trials for Tarceva™ may hinder our ability to obtain regulatory approval of Tarceva™. Any delays in obtaining or failure to obtain regulatory approval will hinder or prevent us from commercializing and generating revenues from Tarceva™.

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

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™ which would require a greater expenditure of financial resources and may cause a delay in launch and market penetration while we build our own commercial operation or seek alternative partners. Although we manage the manufacturing of Tarceva™ for the U.S. market through third party providers, there may be a delay in our ability to scale up if we were requested to replace Roche's manufacturing role in markets outside of the United States.

If our competitors who are developing drugs in the HER1/EGFR field receive FDA approval for their drug candidates and commence marketing such products significantly in advance of our launch of Tarceva™, then our ability to compete for sales in this market may be a greater challenge.

If our competitors, some of whom have greater resources than we do, receive FDA approval for their drugs and begin marketing those products significantly in advance of our launch of Tarceva™, it may be more difficult for us to penetrate the market and our sales may be less than projected. This could negatively impact our potential future profitability and the scope of our operations including research and development of our other oncology drug candidates.

If our competitors succeed in developing products and technologies that are more effective than our own, our products and technologies may be rendered less competitive.

We face significant competition from industry participants that are pursuing similar products and technologies as we are and are developing pharmaceutical products that are competitive with our potential products. Where we are developing products independently, some of the organizations competing with us have greater capital resources, larger overall research and development staffs and facilities, and more extensive experience in drug discovery and development, obtaining regulatory approval and pharmaceutical product

manufacturing and marketing. 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 may result in our compounds, products or processes becoming obsolete before we recover any of the expenses incurred to develop them.

In particular, we face significant competition from other biotechnology and pharmaceutical companies which are currently developing drugs similar to Tarceva™ that could dilute our potential for sales from Tarceva™. We are aware of at least three companies, some of which have resources substantially greater than we do, which currently have drugs similar to Tarceva™ in substantial clinical development programs. In addition to AstraZeneca's Iressa, ImClone/Bristol Myers Squibb and Abgenix/Amgen are developing a different kind of product, humanized antibodies, against the HER1/EGFR target. The ImClone product is currently in Phase III trials, and the Abgenix product is in Phase II trials. If our competitors succeed in developing drugs similar to Tarceva™ that are more effective than our own, our product may not gain widespread market acceptance.

If we are unable to establish a commercial infrastructure for the marketing of our potential oncology products other than Tarceva™, we will need to enter into and maintain arrangements with third parties for commercialization of such products which could substantially diminish our share of the revenues from the sales of such products.

In order to successfully commercialize our other product candidates, we must be able to:

- manufacture our products in commercial quantities at reasonable costs;
- obtain reimbursement coverage for our products;
- compete favorably against other products; and
- market our products successfully.

We may not be successful in establishing a commercial infrastructure to enable us to accomplish the above with respect to our products other than Tarceva™. If we are unsuccessful or delayed in establishing this infrastructure, we would need to enter into and successfully maintain additional co-development and commercialization agreements. This would result in our receipt of a decreased share of the revenues generated from the sale of such products.

If our collaborative partners or other third party contractors give other products greater priority than our products, our products may be subject to delays in research and development, manufacture and commercialization that may impede our ability to take them to market before our competitors. This may render our products obsolete or may result in lower than anticipated revenues for us.

We rely on some of our collaborative partners and certain third party contractors to assist with research and development as well as the manufacture of our potential products in their FDA-approved manufacturing facilities. Some of our collaborative agreements allow these parties significant discretion in electing whether or not to pursue the activities that they have agreed to pursue for us. We cannot control the amount and timing of resources these parties devote to our programs or potential products. Our potential products may be in competition with other products for priority of access to these parties' research and development and manufacturing facilities. If these parties do not give significant priority to the research and development or manufacture of our potential products in an effective or timely manner, the clinical development of our product candidates or their submission for regulatory approval could be delayed, and our ability to deliver products to the market on a timely basis could be impaired. Furthermore, we may not be able to enter into any necessary third-party research and development or manufacturing arrangements on acceptable terms, if at all.

If government agencies do not grant us or our collaborative partners required approvals for any of our potential products, we or our collaborative partners will not be able to manufacture and sell our products.

All of our newly discovered potential products must undergo an extensive regulatory approval process in the United States and other countries. This regulatory process, which includes pre-clinical testing and clinical trials of each compound to establish its safety and efficacy, can take many years and requires the expenditure of substantial resources. Moreover, data obtained from pre-clinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. The FDA and other regulatory agencies may delay or deny the approval of our proposed products. None of our products has yet received governmental approval, and none may ever do so. If we do not receive the required regulatory approvals, we or our collaborative partners will not be able to manufacture and sell our products.

Even if we obtain regulatory approval, a marketed product and its manufacturer are subject to continuing review, including post-marketing surveillance. We may be required to withdraw our product from the market if previously unknown problems are discovered. Violations of regulatory requirements at any stage may result in various unfavorable consequences to us, including the FDA's imposition of criminal penalties against the manufacturer and the holder of the NDA.

Our reliance on third parties such as clinical distributors, manufacturers and 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.

From time to time in the course of product development, we may engage clinical distributors, manufacturers and/or CROs to manufacture and distribute the product candidate and to conduct and manage clinical studies and to assist us in guiding products through the FDA review and approval process. Because we have engaged and intend to engage clinical distributors, manufacturers and 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 clinical distributors, manufacturers and CROs fail to perform their obligations under our agreements with them or fail to manufacture and distribute the product candidate and to perform clinical trials in a satisfactory manner, we may face delays in completing our clinical trials, as well as commercialization of any drug candidate. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our clinical trials and the market approval of drug candidates.

We 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. At September 30, 2002, our accumulated deficit was approximately \$324.2 million. Our losses have resulted principally from costs incurred in research and development, acquired in-process research and development and from general and administrative costs associated with our operations. These costs have exceeded our revenues, and we expect them to continue to do so until we generate significant sales from marketed products.

We expect to continue to incur operating losses over the next few years as a result of our expenses for the development of Tarceva™ and our other clinical products and our research programs. These expenses include enhancements in our drug discovery technologies and increases in the resources we will devote to our internally funded proprietary projects. We do not expect to generate revenues from the sale of our potential products for a number of years, and we expect to continue to incur operating losses during this period.

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

As of September 30, 2002, we held 26 U.S. patents, 93 foreign patents, 32 pending applications for U.S. patents, two of which have been allowed, and 165 applications for foreign patents, two of which have been allowed. Moreover, we jointly hold with Pfizer rights to numerous issued U.S. and foreign patents and pending U.S. and foreign patent applications. We also jointly hold, with North Carolina State University, two issued

U.S. patents and certain U.S. and foreign pending patent applications. We intend to continue to aggressively seek patent protection for all of the product candidates that we have discovered, developed or acquired.

Our success depends, in part, on our ability and our collaborative partners' ability to obtain 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 sizable 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 the 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 issues, and publications in the scientific or patent literature lag behind actual discoveries.

The degree of future protection for our proprietary rights will remain uncertain if our pending patent applications are not approved for any reason or if we are unable to develop additional proprietary technologies that are patentable. 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 which 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 Patent and Trademark Office, 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 which may not be available to us on acceptable terms, if at all. Any litigation, regardless of the outcome, could be extremely costly to us.

If other biotechnology and pharmaceutical companies are not willing to pay appropriate royalties for the use of our patented "gene transcription estate," we may need to expend substantial amounts of funds and resources if we choose to enforce the patents.

We license to other companies rights to use our patented "gene transcription estate" which consists of drug discovery assays that provide a way to identify novel product candidates that can control the activity of genes. We believe technology and practices covered by these patents are in widespread use in the pharmaceutical and biotechnology industries. To date, we have granted seven licenses to use our gene transcription patents. If other pharmaceutical and biotechnology companies which we believe are using our patented technology are not willing to negotiate license arrangements with us on reasonable terms, we may have to choose between abandoning our licensing strategy or initiating legal proceedings against those companies. Legal action, particularly patent infringement litigation, is extremely costly.

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, is currently unknown. If

we or our collaborative partners must obtain licenses from third parties, fees must be paid for such licenses. These fees would reduce the revenues and royalties we may receive on commercialized products.

The use of any of our potential products in clinical trials and the sale of any approved products may expose us to liability claims resulting from the use of products or product candidates.

The nature of our business exposes us to potential liability risks inherent in the testing, manufacturing and marketing of drug discovery candidates and products. Using our drug candidates in clinical trials may expose us to product liability claims. These risks will expand with respect to drugs, if any, that receive regulatory approval for commercial sale. While we currently maintain product liability insurance that we believe is adequate, such insurance may not be available at reasonable rates, if at all, in the future. If we do not or cannot maintain adequate insurance coverage, we may incur significant liability if a product liability claim arises.

If we cannot obtain adequate funding for our research and development efforts or our projected future sales are delayed or diminished, we may have to limit the scope of our proprietary product development in future years or enter into more restrictive arrangements with collaborative partners.

Our future capital requirements will depend on many factors, including the size and complexity of our research and development programs, the progress of pre-clinical testing and early stage clinical trials, the time and costs involved in obtaining regulatory approvals for our product candidates, the costs of manufacturing arrangements and the costs of commercialization activities.

Although we believe our current cash reserves are sufficient for our near-term operating needs, we may choose to raise additional funds through public or private sales of our securities, including equity securities, as well as from collaborative partners in order to further our growth. We may not be able to obtain adequate funding from equity financings on reasonable or acceptable terms, if at all. Furthermore, any additional equity financings may dilute the value of the common stock held by our stockholders. If adequate funds are not available, we may be required to significantly curtail one or more of our research and development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish certain of our rights to a number of our technologies or product candidates.

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 market price of the common stock of biotechnology and pharmaceutical companies and our common stock has been volatile and may remain volatile for the foreseeable future. If our stock price falls, our stockholders may not be able to sell their stock when desired or at desirable prices.

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;
- negative clinical or safety results from our competitors' products;
- changes in government regulation including pricing controls;
- delays with the FDA in the approval process for Tarceva™ and other 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.

Our outstanding indebtedness has increased substantially with the issuance of Convertible Senior Subordinated Notes in February 2002, and we may not be able to pay these notes and our other obligations.

As a result of the sale of the Convertible Senior Subordinated Notes in February 2002 and the subsequent repurchase of a portion of these notes in August and September 2002, our long-term debt relating to these notes was \$160 million as of September 30, 2002. This 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;
- significantly increase our interest expense and related debt service costs; and
- make us more vulnerable in the event of a downturn in our business.

Currently, we do not have any product sales and we are not generating sufficient cash flow to satisfy the annual debt service payments that will be required as a result of the consummation of the sale of the notes. This may require us to use a portion of the proceeds from the sale of the notes to pay interest or borrow additional funds or sell additional equity to meet our debt service obligations after the first three years when the payment of interest on the notes is no longer secured. If we are unable to satisfy our debt service requirements, or do not have the funds to repay the notes upon maturity in 2009, we will default on the notes and liquidity problems could result.

Our corporate governance documents and state law provide certain anti-takeover measures which will discourage certain types of transactions involving an actual or potential change in control of our company.

Under our certificate of incorporation, 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. Since January 1999, we have had a shareholders rights plan, which was subsequently replaced with a new plan, commonly referred to as a "poison pill." 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 an interested stockholder.

ITEM 2. PROPERTIES

We currently lease three facilities in New York, one located at 58 South Service Road, Melville, New York, consisting of approximately 37,000 square feet, one located at 106 Charles Lindbergh Boulevard, Uniondale, New York, consisting of 30,000 square feet, and one located at 1 Bioscience Park Drive, Farmingdale, New York, consisting of approximately 53,000 square feet. The Melville facility houses our principal executive, finance, legal and administrative offices. The Uniondale and Farmingdale facilities house our drug discovery and pre-clinical laboratories.

In August 2002, we entered into a Termination and Surrender Agreement with our landlord at our Tarrytown, New York facility whereby we were released from our obligations under the lease. Our Tarrytown research operations were consolidated primarily into our Farmingdale facility.

In December 2001, in connection with our acquisition of Gilead's pipeline of clinical candidates in oncology, we acquired the leases to three facilities, one located at 2860 Wilderness Place, Boulder, Colorado, consisting of 60,000 square feet, one located at 2900 Center Green Court South, Boulder, Colorado, consisting of approximately 10,000 square feet, and one located at 2970 Wilderness Place, Boulder, Colorado, consisting of approximately 26,000 square feet. The Boulder facilities house our clinical research, regulatory affairs and drug development personnel.

Our subsidiary, OSI Pharmaceuticals (UK) Limited, leases three facilities, one located at 10 Holt Court South, Aston Science Park, Birmingham, England, consisting of approximately 26,000 square feet, 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. We ceased operations at our Aston Science Park, Birmingham, England facility in March 2002 and have consolidated the Birmingham operations into the Oxford facilities. Our leases at the Birmingham facility expire at dates through January 2006. The Oxford facilities house our research and development laboratories and administrative offices.

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 2002.

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, 2000 through September 30, 2002 as reported on the NASDAQ National Market:

	<u>2002 FISCAL YEAR</u>	<u>HIGH</u>	<u>LOW</u>
First Quarter		\$50.94	\$31.91
Second Quarter		49.05	35.11
Third Quarter		39.45	20.52
Fourth Quarter		33.81	11.50
	<u>2001 FISCAL YEAR</u>	<u>HIGH</u>	<u>LOW</u>
First Quarter		\$86.38	\$54.00
Second Quarter		79.19	30.19
Third Quarter		57.46	32.38
Fourth Quarter		55.17	31.60

Holder and Dividends

As of November 29, 2002, there were approximately 436 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, 2002

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted-average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans</u>
Equity compensation plans approved by security holders(a)	3,728,460	\$21.89	4,226,127(d)
Equity compensation plans not approved by security holders(b)	<u>881,844(c)</u>	<u>\$43.42</u>	<u>—</u>
Total	<u>4,610,304</u>	<u>\$26.00</u>	<u>4,226,127</u>

(a) Consists of six plans: 1985 Stock Option Plan, 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 2001 Incentive and Non-Qualified Stock Option 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 Pharmaceutical 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, options granted to employees of our subsidiary OSI-UK and options granted to outside directors.
- (d) Includes 675,624 shares reserved for issuance under the 1993 Employee Stock Purchase Plan, 1995 Employee Stock Purchase Plan and a stock purchase plan for employees of OSI-UK. (See note 10(d) to the accompanying consolidated financial statements.)

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

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

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, 2002. 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)				
	2002(a)	2001(b)	2000(c)	1999(d)	1998(e)
Consolidated Statement of Operations Data:					
Revenues	\$21,816	\$26,022	\$28,652	\$22,652	\$19,468
Expenses:					
Research and development	102,202	56,038	39,622	24,996	20,303
Acquired in-process research and development	130,200	—	—	—	—
Selling, general and administrative	28,069	15,771	10,938	8,679	8,265
Amortization of intangibles	1,255	742	870	1,469	1,461
Production and service costs	77	262	835	1,753	813
Loss from operations	<u>\$(239,987)</u>	<u>\$(46,791)</u>	<u>\$(23,613)</u>	<u>\$(14,245)</u>	<u>\$(11,374)</u>
Other income — net	7,904	25,661	3,519	1,156	1,190
Gain on sale of Anaderm common stock	—	—	—	3,291	—
Gain on sale of diagnostic business	1,000	—	3,746	—	—
Gain on early retirement of convertible senior subordinated notes — net business	12,604	—	—	—	—
Loss before cumulative effect of accounting change ...	<u>\$(218,479)</u>	<u>\$(21,130)</u>	<u>\$(16,348)</u>	<u>\$(9,798)</u>	<u>\$(10,184)</u>
Cumulative effect of the change in accounting for the recognition of upfront fees	—	\$ (2,625)	—	—	—
Net loss	<u>\$(218,479)</u>	<u>\$(23,755)</u>	<u>\$(16,348)</u>	<u>\$(9,798)</u>	<u>\$(10,184)</u>
Basic and diluted net loss per common share:					
Loss before cumulative effect of change in accounting policy	\$(6.07)	\$(0.62)	\$(0.67)	\$(0.46)	\$(0.48)
Cumulative effect of change in accounting policy ...	—	\$(0.08)	—	—	—
Net loss	<u>\$(6.07)</u>	<u>\$(0.70)</u>	<u>\$(0.67)</u>	<u>\$(0.46)</u>	<u>\$(0.48)</u>
Weighted average number of shares of common stock outstanding	35,978	33,852	24,531	21,451	21,373
	AS OF SEPTEMBER 30,				
	2002(a)	2001(b)	2000(c)	1999(d)	1998(e)
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investment securities (unrestricted and restricted)	\$476,277	\$551,479	\$85,065	\$18,862	\$24,418
Receivables	6,981	6,633	1,049	5,194	2,411
Working capital	444,556	533,435	80,104	14,562	22,268
Total assets	579,044	591,689	99,776	47,031	50,418
Long-term liabilities	168,734	14,061	2,719	3,085	2,001
Stockholders' equity	379,108	549,831	89,882	33,365	43,059

- (a) 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 issuance of \$200.0 million of convertible senior subordinated notes for net proceeds of approximately \$193.0 million; 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, 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(a), 5(b) and 9 to the accompanying consolidated financial statements.)

- (b) 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 Tarrytown, New York and Birmingham, England facilities. (See notes 1(b), 3(b), 5(a), 10(f), 10(g), 16(a) and 16(b) to the accompanying consolidated financial statements.)
- (c) The fiscal 2000 consolidated financial statements include a charge to operations of \$700,000 representing the cost of a license to use and practice certain of Cadus Pharmaceutical Corporation's technology and patents; 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; and a \$3.7 million gain resulting from the sale of our diagnostics business, including the assets of our wholly-owned subsidiary, OSDI, Inc., to The Bayer Corporation. (See notes 5(c), 10(a), 10(e), and 17 to the accompanying consolidated financial statements.)
- (d) The fiscal 1999 consolidated financial statements include the acquisition of Cadus Pharmaceutical Corporation's research business for \$2.2 million in cash, including a \$806,000 charge to operations for in-process R&D acquired; a gain of \$3.3 million on the sale of our Anaderm stock to Pfizer Inc.; and a \$535,000 charge to operations for the estimated costs of closing our facilities in North Carolina. (See note 16(c) to the accompanying consolidated financial statements.)
- (e) The fiscal 1998 consolidated financial statements include approximately \$702,000 of license revenue received upon execution of a license agreement with Aurora Biosciences Corporation.

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

Overview

We are a leading biotechnology company 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. We have established a balanced pipeline of oncology drug candidates that includes both next-generation cytotoxic chemotherapy agents and novel mechanism-based, gene-targeted therapies. We currently have four proprietary candidates in clinical trials and two additional candidates in clinical trials with Pfizer.

Our most advanced drug candidate, Tarceva™ (erlotinib HCl), is a small molecule inhibitor of the epidermal growth factor receptor, or HER1/EGFR. The protein product of the HER1/EGFR gene is a receptor tyrosine kinase that is over-expressed or mutated in many major solid tumors. We believe HER1/EGFR inhibitors represent an exciting new class of relatively safe and well tolerated anti-cancer agents that may have utility in treating a wide range of cancer patients. Tarceva™ is an oral once-a-day small molecule drug designed to specifically block the activity of the HER1/EGFR protein. Currently, Tarceva™ is being developed in an alliance with Genentech, Inc. and Roche. If the drug receives regulatory approval, Genentech will lead the marketing effort in the United States and Roche will market it in the rest of the world. We will receive milestone payments from both Genentech and Roche, an equal profit share from U.S. sales, and royalties on sales outside of the United States. Tarceva™ has demonstrated encouraging indications of anti-cancer activity in single-agent, open label Phase II trials in non-small cell lung cancer, head and neck cancer and ovarian cancer. Tarceva™ is currently in Phase III clinical trials for non-small cell lung cancer and pancreatic cancer.

Behind Tarceva™ we have five additional drug candidates in earlier stages of clinical development. Three of these (OSI-211, OSI-7904L and OSI-7836) are next generation cytotoxic chemotherapy agents and the other two (CP-547,632 and CP-724,714) are gene-targeted therapies currently being developed by Pfizer Inc. We own commercial rights to the first three and will receive royalty payments on the latter two if they are successfully commercialized.

Our next generation cytotoxic chemotherapy candidates are designed to improve upon currently marketed products in the same drug class. OSI-211 is a liposomal formulation of lurtotecan, a topoisomerase-1 inhibitor, that is being developed to compete with topotecan (Hycamptin®). OSI-7904L is a liposomal formulation of a thymidylate synthase inhibitor, GW1843, that is being developed as a potential competitor to 5-Fluorouracil (5-FU) and capecitabine (Xeloda®), and OSI-7836 is a nucleoside analog being developed to compete with gemcitabine (Gemzar®). OSI-211 is in Phase II clinical trials, and OSI-7904L and OSI-7836 are in Phase I clinical trials. Like Tarceva™, the two gene-targeted therapies are receptor tyrosine kinase inhibitors. CP-547,632 is a small molecule targeting the vascular endothelial growth factor receptor, or VEGFR, and CP-724,714 is a small molecule targeting HER2/erbB2. Both agents are currently in Phase I clinical trials.

In order to support our clinical pipeline, we have established (through acquisition and internal investment) a high quality oncology clinical development and regulatory affairs capability and a pilot scale chemical manufacturing and process chemistry group. Behind our clinical pipeline we have an extensive, fully integrated small molecule drug discovery organization designed to generate a pipeline of high quality oncology drug candidates to move into clinical development. This research operation has been built upon our historical strengths in high throughput screening, chemical libraries, medicinal and combinatorial chemistry, and automated drug profiling technology platforms.

Key Business Transactions During Fiscal 2002

We believe that Tarceva™ has established a corporate presence for us in the oncology field. Our strategy over the last several years has been designed to capitalize upon this presence and to re-orient our business toward becoming a world class oncology organization. To this end, we have raised capital, formed alliances and engaged in merger and acquisition activity as set forth below.

On December 21, 2001, we acquired certain oncology assets from Gilead Sciences, Inc., which included a pipeline of three clinical oncology candidates and certain related intellectual property, as well as Gilead's Boulder, Colorado operations, including clinical research and drug development personnel, infrastructure and facilities. The Gilead employees retained by us provide us with extensive expertise in clinical development, regulatory affairs, toxicology and *in vivo* pharmacology. The acquisition forms a key part of our strategy to build a completely integrated and high quality drug discovery, development and commercial organization in oncology. The acquisition has complemented and enhanced our ability to successfully execute key components of our business strategy, including carrying out our obligations for the development and registration of Tarceva™ in our alliance with Genentech and Roche. In consideration for these assets, we paid Gilead \$130 million in cash and issued to Gilead 924,984 shares of common stock valued at \$40 million. We will also be obligated to pay up to an additional \$30 million in either cash, stock or a combination of cash and common stock upon the achievement of certain milestones related to the development of OSI-211 (formerly NX211). We also assumed certain royalty and milestone obligations to third parties in connection with these oncology products.

At the conclusion of fiscal 2001, we completed a transaction with British Biotech plc whereby we assumed the leases for two state-of-the-art research and development facilities in Oxford, England and acquired 58 employees, of whom 42 were engaged in research and development activities with the remainder in administrative positions. During fiscal 2002, we ceased operations at our Birmingham, England facility and relocated those operations and certain personnel to our new Oxford facility and integrated the assets acquired from British Biotech into our existing operations.

On February 1, 2002, we issued \$200.0 million aggregate principal amount of convertible senior subordinated notes in a private placement for net proceeds to us of approximately \$193.0 million. The notes are convertible into shares of our common stock at a conversion price of \$50 per share and mature on February 1, 2009. We are planning to use the proceeds from the sale of the notes for continued development of our product pipeline, licensing and acquisition opportunities that add oncology products and drug candidates, and general corporate purposes. In August and September 2002, taking advantage of a market opportunity, we retired a total of \$40.0 million in principal amount of the notes for an aggregate purchase price of \$26.2 million, including accrued interest of \$133,000.

With oncology as our focus, we have made the strategic decision to divest all non-oncology research programs by the end of our second quarter in fiscal 2003, and realign our internal resources toward an oncology strategy. In July 2002, we agreed to accelerate the conclusion of the phase-down period of our funded research alliance with Anaderm Research Corporation, a wholly-owned subsidiary of Pfizer focused on the development of novel treatments for skin and hair conditions. As of September 30, 2002, we received \$4.5 million of a total \$8.0 million phase-down fee for transferring to Anaderm all of our research related to this collaboration. We will also receive royalties on the sale of products for these treatments which may arise from compounds that we have identified. We expect the transfer to be completed by January 2003. We also plan to divest our diabetes program and certain of our adenosine receptor assets into a newly formed and externally funded entity in which we will maintain a minority interest. Our diabetes program includes a partnership with the Vanderbilt University Diabetes Center, a funded alliance with Tanabe Seiyaku Co. Ltd., and six proprietary gene-targeted discovery programs in the lead seeking and lead optimization phases, primarily focused in the glucose regulation and obesity fields. We also intend to transfer to this entity our existing diabetes teams comprised of approximately 24 employees. If we are unable to obtain external funding for this newly formed entity, we will consider other alternatives to discontinue the diabetes program, including the out-licensing of diabetes assets and employee headcount reductions.

Historically, our research organization had been established to provide early stage discovery research services to our pharmaceutical industry partners who funded these activities. Since some of our employee skill sets were from this multi-disease drug discovery service focus of our past collaborations and not ideally suited to an oncology-only strategy, in October 2002, we made the decision to reduce our employee headcount by approximately 9% as we strive to better balance our staff and skill sets to focus on oncology while maintaining strict fiscal control of the business. This action left us with 429 employees and will now allow us to hire additional oncology expertise, as needed.

To date, none of our proprietary or collaborative programs have resulted in commercial products; therefore, we have not received any revenues or royalties from the sale of products by us or by our collaborators. Since our inception, we have funded our operations primarily through public and private placements of common stock, the private placement of convertible debt securities and payments under collaborative research agreements with major pharmaceutical companies.

Critical Accounting Policies

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States. 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 revenue and expenses during the periods presented. Actual results could differ significantly from those estimates 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

We recognize all nonrefundable upfront license fees, including upfront technology access fees, as revenue over the term of the related research collaboration period 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, or SAB No. 101. Our most significant application of this policy, to date, is the \$25 million in upfront fees received from Genentech and Roche in January 2001 which was originally being recognized evenly over the expected three-year term of our required research and development efforts under the terms of the agreement. The expected term is subject to change based upon the parties' continuous monitoring of current research data and their projections for the remaining development period. A change in this expected term impacts the period over which the remaining deferred revenue would be recognized. In the fourth quarter of fiscal 2002, the expected term was changed 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. As a result of this revision, we recorded revenues of \$1.3 million in the fourth quarter compared to \$2.1 million had the upfront fees continued to be recognized over a three-year period. 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. Other revenues are recognized pursuant to the terms of grants which provide reimbursement of certain expenses related to our other research and development activities. Collaborative and other revenues are accrued for expenses incurred in advance of the reimbursement and deferred for cash payments received in advance of expenditures. Such deferred revenues are recorded as revenue when earned.

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. Actual results could differ significantly from those estimates under different assumptions.

Intangible and Long-Lived Assets

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

Comparison of Fiscal 2002 and Fiscal 2001

Results of Operations

Our fiscal 2002 net loss of \$218.5 million increased \$194.7 million compared to our fiscal 2001 net loss of \$23.8 million. The increase in the net loss was primarily related to the one-time in-process research and development, or in-process R&D, charge of \$130.2 million in connection with the acquisition of Gilead's oncology assets. Excluding the non-recurring charge of \$130.2 million related to the in-process R&D acquired, the net loss for fiscal 2002 would have been \$88.3 million or \$2.45 per share, an increase of \$64.5 million compared to fiscal 2001. This increase in the net loss is primarily due to an increase in development costs associated with Tarceva™ and the three clinical candidates acquired from Gilead. Included in the net loss for fiscal 2001 was a non-cash charge of \$2.6 million related to the cumulative effect of a change in accounting principle for the recognition of upfront fees upon the adoption of SAB No. 101 (see note 1(b)) to the accompanying consolidated financial statements). Excluding the effect of this change in accounting principle, the net loss for fiscal 2001 would have been \$21.1 million or \$0.62 per share.

Revenues

Total revenues of \$21.8 million in fiscal 2002 decreased \$4.2 million or 16% compared to fiscal 2001. Total collaborative program revenues of \$12.0 million in fiscal 2002 decreased \$6.0 million or 33% compared to fiscal 2001. These decreases were primarily due to the phase-down of our collaboration with Anaderm commencing in April 2002 and the conclusions of our funded collaborations with Pfizer in April 2001, Sankyo Co., Ltd. in December 2001 and Solvay Pharmaceuticals, Inc. in December 2000. In July 2002, we entered into an agreement with Pfizer to accelerate the phase-down period of the collaboration with Anaderm so that it will terminate no later than April 23, 2003. In consideration for the work to be performed by us during the accelerated phase-down period, we received \$4.5 million in September 2002 and will receive \$3.5 million upon the successful completion of the transition period. The \$4.5 million will be recognized as revenue ratably over the expected term of the transition period and the \$3.5 million will be recognized upon the successful completion of the transition. We expect this transition to be completed by January 2003. For fiscal 2002, we recognized \$1.8 million of revenue related to the phase-down. As we continue to focus our business away from collaborative-based to independent drug discovery and development, we expect collaborative revenue to continue to decrease.

License and related revenues of \$8.7 million in fiscal 2002 increased \$1.3 million or 17% compared to fiscal 2001. This increase was due primarily to the recognition of the pro rata portion of the \$25 million upfront fees received from Genentech and Roche for 12 months in fiscal 2002 compared to only nine months in fiscal 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 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 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 Change," the remaining deferred revenue will be recognized prospectively over the revised term. As a result, we recorded revenues of \$1.3 million in the fourth

quarter of fiscal 2002 compared to \$2.1 million had we continued to recognize the upfront fees over a three-year period.

Other revenues of \$1.2 million in fiscal 2002 were primarily related to transition assistance services provided to Gilead and certain administrative services provided to British Biotech during the transition periods under our respective agreements with each of them.

Expenses

Operating expenses of \$261.8 million increased \$189.0 million or 260% in fiscal 2002 compared to fiscal 2001. Operating expenses primarily included (i) research and development, or R&D, expenses, which include expenses related to the development of our lead clinical candidate, Tarceva™, and proprietary and collaborative-based research; (ii) the \$130.2 million charge related to the acquired in-process R&D related to the oncology assets acquired from Gilead; (iii) selling, general and administrative expenses; and (iv) amortization of intangibles. We intend to hold our core operating costs, including expenses related to Tarceva™ development, to approximately \$140-145 million over the next year.

Research and development expenses increased \$46.2 million or 82% in fiscal 2002 compared to fiscal 2001. The increase was related primarily to increased costs associated with (i) the clinical development of Tarceva™ under our Tripartite Agreement with Genentech and Roche, (ii) increased investments in our proprietary cancer programs, including oncology candidates acquired from Gilead in December 2001; and (iii) increased investments in our core proprietary research programs and facilities. These increases were slightly offset by a decrease in collaborative-based research expenses, a reduction in certain stock option based compensation charges in comparison to the prior year, and a restructuring charge included in fiscal 2001 of approximately \$4.4 million. This restructuring charge related to the closing of our Tarrytown, New York and Birmingham, England facilities, as further discussed below.

On August 17, 2000, the Board of Directors granted non-qualified stock options to purchase up to 250,000 common shares to our then new President and Head of Research and Development. The terms of this grant provided for an option to purchase 100,000 shares of common stock with an exercise price equal to 50% of the fair market value on the grant date vesting immediately upon his employment date on September 28, 2000 (i.e., the measurement date), and an option to purchase 150,000 shares of common stock with an exercise price equal to the fair market value on the grant date vesting one-third in a year from the measurement date and monthly thereafter for twenty-four months. The granting of the options at 50% of fair market value resulted in a compensation charge of \$5.0 million in fiscal 2000. The granting of the other options resulted in deferred compensation of \$4.4 million as of September 30, 2000, which was to be recognized as compensation expense over the vesting period. A significant portion of this compensation expense was due to the high volatility of our common stock price between the grant date and the measurement date. In fiscal 2002, \$485,000 of compensation expense was included in R&D expenses compared to \$1.5 million in fiscal 2001. As a result of his resignation as an employee effective February 1, 2002, no additional compensation expense has been recorded subsequent to February 1, 2002 and the remaining deferred compensation of \$2.4 million was reversed. In addition, other stock options granted to non-employees in connection with their consulting arrangements resulted in the recognition of \$503,000 and \$1.5 million in fiscal 2002 and fiscal 2001, respectively, and deferred compensation of \$49,000 and \$1.0 million as of September 30, 2002 and 2001, respectively. In accordance with EITF Issue 96-18, "Accounting for Equity Instruments that Are Issued to Other Than Employees for Acquiring, or In Conjunction with Selling, Goods or Services," the amount of compensation expense to be recorded in future periods related to the non-employee grants is subject to change each reporting period based upon the then fair value of these options, using a Black-Scholes option pricing model, until expiration of the vesting period.

In connection with the acquisition of certain assets from Gilead in fiscal 2002, we recorded an in-process R&D charge of \$130.2 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(a) to the accompanying consolidated financial statements). We obtained a third party valuation to assist us in determining the fair value of certain assets. The value was determined by estimating the costs to develop the

purchased in-process technology into commercially viable products, estimating the resulting net cash flow from such projects and discounting the net cash flows back to their present value. These cash flows were probability-adjusted to take into account the uncertainty surrounding the successful development and commercialization of the acquired in-process technology. The resulting net cash flows were based on estimated revenue, cost of sales, R&D costs, selling, general and administrative costs, and the net cash flow reflects the assumptions that would be used by market participants. In determining the value of the in-process R&D, the assumed commercialization dates for these products ranged from 2004 to 2008. We believe that the assumptions used in the valuation of purchased in-process technology represented a reasonable estimate of the future benefits attributable to the purchased in-process technology at the time of the acquisition. No assurance can be given that actual results will not deviate from those assumptions in future periods. The cumulative value of the R&D projects we acquired from Gilead was divided between the three principal projects, OSI-211 (Phase II), OSI-7836 (Phase I), and OSI-7904L (Phase I). Value was assigned to each program (\$19.9 million to OSI-211; \$96.9 million to OSI-7836; \$13.4 million to OSI-7904L) based on the assessment of estimated value at the date of acquisition.

As of September 30, 2002, the technological feasibility of these three projects had not yet been reached. For each project, we need to successfully complete a series of clinical trials and to receive FDA or other regulatory approvals prior to commercialization. Our current estimates of the required investments for the overall development and registration for these next generation cytotoxic drugs range from \$80 to \$120 million per drug. There can be no assurances that any of these projects will ever reach feasibility or develop into products that can be marketed profitably, nor can there be assurance we will be able to develop and commercialize these products prior to the development of comparable products by our competitors. If it is determined that it is not cost beneficial to pursue the further development of any of these projects, we may discontinue such further development of certain or all of these projects.

Selling, general and administrative expenses increased \$12.3 million or 78% in fiscal 2002 compared to fiscal 2001. The increase was primarily attributable to the increased expenses for additional management and administrative personnel and consultants, as well as an increase in facility and information technology expenses and other professional fees associated with our expansion, corporate development and governance activities. The increase was also due to increased commercialization and marketing costs relating to Tarceva™ which are shared with Genentech in accordance with the OSI/Genentech Agreement. Consulting expenses include stock options granted to non-R&D consultants in connection with their consulting arrangements which resulted in \$109,000 in compensation expenses in fiscal 2002 compared to \$324,000 in fiscal 2001. We anticipate that general and administrative expenses will remain relatively steady during fiscal 2003 with an increase in commercialization and marketing cost as we expand our commercial operations in preparation for the launch of Tarceva™ and other development programs.

During fiscal 2001, we made the strategic decision to (i) close our Birmingham, England facility and relocate our Birmingham personnel to our new Oxford, England facilities as a result of the acquisition of assets from British Biotech, and (ii) close our Tarrytown, New York facility and relocate the Tarrytown, New York personnel to our new research facility in Farmingdale, New York. The estimated cost of closing these facilities of \$5.1 million was accrued as of September 30, 2001, of which \$4.4 million was included in R&D expenses and \$613,000 in selling, general and administrative expenses in fiscal 2001. Included in the closing costs were amounts associated with severance for employees who would not be relocated, the lease cost from the anticipated closing date through the lease termination date and the value of related leasehold improvements and other capital items which were not being relocated.

Amortization of intangibles of \$1.3 million were primarily related to the amortization of the capitalized workforce and library license acquired from British Biotech in September 2001.

Other Income and Expense

Net investment income decreased \$11.2 million or 43% in fiscal 2002 compared to fiscal 2001. The decrease was primarily attributable to a decrease in the average rate of return on our investments and to less funds available for investment. Interest expense increased \$5.2 million in fiscal 2002 compared to fiscal 2001,

primarily due to the interest expense incurred on the convertible senior subordinated notes issued in February 2002 (see note 9 to the accompanying consolidated financial statements), a portion of which were retired in August and September 2002. The convertible senior subordinated notes bear interest at 4% per annum, payable semi-annually, and mature on February 1, 2009. For fiscal 2002 and 2001, other expenses-net were approximately \$1.6 million and \$228,000, respectively. Included in fiscal 2002 was the amortization of debt issuance costs of \$642,000 and a charge of \$500,000 related to the writedown of our investment in a privately-owned healthcare information company (see note 4(b) to the accompanying consolidated financial statements). With respect to the early retirement of these notes, 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 9 to the accompanying consolidated financial statements). Also in fiscal 2002, we recognized the \$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 (see note 17 to the accompanying consolidated financial statements).

Comparison of Fiscal 2001 and Fiscal 2000

Results of Operations

Our fiscal 2001 net loss of \$23.8 million increased \$7.4 million or 45% compared to our fiscal 2000 net loss of \$16.3 million. This increase was primarily related to the launch of the development program associated with Tarceva™, an increased focus on our proprietary research and the closing and consolidation of certain facilities. The increase in net loss was partially offset by the recognition of \$6.3 million of the upfront fees from Genentech and Roche (see note 5(a) to the accompanying consolidated financial statements), and higher interest income resulting from increased funds available for investment as more fully discussed in "Other Income and Expense" below. Included in the fiscal 2001 net loss was a non-cash charge of \$2.6 million related to the cumulative effect of a change in accounting principle for the recognition of upfront fees upon the adoption of SAB No. 101 (see note 1(b) to the accompanying consolidated financial statements). Excluding the net effect of this change in accounting principle, the fiscal 2001 net loss would have been \$22.0 million, or \$.65 per share.

Revenues

Total revenues of \$26.0 million in fiscal 2001 decreased \$2.6 million or 9% compared to fiscal 2000 due to the focus of our business away from collaborative-based to independent drug discovery and development. Total collaborative program revenues of \$18.0 million in fiscal 2001 decreased approximately \$5.7 million or 24% compared to fiscal 2000. This decrease was primarily due to the conclusion of our funded collaborations with Aventis in September 2000, Solvay in December 2000, and Pfizer in April 2001. These decreases were partially offset by increased revenues from the Tanabe collaboration.

License and related revenues of \$7.4 million in fiscal 2001 increased \$3.7 million or 99% compared to fiscal 2000. This increase was due to the recognition of upfront fees received from Genentech and Roche of \$6.3 million (see note 5(a) to the accompanying consolidated financial statements). In accordance with the provisions of SAB No. 101, we were recognizing the \$25 million received from Genentech and Roche evenly over the expected three-year development phase of our agreement. 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 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 development involvement. The fiscal 2001 increase was offset by a one-time technology access fee of \$3.5 million from Tanabe recognized in fiscal 2000. In connection with a change in accounting principle effective October 1, 2000 (see note 1(b) to the accompanying consolidated financial statements) to comply with the provisions of SAB No. 101, we will recognize this previously recognized technology access fee over the expected term of the agreement, resulting in approximately \$875,000 in revenue recognition in fiscal 2001. Assuming the technology access fee received from Tanabe had

been recognized over the term of the agreement in fiscal 2000, total revenues would have been \$26 million in fiscal 2000.

Other revenues of \$613,000 in fiscal 2001 decreased \$656,000 or 52% compared to fiscal 2000. This decrease related to a decrease in sales of products and services derived from pharmaceutical services of OSI Pharmaceuticals (UK) Ltd., our UK subsidiary, as we shifted in focus from external programs to internal programs. This decrease was also due to a decrease in our revenues from research relating to governmental and private research grants.

Expenses

Operating expenses increased \$20.5 million or 39% in fiscal 2001 compared to fiscal 2000. Operating expenses primarily included (i) research and development expenses, which include expenses related to the development of our lead clinical candidate Tarceva™, and proprietary and collaborative-based research expenses; (ii) selling, general and administrative expenses; and (iii) amortization of intangibles.

Research and development expenses increased \$16.4 million or 41% in fiscal 2001 compared to fiscal 2000. The increase was related primarily to increased costs associated with (i) the clinical development of Tarceva™ under our Tripartite Agreement with Genentech and Roche; (ii) increased investments in our proprietary drug discovery programs, including cancer, diabetes, and other new opportunities arising from our existing research and development programs; and (iii) consolidating laboratory facilities. These increases were offset by a shift of collaborative-based research expenses from Aventis, Solvay, and Pfizer to independent based drug discovery efforts and a reduction in certain stock option based compensation charges in comparison to the prior year.

As discussed in the "Comparison of Fiscal 2002 to Fiscal 2001 Expenses" section above, on August 17, 2000, the Board of Directors granted non-qualified stock options to purchase up to 250,000 common shares to our then new President and Head of Research and Development. The granting of these options resulted in a compensation charge of \$5.0 million in fiscal 2000 and deferred compensation of \$4.4 million as of September 30, 2000, which was to be recognized as compensation expense over the vesting period. In fiscal 2001, \$1.5 million of this deferred compensation was recognized as compensation expense. A significant portion of this compensation expense was due to the high volatility of the price of our common stock between the grant date and the measurement date. In addition, in accordance with EITF Issue 96-18, other stock options granted to non-employees in connection with their consulting arrangements resulted in the recognition of \$1.5 million and \$971,000 in fiscal 2001 and fiscal 2000, respectively, and deferred compensation of \$1.0 million and \$4.4 million as of September 30, 2001 and 2000, respectively.

Also included in R&D expenses in fiscal 2001 was \$4.4 million relating to the closing of the Birmingham, England and Tarrytown, New York facilities, as discussed in the "Comparison of Fiscal 2002 to Fiscal 2001" section above.

Selling, general and administrative expenses increased \$4.8 million or 44% in fiscal 2001 compared to fiscal 2000. The increase was primarily attributable to the increased expenses for additional management and administrative personnel and consultants, as well as an increase in facility expenses and other professional fees associated with our expansion and corporate development activities. Consulting expenses included stock options granted to non-R&D consultants in connection with their consulting arrangements which resulted in \$324,000 in compensation expense in fiscal 2001 compared to \$812,000 in compensation expenses in fiscal 2000. Also included in selling, general and administrative expenses in fiscal 2001 was \$612,000 relating to the closing of the Birmingham, England and Tarrytown, New York facilities, as discussed in the "Comparison of Fiscal 2002 to Fiscal 2001 Expenses" section above.

Amortization of intangibles in fiscal 2001 primarily represented amortization of goodwill from the acquisition of Aston, which was fully amortized as of September 30, 2001.

Other Income and Expense

Net investment income increased \$22.2 million to \$25.9 million in fiscal 2001 compared to \$3.7 million in fiscal 2000. The increase in fiscal 2001 was largely due to investment of funds generated from: (i) a private sale of common stock to Genentech and Roche in January 2001; and (ii) the underwritten public offering of our common stock in November 2000. In fiscal 2000, we recorded a gain of \$3.7 million relating to the sale of our diagnostics business unit to Bayer in November 1999.

Liquidity and Capital Resources

At September 30, 2002, working capital, representing primarily cash, cash equivalents, and restricted and unrestricted short-term investments, aggregated \$444.6 million compared to \$533.4 million at September 30, 2001. This decrease of \$88.9 million resulted primarily from the net cash paid for the acquisition of Gilead's oncology assets in December 2001 and our net operating cash burn for the year. This decrease was offset by the net proceeds from the issuance of the convertible senior subordinated notes in February 2002, (less the early retirement of a portion of the notes in August and September 2002) and cash proceeds from the exercise of stock options.

On December 21, 2001, we acquired certain assets from Gilead pursuant to the terms of an Asset Purchase Agreement dated as of November 26, 2001. The assets purchased include: (a) a pipeline of three clinical oncology candidates, (b) 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. The results of operations of the acquired Gilead oncology assets have been included in the consolidated statement of operations since the date of closing. In consideration for the assets, we paid \$135.7 million in cash, which includes professional fees and the assumption of certain liabilities, and issued 924,984 shares of common stock, valued at \$40.0 million. We are obligated to pay contingent consideration of up to an additional \$30.0 million in either cash or a combination of cash and common stock, at our option, upon the achievement of certain milestones related to the development of OSI-211. Additionally, we assumed certain royalty and milestone obligations to third parties in connection with the oncology candidates acquired as part of the acquisition.

On February 1, 2002, we issued \$200.0 million aggregate principal amount of convertible senior subordinated notes in a private placement for net proceeds to us of approximately \$193.0 million. The notes bear interest at 4% per annum, payable semi-annually, and mature on February 1, 2009. We pledged \$22.9 million of U.S. government securities which will be sufficient to provide for the payment in full of the first six scheduled interest payments on the notes when due. The notes are convertible into shares of our common stock at a conversion price of \$50 per share, subject to adjustment in certain circumstances. We may redeem the notes, in whole or in part, at any time before February 1, 2005 if the closing price of our common stock has exceeded 150% of the conversion price then in effect for a specified period of time. Upon any such early redemption, we are required to pay interest that would have been due through February 1, 2005. We may also redeem some or all of the notes at any time on or after February 1, 2005 if the closing price of our common stock has exceeded 140% of the conversion price then in effect for a specified period of time. Upon a change in control, as defined in the indenture governing the notes, the holders of the notes will have the right to require us to repurchase all of the notes, or a portion thereof, not previously called for redemption at a purchase price equal to 100% of the principal amount of the notes purchased, plus accrued and unpaid interest. We may elect to pay the purchase price in common stock instead of cash. Accordingly, our liquidity position would not be affected by such a call by the holders of the notes if we elect to pay the purchase price in stock. The number of shares of common stock a holder would receive would equal the repurchase 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 repurchase date. If all or any portion of the notes have not been converted into common stock prior to their maturity date of February 1, 2009, we will be required to pay, in cash, the outstanding principal amount of the notes plus any accrued but unpaid interest. This could have a significant impact on our liquidity depending on our cash position at the 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 our debt obligations. In August and September 2002, we retired a total of \$40.0 million in principal amount of the

notes for an aggregate purchase price of approximately \$26.2 million, including accrued interest of \$133,000. The difference between the purchase price and the principal amount of the notes retired and accrued interest resulted in a net gain on the early retirement of the notes in the fourth quarter of fiscal 2002 of approximately \$12.6 million net of the write off of related debt issuance cost. Should conditions warrant, we may from time-to-time continue to enter the market to repurchase additional notes.

We expect to incur continued losses over the next several years as we continue our investment in Tarceva™ and other product candidates in our pipeline. The major expenses associated with the broad-based Phase III development program for Tarceva™ are expected to occur in 2003 and, as a result, we expect our operating expenses and cash burn to increase in fiscal 2003. Beyond fiscal 2003, as the Tarceva™ development expenses begin to wind down, we expect a lower operating expense and cash burn base which we will maintain until a successful Tarceva™ market launch. We have established a goal of achieving profitability and positive cash flow within 18 to 24 months of a successful market launch of Tarceva™. Although we believe that we have sufficient cash for operations for the next few years, if the market launch of Tarceva™ is delayed or if Tarceva™ does not receive FDA approval or if the approval process is delayed or takes longer than expected, such events could have a negative impact on our liquidity position, assuming our current cash burn.

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. The ability and time required to reach profitability is uncertain. We believe that our existing cash resources provide a strong financial base from which to fund our operations and capital requirements for at least the next several years.

Commitments and Contingencies

Our major outstanding contractual obligations relate to our senior subordinated convertible debt and our facility leases. The following table summarizes our significant contractual obligations at September 30, 2002 and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008 & Thereafter</u>	<u>Total</u>
Contractual Obligations:							
Senior convertible debt(a)	\$6,400	\$6,400	\$6,400	\$6,400	\$6,400	\$169,600	\$201,600
Operating leases	6,952	7,047	6,982	5,567	4,232	55,443	86,223
Construction commitments	510	—	—	—	—	—	510
Loans payable(b)	550	14	—	—	—	—	564
Total contractual obligations	<u>\$14,412</u>	<u>\$13,461</u>	<u>\$13,382</u>	<u>\$11,967</u>	<u>\$10,632</u>	<u>\$225,043</u>	<u>\$288,897</u>

(a) Includes interest payments at a rate of 4% per annum.

(b) Includes interest payments

Other significant commitments and contingencies include the following:

- We are committed to share equally with Genentech and Roche certain global development costs of Tarceva™.
- In connection with the acquisition of certain of Gilead's oncology assets in December 2001, we are obligated to pay up to an additional \$30.0 million in either cash, common stock 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.
- Under agreements with external clinical research organizations, or CROs, over the next 12 to 24 months we will continue to incur expenses relating to the progress of Tarceva™ clinical trials. These

disbursements can be based upon the achievement of certain milestones, patient enrollment, services rendered or as expenses are incurred by the CROs.

- In connection with our strategic decision to close down our Birmingham, England facility, we expect to pay approximately \$662,000 in non-cancelable lease exit costs.
- We have a retirement plan which provides postretirement 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 approximately \$2.5 million at September 30, 2002.
- Under certain 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.
- Under certain license agreements, we are required to pay license fees for the use of technologies and products in our research and development activities.
- We entered into a letter of credit with a commercial bank in relation to one of our facilities. The irrevocable letter of credit expires annually with a final expiration date of September 27, 2007. The amount under this letter of credit is \$2.1 million of which the full amount was available on September 30, 2002.

Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued 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 future 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 with indefinite useful lives no longer be amortized, but instead tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also 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. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." SFAS No. 141 and No. 142 are effective for fiscal years beginning on or after December 15, 2001; however, both of these statements were effective for acquisitions and other intangibles acquired on or after July 1, 2001. We adopted the applicable provisions of these statements for the accounting of the Gilead and the British Biotech acquisitions, which both occurred after July 1, 2001.

Upon full adoption of these standards in fiscal 2003, we will evaluate our existing intangible assets that were acquired in prior purchase business combinations and make any necessary reclassifications in order to conform with the new criteria in SFAS No. 141 for recognition apart from goodwill. We will be required to reassess the useful lives and residual values of all intangible assets acquired and make any necessary amortization period adjustments. In addition, we will be required to test goodwill and, to the extent an intangible asset is identified as having an indefinite useful life, the intangible asset for impairment in accordance with SFAS No. 142. Any impairment loss will be measured as of the date of adoption and recognized as the cumulative effect of a change in accounting principle. As a result of the acquisition of certain assets from Gilead on December 21, 2001, we have \$36.5 million in goodwill as of September 30, 2002 which, in accordance with SFAS No. 142, is not amortized and identifiable intangible assets in the amount of \$2.6 million. As of September 30, 2001, we had goodwill which was fully amortized and unamortized identifiable intangible assets in the amount of \$3.7 million.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" which supercedes SFAS No. 121. 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. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections." SFAS No. 145, among other things, rescinds SFAS No. 4, which required all gains and losses from the extinguishment of debt to be classified as an extraordinary item and amends SFAS No. 13 to require that certain lease modifications that have economic effects similar to sale-leaseback transactions be accounted for in the same manner as sale-leaseback transactions. We adopted SFAS No. 145 effective April 1, 2002, which was the beginning of the fiscal quarter in which this statement was issued. As a result, we did not classify the net gain of \$12.6 million realized in the fourth quarter of fiscal year 2002 from the early retirement of a portion of the our notes as an extraordinary item in the accompanying consolidated statements of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities", effective for exit or disposal activities that are initiated after December 31, 2002. Under SAFS No. 146, a liability for a cost associated with an exit or disposal activity must only be recognized when the liability is incurred. Under the previous guidance of EITF 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity including Certain Costs Incurred in a Restructuring", we recognized a liability for an exit or disposal activity cost at the date of our commitment. If we were to commit to further exit or disposal activities subsequent to the effective date, we would be subject to the new rules regarding expense recognition.

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 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, we pledged \$22.9 million of U.S. government securities (restricted investment securities) with maturities at various dates through November 2004. Upon maturity, the proceeds of the restricted investment securities will be sufficient to pay the first six scheduled interest payments on the convertible senior subordinated notes when due (see note 9 to the accompanying consolidated financial statements). We consider our restricted investment securities to be "held-to-maturity," as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." 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. 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. It is uncertain whether other-than-temporary losses will be material to our results of operations in the future. We do not currently hedge these exposures. We at times minimize risk by hedging the foreign currency exchange rates exposure through forward contracts as more fully described in note 12(d) to the accompanying consolidated financial statements. We did not have any forward foreign exchange contracts as of September 30, 2002.

At September 30, 2002, 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 containing financial instruments of which approximately 13% have original maturities of less than 12 months. These financial instruments, principally comprised of government and government agency obligations and corporate obligations, are subject to interest rate risk and will decline in value if interest rates increase. A hypothetical 10% change in interest rates during the year ended September 30, 2002 would have resulted in approximately a \$1.5 million change in our net loss. We have not used or held derivative financial instruments in our investment portfolio.

Our long-term debt totaled approximately \$160.0 million at September 30, 2002 and was primarily comprised of the convertible senior subordinated notes. The convertible senior subordinated notes bear interest at a fixed rate of 4%.

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 AND SUPPLEMENTARY DATA

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INDEPENDENT AUDITORS' REPORT

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, 2002 and 2001, 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, 2002. 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 auditing standards generally accepted in the United States of America. 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, 2002 and 2001, and the results of their operations and their cash flows for each of the years in the three-year period ended September 30, 2002, in conformity with accounting principles generally accepted in the United States of America.

As discussed in note 1(b) to the consolidated financial statements, the Company changed its method of revenue recognition for certain upfront non-refundable fees in 2001.

As discussed in notes 1(d) and 19 to the consolidated financial statements, the Company adopted provisions of Statement of Financial Accounting Standards No. 141, "Business Combinations" and No. 142, "Goodwill and Other Intangible Assets", for acquisitions consummated on or after July 1, 2001.

As discussed in notes 9 and 19 to the consolidated financial statements, the Company adopted provisions of 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 22, 2002

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
September 30, 2002 and 2001
(In thousands except per share data)

	September 30,	
	2002	2001
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 152,578	\$ 225,150
Investment securities	304,388	326,329
Restricted investment securities — short-term	7,938	—
Receivables, including amounts due from related parties of \$3,000 and \$2,360 at September 30, 2002 and 2001, respectively	3,253	2,813
Interest receivable	3,728	3,820
Prepaid expenses and other current assets	3,873	3,120
Total current assets	475,758	561,232
Restricted investment securities — long-term	11,373	—
Property, equipment and leasehold improvements — net	46,175	25,347
Debt issuance costs — net	5,145	—
Intangible assets — net	39,106	3,684
Other assets	1,487	1,426
	\$ 579,044	\$ 591,689
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including amounts due to related parties of \$2,190 and \$276 at September 30, 2002 and 2001, respectively	\$ 22,062	\$ 18,063
Unearned revenue — current; including amounts received in advance from related parties of \$7,687 and \$8,677 as of September 30, 2002 and 2001, respectively	8,613	9,622
Loans payable — current	527	112
Total current liabilities	31,202	27,797
Other liabilities:		
Unearned revenue — long-term, including amounts received in advance from related parties of \$6,250 and \$10,679 as of September 30, 2002 and 2001, respectively ...	6,250	11,554
Loans payable — long-term	14	52
Convertible senior subordinated notes	160,000	—
Deferred acquisition costs	—	375
Accrued postretirement benefit cost	2,470	2,080
Total liabilities	199,936	41,858
Stockholders' equity:		
Preferred stock, \$.01 par value; 5,000 shares authorized; no shares issued at September 30, 2002 and 2001	—	—
Common stock, \$.01 par value; 200,000 shares authorized, 37,335 and 35,901 shares issued at September 30, 2002 and 2001, respectively	373	359
Additional paid-in capital	708,435	664,095
Deferred compensation	(49)	(3,922)
Accumulated deficit	(324,223)	(105,744)
Accumulated other comprehensive income	1,005	1,476
	385,541	556,264
Less: treasury stock, at cost; 940 shares at September 30, 2002 and 2001.	(6,433)	(6,433)
Total stockholders' equity	379,108	549,831
Commitments and contingencies		
	\$ 579,044	\$ 591,689

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,		
	2002	2001	2000
Revenues:			
Collaborative program revenues, including \$7,824, \$12,163 and \$17,182 from related parties in 2002, 2001 and 2000, respectively	\$ 11,976	\$ 17,984	\$ 23,658
License and related revenues, including \$7,500 and \$6,250 from related parties in 2002 and 2001, respectively	8,683	7,425	3,725
Other revenues	1,157	613	1,269
	<u>21,816</u>	<u>26,022</u>	<u>28,652</u>
Expenses:			
Research and development	102,202	56,038	39,622
Acquired in-process research and development (note 3(a))	130,200	—	—
Selling, general and administrative	28,069	15,771	10,938
Amortization of intangibles	1,255	742	870
Production and service costs	77	262	835
	<u>261,803</u>	<u>72,813</u>	<u>52,265</u>
Loss from operations	(239,987)	(46,791)	(23,613)
Other income (expense):			
Investment income — net	14,729	25,910	3,737
Interest expense	(5,235)	(21)	(33)
Other expense — net	(1,590)	(228)	(185)
Gain on early retirement of convertible senior subordinated notes — net	12,604	—	—
Gain on sale of diagnostics business	1,000	—	3,746
	<u>(218,479)</u>	<u>(21,130)</u>	<u>(16,348)</u>
Loss before cumulative effect of accounting change			
Cumulative effect of the change in accounting for the recognition of upfront fees	—	(2,625)	—
Net loss	<u><u>\$ (218,479)</u></u>	<u><u>\$ (23,755)</u></u>	<u><u>\$ (16,348)</u></u>
Basic and diluted net loss per common share:			
Loss before cumulative effect of change in accounting policy	\$ (6.07)	\$ (0.62)	\$ (0.67)
Cumulative effect of change in accounting policy	\$ —	\$ (0.08)	\$ —
Net loss	<u><u>\$ (6.07)</u></u>	<u><u>\$ (0.70)</u></u>	<u><u>\$ (0.67)</u></u>
Weighted average shares of common stock outstanding	<u>35,978</u>	<u>33,852</u>	<u>24,531</u>
Proforma information assuming new revenue recognition policy had been applied retroactively:			
Net loss		<u><u>\$ (21,130)</u></u>	<u><u>\$ (18,973)</u></u>
Basic and diluted net loss per common share		<u><u>\$ (0.62)</u></u>	<u><u>\$ (0.77)</u></u>

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended September 30, 2002, 2001 and 2000
(In thousands)

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity
	Shares	Amount						
Balance at September 30, 1999	22,404	\$224	\$105,173	\$ —	\$ (65,641)	\$ (334)	\$ (6,058)	\$ 33,364
Comprehensive income (loss):								
Net loss	—	—	—	—	(16,348)	—	—	(16,348)
Unrealized holding loss on investment securities, net of reclassification adjustment	—	—	—	—	—	(80)	—	(80)
Translation adjustment	—	—	—	—	—	(530)	—	(530)
Total comprehensive loss								(16,958)
Options exercised	2,371	24	13,237	—	—	—	—	13,261
Warrants exercised	174	2	1,309	—	—	—	—	1,311
Compensation expense in connection with options issued to an employee below market	—	—	4,975	—	—	—	—	4,975
Issuance of common stock for employee purchase plan and other	8	—	60	—	—	—	—	60
Proceeds from issuance of common stock, in connection with a private placement, net	3,325	33	52,683	—	—	—	—	52,716
Accrued expenses in connection with public offering of common stock	—	—	(318)	—	—	—	—	(318)
Deferred compensation	—	—	10,612	(10,612)	—	—	—	—
Amortization of deferred compensation	—	—	—	1,845	—	—	—	1,845
Purchase of treasury stock	—	—	—	—	—	—	(375)	(375)
Balance at September 30, 2000	<u>28,282</u>	<u>283</u>	<u>187,731</u>	<u>(8,767)</u>	<u>(81,989)</u>	<u>(944)</u>	<u>(6,433)</u>	<u>89,881</u>
Comprehensive income (loss):								
Net loss	—	—	—	—	(23,755)	—	—	(23,755)
Unrealized holding gain on investment securities, net of reclassification adjustment	—	—	—	—	—	2,738	—	2,738
Translation adjustment	—	—	—	—	—	(318)	—	(318)
Total comprehensive loss								(21,335)
Options exercised	538	5	3,699	—	—	—	—	3,704
Issuance of common stock for employee purchase plan and other	4	—	115	—	—	—	—	115
Proceeds from issuance of common stock, in connection with public offerings, net	6,152	62	404,141	—	—	—	—	404,203
Change in deferred compensation	—	—	(1,560)	1,560	—	—	—	—
Amortization of deferred compensation	—	—	—	3,285	—	—	—	3,285
Proceeds from issuance of common stock, in connection with collaboration agreements, net	925	9	69,969	—	—	—	—	69,978
Balance at September 30, 2001	<u>35,901</u>	<u>359</u>	<u>664,095</u>	<u>(3,922)</u>	<u>(105,744)</u>	<u>1,476</u>	<u>(6,433)</u>	<u>549,831</u>
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	<u>37,335</u>	<u>\$373</u>	<u>\$708,435</u>	<u>\$ (49)</u>	<u>\$(324,223)</u>	<u>\$1,005</u>	<u>\$(6,433)</u>	<u>\$ 379,108</u>

See accompanying notes to consolidated financial statements.

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

	Years ended September 30,		
	2002	2001	2000
Cash flow from operating activities:			
Net loss	\$(218,479)	\$ (23,755)	\$(16,348)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Gain on early retirement of convertible senior subordinated notes — net	(12,604)	—	—
Gain on sale of diagnostic business	(1,000)	—	(3,746)
Loss/(gain) on sale of investments	143	(278)	(488)
Loss on sale and disposals of equipment and leasehold improvements	359	115	61
Depreciation and amortization of equipment and leasehold improvements	8,439	3,836	2,941
In-process research and development charge on acquisition of Gilead's oncology assets	130,200	—	—
Amortization of intangible and other assets	2,663	2,149	2,736
Accretion of deferred acquisition costs	—	19	19
Non-cash compensation charges	1,606	3,286	6,820
Write down of investment in privately-owned company	500	—	—
Bad debt expense	178	—	—
Cumulative effect of accounting change	—	2,625	—
Changes in assets and liabilities, net of the effects of acquisitions and sale of a business:			
Receivables	(520)	(5,586)	4,129
Prepaid expenses and other current assets	(686)	(1,325)	(137)
Other assets	304	37	(9)
Accounts payable and accrued expenses	2,250	11,648	1,228
Unearned revenue	(6,312)	17,526	(4,348)
Accrued postretirement benefit cost	390	194	427
Net cash provided by (used in) operating activities	(92,569)	10,491	(6,715)
Cash flows from investing activities:			
Payments for acquisitions	(135,742)	(13,869)	—
Net proceeds from sale of diagnostic business	1,000	—	8,636
Purchases of investments (restricted and unrestricted)	(400,951)	(535,099)	(31,005)
Maturities and sales of investments (restricted and unrestricted)	402,318	248,458	4,988
Additions to property, equipment and leasehold improvements	(18,295)	(10,625)	(2,728)
Additions to compound library assets	(92)	—	—
Proceeds from sale of equipment and leasehold improvements	114	35	375
Investments in privately-owned companies	(870)	(420)	—
Net cash used in investing activities	(152,518)	(311,520)	(19,734)
Cash flows from financing activities:			
Net proceeds from the issuance of common stock	—	474,181	52,716
Proceeds from the exercise of stock options, stock warrants, employee purchase plan, and other	6,247	3,819	13,939
Proceeds from the issuance of convertible senior subordinated notes	200,000	—	—
Retirement of convertible senior subordinated notes	(26,098)	—	—
Debt issuance costs	(7,084)	—	—
Payments on loans and capital leases payable — net	(268)	(149)	(131)
Purchase of treasury stock	—	—	(375)
Net cash provided by financing activities	172,797	477,851	66,149
Net increase (decrease) in cash and cash equivalents	(72,290)	176,822	39,700
Effect of exchange rate changes on cash and cash equivalents	(282)	(65)	(171)
Cash and cash equivalents at beginning of year	225,150	48,393	8,864
Cash and cash equivalents at end of year	\$ 152,578	\$ 225,150	\$ 48,393
Non-cash activities:			
Issuance of common stock in satisfaction of deferred acquisition costs	\$ 375	\$ —	\$ 375
Issuance of common stock in connection of acquisition of Gilead's oncology assets	\$ 40,000	\$ —	\$ —
Issuance of common stock to employees	\$ 450	\$ —	\$ —

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years ended September 30, 2002, 2001 and 2000

(1) Summary of Significant Accounting Policies

(a) Principles of Consolidation

The consolidated financial statements of the Company include the accounts of OSI Pharmaceuticals, Inc., and its wholly-owned subsidiaries, OSI Pharmaceuticals (UK) Limited (OSI-UK), MYCOsearch, Inc., OSDI, Inc., and Applied bioTechnology, Inc. All intercompany balances and transactions have been eliminated in consolidation. The Company operates in one segment. The Company is 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

Included in license and related revenues are patent license fees, maintenance fees, and technology access and other upfront fees. Prior to October 1, 2000, the Company recognized all nonrefundable license fees, including upfront and technology access fees, as revenue when received and when all contractual obligations of the Company relating to such fees had been fulfilled. Effective October 1, 2000, the Company changed its method of accounting for upfront nonrefundable technology access and other upfront fees to recognize such fees over the term of the related research collaboration period 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. The Company received a total of \$25.0 million in upfront fees from Genentech, Inc. and Roche in January 2001 which was being recognized on a straight-line basis evenly over the expected three-year term of the Company's required research and development efforts under the terms of the agreement. In the fourth quarter of fiscal 2002, the expected term was changed to four years to reflect the Company's revised estimate of the term of the continued involvement in the research and development efforts under the Tripartite Agreement (see note 5(a)). 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 development involvement. In accordance with Accounting Principle Board Opinion No. 20 "Accounting Change," the remaining deferred revenue will be recognized prospectively over the revised term. As a result, the Company recorded revenues of \$1.3 million in the fourth quarter of fiscal 2002 compared to \$2.1 million had the upfront fees continued to be recognized over a three-year period. This change in estimate increased the basic and diluted loss by \$.02 per share for fiscal 2002.

For the year ended September 30, 2000, the Company recognized as revenue the full \$3.5 million technology access fee received from Tanabe Seiyaku Co., Ltd. related to a four-year term collaboration. The Company's adoption of SAB No. 101 effective October 1, 2000 resulted in a \$2.6 million cumulative effect of a change in accounting principle related to the Tanabe fee which was reported as a charge in the quarter ended December 31, 2000. The cumulative effect was initially recorded as unearned revenue and is being recognized as revenue over the remaining term of the collaboration agreement. During the year ended September 30, 2001, the impact of the change in accounting principle increased the net loss by approximately \$1.8 million, or \$.05 per share, comprised of the \$2.6 million cumulative effect of the change as described above (\$.08 per share), net of the \$0.9 million of related deferred revenue that was recognized as revenue during the year ended September 30, 2001 (\$.03 per share). Had the change in accounting principle been applied retroactively, the net loss for the year ended September 30, 2000 would have increased by \$2.6 million, or \$.11 per basic and diluted shares.

Collaborative program revenues represent funding arrangements for research and development, (R&D), in the field of biotechnology and are recognized when earned in accordance with the terms of the contracts and the related development activities undertaken. Collaborative revenues are accrued for expenses incurred in advance of the reimbursement and deferred for cash payments received in advance of expenditures. Such deferred revenues are recorded as revenue when earned.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years ended September 30, 2002, 2001 and 2000

Other revenues are recognized pursuant to the terms of arrangements, which provide reimbursement of certain expenses related to the Company's other research and development activities. Other revenues are accrued for expenses incurred in advance of the reimbursement and deferred for cash payments received in advance of expenditures

(c) Accrual for clinical research organization and clinical site costs

The Company records accruals for estimated clinical study costs. Clinical study costs represent costs incurred by clinical research organizations (CROs) and clinical sites. These costs are recorded as a component of R&D expenses. Management accrues costs for these clinical studies based on 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, 2002 and 2001 were \$3.1 million and \$1.3 million, respectively.

(d) Goodwill and Intangible Assets

In July 2001, the Financial Accounting Standards Board issued 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 future 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 with indefinite useful lives no longer be amortized, but instead tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also 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. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of."

SFAS No. 142 is effective for fiscal years beginning on or after December 15, 2001; however this statement was effective for acquisitions and other intangibles acquired on or after July 1, 2001. For the Company's two acquisitions consummated after June 30, 2001, goodwill was not amortized during 2002 in accordance with SFAS No. 142. All intangible assets acquired prior to July 1, 2001 and intangible assets with finite lives acquired after June 30, 2001 were amortized on a straight-line basis over their estimated periods to be benefited. Goodwill that was acquired prior to July 1, 2001 was amortized on a straight-line basis over five years and was fully amortized as of September 30, 2001. Upon full adoption of these standards in fiscal 2003, the Company will evaluate its existing intangible assets that were acquired in prior business combinations, and make any necessary reclassifications in order to conform with the new criteria in SFAS No. 141 for recognition apart from goodwill. The Company will be required to reassess the useful lives and residual values of all intangible assets acquired and make any necessary amortization period adjustments. In addition, the Company will be required to test goodwill and, to the extent an intangible asset is identified as having an indefinite useful life, the intangible asset for impairment in accordance with SFAS No. 142. Any impairment loss will be measured as of the date of adoption and recognized as the cumulative effect of a change in accounting principle. As of September 30, 2002, the carrying amount of goodwill was \$36.5 million and the carrying amount of identifiable intangible assets was \$2.6 million. The Company is currently assessing the impact of the adoption of these accounting standards.

As a result of the Company's R&D programs, including programs funded pursuant to R&D funding agreements (see note 5), the Company has applied for a number of patents in the United States and abroad.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years ended September 30, 2002, 2001 and 2000

Costs incurred in connection with patent applications for the Company's R&D programs have been expensed as incurred.

(e) Deferred Acquisition Costs

Deferred acquisition costs represent common stock purchase rights issued in connection with the Company's acquisition of OSI-UK on September 19, 1996. The Company issued rights exercisable at the end of three and five years following the closing date which was September 19, 1996 (for an aggregate exercise price of \$7,500) to obtain a number of shares of the Company's common stock having an aggregate value of \$750,000 (based on the current market value on the date of exercise). In December 1999, one half of these rights were exercised in exchange for 74,255 shares of the Company's common stock. Following this exercise, the Company purchased these shares at the fair market value for \$375,000. These shares are currently held in treasury stock. The present value of such remaining rights amounted to \$375,000 as of September 30, 2001. In December 2001, the remaining rights were exercised in exchange for 10,543 shares of the Company's common stock.

(f) Research and Development Costs

Research and development 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 2002, 2001 and 2000, R&D activities included \$95.1 million, \$44.6 million and \$20.7 million respectively, of independent R&D. Independent R&D includes the Company's proportionate share of development expenses related to the Tripartite Agreement (see note 5(a)), and R&D activities funded by government research grants and other proprietary R&D programs. The balance of R&D represents expenses under the collaborative agreements and co-ventures with Pfizer Inc., Anaderm Research Corporation, Tanabe, Vanderbilt University, Sankyo Co., Ltd., Aventis Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc., Helicon Therapeutics, Inc., and The Bayer Corporation. Included in R&D expense is the impact of stock options granted to non-employees over the past three years that have resulted in approximately \$503,000, \$1.5 million and \$971,000 of compensation expense in fiscal 2002, 2001 and 2000, respectively (see note 10(a)). Also included in R&D expense in fiscal 2002 and 2001 is approximately \$534,000 and \$4.4 million, respectively, related to the closing of the Tarrytown, New York and Birmingham, England facilities (see notes 16(a) and 16(b)). Included in R&D expenses in fiscal 2002, 2001 and 2000 is \$485,000, \$1.5 million and \$5.0 million, respectively of compensation expense related to the issuing of an option to purchase shares of common stock to the Company's then President and Head of Research and Development (see note 10(a)).

(g) Depreciation and Amortization

Depreciation of equipment is recognized over the estimated useful lives of the respective asset groups on a straight-line basis utilizing the half-year convention. 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 the fungal cultures and compounds acquired in connection with the acquisition of the research business of Cadus Pharmaceutical Corporation in fiscal 1999, the acquisition of a compound library license from The Dow Chemical Company in fiscal 1997, and the acquisition of MYCOsearch, Inc. in fiscal 1996 are on a straight-line basis over five years.

(h) 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

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years ended September 30, 2002, 2001 and 2000

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.

(i) Investments

Investment securities at September 30, 2002 and 2001 consist of U.S. Treasury obligations, municipal obligations and corporate debt and equity securities. The Company classifies its investments as available-for-sale. 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 February 2002, in connection with the issuance of convertible senior subordinated notes (see note 9), the Company pledged \$22.9 million of U.S. government securities (restricted investment securities) with maturities at various dates through November 2004. Upon maturity, the proceeds of the restricted investment securities will be sufficient to pay the first six scheduled interest payments on the convertible senior subordinated notes when due. The Company considers its restricted investment securities to be held-to-maturity, as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." 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.

As further discussed in note 5(f), the Company received an equity interest in a research and development company in exchange for research services provided. The Company has recorded its investment in the company based on the cost of services rendered. The Company recognized its share of the operating losses of this company based on its percentage ownership interest under the equity method of accounting.

The Company has 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) 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 period. The diluted loss per share presented excludes the effect of common share equivalents (stock options, warrants and convertible debt), since such inclusion in the computation would be anti-dilutive. Such common share equivalents (options and convertible debt) amounted to 4,894,588 for fiscal 2002. Such common share equivalents (options and warrants) amounted to 2,105,676 and 1,511,821 for fiscal 2001 and 2000, respectively.

(k) Accounting for Stock-Based Compensation

The Company follows the provisions of SFAS No. 123, "Accounting for Stock-Based Compensation". The provisions of SFAS No. 123 allow the Company 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)

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
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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. The Company has elected to continue to apply APB No. 25 in accounting for stock options issued to employees.

(l) Cash and Cash Equivalents

The Company includes as cash equivalents reverse repurchase agreements, treasury bills and time deposits with original maturities of three months or less. Such cash equivalents amounted to \$142.8 million and \$220.4 million as of September 30, 2002 and 2001, respectively.

(m) Use of Estimates

The Company has made a number of estimates and assumptions related to the reporting of assets and liabilities and the disclosure of contingent assets and liabilities to prepare these consolidated financial statements in conformity with accounting principles generally accepted in the United States. Actual results could differ from those estimates.

(n) Foreign Currency Translation

The assets and liabilities of the Company's non-U.S. subsidiary, OSI-UK, which operates in its local currency is 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.

(o) Comprehensive Income (Loss)

Comprehensive income includes foreign currency translation adjustments and unrealized gains or losses on the Company's available-for-sale securities.

As of September 30, the components of accumulated other comprehensive income were as follows (in thousands):

	2002	2001
Cumulative foreign currency translation adjustment	\$ (320)	\$(1,015)
Unrealized gains on available-for-sale securities	1,325	2,491
Accumulated other comprehensive income	\$1,005	\$ 1,476

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

The Company accounts for its long-lived assets in accordance with the provisions of SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of." SFAS No. 121 requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by comparison of the carrying amount of an asset to the future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceed the fair value of assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less cost to sell.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years ended September 30, 2002, 2001 and 2000

(q) Computer Software Costs

The Company records the costs of computer software in accordance with AICPA Statement of Position 98-1, "Accounting for the Costs of Computer Software Development 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.

(r) Derivatives

The Company accounts for its derivative instruments and hedging activities in accordance with SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," as amended. SFAS No. 133 establishes accounting and reporting standards for derivative instruments as either assets or liabilities in the statement of financial position based on their fair values. Changes in the fair values are reported in earnings or other comprehensive income depending on the use of the derivative and whether it qualifies for hedge accounting. Derivative instruments are designated and accounted for as either a hedge of a recognized asset or liability (fair value hedge) or a hedge of a forecasted transaction (cash flow hedge). For derivatives designated as effective cash flow hedges, changes in fair values are recognized in other comprehensive income. Changes in fair values related to fair value hedges as well as the ineffective portion of cash flow hedges are recognized in earnings. Changes in the fair value of the underlying hedged item of a fair value hedge are also recognized in earnings.

(s) Basis of Presentation

Certain reclassifications have been made to the prior period consolidated financial statements to conform them to current presentations.

(2) License Agreements

The Company has entered into various license agreements with third parties to grant the use of the Company's proprietary assets. These licenses include the use of the Company's patented gene transcription estate which consists of drug discovery assays that provide a way to identify novel product candidates that can control the activity of genes. Licensees may be obligated to pay the Company 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. To date, the Company has granted seven licenses to use our gene transcription patent. In fiscal 2002, 2001, and 2000, total license revenues were \$308,000, \$300,000, and \$225,000 respectively.

(3) Acquisitions

(a) Gilead's Oncology Assets

On December 21, 2001, the Company acquired certain assets from Gilead Sciences, Inc. pursuant to the terms of an Asset Purchase Agreement dated as of November 26, 2001. Gilead is a biopharmaceutical company that discovers, develops, manufactures and commercializes proprietary therapeutics for infectious diseases. The assets purchased by the Company 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, the Company 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, the Company paid approximately \$135.7 million, which includes professional fees and the assumption of

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
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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 the Company's stock for the five days prior to the date of closing. The Company 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 (formerly NX211), the most advanced of Gilead's oncology product candidates acquired by the Company. Additionally, the Company assumed certain royalty and milestone obligations to third parties in connection with the oncology candidates, acquired as part of the acquisition.

Included in the assets acquired were certain employee home purchase loans and a home bridge loan in connection with the acquisition. The total amount of the loans acquired amounted to \$623,000. Under the terms of the home purchase loan agreements, 50% of the original principal is forgiven over years six to ten of the loan provided the employees are continuously employed during the term of the loan. If the employee is terminated, the loan is due within 90 days from date of termination. The loans are non-interest bearing unless the employee terminates. During fiscal 2002, the home bridge loan in the amount of \$250,000 was repaid in full. The carrying amount of the remaining loans outstanding was \$344,000 and is included in other assets, on the accompanying consolidated balance sheet as of September 30, 2002.

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 Company obtained a third-party valuation to assist management in determining the fair value of certain assets. 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, the Company recorded an increase of \$800,000 to the goodwill for additional payments to Gilead for acquisition-related costs. In accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," which is applicable to acquisitions occurring after July 1, 2001, such goodwill will not be amortized. 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 (formerly NX211), a liposomal lurtotecan (\$19.9 million), OSI-7904L (formerly GS7904L), a liposomal thymidylate (\$13.4 million) and OSI-7836 (formerly GS7836), 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	<u>663</u>
Total assets and in-process R&D acquired	177,920
Less liabilities assumed	<u>(2,178)</u>
Cash and common stock paid	<u>\$175,742</u>

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

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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, the Company adopted a Non-Qualified Stock Option Plan for Former Employees of Gilead Sciences, Inc. The Company granted ten-year options to purchase an aggregate of 693,582 shares of common stock of the Company at a purchase price of \$45.01 per share, which represents the fair value of the Company's stock at the date granted. The options vest one-third in a year from the date of grant and monthly thereafter for 24 months.

The following unaudited pro forma financial information presents a summary of the consolidated results of operations of the Company for the years ended September 30, 2002 and 2001 assuming the acquisition had taken place as of October 1, 2001 and 2000, respectively (in thousands, except per share information):

	Year Ended September 30,	
	2002	2001
Revenues	\$ 21,816	\$ 26,022
Loss before non-recurring charge related to the acquisition and cumulative effect of accounting change	\$(98,922)	\$(59,654)
Loss before non-recurring charge related to the acquisition	\$(98,922)	\$(62,279)
Basic and diluted loss per share:		
Before non-recurring charge related to acquisition and cumulative effect of accounting change	\$ (2.70)	\$ (1.71)
Cumulative effect of accounting change	\$ —	\$ (0.08)
Before non-recurring charge related to the acquisition	<u>\$ (2.70)</u>	<u>\$ (1.79)</u>

The unaudited pro forma financial information has been prepared for comparative purposes only. The pro forma information includes the historical unaudited results of Gilead's oncology assets for the respective periods. The pro forma financial information includes adjustments to the Company's historical results to reflect incremental depreciation expense related to the mark-up of fixed assets to fair value, reduced interest income generated from cash that was used for the acquisition, additional interest expense and the issuance of 924,984 shares of common stock and excludes the nonrecurring charge of \$130.2 million related to the acquired in-process R&D. The pro forma information does not purport to be indicative of operating results that would have been achieved had the acquisition taken place on the dates indicated or the results that may be obtained in the future.

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(b) British Biotech

On September 28, 2001, the Company acquired certain assets from British Biotech plc for \$13.9 million in cash, which includes professional fees and other related costs. Accordingly, the acquisition was accounted for as an asset acquisition and the purchase price was allocated to the tangible and intangible assets based on the relative fair values at the date of acquisition. The purchase price was allocated as follows (in thousands):

Equipment and leasehold improvements	\$ 9,537
Work force intangible	3,040
License to compound libraries	657
Prepaid expenses	<u>635</u>
Total assets acquired	<u>\$13,869</u>

The Company also assumed two British Biotech facility leases in Oxford, England as of September 28, 2001. The leases for these two facilities expire in August 2009 and April 2021. In connection with the acquisition, the Company acquired a non-exclusive license to compound libraries and the Company agreed to pay royalties of 2.5% on the sales of products arising out of the use of these libraries. The cost of the license is being amortized on a straight-line basis over three years, which represents the estimated period over which the compound will be used. Also in connection with the acquisition, the Company acquired 58 employees of which 42 were in research and development, two were in information technology and the remainder were in administrative positions.

In relation to one of the facility leases, the Company entered into a letter of credit with a commercial bank. The irrevocable letter of credit expires annually on September 27th, with a final expiration date of September 27, 2007. The amount under this letter of credit is \$2.1 million of which the full amount was available on September 30, 2002. The Company maintains a collateralized investment account with the same commercial bank for securities held as collateral against the letter of credit. Included in the accompanying consolidated balance sheet as of September 30, 2002 in cash and cash equivalents and investment securities is \$1.0 and \$2.0 million, respectively, relating to these collateralized securities.

(4) Investments

(a) Investment Securities

The Company invests its excess cash in U.S. Government securities, municipal obligations and debt and equity instruments of financial institutions and corporations with strong credit ratings. The Company has established guidelines relative to diversification of its 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):

<u>2002</u>	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Fair Value</u>
U.S. Treasury securities and obligations of U.S. Government agencies	\$210,509	\$ 513	\$211,022
Municipal securities	4,000	—	4,000
Corporate debt securities	<u>88,507</u>	<u>859</u>	<u>89,366</u>
Total	<u>\$303,016</u>	<u>\$1,372</u>	<u>\$304,388</u>

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<u>2001</u>	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Fair Value</u>
U.S. Treasury securities and obligations of U.S. Government agencies	\$232,036	\$1,968	\$234,004
Corporate debt securities	<u>91,802</u>	<u>523</u>	<u>92,325</u>
Total	<u>\$323,838</u>	<u>\$2,491</u>	<u>\$326,329</u>

Government and corporate debt securities include \$15.7 million and \$20.0 million as of September 30, 2002 and 2001, respectively, of interests in mutual funds which are invested principally in government and corporate debt securities. Net realized gains (losses) on sales of investments during fiscal 2002, 2001 and 2000 were \$(143,000), \$278,000, and \$488,000, respectively.

Maturities of debt securities classified as available-for-sale were as follows at September 30, 2002 (in thousands):

	<u>Cost</u>	<u>Fair Value</u>
2003	\$129,096	\$129,768
2004	79,427	79,733
2005	77,643	77,691
2006	—	—
2007	72	73
2008 and thereafter	<u>1,396</u>	<u>1,412</u>
	<u>\$287,634</u>	<u>\$288,677</u>

(b) Other Investments

As further discussed in notes 5(b) and 5(f), the Company has collaborative research agreements with Anaderm and Helicon, and the Company's investments in such companies were carried based on the equity method of accounting. On September 23, 1999, the Company exercised its right to require Pfizer to purchase all of its shares of Anaderm common stock at a sale price of \$3.6 million. As of September 30, 1999, the Company recognized a gain of \$3.3 million on the sale of the Anaderm common stock and recorded a receivable of \$3.6 million. On November 10, 1999, the Company received a cash payment of this receivable from Pfizer. As of September 30, 2002 and 2001, the Company fully reserved its investment in Helicon as more fully discussed in note 5(f).

The Company has an investment in and a license and technology development agreement with a privately-owned healthcare information company that develops and provides web-based products and services for the clinical trial process, including facilitation of patient accrual. During fiscal 2002, the Company 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. The investment was fully reserved as of September 30, 2002. In addition, in fiscal 2002 the Company 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.

As of September 30, 1999, the Company had an investment in Tularik, Inc. amounting to \$250,000 which was carried at cost and approximated fair market value (see note 13). In December 1999, the Company sold

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its investment in Tularik resulting in a gain of approximately \$488,000 which is included in net investment income in the accompanying consolidated statement of operations for fiscal 2000.

(5) Product Development Contracts

(a) Roche and Genentech

On January 8, 2001, the Company entered into certain agreements with Genentech and Roche for the global co-development and commercialization of the Company's lead anti-cancer drug, Tarceva™. The Company received upfront fees of \$25.0 million related to these agreements, which was being recognized evenly over the expected three-year term of the Company's required R&D efforts under these agreements. In the fourth quarter of fiscal 2002, the expected term was revised to four years to more accurately reflect the Company's continued involvement in the R&D efforts 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 development involvement. In accordance with Accounting Principle Board Opinion No. 20 "Accounting Change," the remaining deferred revenue will be recognized prospectively over the revised term. For the years ended September 30, 2002 and 2001, the Company recognized \$7.5 and \$6.3 million, respectively, of the upfront fees which is included in license and related revenues in the accompanying consolidated statements of operations.

Under the OSI/Genentech Agreement, the Company and Genentech agreed to collaborate in the product development of Tarceva™ with the goal of obtaining regulatory approval for commercial marketing and sale in the United States, its territories and Puerto Rico, of products resulting from the collaboration. The parties are conducting clinical trials of indications for licensed products as defined in the OSI/Genentech Agreement in accordance with such agreement. Consistent with the parties' development plan under the OSI/Genentech Agreement, and with the approval of the joint steering committee, the parties will agree as to who will own and be responsible for the filing of drug approval applications with the U.S. Food and Drug Administration other than the first new drug application which the Company will own and be responsible for filing and the first supplemental new drug application which the Company will 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. The Company has certain co-promotion rights that may be enacted by mutual agreement at any time provided that the Company has established a commercial operation independent of Tarceva™. Genentech will pay the Company certain milestone payments and the Company will share equally in the operating profits or losses on products resulting from the collaboration.

Under the OSI/Genentech Agreement, the Company granted to Genentech a non-transferable (except under certain circumstances), non-sublicensable (except under certain circumstances), co-exclusive license under the Company's 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 the Company 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. The Company has primary responsibility for patent filings for the base patents protecting Tarceva™ and, in addition, has the right, but not the obligation, to institute, prosecute and control patent infringement claims relating to the base patents. The term of the OSI/Genentech Agreement continues until the date on which both the Company and Genentech are no longer entitled to receive a share of the operating profits or losses on any products resulting from the collaboration. The OSI/Genentech Agreement is subject to early termination in the event of certain defaults. The agreement is also subject to early termination under certain circumstances.

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Under the OSI/Roche Agreement, the Company granted to Roche a license under the Company's intellectual property rights with respect to Tarceva™. Roche is collaborating with the Company 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™ in the world, other than the territories covered by the OSI/Genentech 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 milestone and royalty payments to the Company on sales of products resulting from the collaboration. The Company has primary responsibility for patent filings for the base patents protecting Tarceva™ and, in addition, has the right, but not the obligation, to institute, prosecute and control patent infringement claims relating to the base patents. The term of the OSI/Roche Agreement continues until the date on which the Company is no longer entitled to receive a royalty on products resulting from the development of Tarceva™. The OSI/Roche Agreement is subject to early termination in the event of certain defaults. In addition, after two and one half years from the effective date, Roche may terminate the agreement on a country-by-country basis. The Company may also have the right to terminate the agreement on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

Under the Tripartite Agreement, the Company, Genentech and Roche agreed 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 approvals of Tarceva™ products 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™. The Tripartite Agreement requires each party to spend equally up to a specified amount for the further development of Tarceva™. Each party 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 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.

As discussed in note 10(g), concurrent with the execution of these agreements, the Company entered into separate Stock Purchase Agreements on January 8, 2001 with each of Genentech and Roche Holdings, Inc. for the sale to each of 462,570 newly-issued shares of the Company's common stock for \$35.0 million each.

(b) Anaderm

On April 23, 1996, the Company formed Anaderm with Pfizer 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, the Company amended a prior research agreement with Pfizer and Anaderm to expand the collaborative program. On September 23, 1999 the Company sold its interest in Anaderm to Pfizer. The amended research agreement expired in April 2002, followed by a three-year phase-down period. On April 24, 2002, pursuant to the terms of the Collaborative Research Agreement, the Company entered into the phase-down period of the collaboration. In July 2002, the Company entered into an agreement with Pfizer to accelerate such phase-down period so that it will terminate no later than April 23, 2003. During the phase-down period, the Company will transfer to Anaderm all of the research related to the collaboration. In consideration for the work to be performed by the Company during the accelerated phase-down period, the Company received \$4.5 million in September 2002 and will receive \$3.5 million upon the successful

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completion of the transition period. The Company will retain its rights to receive royalties on the sales of products resulting from the collaboration. The \$4.5 million will be recognized as revenue ratably over the expected term of the transition period and the \$3.5 million will be recognized upon the successful completion of the transition. For the year ended September 30, 2002, the Company recognized approximately \$1.8 million of collaborative program revenues relating to the phase-down.

(c) Tanabe

Effective as of October 1, 1999, the Company entered into a Collaborative Research and License Agreement with Tanabe focused on discovering and developing novel pharmaceutical products to treat diabetes. Under the agreement, the Company is responsible for identification of targets (subject to Tanabe's approval), assay development, screening of compounds from the Company's library and Tanabe's library against identified targets, identification of seed compounds meeting certain criteria specified in the agreement, optimization of these seed compounds and identification of lead compounds meeting certain criteria specified in the agreement. Tanabe maintains responsibility for further development and marketing of a lead compound in exchange for milestone and royalty payments to the Company. If Tanabe determines not to initiate further development of a lead compound or if Tanabe discontinues development of candidate compounds, the Company will have the sole and exclusive right to develop, use, manufacture and sell all products resulting from the collaboration, and it will pay royalties to Tanabe.

The agreement is for a term of four years, with the option to extend for an additional two-year period. On September 28, 1999, the Company received approximately \$4.3 million from Tanabe, which represented advanced funding of the technology access fee of \$3.5 million and research funding of \$812,500 for the first quarter of fiscal 2000. During the first quarter ended December 31, 1999, the Company recognized as revenue the technology access fee of \$3.5 million in accordance with its accounting policy at that time. As a result of the adoption of SAB No. 101 on October 1, 2000, the Company changed its method of accounting for such non-refundable upfront fees to recognize such fees over the term of the related research agreement. This change resulted in a cumulative effect of an accounting change of \$2.6 million recorded in the accompanying consolidated statement of operations for fiscal 2001 (see note 1(b)).

(d) Vanderbilt

Effective as of April 28, 1998, the Company 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. The agreement was for a term of one year, and was extended until the Company executed a third-party research collaboration agreement, which the Company entered into with Tanabe.

Concurrently with the execution of the Tanabe agreement, the Company entered into an Amended and Restated Collaborative Research, License and Alliance Agreement with Vanderbilt and Tanabe with an effective date of August 31, 1999. The term of the research program conducted by the Company and Vanderbilt commenced on April 28, 1998 and will end upon termination of the contract period under the Tanabe agreement unless mutually extended by the Company and Vanderbilt.

The Company is providing funding to Vanderbilt to conduct the OSI/Vanderbilt research program. A portion of this funding comes from Tanabe's funding of the OSI/Tanabe research program. The Company will also 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.

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(e) Pfizer

In April 1986, the Company entered into a collaborative research agreement and a license agreement with Pfizer. The Company 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 the Company a royalty if ultimately commercialized. The Company continues to have rights in joint technology developed during the collaboration.

In June 2000, the Company gained full development and marketing rights to Tarceva™ in order to allow Pfizer to meet certain requirements of the U.S. Federal Trade Commission arising from the FTC's review of Pfizer's merger with 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, the Company received a royalty-free license to all rights for the further development and commercialization of Tarceva™. The terms of the agreement did not require the Company to make any payments to Pfizer for the license. In January 2001, the Company entered into a co-development and marketing partnership with Genentech and Roche for Tarceva™ (see note 5(a)).

(f) Helicon

In July 1997, the Company, Cold Spring Harbor Laboratory and Roche formed Helicon Therapeutics, Inc., a Delaware corporation. In exchange for approximately 30% of Helicon's outstanding capital stock, the Company 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, 2002 and 2001, the Company's investment in Helicon was fully reserved.

Effective as of August 15, 2001, the Company entered into a new compound screening and technology license agreement to provide molecular screening services to Helicon. Under the terms of the agreement, Helicon retains the right to use the screening data solely for its own internal research purposes. Helicon maintains the right for further development of the selected compound in exchange for royalties and milestone payments to the Company. If Helicon determines to further develop the selected compounds identified by the Company, the Company will grant to Helicon a worldwide exclusive license to, among other things, use, manufacture and sell these compounds in exchange for milestones and royalties on product sales. If Helicon determines not to further develop any of the identified selected compounds, the selected compounds and all related data shall be returned to the Company.

(g) Bayer

Effective January 1, 1997, the Company and Bayer entered into an agreement to develop serum-based cancer diagnostic products. Upon the sale of the Company's diagnostic business to Bayer, the agreement terminated. See note 17 for sale of the Company's diagnostic business to Bayer on November 30, 1999.

(h) Other

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

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Total collaborative program revenues under the Company's collaborative research agreements are as follows (in thousands):

	<u>Years Ended September 30,</u>		
	<u>2002</u>	<u>2001</u>	<u>2000</u>
Related Parties:			
Anaderm	\$ 7,649	\$10,244	\$10,288
Pfizer	—	1,909	3,898
Aventis	—	—	2,996
Helicon	<u>175</u>	<u>10</u>	<u>—</u>
Total related parties	7,824	12,163	17,182
Tanabe	4,077	4,335	2,751
Sankyo	75	1,007	1,268
Solvay	—	479	2,240
Bayer	—	—	167
Other	<u>—</u>	<u>—</u>	<u>50</u>
Total	<u>\$11,976</u>	<u>\$17,984</u>	<u>\$23,658</u>

(6) Property, Equipment and Leasehold Improvements

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

	<u>Estimated Life (Years)</u>	<u>September 30,</u>	
		<u>2002</u>	<u>2001</u>
Laboratory equipment	5-15	\$25,639	\$20,166
Office furniture & equipment and computer equipment	3-10	12,536	7,822
Capitalized software	3	2,718	1,580
Leasehold improvements	Life of lease	<u>29,146</u>	<u>14,772</u>
		70,039	44,340
Less: accumulated depreciation and amortization		<u>23,864</u>	<u>18,993</u>
Property, equipment and leasehold improvements — net		<u>\$46,175</u>	<u>\$25,347</u>

The Company capitalized \$2.7 and \$1.6 million of computer software cost as of September 30, 2002 and 2001, respectively, of which \$980,000 and \$263,000 was amortized as of September 30, 2002 and 2001, respectively.

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(7) Intangible Assets

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

	September 30,	
	2002	2001
Goodwill	\$36,528	\$ —
License to compound libraries	458	647
Acquired work force	2,120	3,037
	\$39,106	\$3,684

The above amounts reflect accumulated amortization for license to compound libraries and acquired work forces of \$1.4 million and \$105,000 as of September 30, 2002 and 2001, respectively. The goodwill acquired in connection with the acquisition of certain oncology assets from Gilead, which occurred after July 1, 2001 is not being amortized, in accordance with the provisions of SFAS No. 142. Goodwill acquired prior to July 1, 2001 was fully amortized as of September 30, 2002 and 2001.

(8) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses at September 30, 2002 and 2001 are comprised of (in thousands):

	September 30,	
	2002	2001
Accounts payable	\$ 1,949	\$ 5,332
Accrued future lease escalations	1,144	319
Accrued payroll and employee benefits	2,050	775
Accrued incentive compensation	2,300	1,315
Accrued facility closing costs (see note 16(b))	1,630	5,059
Accrued interest (see note 9)	1,067	—
Accrued clinical research organization and site costs	3,061	1,297
Other accrued expenses	8,861	3,966
	\$22,062	\$18,063

(9) Convertible Senior Subordinated Notes

On February 1, 2002, the Company issued \$200.0 million aggregate principal amount of convertible senior subordinated notes (Notes) in a private placement for net proceeds to the Company of \$192.9 million. The Notes bear interest at 4% per annum, payable semi-annually, and mature on February 1, 2009. The Notes are convertible into shares of the Company's common stock at a conversion price of \$50 per share, subject to normal and customary adjustments such as stock dividends or other dilutive transactions. The Company may redeem the Notes, in whole or in part, at any time before February 1, 2005 if the closing price of the Company's common stock has exceeded 150% of the conversion price then in effect for a specified period of time (Provisional Redemption). Upon any such Provisional Redemption, the Company is required to pay interest that would have been due through February 1, 2005. The Company may also redeem some or all of the Notes at any time on or after February 1, 2005 if the closing price of the Company's common stock has exceeded 140% of the conversion price then in effect for a specified period of time. Upon a change in control, as defined in the indenture governing the Notes, the holders of the Notes will have the right to require the

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Company to repurchase all of the Notes, or a portion thereof, not previously called for redemption at a purchase price equal to 100% of the principal amount of the Notes purchased, plus accrued and unpaid interest. The Company 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 repurchase price divided by 95% of the average of the closing prices of the Company's common stock for the five-trading day period ending on the third business day prior to the repurchase date. The related debt issuance costs of \$7.1 million were deferred and are being amortized on a straight-line basis over the term of the Notes.

With respect to the Notes, the Company pledged \$22.9 million of U.S. government securities (Restricted Investment Securities) with maturities at various dates through November 2004. Upon maturity, the proceeds of the Restricted Investment Securities will be sufficient to pay the first six scheduled interest payments on the Notes when due. The Company considers its Restricted Investment Securities to be held-to-maturity, as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." 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 aggregate fair value and amortized cost of the Restricted Investment Securities at September 30, 2002 were \$19.6 million and \$19.3 million, respectively.

In August and September 2002, the Company retired a total of \$40.0 million in principal amount of the 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 Notes retired and accrued interest, resulted in a net gain on the early retirement of the 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. The Company adopted SFAS No. 145, "Recission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections," effective April 1, 2002 and as a result, the Company did not classify the net gain of \$12.6 million realized in the fourth quarter of fiscal 2002 as an extraordinary item in the accompanying consolidated statements of operations.

At September 30, 2002, the fair value of the outstanding Notes was approximately \$105.9 million based on quoted market value.

(10) Stockholders Equity

(a) Stock Option Plans

The Company has established eight stock option plans for its employees, officers, directors and consultants, including the 2001 Incentive and Non-Qualified Stock Option Plan and two stock option plans adopted upon the acquisitions of Gilead's oncology assets in December 2001 (see note 3(a)) and certain assets from Cadus in July 1999. 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.

The Board of Directors adopted the 2001 Incentive and Non-Qualified Stock Option Plan, effective June 13, 2001, which was approved by the stockholders at the annual meeting of stockholders on March 13, 2002. Under the plan the Company 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 directors, officers, employees and consultants of the Company or a parent or subsidiary of the Company. The plan also continues the automatic, formula-based grants of non-qualified stock options to directors who are not employees of the Company. Persons elected to the board after June 13, 2001 are entitled to an initial grant of a non-qualified option to purchase 30,000 shares of common stock upon their initial election with annual grants of options to purchase

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7,500 shares thereafter upon re-election to the board. Persons elected to the board prior to June 13, 2001 will continue to be eligible 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).

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 related to clinical trial operations, options granted to employees of OSI-UK, and options granted to outside directors:

	Shares (In thousands)	Exercise Price		Weighted Average
		Low	High	
Balance at September 30, 1999 — Unexercised	4,575	\$ 1.75	\$ 9.32	\$ 5.70
Granted	1,243	5.38	41.25	23.70
Exercised	(2,371)	1.75	9.32	5.49
Forfeited	<u>(139)</u>	<u>4.25</u>	<u>23.25</u>	<u>5.90</u>
Balance at September 30, 2000 — Unexercised	3,308	\$ 3.25	\$41.25	\$12.68
Granted	1,043	33.68	60.06	48.59
Exercised	(538)	3.25	23.25	7.05
Forfeited	<u>(55)</u>	<u>4.25</u>	<u>51.80</u>	<u>29.03</u>
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	<u>(533)</u>	<u>3.50</u>	<u>60.06</u>	<u>41.73</u>
Balance at September 30, 2002 — Unexercised	<u>4,610</u>	<u>\$ 3.25</u>	<u>\$60.06</u>	<u>\$26.00</u>

At September 30, 2002, the Company has reserved 8,160,807 shares of its authorized common stock for all shares issuable under options. At September 30, 2002, 2001 and 2000 the number of options exercisable were 2,291,689, 2,147,374, and 1,752,084, respectively.

Information regarding stock options outstanding as of September 30, 2002, is as follows:

Price Range	Shares (in thousands)	Options Outstanding		Options Exercisable	
		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Shares (in thousands)	Weighted Average Exercise Price
\$0.00 - \$10.00	1,368	\$ 6.14	4.5	1,367	\$ 6.14
\$10.01 - \$20.00	110	15.24	7.9	83	15.70
\$20.01 - \$30.00	1,486	22.26	8.0	470	22.87
\$30.01 - \$40.00	191	35.10	6.9	76	35.36
\$40.01 - \$50.00	901	44.74	9.0	26	46.26
\$50.01 - \$60.00	436	51.80	7.0	201	51.80
\$60.01 - \$70.00	118	60.06	8.2	69	60.06

Stock option grants are generally set at the closing price of the Company's common stock on the date of grant and the related number of shares granted are fixed at that point in time, except for one grant as noted below. Therefore under the principles of APB Opinion No. 25, the Company does not recognize compensation

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expense associated with the grant of stock options. SFAS No. 123, "Accounting for Stock-Based Compensation," requires the use of option valuation models to determine the fair value of options granted after 1995. Pro forma information regarding net loss and loss per share shown below was determined as if the Company had accounted for its employee stock options and shares sold under its 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 weighted-average assumptions for fiscal 2002, 2001 and 2000, respectively: risk-free interest rates of 3.86 %, 3.28% and 5.95%, dividend yields of 0%; volatility factors of the expected market price of the Company's common stock of 77.19%, 81.9% and 84.0%; expected life of the employees' options of 3.0 years, 3.0 years, and 4.2 years; and expected life of the consultants' options equal to the remaining contractual life of the options. These assumptions resulted in weighted-average fair values of \$17.19, \$25.29 and \$23.08 per share for stock options granted in fiscal 2002, 2001 and 2000, respectively.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized over the options' vesting periods. The pro forma effect on net loss for the periods presented is not representative of the pro forma effect on net income or loss in future years because it does not take into consideration pro forma compensation expense related to grants made prior to fiscal 1996. The Company's pro forma information is as follows (in thousands, except per share information):

	September 30,		
	2002	2001	2000
Pro forma net loss	\$(235,584)	\$(34,223)	\$(21,542)
Pro forma basic and diluted net loss per share	\$ (6.55)	\$ (1.01)	\$ (0.88)

On August 17, 2000, the Board of Directors granted non-qualified options to purchase up to 250,000 shares of common stock to the Company's then new President and Head of Research and Development. The terms of this grant provided for an option to purchase 100,000 shares of common stock with an exercise price equal to 50% of the fair market value on the grant date, vesting immediately upon his employment on September 28, 2000 and an option to purchase 150,000 shares of common stock with an exercise price equal to the fair market value on the grant date, vesting one-third in a year from the effective date of his employment and monthly thereafter for twenty-four months. Compensation expense resulting from these awards was measured as of September 28, 2000, the effective date of employment. The granting of the options at 50% of fair market value resulted in a compensation charge of \$5.0 million, which is included in R&D expense in the accompanying consolidated statement of operations for fiscal 2000. The granting of the other options resulted in deferred compensation of \$4.4 million which was to be recognized as compensation expense on a straight-line basis over the vesting period. In fiscal 2002 and 2001, \$485,000 and \$1.5 million was recognized as compensation expense. As a result of his resignation as an employee effective February 1, 2002, no additional compensation expense has been recorded subsequent to February 1, 2002 and the remaining deferred compensation of \$2.4 million was reversed.

On August 17, 2000, one member of the Company's Board of Directors retired as a director but continues to provide consulting services to the Company under an existing consulting arrangement. In connection with his retirement, the Board of Directors declared the then outstanding unvested options held by this director as immediately vested. Absent this acceleration in vesting, the unvested options would have continued to vest pursuant to the original terms of the option award. The modification to the vesting schedule caused a new measurement date for the unvested options which resulted in an incremental intrinsic value of \$1.6 million. The incremental intrinsic value was not reflected as compensation in the accompanying consolidated statements of operations as the individual continued to provide services to the Company through the original vesting period of such options. In fiscal 2002, 2001 and 2000, the Company granted options to certain non-

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employees to purchase 8,500, 127,000 and 80,000 shares of common stock, respectively. Such options vest over a three year period, based upon future service requirements. The Company recorded net deferred compensation of \$49,000 and \$1.0 million based on the fair value of such options as of September 30, 2002 and 2001, respectively, as determined using a Black-Scholes option pricing model (see above for weighted average assumptions used). Such compensation cost is amortized to expense using the methodology prescribed in FASB Interpretation No. 28 over the respective vesting periods. In accordance with EITF Issue 96-18, "Accounting For Equity Instruments that Are Issued to Other Than Employees for Acquiring, or In Conjunction with Selling, Goods or Services," the amount of compensation expense to be recorded in future periods related to the non-employee grants is subject to change each reporting period based upon the then fair value of these options, using a Black-Scholes option pricing model, until expiration of the grant vesting period. The Company recorded compensation expense in fiscal 2002 of \$612,000 for shares granted in fiscal 2002, 2001 and 2000. The Company recorded compensation expense in fiscal 2001 of \$1.8 million for shares granted in fiscal 2001, 2000 and 1999. The Company recorded compensation expense in fiscal 2000 of \$1.8 million for shares granted in fiscal 2000, 1999 and 1998.

In April 1999, new tax regulations became effective in the UK requiring employers to remit a national insurance contribution (NIC) tax on gains on the exercise of stock options by employees. This NIC tax applies to the Company's grants of options to its UK employees in 1999, 2000 and 2001. On June 12, 2001, the Company obtained Inland Revenue approval to statutorily transfer the employer NIC liability to the employee.

(b) Shareholder Rights Plan

On September 27, 2000, the 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 the Company's then current shareholder rights plan. The Company 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 the outstanding common stock of the Company 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 the Company merges with, or sells 50% or more of its 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 the Company 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.

The Company can redeem the rights at any time before (but not after) a person has acquired 17.5% or more of the Company's 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

The Company has 200,000,000 shares of authorized common stock, with a par value of \$.01 and 5,000,000 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 the Company's Board of Directors.

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(d) Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan under which eligible employees may contribute up to 10% of their base earnings toward the quarterly purchase of the Company's 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 2002, 2001 and 2000, 19,046, 3,350 and 6,811 shares were issued with 163, 57 and 48 employees participating in the plan, respectively. At September 30, 2002, the Company has reserved 608,704 shares of its authorized common stock in connection with this plan.

The Company sponsors a stock purchase plan for employees of OSI-UK, its 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 the Company's 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. A maximum of 100,000 shares may be issued under the plan. As of September 30, 2002, there were 94 employees, eight employees and 17 employees participating in the 2002, 2001 and 2000 stock purchase plans, respectively. At September 30, 2002, the Company has reserved 66,920 shares of its common stock in connection with this plan.

(e) Private Placement

On February 28, 2000, the Company sold 3.325 million newly-issued shares of its common stock to a select group of institutional investors for net proceeds of approximately \$53 million.

(f) Public Offering

On November 6, 2000, the Company concluded a public offering of 5.35 million shares of common stock at a price of \$70.00 per share. Gross proceeds totaled \$374.5 million with net proceeds of approximately \$351.4 million after all underwriting and other related fees were deducted. In addition, on November 21, 2000, the underwriters associated with this offering exercised their over-allotment option to purchase an additional 802,500 shares of common stock at a price of \$70.00 per share. Gross proceeds from the exercise of the over-allotment option totaled \$56.2 million with net proceeds of \$52.8 million.

(g) Stock Purchase Agreements

Concurrently with the execution of the collaboration agreements described in note 5(a), the Company entered into separate Stock Purchase Agreements on January 8, 2001 with each of Genentech and Roche Holdings for the sale to each of 462,570 newly-issued shares of the Company's common stock. The purchase price was \$75.664 per share, or an aggregate purchase price of \$35 million each. No underwriters or placement agents were involved in the purchase and sale of the securities. The transactions contemplated under the collaboration agreements and Stock Purchase Agreements closed on January 30, 2001.

(h) Issuance of Common Stock to Gilead

On December 21, 2001, in connection with the acquisition of certain oncology assets from Gilead, the Company issued 924,984 shares of common stock valued at \$40.0 million (see note 3(a)).

(i) Convertible Notes

On February 1, 2002, the Company issued \$200.0 million aggregate principal amount of the notes in a private placement. In August and September 2002, the Company retired a total of \$40.0 million in principal amount of the Notes for an aggregate purchase price of approximately \$26.2 million. The Notes are

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convertible into shares of the Company's common stock at a conversion price of \$50 per share, subject to normal and customary adjustments such as stock dividends or other dilutive transactions (see note 9).

(11) Income Taxes

There is no provision (benefit) for federal or state income taxes, since the Company has incurred operating losses since inception and has 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,	
	2002	2001
Deferred tax assets:		
Net operating loss carry forwards	\$ 95,713	\$ 48,174
Research and development credits	6,203	1,295
Intangible assets	—	686
Unearned revenue	5,460	9,485
Purchased research and experimental expenditures	51,642	—
Other	9,112	7,536
	168,130	67,176
Valuation allowance	(167,970)	(67,176)
	160	—
Deferred tax liability:		
Intangible assets	(160)	—
	(160)	—
	\$ —	\$ —

As of September 30, 2002, the Company has available federal net operating loss carry forwards of approximately \$241 million which will expire in various years from 2003 to 2022, and may be subject to certain annual limitations. The Company's research and development tax credit carry forwards expire in various years from 2005 to 2022.

Of the \$168 million valuation allowance at September 30, 2002, \$88 million relates to deductions for employee stock options for which the tax benefit will be credited to additional paid in capital if realized.

(12) Commitments and Contingencies

(a) Lease Commitments

The Company leases office, operating and laboratory space under various lease agreements.

Rent expense was approximately \$6.2, \$2.1 and \$2.0 million for fiscal 2002, 2001 and 2000, respectively. The rent expense for fiscal 2002 includes the Oxford, England facility leases (acquired in September 2001), the Boulder, Colorado facility leases (acquired in December 2001), the Farmingdale, New York lease (commenced in June 2002) and the expansion of the Melville, New York facility (commenced June 2002). This was offset by the termination of the Tarrytown, New York lease (August 2002). Beginning in April 2002, rental payments for the Birmingham, England facility were charged against the closing cost accrual (see note 16(b)).

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The following is a schedule of future minimum rental payments for the next five fiscal years and thereafter required as of September 30, 2002, assuming expiration of the leases for the Birmingham, England facility by January 4, 2006, the Uniondale facility on June 30, 2006, the Melville, New York facility on December 31, 2009, the two Oxford, England facilities on August 24, 2009 and March 31, 2021, respectively, the Farmingdale facility on May 31, 2022, and the Boulder facilities by October 16, 2006. Also included in the amounts below are commitments for equipment under various operating leases (in thousands).

2003	\$ 6,952
2004	7,047
2005	6,982
2006	5,567
2007	4,232
2008 and thereafter	<u>55,443</u>
	<u>\$86,223</u>

As of September 30, 2002, the Company has entered into capital commitments of approximately \$510,000 relating to the refurbishment and upgrading of the two Oxford facilities and one of the Boulder facilities.

(b) Contingencies

From time to time, the Company has received several letters from other companies and universities advising the Company that various products under research and development by the Company may be infringing on existing patents of such entities. These matters are reviewed by management and outside counsel for the Company. Where valid patents of other parties are found by the Company to be in place, management will consider entering into licensing arrangements with the universities and/or other companies or modify the conduct of its research. The Company's future royalties, if any, may be reduced by up to 50% if its licensees or collaborative partners are required to obtain licenses from third parties whose patent rights are infringed by the Company's products, technology or operations. In addition, should any infringement claims result in a patent infringement lawsuit, the Company could incur substantial costs in defense of such a suit, which could have a material adverse effect on the Company's business, financial condition and results of operations, regardless of whether the Company were successful in the defense.

(c) Borrowings

As of September 30, 2002, the Company had a line of credit with a commercial bank in the amount of \$10.0 million. This line expires annually on March 31st, and its current rate of interest is prime plus $\frac{3}{4}$. There were no amounts outstanding under the line of credit as of September 30, 2002. In addition, in 1999, the Company obtained a secured loan of \$500,000 from the same bank. The loan was payable over a three-year period, with monthly principal payments of \$13,888, plus interest at 8.12%. The loan balance as of September 30, 2001 was \$111,000 and was fully repaid as of September 30, 2002.

In connection with the acquisition of certain assets from Gilead in December 2001 (see note 3(a)), the Company assumed certain liabilities from Gilead including loans utilized to finance equipment. The loans have fixed interest rates ranging from 11.50% to 11.90% and are due in full by June 2003. The loan balance as of September 30, 2002 was \$275,000. The Company's wholly-owned subsidiary, OSI-UK, also maintains certain loans to finance equipment. The loans have interest rates ranging from 10.98% to 16.30% and are due in full by October 2003. The loan balance as of September 30, 2002 was \$265,000.

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(d) Derivative Financial Instruments

The Company, at times, minimizes risk by hedging the foreign currency exposure of the Company's net investment in foreign operations through the purchase of forward foreign exchange contracts. At September 30, 2000, the Company had \$1.0 million in such contracts, with remaining terms not exceeding six months. The difference between the foreign currency rate in the contract and such rate as of September 30, 2000 was immaterial to the results of operations for fiscal 2000.

During fiscal 2002 and 2001, the Company did not have any forward foreign currency exchange contracts or other derivative instruments. The Company does not enter into derivative instruments for any purpose other than cash flow hedging; the Company does not speculate using derivatives.

(13) Related Party Transactions

One director is a partner in a law firm which represents the Company on its patent and license matters. Fees paid to this firm in fiscal 2002, 2001 and 2000 were approximately \$504,000, \$546,000 and \$482,000, respectively. One director is a controlling member of Mehta Partners LLC with which the Company has a strategic and financial services arrangement. In fiscal 2002, 2001 and 2000, the Company paid Mehta approximately \$175,000, \$175,000 and \$490,000 for consulting services received. In addition, the Company has compensated other directors for services performed pursuant to consultant arrangements. In fiscal 2002, 2001 and 2000, consulting fees in the amounts of approximately \$153,000, \$151,000 and \$292,000, respectively, were paid by the Company pursuant to these arrangements. A director is an officer of Cold Spring Harbor Laboratory which was a founder of Helicon and Amplicon (which was acquired by Tularik). The Company's former chairman was a member of the board of directors of Anaderm through September 1999 and is on the board of directors of Helicon. An executive officer of the Company was vice president of Helicon through November 2002 and vice president of Anaderm through November 2001. A director was the chief executive officer of Helicon through December 1999. The Company has a fully reserved investment in Helicon and sold its investment in Tularik in December 1999 (note 4). A director is on the faculty of Vanderbilt with which the Company has a collaborative research agreement, and also has a consulting agreement with the Company. A director is a non-executive director of Genentech and is an advisor to Roche, both entities with which the Company has collaboration agreements.

An officer and a vice president of the Company have outstanding loans with the Company aggregating \$200,000 with a carrying amount of \$184,000 as of September 30, 2002. The Company assumed these loans in connection with the acquisition of certain assets from Gilead on December 21, 2001 (see note 3(a)).

(14) Employee Savings and Investment Plan

The Company sponsors an Employee Savings and Investment Plan under Section 401(k) of the Internal Revenue Code. The plan allows 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, the Company will contribute an additional 50 cents into the funds. For fiscal 2002, 2001 and 2000, the Company's expenses related to the plan were approximately \$502,000, \$350,000 and \$277,000, respectively.

The Company also sponsors four pension plans covering the employees of OSI-UK, its wholly-owned subsidiary. 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. The Company 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 (see note 3(b)), as well as certain former employees of British

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Biotech hired by the Company 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, the Company will contribute up to 9% into the funds. The Company also sponsors 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, the Company will contribute up to 9% into the funds. For fiscal 2002, 2001, and 2000, the Company's expenses related to the plans were approximately \$602,000, \$186,000 and \$190,000, respectively.

(15) Employee Retirement Plan

On November 10, 1992, the Company 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.

The Company follows SFAS No. 106, "Employer's Accounting for Postretirement Benefits Other Than Pensions" to account for 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.

Net postretirement benefit cost for fiscal 2002, 2001 and 2000 includes the following components (in thousands):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Service cost for benefits earned during the period	\$255	\$159	\$152
Interest cost on accumulated postretirement benefit obligation	189	156	156
Amortization of initial benefits attributed to past service	<u>6</u>	<u>6</u>	<u>6</u>
Net postretirement benefit cost	<u>\$450</u>	<u>\$321</u>	<u>\$314</u>

The accrued postretirement benefit cost at September 30, 2002 and 2001 was as follows (in thousands):

	<u>2002</u>	<u>2001</u>
Accumulated postretirement benefit obligation	\$3,508	\$2,246
Unrecognized cumulative net loss	(930)	(53)
Unrecognized transition obligation	<u>(108)</u>	<u>(113)</u>
Accrued postretirement benefit cost	<u>\$2,470</u>	<u>\$2,080</u>

The changes in the accumulated postretirement benefit obligation during fiscals 2002 and 2001 were as follows (in thousands):

	<u>2002</u>	<u>2001</u>
Balance at beginning of year	\$(2,246)	\$(2,142)
Benefit payments	60	127
Gain/(loss) experience	(878)	84
Service cost	(255)	(159)
Interest cost	<u>(189)</u>	<u>(156)</u>
Balance at end of year	<u>\$(3,508)</u>	<u>\$(2,246)</u>

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The accumulated postretirement benefit obligation was determined using a discount rate of 6.75% and 7.5% in 2002 and 2001, respectively. In fiscal 2002, the health care cost trend was increased to an initial level of 8%, decreasing to an ultimate rate of 5% by 2016. The health care cost trend rate used in 2001 was a fixed 5%. 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, 2002 by approximately \$736,000 and the fiscal 2003 net postretirement service and interest cost by approximately \$191,000. Benefits paid during fiscal 2002, 2001 and 2000 were \$60,000, \$127,000 and \$119,000, respectively.

(16) Consolidation of Facilities

(a) Tarrytown

During the fourth quarter of fiscal 2001, the Company announced its strategic decision to close down its Tarrytown, New York facility and consolidate its operations into its Farmingdale, New York facility. The operations at the facility ceased on June 30, 2002 and the Company closed the facility in August 2002. The fungal extract libraries and certain furniture and equipment from the Tarrytown, New York facility were relocated to the other company 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, the Company entered into a Termination and Surrender Agreement with the landlord of the Tarrytown facility whereby it was released from its obligations under the lease.

The estimated cost of closing this facility as of September 30, 2001 was \$775,000, and has been included in the accompanying consolidated balance sheet in accrued expenses as of September 30, 2001, and in R&D expense (\$673,000) and in selling, general and administrative expenses (\$102,000) in the accompanying consolidated statement of operations for fiscal 2001. The charge consists of write down of equipment and leaseholds, which were not relocated, of \$384,000, and severance costs of \$391,000.

During fiscal 2002, the Company paid \$418,000 in severance costs, of which \$391,000 was charged against the closing costs accrual, and \$19,000 has been included in R&D and \$8,000 has been included in selling, general and administrative costs in the accompanying consolidated statement of operations for fiscal 2002. The Company also wrote-off \$511,000 of leasehold improvements and furniture and equipment which were not relocated to the other facilities, net of cash proceeds received from the sale of furniture and equipment. The Company charged \$384,000 of this write-off against the closing costs accrual and \$126,000 is included in the accompanying consolidated statement of operations for fiscal 2002. As of September 30, 2002, there are no accrued closing costs in the accompanying consolidated balance sheet relating to the Tarrytown facility. The consolidation activity for the fiscal year ended September 30, 2002 was as follows (in thousands):

	<u>Severance Costs</u>	<u>Writedown of Equipment and Leaseholds</u>	<u>Total</u>
Balance at September 30, 2001	\$ 391	\$ 384	\$ 775
Cash Paid/writedowns	<u>(391)</u>	<u>(384)</u>	<u>(775)</u>
Balance at September 30, 2002	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

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(b) Birmingham

During the fourth quarter of fiscal 2001, the Company announced the decision to consolidate its Birmingham, England facility with the newly acquired Oxford, England facility as a result of the acquisition of the British Biotech assets (see note 3(b)). The operations at the facility ceased on March 31, 2002; however, the Company is still in the process of closing down the facility. 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 and has been included in the accompanying consolidated balance sheet in accrued expenses as of September 30, 2001, in R&D expense (\$3.8 million) and selling, general and administrative expenses (\$511,000) in the accompanying consolidated statement of operations for fiscal 2001. The charge consists 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 are not being relocated of \$2.1 million, and severance costs of \$190,000.

During fiscal 2002, the Company paid \$244,000 in severance costs, of which \$185,000 was charged against the closing costs accrual, \$28,000 and \$31,000 have been included in R&D expense and selling, general and administrative costs, respectively, in the accompanying consolidated statement of operations for fiscal 2002. During fiscal 2002, the Company has also paid rental expense and costs to restore the facility to its original condition in the amount of \$932,000, which have been charged against the closing costs accrual. The Company adjusted the accrual for lease exit costs based on a revised estimate of costs to restore the facility to its original condition. As a result, a credit of \$69,000 is included in selling, general and administrative costs in the accompanying consolidated statement of operations for fiscal 2002. An adjustment of \$537,000 was also made to the accrual to reflect a longer-than expected lease term relating to one of the leases at the Aston facility. As a result, a charge of \$486,000 and \$51,000 is included in R&D expense and selling, general and administrative costs, respectively, in the accompanying consolidated statement of operations for fiscal 2002. The Company also wrote-off approximately \$2.3 million of leasehold improvements and furniture and equipment which were not relocated to the Oxford facility. The Company charged \$2.2 million of this write-off against the closing costs accrual and \$97,000 is included in the accompanying consolidated statement of operations for fiscal 2002. As of September 30, 2002, the remaining restructuring reserve relating to the consolidation of this facility was \$1.6 million relating to non-cancelable lease exit costs. The consolidation activity for the fiscal year ended September 30, 2002 was as follows (in thousands):

	<u>Severance Costs</u>	<u>Lease Exit Costs</u>	<u>Writedown of Equipment and Leaseholds</u>	<u>Total</u>
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	<u>\$ —</u>	<u>\$1,630</u>	<u>\$ —</u>	<u>\$ 1,630</u>

(c) North Carolina

During fiscal 1999, the Company made the strategic decision to close down its facilities in North Carolina and consolidate its natural products operations into its Tarrytown, New York facility. This close-down occurred on March 31, 2000. The fungal extract libraries and certain equipment were relocated to the

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Tarrytown facility. None of the employees at the North Carolina facility were relocated. Under the plan for relocating this facility, 16 research and administrative employees received a severance package, which included continued payments of four months salary, plus four months of continuous health insurance. The leases in North Carolina were scheduled to expire in 2004. The Company accrued an estimate of a reserve for an expected delay in finalizing a new tenant and its assumption of the Company's existing lease.

The estimated cost of closing this facility was \$535,000, and was included in the consolidated balance sheet in accrued expenses as of September 30, 1999, in R&D expense (\$395,000) and in selling, general and administrative expenses (\$140,000) in the consolidated statement of operations for fiscal 1999. During fiscal 2000, the Company incurred approximately \$432,000 principally in severance and subleasing-related costs, including a \$61,000 loss resulting from the assumption of a lease and related leasehold improvements by a third party. At September 30, 2001, the plan was completed and no liability remains.

(17) Sale of Diagnostics Business

On November 30, 1999, the Company sold assets of its diagnostics business to Bayer including the assets of the Company's wholly-owned diagnostics subsidiary, OSDI, based in Cambridge, Massachusetts. The assets sold included certain contracts, equipment and machinery, files and records, intangible assets, intellectual property, inventory, prepaid expenses and other assets primarily related to the operations of the diagnostics business. In connection with the sale, the Company and OSDI entered into certain agreements with Bayer including an Assignment and Assumption of Lease with respect to the OSDI facility located in Cambridge. Under the terms of the agreement, the Company received \$9.2 million up-front from Bayer with additional contingent payments of \$1.0 million made to the Company in December 2001.

The Company recorded a gain on the sale of approximately \$3.7 million during fiscal 2000. The net gain was calculated as follows (in thousands):

Cash received from Bayer	\$ 9,151
Accrued expenses assumed by Bayer	599
Net book value of fixed assets sold	(611)
Net book value of patent costs (intangibles)	(4,748)
Professional and legal fees incurred	(172)
Commission costs paid	(315)
Other related costs	<u>(158)</u>
Gain on sale of diagnostics business	<u>\$ 3,746</u>

The Company also recorded a gain on the sale of \$1.0 million during fiscal 2002 upon receipt of the additional contingent payment.

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(18) Quarterly Financial Data (unaudited)

The tables below summarize the Company's unaudited quarterly operating results for fiscal 2002 and 2001.

	Three Months Ended (In thousands, except per share data)			
	December 31, 2001	March 31, 2002	June 30, 2002	September 30, 2002
Revenues	\$ 5,892	\$ 6,770	\$ 4,510	\$ 4,644
Net loss	\$(142,382)	\$(24,515)	\$(29,440)	\$(22,142)
Basic and diluted net loss per weighted average share of common stock outstanding	\$ (4.05)	\$ (0.68)	\$ (0.81)	\$ (0.61)

	Three Months Ended (In thousands, except per share data)			
	December 31, 2000	March 31, 2001	June 30, 2001	September 30, 2001
Revenues	\$ 5,695	\$7,531	\$ 6,339	\$ 6,457
Net (loss) income before cumulative effect of accounting change	\$(3,022)	\$1,351	\$(4,760)	\$(14,699)
Net (loss) income	\$(5,647)	\$1,351	\$(4,760)	\$(14,699)
Basic and diluted net (loss) income per weighted average share of common stock outstanding:				
Before cumulative effect of accounting change	\$ (0.10)	\$ 0.04	\$ (0.14)	\$ (0.42)
After cumulative effect of accounting change	\$ (0.18)	\$ 0.04	\$ (0.14)	\$ (0.42)

The basic and diluted net (loss) income 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) income per common share for the fiscal year.

(19) New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued 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 future 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 with indefinite useful lives no longer be amortized, but instead tested for impairment at least annually in accordance with the provisions of SFAS No. 142. Amortization expense relating to goodwill was \$0, \$694,000 and \$694,000 for the years ended September 30, 2002, 2001 and 2000, respectively. SFAS No. 142 also 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. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." SFAS No. 141 and No. 142 are effective for fiscal years beginning on or after December 15, 2001; however, both of these statements are effective for acquisitions and other intangibles acquired on or after July 1, 2001. The Company adopted the applicable provisions of these statements for the accounting of the acquisition of certain oncology assets from Gilead and the British Biotech asset acquisition,

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which occurred after July 1, 2001 (see notes 3(a) and 3(b) to the consolidated financial statements, respectively).

Upon full adoption of these standards in fiscal 2003, the Company will evaluate its existing intangible assets that were acquired in prior purchase business combinations, and make any necessary reclassifications in order to conform with the new criteria in SFAS No. 141 for recognition apart from goodwill. The Company will be required to reassess the useful lives and residual values of all intangible assets acquired, and make any necessary amortization period adjustments. In addition, the Company will be required to test goodwill and, to the extent an intangible asset is identified as having an indefinite useful life, the intangible asset for impairment in accordance with SFAS No. 142. Any impairment loss will be measured as of the date of adoption and recognized as the cumulative effect of a change in accounting principle. As of September 30, 2002, the Company had goodwill in the amount of \$36.5 million and identifiable intangible assets in the amount of \$2.6 million. The Company is currently assessing the impact of the full adoption of these accounting standards.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" which supercedes SFAS No. 121. 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. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. The Company is currently assessing the impact of adoption of SFAS No. 144.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections." SFAS No. 145, among other things, rescinds SFAS No. 4, which required all gains and losses from the extinguishment of debt to be classified as an extraordinary item and amends SFAS No. 13 to require that certain lease modifications that have economic effects similar to sale-leaseback transactions be accounted for in the same manner as sale-leaseback transactions. The Company adopted SFAS No. 145 effective April 1, 2002, which was the beginning of the fiscal quarter in which this statement was issued. As a result, the Company did not classify the net gain of \$12.6 million realized in the fourth quarter of fiscal year 2002 from the early retirement of a portion of the Company's notes as an extraordinary item in the accompanying consolidated statements of operations.

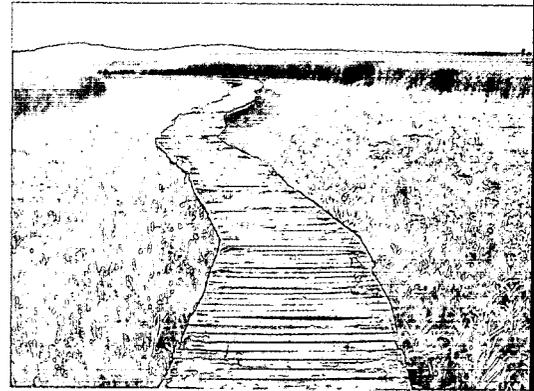
In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities", effective for exit or disposal activities initiated after December 31, 2002. Under SFAS No. 146, a liability for a cost associated with an exit or disposal activity must only be recognized when the liability is incurred. Under the previous guidance of EITF 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity including Certain Costs Incurred in a Restructuring", the Company recognized a liability for an exit or disposal activity cost at the date of its commitment. If the Company were to commit to further exit or disposal activities subsequent to the effective date, it would be subject to the new rules regarding expense recognition.

(20) Subsequent Event

On October 24, 2002, the Company announced certain staffing adjustments, management alignments and business initiatives designed to continue the Company's efforts to refocus its entire business and research development activities into the oncology area. The Company reduced its overall headcount by approximately 40 employees, primarily in the research discovery area, and announced its intention to divest its non-oncology research assets.

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

Not Applicable.



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(osi) pharmaceuticals

58 South Service Road
Suite 110
Melville, NY 11747
631.962.2000 Telephone
631.752.3880 Fax
www.osip.com