ARIS

(osi)™ pharmaceuticals INC

P.E. 9-30-03

ARIS

2003 annual review

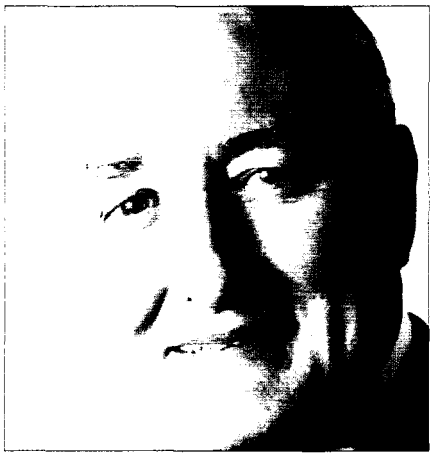
Solving the oncology puzzle

(OSI)™ pharmaceuticals

mission

OSI is 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.

2003 To Our Shareholders



Left to right:
Colin Goddard, Ph.D., *Chief Executive Officer*
Robert A. Ingram, *Chairman of the Board*

WE ARE HAPPY TO REPORT THAT 2003 has been a year of significant progress for OSI as we have continued the process of aggressively building a comprehensive and first-class oncology franchise around our flagship Tarceva™ program. With Tarceva™ continuing to emerge as a unique drug candidate in the anti-HER1/EGFR field, key components of our strategy going into 2003 included obtaining marketed oncology products and clinical development candidates to both enrich our later-stage pipeline and provide a vehicle for seeding a core commercial organization. We have successfully executed this strategy with the timely completion of three major transactions: the addition of Novantrone® to our product portfolio, the acquisition of Cell Pathways, Inc. and a convertible debt financing allowing us to maintain a strong cash position.

2003 was also a year full of momentum in the biotech sector, fueling renewal of investor enthusiasm following one of the most difficult years in the sector's history. In 2003, we witnessed a cascade of high-profile product approvals and clinical trial successes together with the appointment of a Food and Drug Administration (FDA) commissioner, in Mark McClellan, committed to reducing the duration of the product review and approval process. We also saw passage of the landmark Medicare reform bill which has introduced a prescription drug benefit for Medicare patients but also delivered a tough challenge for oncologists in limiting the reimbursement received for IV (intravenous) chemotherapy they administer to cancer patients in their offices. Ironically, both provisions are good news for our flagship product Tarceva™. Assuming approval of Tarceva™ by the FDA, Medicare patients will be able to receive coverage for Tarceva™ taken in the comfort of their own homes. With the change in the reimbursement structure to oncologists, we are also likely to encounter a sea change away from the historical bias of using IV drugs toward innovative and effective oral anti-cancer therapies, like Tarceva™.

Tarceva™—Leading The Way

Firmly in the vanguard of our oncology franchise is Tarceva™, a potent, selective and orally active inhibitor of HER1/EGFR, a receptor that is over-expressed or mutated in a wide variety of solid tumors, including those of the lung, brain, liver, ovary and pancreas. Together with our partners, Genentech and Roche, we have made significant strides forward with our comprehensive global development program, which was carefully designed to study Tarceva™ both in a monotherapy setting and in combination with standard cytotoxics.

We were disappointed, but not surprised, to report in October 2003 the failure of the two front-line, non-small cell lung cancer (NSCLC) studies conducted by our partners, Genentech and Roche. These studies were designed to

assess the concurrent use of Tarceva™ with conventional chemotherapy versus chemotherapy alone in front-line NSCLC; the primary endpoint of both trials was improvement of overall survival. Following the earlier failure of an oral EGFR product being developed by a competitor in August 2002, we anticipated similar results for Tarceva™ and communicated this expectation to our shareholders. Further work is clearly needed to provide more insight into the scheduling and use of EGFR inhibitors in combination with other chemotherapy agents.

Our principal registration study is a worldwide Phase III trial testing Tarceva™ as a monotherapy versus placebo in a second/third-line non-small cell lung cancer setting. The study design was based on the encouraging survival data demonstrated in a Phase II Tarceva™ trial in refractory NSCLC. The study completed enrollment of 730 patients in January 2003, and OSI has been granted Fast Track status from the FDA for this indication. The primary endpoint in the study is improvement in patient survival. We now anticipate top-line data from this Phase III study early in the second quarter of 2004. We believe our Phase II data, the correlations we have observed between dose, rash and survival (which support our high-dose strategy) and the extended timelines we now anticipate to arrive at top-line survival data all support a good level of confidence in a positive outcome for this study. There can be no guarantees until we unblind the data but, assuming positive results, we expect to complete a new drug application (NDA) filing for Tarceva™ by mid-year 2004 and project an approval by the FDA before year's end.

A second Phase III study is evaluating Tarceva™ in pancreatic cancer and compares Tarceva™ in combination with gemcitabine (Gemzar®) versus chemotherapy alone. However, with the previous failure of Tarceva™ in combination with chemotherapy in NSCLC, we consider this study to have a low probability of meeting its survival endpoint.

Clinical data demonstrating encouraging indications of anti-tumor activity for monotherapy Tarceva™ in two disease settings generally considered to be unresponsive to chemotherapy, bronchioloalveolar cell carcinoma (BAC) and glioblastoma multiforme (GBM), were generated in 2003. Genentech, in collaboration with Accelerate Brain Cancer Cure (ABC^2) Clinical Network, has initiated a Phase II study assessing monotherapy Tarceva™ for the treatment of glioblastoma patients.

Behind these registration oriented programs, we have built a comprehensive clinical support program including additional OSI sponsored trials in lung cancer focused on dosing-to-rash and treating earlier stage patients, Genentech sponsored trials combining Tarceva™ with Avastin™ (a novel anti-angiogenic agent) and over 100 supplemental clinical trials investigating Tarceva™ use in different cancer settings and in combination with other cancer treatments.

Plotting the Course: Building a Franchise

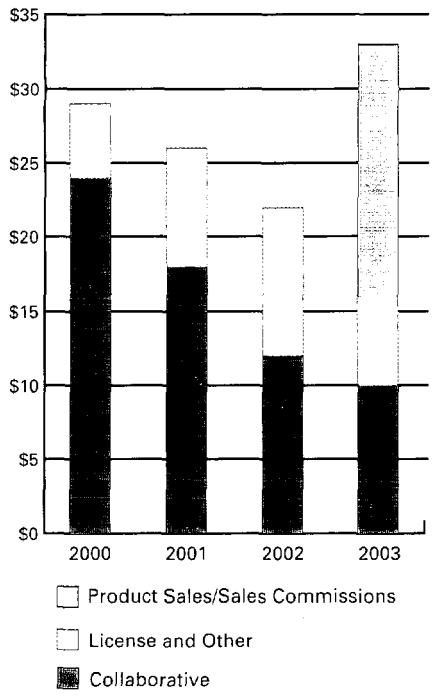
In March 2003, we entered into an agreement with Serono S.A. for OSI to market and promote the drug Novantrone® for oncology uses in the United States. We believe that this was an essential step in the transformation of OSI into a commercial organization, allowing us to plan for sole direct U.S. marketing of future products behind Tarceva™, compete for late-stage development and co-promote license opportunities, and furthermore to provide a framework of commercial support and benefit to Genentech, our U.S. partner for Tarceva™. OSI will receive commissions on net sales of Novantrone® in the U.S. for oncology indications, providing us with a steady cash flow opportunity. Through the first two quarters of promotion by our sales force we have exceeded our revenue targets and expect to generate in excess of $30 million in revenues from this product during 2004.

Around this transaction, we have built a core commercial operation comprising approximately 60 sales, marketing, medical affairs, commercial planning and support personnel including an approximately 30-person sales

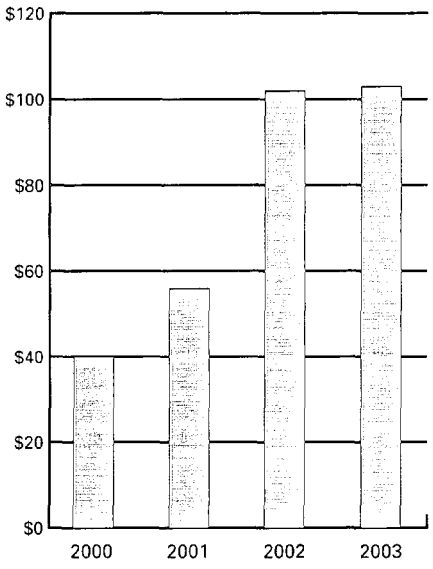
"We have now assembled all of the essential elements that make up a world-class oncology franchise, and we are confident that we have done all that we can to maximize our prospects for success with Tarceva™, a product with the potential to make a real difference in the lives of cancer patients."

COLIN GODDARD, PH.D.
CEO

Revenues (MILLIONS)



R&D Spending (MILLIONS)



From Collaborative-Based to Clinical Development and Commercialization...

After receiving the rights to Tarceva™ back in 2000, OSI transitioned from a research organization engaged in funded collaborations to a fully-integrated research, development and commercial company. We are now focused on proprietary programs in clinical development and are generating commercial revenues from two marketed oncology products.

force. This infrastructure supported the successful re-launch of Novantrone® in the third quarter of 2003 following our first OSI national sales meeting held over the summer.

The second major transaction in 2003 was the acquisition of Cell Pathways in June. Although this acquisition was undertaken primarily to gain access to a well-protected technology platform in apoptosis (one of the key areas of our cancer research and development efforts), it also provided us with an additional oncology product, Gelclair®. This bioadherent oral gel provides relief for the pain associated with oral mucositis, a debilitating side effect often seen in cancer patients undergoing radiation or chemotherapy treatments. Cell Pathways struggled to launch Gelclair® in 2003 through a partnership with Celgene Corporation. Following the closing of the deal, OSI concluded arrangements with Celgene for the return of full North American rights and re-launched the product with our U.S. sales force at the end of the year.

Overall we consider the acquisitions of Novantrone® and Gelclair® to be a pivotal accomplishment in the transformation of the Company into a full-fledged commercial organization. With the re-launch of Novantrone® and Gelclair®, we join a relatively small group of some 30 biotech companies who are promoting more than one product.

The third major transaction of the year was the conclusion of a $150 million offering of subordinated convertible bonds in a private placement for net proceeds of $145.1 million. We used approximately $19 million of these proceeds to re-purchase 503,800 shares of OSI Common Stock in the market with the remainder contributed to our ongoing strategic emphasis on maintaining a strong cash position. We ended our fiscal year with approximately $404 million in cash and investments. We consider this to be a solid accomplishment given the rapid growth of the business and active deal making that we have undertaken over recent years.

Managing the Follow-on Pipeline

Behind Tarceva™ we have a diversified pipeline with product candidates focused in three areas: next-generation targeted therapies, products that induce apoptosis and differentiated cytotoxics.

OSI received two drug candidates from the Cell Pathways acquisition which are currently in clinical development: Aptosyn® and OSI-461. Both are mixed c-GMP phosphodiesterase inhibitors, which cause sustained apoptosis (or programmed cell death). Cell Pathways had completed enrollment of a Phase III study for Aptosyn® in second-line NSCLC prior to the closing of the acquisition. Due to the poor potency of Aptosyn® and the paucity of supporting data, we consider this a high-risk program and it was heavily discounted in the acquisition cost of Cell Pathways. Data will be available in the second half of 2004. We believe that OSI-461, the second Cell Pathways drug candidate, along with additional follow-on molecules, will represent more potent and promising apoptosis drug candidates for treating cancer. Although we are undertaking further Phase I clinical work to optimize dose, exploratory Phase II studies in chronic lymphocytic leukemia, hormone-refractory prostate cancer and renal cell carcinoma are ongoing.

Chemotherapeutic agents have been the mainstay of cancer treatment for decades, and will in our view form a significant component in the physician's arsenal for many years to come. Our differentiated cytotoxic drug candidates are designed to improve upon currently marketed products with similar mechanisms of action. The most advanced of these drug candidates is OSI-7904L, a liposomal formulation of a thymidylate synthase inhibitor. This well-established class of agents is often used to treat metastatic gastrointestinal (including colorectal) and breast cancers. OSI-7904L is currently in a Phase II program, which includes a monotherapy Phase II trial in gastric and gastric-esophageal junction cancers and combination Phase I trials with other chemotherapy agents.

On the targeted therapies front, we have advanced a promising c-kit/KDR

dual kinase inhibitor into late stage pre-clinical development and three molecules are in clinical trials arising from our historical drug discovery program with Pfizer: CP-547,632, a potent and selective inhibitor of the vascular endothelial growth factor receptor (VEGFR), a promising anti-angiogenic agent, which is undergoing a Phase II program; CP-724,714 (designed to target the HER2 gene); and CP-868,596 (designed to target the platelet-derived growth factor receptor). The latter two are both currently in Phase I clinical trials.

Building a Quality Business

We have continued to strengthen the leadership of the Company and our Board of Directors. In May, we appointed Gabriel Leung as Executive Vice President and President, Oncology Business. Before joining OSI, Gabe was with Pharmacia Corporation, where he was a Group Vice President, Global Prescription Business and Head of the successful Pharmacia Global Oncology franchise. Gabe now heads our high-quality core commercial unit which supports marketing, sales and business development.

In June, we appointed Michael G. Atieh to our Board of Directors. Mike is currently Group President of Dendrite International and prior to this was a senior financial executive at Merck & Company. In October, Mike assumed chairmanship of OSI's audit committee. Mike's credentials and experience on the financial side of the pharmaceutical business should provide shareholders with the reassurance that our Audit Committee provides qualified oversight.

We steadfastly heed our goal of building an organization whose moral compass is pointed in the right direction. 2003 has seen us embrace a code of conduct, institute required Sarbanes-Oxley reforms ahead of schedule and emphasize integrity in pursuit of our mission. We are also proud of the spirit of volunteerism amongst our employees as we have proactively reached out to our local communities in support and sponsorship of cancer charity benefits and other worthy fund-raising events.

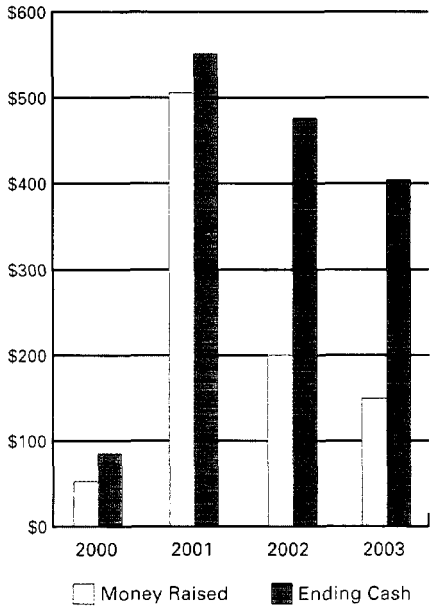
Our Commitment to the Future

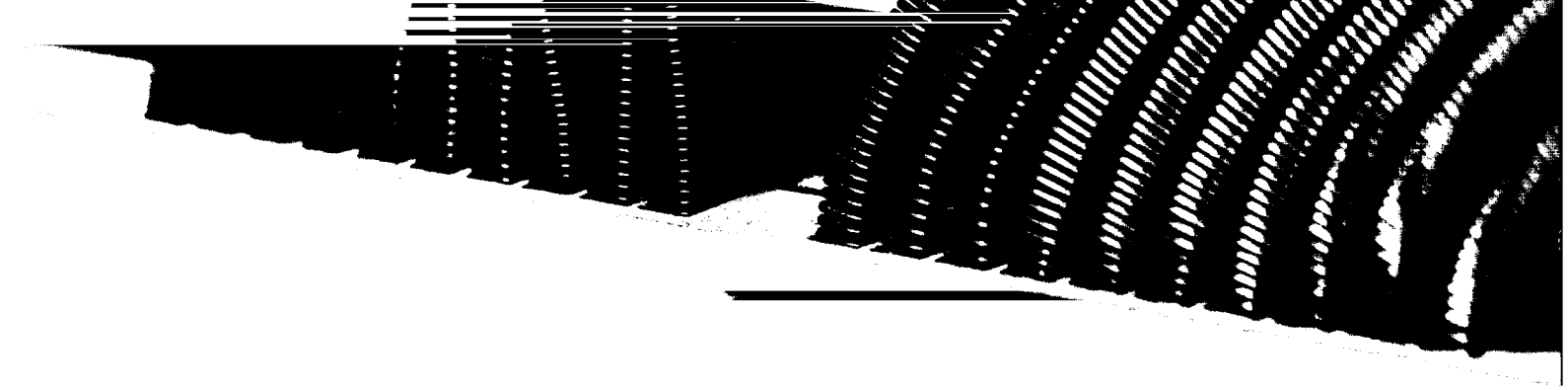
OSI's momentum going into 2004 is driven by the fact that we now have all of the elements in place to allow us to capitalize on the anticipated success of Tarceva™, our flagship program. We have established a winning business model focused on quality and supported by our ability to raise capital and tactically implement an M&A program. This, together with our first-class research and development, regulatory, sales, marketing and commercialization teams, gives us the confidence that we have done all that we can to allow for the successful development and registration of Tarceva™, a product that has the potential to help thousands of cancer patients today and millions more tomorrow. 2003 stands as one of the most momentous years in the history of OSI as we are now solidly positioned for an exciting future as a leading oncology company. Going into 2004, our commitment to you, our shareholders, is that we will be relentless in our drive for excellence as we pursue, on your behalf, our goal of bringing new medicine and new hope to the millions of patients around the world who suffer from cancer. In doing so, we will reward the trust you have invested in us.

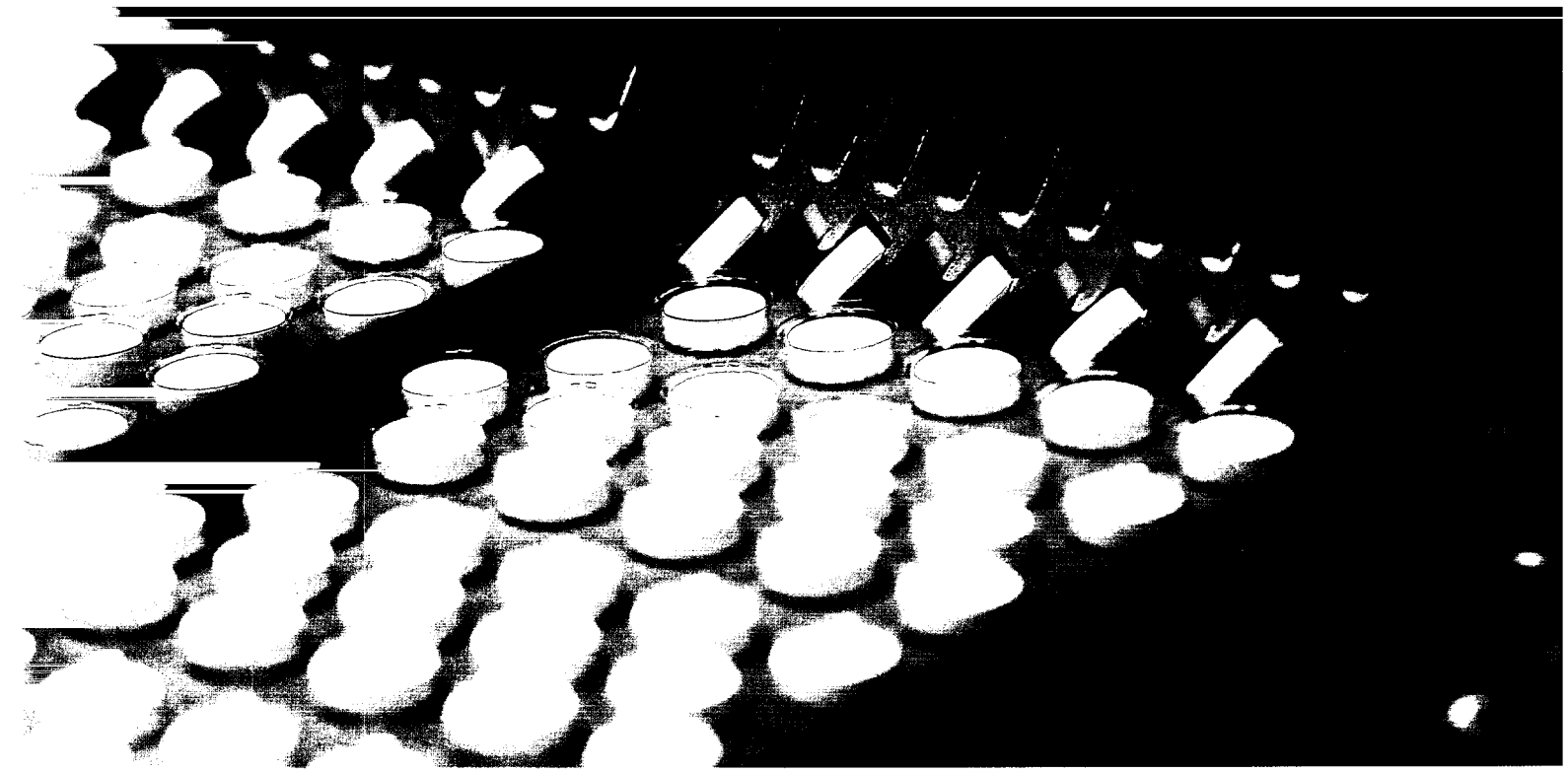
Colin Goddard, Ph.D.
Chief Executive Officer

Robert A. Ingram
Chairman of the Board

Money Raised/Ending Cash and Investments (MILLIONS)







r(evolution)ary

Targeted therapy represents an exciting and important new chapter in cancer treatment. At OSI, we are at the hub of this revolution in discovering, developing and commercializing anti-cancer drugs that can target cancer cells while having minimal side effects on the rest of the body.

Tarceva™

Next-Generation Targeted Therapy

Targeted Therapy—Revolutionizing Cancer Treatment

Cancer remains one of the fields of medical research with many unmet needs. Tremendous private and public resources have been committed to address the devastating healthcare impact of the myriad of individual diseases that comprise cancer. This has resulted in a revolution in our understanding of these diseases at the cellular level and is now leading to innovative advances in the treatment of cancer. Recently, targeted therapeutics have emerged as one of the most significant advancements in cancer research in decades. We have entered into a modern era of targeted therapy for cancer as medications that can target cancer cells with only a limited impact on the rest of the body have become an important part of oncology's cutting edge. At OSI, we are contributing greatly to the evolution of this new era by pioneering and developing anti-cancer drugs that target the multiple underlying mechanisms of cancer.

Tarceva™—Forging the Way

Many of these novel anti-cancer drugs are designed to target growth-regulating genes that can cause cancer when they are either over-expressed or mutated in cancer cells. One of the most important of these oncogenes is the epidermal growth factor receptor (HER1/EGFR). HER1/EGFR is mutated or over-expressed in a variety of tumor types that impact a significant number of the approximately 1.3 million patients newly diagnosed with cancer in the United States each year.

Our most advanced drug candidate, Tarceva™, is a small molecule inhibitor of the epidermal growth factor receptor, or HER1/EGFR. Tarceva™ is designed as a once-a-day pill to inhibit the tyrosine kinase activity of the HER1 signaling pathway inside the cell, which blocks tumor cell growth. We are developing Tarceva™ in a global alliance with Genentech and Roche. Our co-development plan is designed to obtain an effective registration for Tarceva™ while maintaining a competitive position against other EGFR inhibitors.

Tarceva™ has been developed both as a monotherapy (based on a series of positive Phase II trials) and in combination with cytotoxic chemotherapy where we built a Phase III program in front-line non-small cell lung cancer (NSCLC) in response to a competitor's program in this setting. The failure of the competitor's trials in 2002, and the subsequent and anticipated failure of Tarceva™ in similar trials has shown us that the concurrent dosing of oral EGFR inhibitors with cytotoxic chemotherapy regimens in NSCLC is ineffective and that we still have much to learn in this area.

The focal point of our registration program is a worldwide 730 patient

Tarceva™
erlotinib HCl

Tarceva™

Phase III trial testing monotherapy Tarceva™ versus placebo in a second/third-line NSCLC setting with survival as the primary endpoint, while secondary endpoints include progression-free survival, time to symptomatic deterioration and response rate. We are conducting this trial in collaboration with the National Cancer Institute of Canada's Clinical Trial Group. This is the most advanced single-agent, controlled Phase III study of an EGFR-targeted agent designed to detect a survival advantage. Tarceva™ has demonstrated encouraging indications of activity in multiple disease settings (including advanced NSCLC) when used as a single agent and we remain optimistic about our potential for success with this study and expect data in early 2004.

Another Phase III trial being conducted by the alliance is evaluating Tarceva™ in front-line pancreatic cancer comparing Tarceva™ in combination with standard chemotherapy versus chemotherapy alone. Enrollment was complete in January 2003 with top-line results expected in mid-2004. It should be noted that due to the failure of Tarceva™ when used with concurrent chemotherapy in NSCLC, we consider this pancreatic front-line study to be high-risk. The near-term focus for ongoing Tarceva™ development is on its use as a monotherapy and in combination with novel targeted therapies.

Encouraging data in this regard was presented at the 2003 American Society of Clinical Oncology (ASCO) and NCI/EORTC meetings, suggesting that Tarceva™ has a broad range of activity in a number of solid tumor types including bronchioloalveolar cell carcinoma (BAC), hepatobiliary carcinoma and glioblastoma (brain cancer). These cancers are generally considered difficult to treat and unresponsive to chemotherapy.

In the BAC Phase II trial, 50 patients were treated with Tarceva™. Of these 50 patients, 13 (26%) achieved a partial response. The median duration of response has not yet been reached and the study has been expanded to 100 patients.

In a glioblastoma multiforme Phase I study, out of a total of 49 evaluable patients, 8 partial responses (16%), 3 minor responses (6%) and 11 stable disease (22%) were observed. As a result of this encouraging data, Genentech in collaboration with the Accelerate Brain Cancer Cure (ABC^2) Clinical Network initiated a Phase II trial in patients with malignant glioma in August 2003. Top-line data for this ongoing trial is expected in 2004. Tarceva™ was also granted orphan drug status by the FDA in this setting.

In all Tarceva™ trials, an acneiform rash is the most commonly reported side effect. We have now observed a strong correlation between rash and survival in three single-agent Phase II trials using 150 mg/day of Tarceva™ and totaling over 200 patients with refractory NSCLC, head and neck and ovarian cancers that were retrospectively analyzed. The incidence of rash in these studies was approximately 80%. In all trials, patients with rash had longer survival than those without rash. This analysis supports our belief that our higher dose strategy (Tarceva™ induces more rash than a competitive agent at its recommended dose) may translate into an improved survival benefit in larger, randomized and controlled Phase III studies. In November 2003, we announced the initiation of a Phase II dose-to-rash escalation study designed to evaluate the feasibility of safety and effectively dose escalating Tarceva™ to induce tolerable rash.

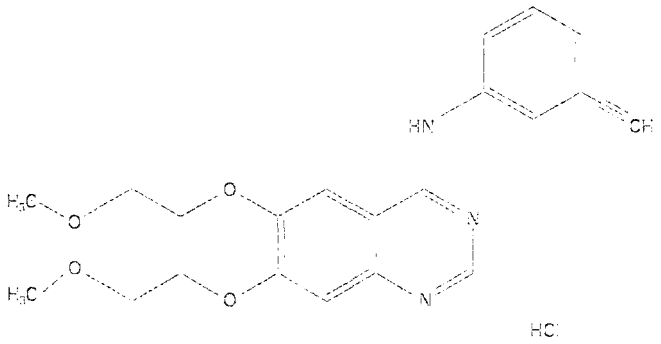
We have also explored combinations of novel targeted therapies. Studies in NSCLC with Tarceva™ used in combination with the anti-angiogenic agent Avastin™ have demonstrated an encouraging initial response rate in the early stages of an ongoing study and a similar study in renal cancer is under way. These studies form part of an extensive clinical program investigating Tarceva™ use in over 100 clinical trial initiatives. Thirty-two of these studies are being conducted in collaboration with the National Cancer Institute's CTEP program and 81 trials are currently approved as part of the alliance's Investigator-Sponsored Trial program.

"The observed correlation between rash and survival previously reported with Tarceva™ and some other agents targeting the HER1/EGFR pathway is intriguing and of particular interest to the oncology community. The preliminary data suggest that it may provide an opportunity to maximize the clinical benefit of Tarceva™ in cancer patients."

ERIC ROWINSKY, M.D.
Institute for Drug Development
Director of Clinical Research

These trials will be supplemented with additional company-sponsored studies as we seek to broaden Tarceva™'s utility to chemotherapy-naïve, front-line NSCLC patients, explore adjuvant use of Tarceva™ subsequent to radiotherapy or chemotherapy, examine Tarceva™'s utility in combination with other novel targeted therapies and explore all-oral cancer drug regimens therapy. This extensive clinical development program is designed to position the product on the forefront of cutting-edge cancer therapy.

In Tarceva™ we continue to believe that we have a cancer blockbuster product in the making with the potential of providing a real difference to the lives of millions of cancer patients around the world.



Tarceva™ erlotinib HCl

Trials

REGISTRATION PROGRAMS	STATUS	ANTICIPATED DATA	
Second/third-line non-small cell lung cancer	Fully enrolled, Phase III	2Q	2004
First-line pancreatic cancer	Fully enrolled, Phase III	2Q/3Q	2004
Glioblastoma multiforme (brain cancer)	Enrollment ongoing, Phase II	2Q/3Q	2004

KEY COMPANY-SPONSORED TRIALS			
Dose-to-rash in non-small cell lung cancer	Enrollment ongoing, Phase II	3Q/4Q	2004
PS 2 monotherapy non-small cell lung cancer	Initiation of Phase II		2005
Tarceva™/Avastin™ in non-small cell lung cancer	Enrollment ongoing, Phase II	3Q/4Q	2004
Tarceva™/Avastin™ in renal cell carcinoma	Enrollment ongoing, Phase II	3Q/4Q	2004

COLLABORATIVE PROGRAMS AND INVESTIGATOR SPONSORED STUDIES		
NCI's Cancer Therapy Evaluation Program	32 Phase I / Phase II trials in various tumor types, both as monotherapy and in combination w/ chemotherapy	2004–2005
Alliance Investigator-Sponsored Trial Program	81 Phase I / Phase II trials in various tumor types, both as monotherapy and in combination w/ chemotherapy	2004–2005

"I was in my early 40s when I was diagnosed with prostate cancer. As a registered nurse caring for men with prostate cancer, I knew I had to make some serious decisions. As part of my treatment, chemotherapy which included Novantrone® offered me as much hope as possible in my fight against this disease. It has now been two years and several months and there is no detectable cancer and I am happy to say that I am feeling good..."

PHILIP BACON
Cancer Survivor

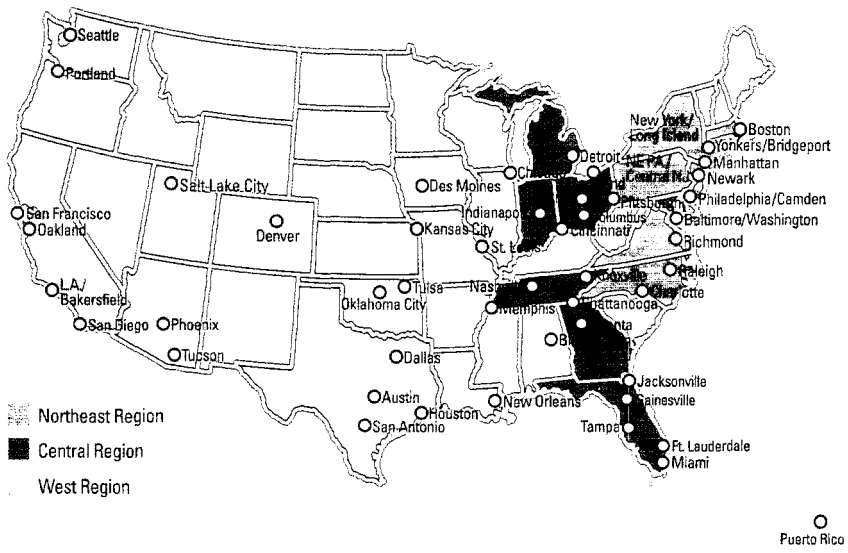
Products

We're now a complete oncology franchise

Assembling a Quality Commercial Operation

Around our two marketed oncology products, Novantrone® and Gelclair®, we have now been able to assemble a quality commercial operation in the United States. Obtaining the marketing rights to these products has been an essential step in the process of becoming a fully integrated oncology franchise and allows us to be well prepared for the potential launch of Tarceva™ in the United States.

OSI'S ESTABLISHED SALES REGIONS

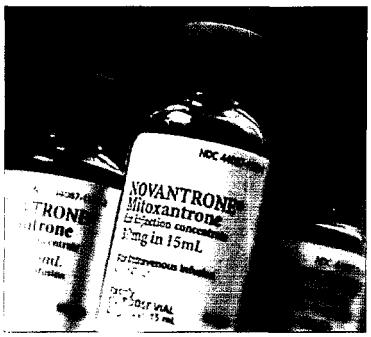


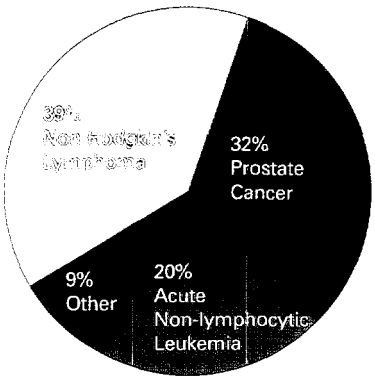
OSI has an established core commercial operation of approximately 60 people including about 30 sales representatives covering the major territories in the United States.

Novantrone®
mitoxantrone
for injection concentrate

Novantrone® is a synthetic antineoplastic anthracenedione used intravenously as an anti-cancer agent. The FDA approved the product in 1987 for acute nonlymphocytic leukemia (ANLL) and in 1996 for the relief of pain associated with hormone-refractory prostate cancer (HRPC), or prostate cancer that no longer responds to hormone therapy. It was also registered for multiple sclerosis (MS)

Novantrone®
mitoxantrone
for injection concentrate





Oncologists use Novantrone® in three main treatment settings in the U.S.

Source: Tandem Cancer Audit 2002 Data

Note: Use of Novantrone® in Non-Hodgkin's Lymphoma is approved ex-U.S. only.

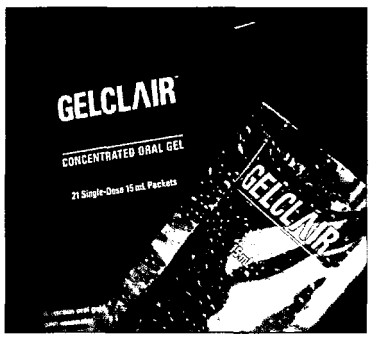
indications in October 2000. In March 2003, OSI entered into an agreement with Serono to market and promote Novantrone® in the oncology marketplace in the United States. To support sales of Novantrone®, the company has built a core commercial operation comprising approximately 60 sales, marketing, medical affairs, commercial planning and support personnel including an approximately 30 person sales force. We have also successfully executed the re-launch of Novantrone® and are actively selling the product across the country. Commissions through our first two quarters of promotion exceeded our estimates and we expect to generate in excess of $30 million in commission revenues in 2004.

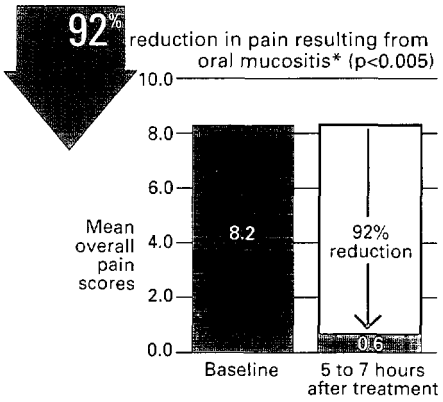
GELCLAIR™
BIOADHERENT ORAL GEL

An estimated 300,000 cancer patients in the United States suffer from oral mucositis, an inflammation and ulceration of the surface of the mouth and throat commonly associated with cancer treatment. Patients receiving high-dose chemotherapy and/or radiation therapy often perceive oral mucositis as the most debilitating toxicity associated with their therapy. In addition, many patients indicate that they receive either no symptom control or only a marginal improvement of their symptoms with current treatment. Symptoms of oral mucositis may include painful ulcerations, redness, and swelling in the mouth. More severe symptoms include extreme pain that may prevent the patient from eating and pose a serious risk of infection resulting in the interruption of cancer therapy. The problem has been a significant unmet need in the management of a cancer patient's health and well-being.

We obtained our second marketed product, Gelclair®, from our acquisition of Cell Pathways. We believe that Gelclair® could be widely used by oncology patients suffering from chemotherapy- or radiotherapy-induced mucositis, as well as any other patient with mucosal oral lesions. Gelclair® is a bioadherent oral gel indicated for the management and relief of oral pain. It provides rapid and durable oral pain relief by adhering to the mucosal surface of the mouth, forming a protective barrier over the mouth and throat, shielding and soothing the exposed and sensitized nerves. We estimate that the product has the potential to grow to an annual net revenue stream in excess of $25 million per year to OSI over the next five years.

The additions of Novantrone® and Gelclair® to our portfolio represent major steps forward as we continue our mission of building a first-class oncology franchise.





* Innocenti, M; Moscatelli, G; Lopes S. Efficacy of Gelclair® in reducing pain in palliative care patients with oral lesions: preliminary findings from an open pilot study. *J Pain Symptom Manage*, 2002; 24:456-457.

for more information

www.gelclair.com
www.novantrone.com

"Eating is something we do every day without thinking about it; however, when going through my chemotherapy treatments the sores in my mouth were so painful, it was difficult to do the simplest of things like swallow. Gelclair® helped me get through my treatments by allowing me to eat and drink... it was an essential part to my recovery."

EDWARD MASTELLONE
Cancer Survivor

R&D

Targeting the Genetic, Molecular and Cellular Basis of Cancer

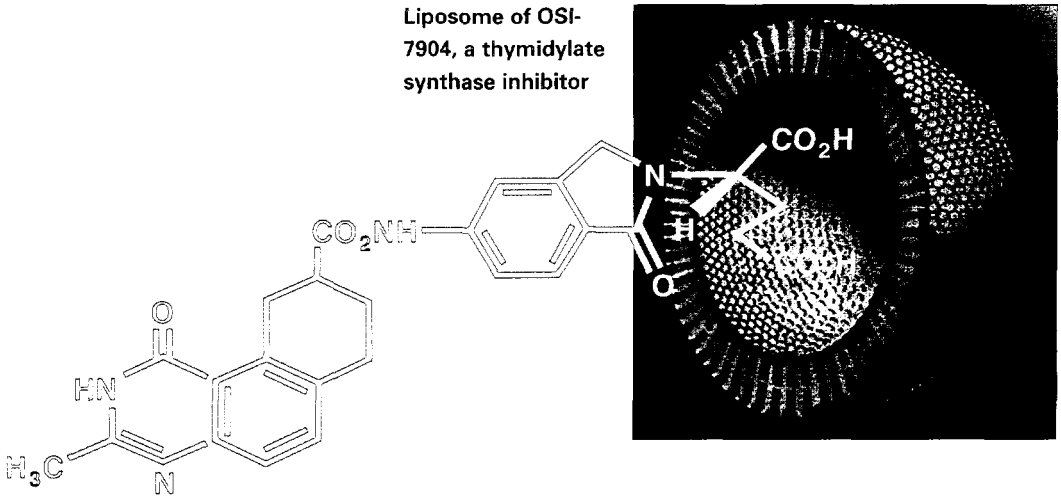
(osi) pharmaceuticals

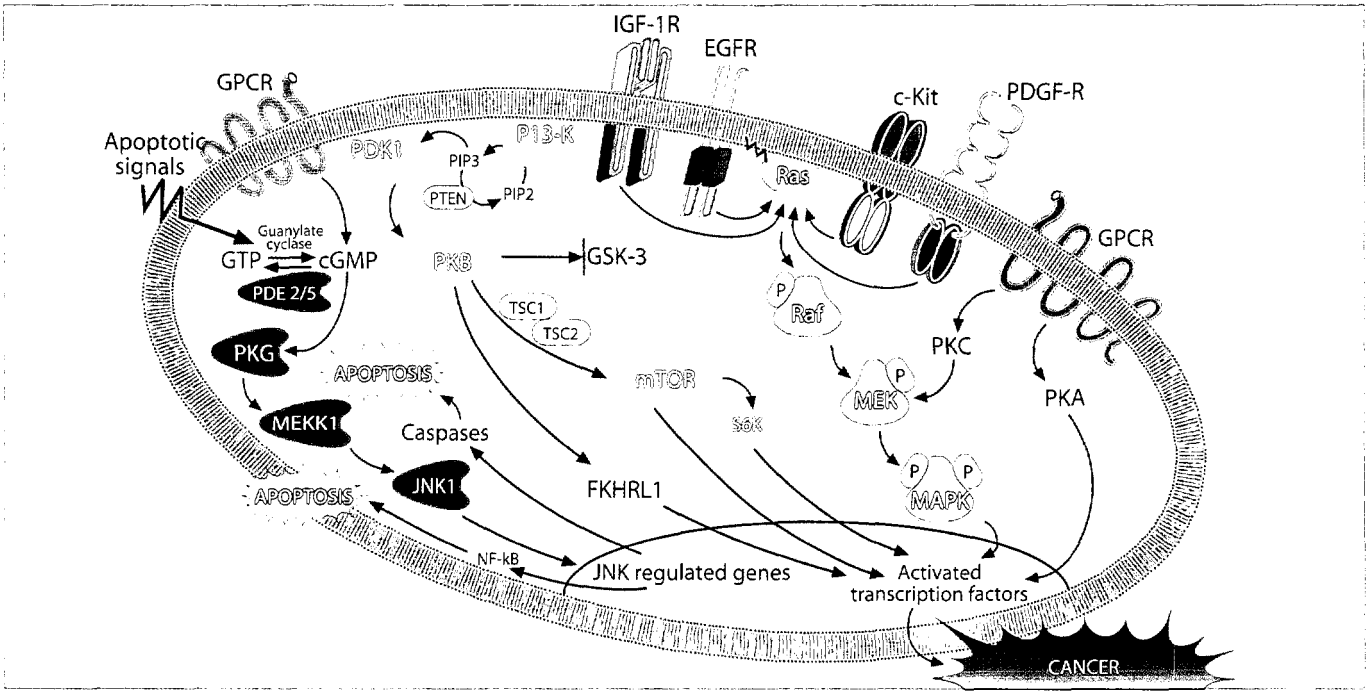
Managing our Pipeline for a Successful Future

PRODUCT	IND TRACK	PHASE I	PHASE II	PHASE III
OSI-7904L (Liposomal TS Inhibitor)				
OSI-461 (Apoptosis Inducer)				
Oncology				
Inflammatory Bowel Disease				
Aptosyn® (Apoptosis Inducer)				
OSI-930 (c-kit/KDR)				
Pfizer Development:				
CP-547,632 (VEGFR)				
CP-724,714 (HER2)				
CP-868,596 (PDGFR)				

In addition to developing targeted therapeutics designed to modulate cell signaling genes involved in apoptosis and the regulation of cellular growth, our approach to cancer therapy also includes next-generation cytotoxics. OSI-930, like Tarceva™ is one of many discovery programs targeting genes involved in the abnormal growth of cancer cells. The apoptosis program utilizes apoptosis inducers to restore and enhance programmed cell death in cancer cells that no longer respond to this tightly regulated process. Our differentiated cytotoxic program is developing new cytotoxic agents which represent improvements in activity or technological innovations of existing therapies.

Liposome of OSI-7904, a thymidylate synthase inhibitor





Apoptosis Program

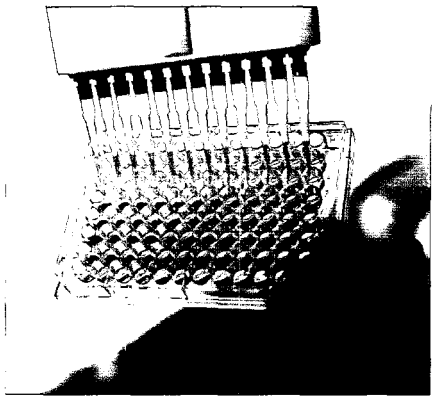
The Cell Pathways acquisition gave us access to a broad technology platform in apoptosis. We acquired an extensive intellectual property estate including rights to two development candidates, Aptosyn® and OSI-461. These products are mixed c-GMP phosphodiesterase inhibitors. In March 2003, Cell Pathways completed enrollment of a 600-patient Phase III study for Aptosyn® in second-line NSCLC prior to the closing of the deal. Based upon the absence of clinical data in NSCLC and the lack of potency exhibited in pre-clinical models, we consider Aptosyn® to be a high-risk drug candidate and the focus of our attention has been on OSI-461 and other follow-on molecules that represent more potent and effective second-generation candidates to Aptosyn®. We are currently optimizing the dose for OSI-461 in extended Phase I trials, although exploratory Phase II studies in chronic lymphocytic leukemia, hormone refractory prostate cancer and renal cell carcinoma are ongoing.

Next-Generation Cytotoxics

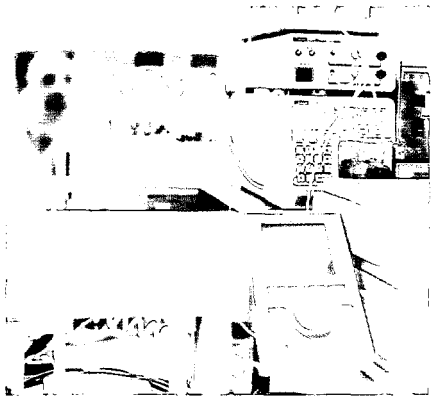
Our lead product candidate in this area is OSI-7904L, a liposomal formulation of the thymidylate synthase inhibitor, GW1843. Thymidylate synthase inhibitors, or TSIs, are a well-proven class of cytotoxic chemotherapy agents that include 5-fluorouracil (5-FU) and Xeloda™. 5-FU remains the most prescribed anti-cancer agent used in the treatment of cancer, especially gastrointestinal and breast cancers. Data have demonstrated that a long-term infusion schedule of 5-FU, although inconvenient to administer, improves its activity. OSI-7094L was formulated in liposomes with a goal of extending its pharmacokinetic half-life, thereby mimicking long infusion 5-FU and improving its therapeutic index as a direct competitor to bolus 5-FU. Data from a Phase I study, demonstrated that OSI-7904L extended the exposure of the drug in patients' blood. We have therefore initiated a Phase II program for OSI-7904L which includes testing the drug in patients with previously untreated advanced gastric or gastro-esophageal junction cancer.

Targeting Cancer Cell Growth

In addition to Tarceva™, we also have three molecules currently in clinical trials resulting from our historical relationship with Pfizer in cancer drug discovery. CP-547,632, a potent and selective inhibitor of the vascular endothelial growth factor receptor (VEGFR), has been advanced to a Phase II study in ovarian cancer patients with minimal



OSI's research operation is equipped with highly automated lead seeking technologies, complemented by world-class biology and chemistry. Our research teams target the genetic, molecular, and cellular basis of cancer.



disease and continues in a Phase I/II study in NSCLC. Phase I trials have been initiated for CP-868,596, a platelet-derived growth factor receptor of PDGF receptor inhibitor. Phase I studies also continue for CP-724,714, an oral HER2 receptor inhibitor.

Research

We have focused our pre-clinical research activities on the discovery of small molecule drugs targeting two core biological processes, namely signal transduction pathways that either drive cancer cell proliferation or prevent apoptosis. Building upon our historical strengths in automated screening, combinatorial chemistry and lead profiling, we have been partnering extensively with academic institutions and biotech companies to create a comprehensive technology and knowledge base for our research organization. The group also chalked up its first success this year moving our dual c-kit/KDR co-inhibitor program to the IND-track stage of development. c-kit and KDR are both receptor tyrosine kinases which function as key regulators in the control of small cell lung cancer growth and angiogenesis respectively.

In Conclusion

Performance has been the key to another busy and successful year at OSI. The Company is now well positioned as a world-class oncology franchise with the ability to meet the challenges inherent in a competitive marketplace. We are entering 2004 with a high degree of optimism in our prospects of success with Tarceva™, a robust cash position, two marketed products and a solid pipeline. As we move forward, our commitment to you, our shareholders, is that we will continue to build an enduring company with the capacity to discover, develop and commercialize high-quality oncology products that will both extend life and improve the quality-of-life for cancer patients around the world.

BOARD OF DIRECTORS

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Chairman of the Board
Executive Chairman, Pharmaceuticals
GlaxoSmithKline

Colin Goddard, Ph.D.
Chief Executive Officer

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

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Senior Vice President
Delphi International

J. Morgan Browne
Former Chief Financial Officer
and Administrative Director
The Cancer Center Laboratory

John H. French II
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Gary K. Granner, M.D.
Director, Vanderbilt Diabetes
Center; Professor, Molecular
Physiology and Biophysics,
Vanderbilt University

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

Hiren Mehta
Delta Partners LLC

Sir Mark Richmond
Formerly Head of Research and
Global Assignments,
Head Research & Development

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

EXECUTIVE MANAGEMENT COMMITTEE

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Chief Executive Officer

Gabriel Leung
Executive Vice President and
President, Oncology Business

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

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Vice President and
Chief Financial Officer

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

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

Neil Gibson, Ph.D.
Vice President, Research

CORPORATE HEADQUARTERS

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

OTHER COMPANY LOCATIONS

OSI Pharmaceuticals (UK)
Limited
Watlington Road
Oxford, OX4 6LT
United Kingdom

OSI Pharmaceuticals (Boulder)
3860 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
1-800-524-4458
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 17, 2004 at 10:00AM at OSI Pharmaceuticals, Inc. Corporate Headquarters 58 South Service Road Melville, New York 11747

ANNUAL REPORT ON FORM 10-K

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

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

STOCK LISTING

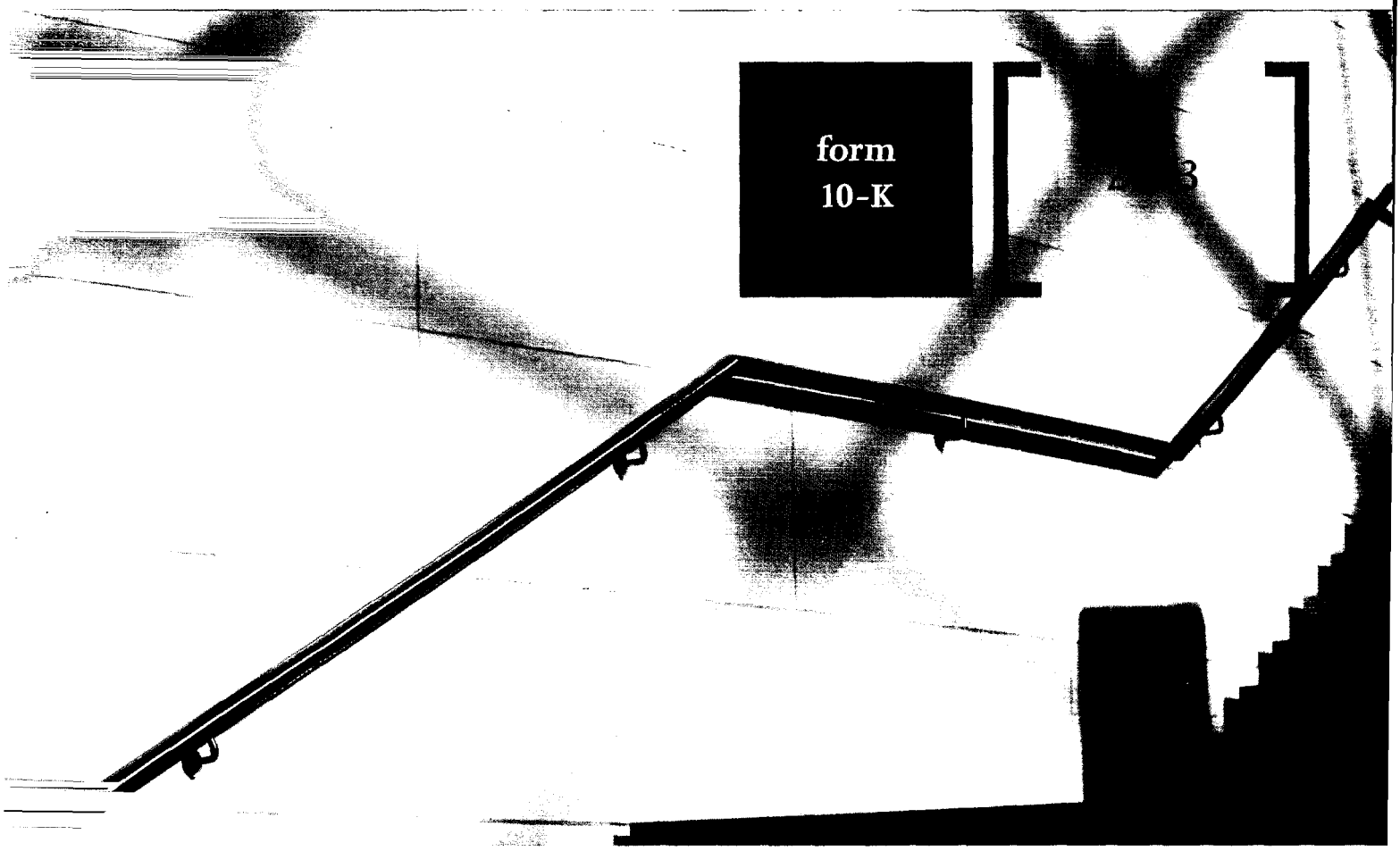
Nasdaq: OSIP

Design: Rose Collora & Lavery, Inc.
www.rclnyc.com
Photography: Mark Asnin, Peter Vidor,
Christ Sendrowski

(osi) pharmaceuticals

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

(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, 2003 or

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

For the transition period from to

Commission file number: 0-15190

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

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

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

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

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

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

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

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

As of March 31, 2003, the aggregate market value of the Registrant's voting stock held by non-affiliates was $360,419,200. For purposes of this calculation, shares of common stock held by directors, officers and stockholders whose ownership exceeds five percent of the common stock outstanding at March 31, 2003 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 3, 2003, there were 38,878,587 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 2004 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 2, 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 with exhibits, as filed with the Securities and Exchange Commission 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 novel mechanism based, targeted therapies in the areas of signal transduction and apoptosis and next-generation cytotoxic chemotherapy agents. We also market two products: Novantrone® and Gelclair®. We acquired the rights to market and promote Novantrone® (mitoxantrone concentrate for injection) for approved oncology indications in the United States and to market and distribute Gelclair® Bioadherent Oral Gel in North America during fiscal 2003.

Our most prominent 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 including lung and pancreatic cancers. The HER1/EGFR gene is also amplified in certain tumors including glioblastoma multiforme, an aggressive form of brain cancer. 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, we are developing Tarceva™ in a global 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 the drug 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 I and Phase II trials in non-small cell lung cancer, or NSCLC, bronchioloalveolar cell carcinoma, or BAC (a form of lung cancer), glioblastoma multiforme, head and neck cancer and ovarian cancer. Based upon these data, the alliance embarked upon a comprehensive global development plan in 2001 designed to both register Tarceva™ and maintain a competitive position against other EGFR inhibitors. In October 2003, we announced that two Tarceva™ Phase III clinical trials for front-line NSCLC (in combination with conventional chemotherapy versus chemotherapy alone) did not meet their primary endpoints of improving overall survival. We had considered these trials high risk as a result of a competitor's previously announced failure of its EGFR inhibitor in this setting which had demonstrated that combining an EGFR inhibitor concomitantly with conventional chemotherapy drug regimens did not result in improved patient benefit. Tarceva™ is currently in a fully enrolled 730 patient Phase III clinical trial for second/third-line NSCLC patients, which is our primary registration study. This study compares the use of Tarceva™ as a monotherapy versus placebo in lung cancer patients who have failed conventional chemotherapy treatments. The study is designed to detect a survival advantage as its primary endpoint with secondary endpoints that include symptom relief and improvement of quality of life. Based on encouraging data from a Phase I study in glioblastoma, our partner, Genentech, initiated a Phase II program for this indication in August 2003. Tarceva™ is also in a Phase III trial for pancreatic cancer where it is being tested in combination with gemcitabine versus gemcitabine plus placebo. We expect top-line data for the ongoing Phase III trials and Phase II glioblastoma trial during 2004. We estimate the approval of Tarceva™ by the U.S. Food and Drug Administration in the fourth quarter of calendar 2004 if the second/third-line NSCLC study successfully meets its endpoint.

Behind Tarceva™, we have multiple drug candidates in clinical development. OSI-7904L, the most promising of our next generation cytotoxic chemotherapy candidates, is a liposomal formulation of a thymidylate synthase inhibitor. It is being developed as a potential competitor to 5-fluorouracil, or 5-FU, and capecitabine (Xeloda®). OSI-7904L is in a Phase II program which includes a Phase II trial in gastric and gastric esophageal junction cancers and combination Phase I trials with cisplatin (Platinol®) and oxaliplatin (Eloxatin™). Aptosyn® (exisulind) was added to our pipeline with the acquisition of Cell Pathways, Inc. in June 2003 and is currently in a Phase III trial in combination with docetaxel (Taxotere®) for the treatment of advanced NSCLC. Although Cell Pathways had advanced Aptosyn® to Phase III trials, we consider it to be a

higher risk prototype drug candidate arising from the apoptosis platform acquired from Cell Pathways. We believe OSI-461 (formerly CP461), the second drug candidate acquired from Cell Pathways, to be a more promising second-generation molecule that is currently being evaluated in a dose ranging Phase I study and a series of exploratory Phase II studies in chronic lymphocytic leukemia, renal cell carcinoma and prostate cancer. OSI-211 and OSI-7836 are two additional next generation cytotoxic agents currently undergoing Phase II and Phase I trials, respectively. Final data from the on-going Phase I and Phase II studies is expected from both programs during the coming year. We currently view the continued development of these two candidates beyond these studies to be unlikely. Three molecules, CP-547,632 (targeting the vascular endothelial growth factor receptor, or VEGFR, gene), CP-724,714 (targeting the HER2 gene) and CP-868,596 (targeting the platelet derived growth factor receptor, or PDGFR, gene) that were discovered as part of our historical alliance with Pfizer Inc. are currently in clinical trials conducted by Pfizer. We will receive royalty payments on the Pfizer candidates if they are successfully commercialized.

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 and is focused in the areas of signal transduction inhibitors (targeting the uncontrolled cell growth exhibited by many cancers) and apoptosis (targeting the ability of many cancer cells to avoid the tightly regulated process of programmed cell death or apoptosis).

In March 2003, we entered into an agreement to market and promote Novantrone® for approved oncology indications in the United States pursuant to the terms of a Co-Promotion Agreement with Ares Tradings, S.A., an affiliate of Serono S.A. Novantrone® is approved by the FDA for the treatment of acute nonlymphocytic leukemia, or ANLL, which includes myelogenous, promyelocytic, monocytic and erythroid acute leukemias, and the relief of pain associated with advanced hormone-refractory prostate cancer, or HRPC. The drug is also approved for certain advanced forms of multiple sclerosis. We initiated our sales activity for Novantrone® during the third quarter of fiscal 2003. Serono will continue to market Novantrone® for the multiple sclerosis indications. These exclusive rights to a high quality marketed oncology product have allowed us to establish a commercial organization and begin to build a revenue base. To support Novantrone®, we have built a core commercial operation comprising approximately 60 sales, marketing, medical affairs, commercial planning and other support personnel including an approximately 30 person sales force. We believe that the tangible and intangible benefits of this commercial capability are significant in that it allows us to pursue additional in-licensing and co-promotion arrangements for other marketed products, enables us to directly market our future pipeline products in the United States, and further validates OSI as a quality development and commercialization partner for oncology development candidates. In addition, it allows us to pursue our co-promotion rights for Tarceva™ in the United States with our partner, Genentech. The exclusive marketing and distribution rights to Gelclair® in North America acquired as part of the Cell Pathways transaction have provided us with an additional product that provides relief for the treatment of pain associated with oral mucositis, a debilitating side effect often seen in cancer patients undergoing radiation treatment or chemotherapy. We re-launched Gelclair® in October 2003.

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 direct 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:

- support and enable the successful development, registration and commercialization of Tarceva™ by reducing program execution and registration risk and by maximizing Tarceva™'s differentiation and competitive positioning; and

- establish a first-class oncology franchise around Tarceva™ by assembling, through mergers, acquisitions and internal growth, a full complement of capabilities and technology and a diversified risk balanced portfolio and pipeline of drug candidates.

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 formulated a comprehensive, global development program for Tarceva™. Since the beginning of the alliance, we, with our partners, have collectively initiated numerous clinical trials, including four Phase III registration-oriented trials in lung and pancreatic cancers. This registration strategy has focused on the execution of adequate, controlled and well-designed studies to support a worldwide registration program. All four Phase III trials were designed as large-scale, placebo controlled, double-blinded trials with a primary endpoint of survival and several secondary endpoints that include symptom relief and improvement of quality of life. The key registration study in this program is the Phase III study of Tarceva™ as a single agent in second/third-line NSCLC which last year was expanded and adjusted to allow for the detection of a 33% improvement in survival, thereby increasing the probability of success in this study. Another Phase III trial evaluating Tarceva™ in patients with previously untreated advanced pancreatic cancer is currently ongoing. This study accrued over 450 patients and is designed to test Tarceva™ plus gemcitabine versus gemcitabine plus placebo. Genentech initiated a Phase II trial evaluating the safety and efficacy of Tarceva™ in patients with malignant glioma. The generation of compelling clinical data from this trial could represent a possible registration option through an accelerated approval submission to the FDA. The FDA has also granted orphan drug status for Tarceva™ in glioblastoma. We have established a goal of achieving profitability within 24 months of a successful market launch of Tarceva™.

Licensing and Acquiring Oncology Products and Clinical Candidates. In order to effectively manage the risks inherent in biotechnology research and development and to complement our internal research efforts, we believe it is essential that we continue to aggressively manage our pipeline and to explore licensing and acquisition initiatives designed to add oncology products and clinical candidates to our pipeline in order to further strengthen our growing position in oncology. During fiscal 2003, we continued to execute on this strategy through the acquisition of the rights to Novantrone® and through the Cell Pathways acquisition. With these transactions, we acquired two marketed products in Novantrone® and Gelclair®. We anticipate over $35 million in sales commissions and revenues from these two products in fiscal 2004 and these acquisitions have allowed us to begin to establish a commercial presence in the oncology community. In addition, through the Cell Pathways acquisition, we acquired Aptosyn® and OSI-461, two clinical candidates focused on the indication of apoptosis. With these and the Gilead Sciences, Inc. and British Biotech plc transactions completed in prior years, we have rounded out our capabilities set from research through to commercialization. With a full array of cancer drug discovery, development and commercialization capabilities and a strong cash position, we expect to be well positioned to compete for premier in-licensing and acquisition opportunities.

Strengthening Commercial Operations. A key corporate goal for us has been to secure rights to a marketed therapeutic product as a vehicle to enable us to establish a sales and marketing organization and continue our mission of building a first class oncology franchise. We believe that through the Novantrone® and Cell Pathways transactions we have accomplished this goal. We have rapidly and successfully established an internal sales, marketing and medical affairs infrastructure consisting of sales representatives, sales and marketing operations support personnel and infrastructure needs. To assist in this rapid ramp up of our sales infrastructure, we have secured a short-term transitional arrangement with a contract sales organization to provide additional sales and marketing support.

Marketed Products

Novantrone®. We market and promote Novantrone® for approved oncology indications in the United States and receive commissions from Serono on net oncology sales in the United States. Novantrone® is an anthracenedione used as an intravenous chemotherapy agent. Novantrone® is approved by the FDA for the treatment of ANLL, which includes myelogenous, promyelocytic, monocytic and erythroid acute leukemias,

and the relief of pain associated with advanced HRPC. The drug is also approved for certain advanced forms of multiple sclerosis, a key strategic area for Serono. The drug was licensed by Serono from Amgen, Inc. and we signed a co-promote agreement with Serono to market the drug for its cancer indications in March 2003. Serono will continue to market Novantrone® for the multiple sclerosis indication and to record all U.S. sales in all indications. The key competitor in HRPC is Taxotere® which, although not approved for HRPC, has been taking some market share from Novantrone®. In addition, during the last several years, a lack of Novantrone® marketing support has led to a decline in sales. However, following our co-promote arrangement with Serono we hope to stabilize our market share in this setting. Novantrone® is also used off-label in the treatment of non-Hodgkin's lymphoma for which recently published data have demonstrated activity of a fludarabine/ Novantrone® combination that was at least equivalent to the standard CHOP therapy (cyclophosphamide, adriamycin, vincristine and prednisone) in terms of efficacy but with a better side effect profile. The fludarabine and Novantrone® combination is also active when given with Rituxan®. We currently project that we will receive over $30 million in commission revenues from Serono in fiscal 2004. However, Congress has recently passed legislation, subject to the President's approval which is expected, that materially changes the Medicare reimbursement guidelines for intravenous and oral oncology products which may impact the sales revenues of all intravenous chemotherapy agents. The patent for Novantrone® expires in April 2006.

Gelclair®. We market and distribute Gelclair® in the oncology setting in North America. Gelclair® is a bioadherent oral gel that provides relief for pain associated with oral lesions, including oral mucositis, a debilitating side effect often seen in cancer patients undergoing radiation treatment or chemotherapy. An estimated 320,000 cancer patients undergoing chemotherapy or radiotherapy develop oral mucositis every year. We also have an agreement with John O. Butler Company whereby Butler markets and distributes Gelclair® to the dental market. Gelclair® was cleared for sale as a device by the FDA in 2002. The product was originally licensed from Sinclair Pharmaceutical Ltd. by Cell Pathways which in turn signed a co-promote agreement with Celgene Corporation. We believe that the product was never effectively launched. Following the acquisition of Cell Pathways, we entered into an agreement with Celgene to terminate the co-promote agreement. We re-launched the product in October 2003 and believe that it has the potential to achieve peak sales of over $25 million per year after five years. We make payments for the supply of the product to Helsinn Healthcare, S.A. which licensed the product from Sinclair.

Commercial Operations

We have established a core commercial operation of approximately 60 people which includes approximately 30 sales representatives covering the major territories in the United States. Approximately half of these sales representatives are full-time contractors assigned to us through an agreement with a contract sales organization. We have the right to hire these individuals at anytime. All of our sales representatives have considerable experience in the pharmaceutical industry, and most have ample experience with oncology products. We expect a modest expansion of our sales and commercialization group as we grow Gelclair® and a possible future expansion around the launch of Tarceva™. We intend to market all future products directly in the United States but we may partner with other pharmaceutical companies to support products we own in territories outside of the United States.

Our Research and Development Programs

Research and Development Pipeline

The following table summarizes the status of our more advanced oncology product candidates as of October 31, 2003 and identifies any related collaborator.

Product/Indication	Status*	Drug Type	Collaborator(s)
Tarceva™/NSCLC	Phase III	Epidermal Growth Factor Receptor Inhibitor (HER1/EGFR)	Genentech and Roche
Tarceva™/Pancreatic Cancer	Phase III		
Tarceva™/Glioblastoma Multiforme, BAC, Ovarian and Head and Neck	Phase II		
Tarceva™/various-exploratory	Phase I/II		
Aptosyn®/NSCLC	Phase III	Selective Apoptosis Inducer	OSI-Owned
OSI-461/Prostate, CLL, Renal, IBD	Phase I/II	Selective Apoptosis Inducer	OSI-Owned
OSI-461/various-exploratory	Phase I		OSI-Owned
OSI-7904L/Gastric	Phase II	Liposomal Thymidylate Synthase Inhibitor	OSI-Owned
OSI-7904L/various-exploratory	Phase I		
OSI-211/Ovarian Cancer(1)	Phase II	Liposomal Topoisomerase-1 Inhibitor	OSI-Owned
OSI-211/Small Cell Lung Cancer(1)	Phase II		
OSI-7836/various-exploratory(2)	Phase I	Nucleoside Analog	OSI-Owned
CP-547,632/Ovarian Cancer	Phase II	VEGFR	Pfizer
CP-547,632/NSCLC	Phase I/II		
CP-724,714/various-exploratory	Phase I	HER2/erbB2 Receptor Inhibitor	Pfizer
CP-868,596/various-exploratory	Phase I	PDGFR	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.

(1) We expect the results of these trials during the coming year; it is unlikely that we will continue this program if we are unable to differentiate it from a current competitor's product.

(2) We expect to terminate this program after the first quarter of fiscal 2004 if we are unable to overcome toxicity issues with the candidate.

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 2002 were in excess of $60 billion. The worldwide market for anti-cancer drugs has been estimated to be $14-15 billion 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 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.

Our approach to cancer therapy is focused in three diversified areas in an attempt to improve the available drug treatment options for cancer patients: (1) signal transduction inhibitors targeting aberrant cancer cell growth, (2) apoptosis inducers to restore and enhance programmed cell death in cancer cells that no longer respond to this tightly regulated process, and (3) next-generation cytotoxics. The signal transduction inhibitors and apoptosis inducer programs are focused on the exploitation of our rapidly growing understanding of the genetic basis for cancer in order to develop drugs that directly target the genetic abnormalities present in human cancers or treat their consequences. 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. The next-generation cytotoxics area is focused on the development of new cytotoxic agents which present improvements in activity or technological innovations over existing drugs. Liposomal formulations are technological innovations that are designed to improve targeting of the cytotoxic agent to the tumor or change the exposure profile of the drug molecule, thus improving the therapeutic index (the drug benefits versus its toxic side effects). It is our belief that to be a successful oncology franchise, we should be developing both targeted therapies and next-generation or improved cytotoxic drugs in order to provide an array of effective treatment options for the cancer patient.

Our drug discovery efforts in targeted therapies were for many years (1986-2001) 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 (all of which are in clinical development), the funded discovery phase of which concluded in April 2001. If Pfizer is successful in commercializing any of these drug candidates, we will receive a royalty from Pfizer on the sales of such drugs. These types of drug candidates represent the vanguard of a substantial ongoing in-house research effort directed toward the discovery and development of these next-generation targeted drugs.

The novel, anti-cancer drug candidates, 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 thereby controlling growth. HER1/EGFR can be over-expressed or the gene can be amplified 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. A frequently occurring mutation of the HER1/EGFR gene called EGFRvIII is also found in many tumors. In addition, the HER1/EGFR gene is frequently amplified in glioblastoma 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 less likely than the tyrosine kinase inhibitors 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, we believe that 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™

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 NSCLC 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 the Warner-Lambert Company. In January 2001, we entered into an alliance with Genentech and Roche for the global co-development and commercialization of Tarceva™.

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 clinical programs to result in a registration with the FDA. These trials include a single agent trial for second/third-line 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, and our alliance partners, are also conducting several trials to review the effect of Tarceva™ in combination with other chemotherapy and novel mechanism drugs and additional Phase II studies both independently and in collaboration with the U.S. National Cancer Institute's Cancer Therapy Evaluation Program in a wide array of tumor types including glioblastoma multiforme, head and neck and ovarian.

Clinical Data. Phase I and Phase II trials of Tarceva™ have demonstrated the drug to possess activity as a single agent and to be relatively safe with manageable side effects, principally, a reversible rash and a generally mild diarrhea. Interstitial lung disease is a rare complication of lung cancer and lung cancer treatment that has been associated with a competitor's EGFR inhibitor. However, analysis of our safety database for Tarceva™ indicates that the incidence of possible lung complications of this type appear to be well within the normal range. The dose limiting side effect in the Phase I trials was diarrhea, which was moderate to severe in advanced cancer patients treated at 200mg per day, and 150mg per day was established as the maximum tolerated dose in this study and the recommended Phase II dose. On a 150mg 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. More recently, rash has emerged as a potentially important biomarker of effective Tarceva™ dosing to the individual patient. Some success in treating rash has been observed with antibiotic creams as well as with a variety of other agents. 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.

A Phase I clinical study that evaluated the safety and pharmacokinetics of Tarceva™ in patients with malignant glioma was completed in 2003. Patients were stratified based on the use of enzyme inducing antiepileptic drugs, or EIAEDs, which are used to prevent seizures. These drugs are known to induce enzymes in the liver which metabolize many drugs more quickly. Thus, patients on EIAEDs frequently require higher doses of drugs to achieve the same blood levels of active agent. This was the case for Tarceva™ in this study. Notably, all patients at the higher doses in either the EIAED arm or the non-EIAED arm developed rash on Tarceva™. In addition to receiving Tarceva™, some patients also received temozolomide (Temodar®), a type of chemotherapy. Sixteen percent of the evaluable patients (8/49) achieved a partial response after treatment with Tarceva™. Dose limiting toxicities occurred in six patients, primarily due to skin rash. Response rates of this magnitude were considered noteworthy by the investigators and in August 2003, we, along with Genentech, announced the initiation of a Phase II clinical trial evaluation the safety and efficacy of Tarceva™ in patients with malignant glioma.

In another recent Phase II clinical study, lung cancer patients were enrolled following pathological confirmation that their tumor was either pure bronchioloalveoler cell carcinoma, or BAC, adenocarcinoma with a BAC component, or BAC with focal invasion. Approximately 20% of all NSCLC patients are estimated to fall into these categories; these patients are historically considered to be relatively unresponsive to

chemotherapy. Of the 50 patients who were treated with Tarceva™, 13 patients (26%) achieved a partial response. Also of interest was the observation that 46% of the subset of patients who had never smoked achieved a partial response. Side effects have been similar to those observed in previous Phase II studies of Tarceva™, with all but one patient developing rash and one patient experiencing grade 3 diarrhea.

Our earlier Phase II trials for Tarceva™ in NSCLC, head and neck cancer and ovarian cancer consisted of patients with advanced or metastatic cancer and had generally failed standard treatment regimens. We believe these trials were encouraging because they demonstrated objective clinical responses and noteworthy survival data for patients treated with Tarceva™ as a single agent with generally tolerable side effects. 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 in 206 patients showed that diarrhea was experienced by 45% of the patients, and rash and rash related disorders were seen in 79% of the patients. Mild to moderate rash was seen in 146 of these patients and 16 patients showed severe rash.

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 retrospective analysis of the Phase II study data that was presented at the 2003 Annual Meeting of American Society of Clinical Oncology (ASCO) correlated rash with survival. In all of these trials, patients with rash had longer survival than those without rash and the duration of survival was correlated with the severity of rash. Despite the small size of the studies, the data were statistically significant. The analysis supports our belief that a higher dose strategy leading to increased rash may translate into an improved survival benefit, a strategy that differentiates our approach to Tarceva™ use from our main competitor in EGFR inhibitors, Astra Zeneca plc, who claims no such correlation of rash with benefit for its agent.

Our Phase III clinical trial program includes a single agent trial for second/third-line NSCLC patients as well as combination trials with existing chemotherapy regimens for front-line use in pancreatic cancer. We are managing these two trials in collaboration with the National Cancer Institute of Canada's Clinical Trial Group. The Phase III trials are large scale, placebo controlled registration orientated trials. Improvement in patient survival is the primary endpoint in these studies with symptom relief and improvement of quality-of-life as key secondary endpoints. The Phase III study in second/third-line NSCLC is investigating the potential survival benefit of single agent Tarceva™ at 150mg per day compared to placebo and was based directly on the encouraging activity data seen in an earlier Phase II study in advanced NSCLC. The program also included two front-line Phase III combination trials in NSCLC that were initiated for business reasons in order for us to be competitive with Astra Zeneca which was developing a competitive drug, Iressa®, in this setting. On October 1, 2003, we announced that the two front-line Phase III studies of Tarceva™ plus standard chemotherapy in metastatic NSCLC did not meet their primary endpoints of improving overall survival. We believe these results were widely anticipated based on the competitor's previously announced failure of Iressa® in this front-line setting in August 2002. This failure demonstrated that combining EGFR inhibitors concomitantly with conventional chemotherapy regimens did not result in improved patient benefit in this setting. These two multi-center, randomized, controlled Phase III studies evaluated Tarceva™ at 150mg per day in combination with standard chemotherapy in patients with stage IIIB/IV metastatic NSCLC. The 1,050 patients enrolled in the U.S. study were randomized to receive Tarceva™ plus standard chemotherapy (carboplatin and paclitaxel) or standard chemotherapy plus a Tarceva™ placebo. The study outside of the United States randomized approximately 1,200 patients to receive either Tarceva™ in combination with standard chemotherapy (gemcitabine and cisplatin) or standard chemotherapy plus a Tarceva™ placebo. Genentech and Roche intend to submit abstracts on these studies to a major oncology meeting in 2004 at which point a detailed analysis of the data will be presented for discussion.

Registration Strategy. The following ongoing elements of the clinical development program for Tarceva™ are directed toward the successful registration of the drug in the United States and around the world:

- The second/third-line NSCLC Phase III trial is a fully enrolled 730 patient study in which Tarceva™ is being tested as a single agent to treat second/third-line NSCLC versus a placebo group where

patients receive best supportive care but no additional drug therapy as a control group. We have been given fast track status by the FDA for the indication covered by this trial, and patient enrollment was completed in January 2003. Improvement in patient symptoms is the key secondary endpoint. The study design was based upon our earlier Phase II data with monotherapy Tarceva™ in this type of patient population. This second/third-line NSCLC trial is our highest priority and the key registration study for Tarceva™. We anticipate that we will announce top-line data from this study late in the first quarter of calendar 2004.

- The Phase II trial in malignant glioma is an open label two stage Phase II study with a target of approximately 110 patients. The primary endpoint in this study is response, with duration of response and time to progression as key secondary endpoints. With compelling clinical data, we believe accelerated approval may be an option from this study. The FDA has granted orphan drug status for Tarceva™ in this setting.
- A Phase III front-line pancreatic trial compares Tarceva™ used in combination with gemcitabine (Gemzar®) versus chemotherapy alone. Patient enrollment was completed in January 2003. The results of the Tarceva™ and Iressa® Phase III studies in combination with chemotherapy in lung cancer suggest that there may be issues in using Tarceva™ concurrently with chemotherapy. We, therefore, view a positive outcome from the pancreatic study in combination with chemotherapy to be considered high risk.

Other Proprietary Clinical Development Programs

OSI-7904L. OSI-7904L is a liposomal formulation of the thymidylate synthase inhibitor, GW1843, which was licensed from GlaxoSmithKline and acquired by us as part of the acquisition of Gilead's oncology business in 2001. Thymidylate synthase inhibitors, or TSIs, are a class of cytotoxic chemotherapy agents. OSI-7904L was formulated in liposomes with a goal of extending its pharmacokinetic (or drug exposure) half-life and improving its therapeutic index. The leading TSI used today is 5-FU, a generically available TSI which is extensively used in many tumor types, notably colorectal cancer. Clinical studies with 5-FU have shown that long term, continuous infusions of the drug have shown better activity than more typical regimens. The goal of our OSI-7904L program is to mimic this effect with an infusion of the liposomal formulation of our TSI molecule. In Phase I clinical trials, OSI-7904L demonstrated promising activity in pre-clinical testing for the potential treatment of various solid tumors. Data from the Phase I study indicated that the liposomal formulation has extended the drug exposure profile of OSI-7904L in patients' blood. We have therefore recently initiated a Phase II program for OSI-7904L which includes testing the drug in patients with previously untreated advanced gastric or gastric esophageal junction cancer and conducting two additional Phase I combination studies of OSI-7904L with cisplatin and oxaliplatin, respectively. Milestone and royalty payments are due to GlaxoSmithKline upon successful development of this product.

Aptosyn®. Aptosyn® is a sulfone derivative of the nonsteroidal anti-inflammatory drug, or NSAID, sulindac. The product was originally developed by Cell Pathways to treat familial polyposis. Following rejection of a new drug application, or NDA, by the FDA in September 2000, Cell Pathways initiated a large scale Phase III program comparing a combination of Aptosyn® and Taxotere® versus Taxotere® alone in second-line NSCLC. The trial was based primarily on pre-clinical data. In March 2003, Cell Pathways completed enrollment of an approximately 610 patient Phase III trial. Based upon the absence of clinical data in NSCLC and the lack of potency exhibited by Aptosyn® in pre-clinical models, we consider Aptosyn® to be a high risk drug candidate. Our overall development strategy will require further assessment once top-line data from the Phase III study becomes available.

OSI-461. OSI-461 is a new chemical entity that has composition of matter patents issued or filed in the major world markets. It is a more potent second generation follow-on candidate to Aptosyn®. OSI-461 is an inhibitor of cGMP phosphodiesterases which leads to sustained activation of the intracellular signaling protein, Protein Kinase G, and subsequent stimulation of apoptosis through the C-Jun kinase pathway. Data correlating cGMP phosphodiesterases inhibition with apoptosis markers and the inhibition of growth in various cultured cancer cells *in vitro* supports this mechanism of action. However, OSI-461 also has effects on tubulin and microtubular biology in cells which is a known mechanism of action for other anti-cancer agents.

OSI-461 was exceptionally well tolerated in pre-clinical toxicology studies and we are currently expanding the pre-clinical anti-tumor data set *in vivo*. In 1999, Cell Pathways began a clinical trial program for OSI-461. By the end of 2001, OSI-461 was in pilot Phase IIa trials to investigate its safety and efficacy in three cancer indications — chronic lymphocytic leuxemia, renal cell carcinoma and HRPC. The molecule was formulated as a simple packed powder in gelatin capsules for the exploratory clinical development program conducted by Cell Pathways. We are currently expanding our research knowledge base surrounding OSI-461 and developing both additional formulations and analogs of the molecule. We would likely be required to develop a tablet form of the product before commencing full development. Following the completion of the acquisition of Cell Pathways in June 2003, we completed a detailed review of the OSI-461 program and concluded that further dose optimization studies would be required before committing to a full Phase II program. These studies are ongoing. In July 2002, Cell Pathways also commenced a Phase II trial of OSI-461 in the non-cancerous area of inflammatory bowel disease. We expect to complete this study during the next six months and will determine how best to proceed in this indication at that time.

OSI-211. OSI-211 is a proprietary liposomal formulation of the active topoisomerase-1 inhibitor lurtotecan. It is a member of the camptothecin class of cytotoxics that act as topoisomerase-1 inhibitors. OSI-211 has been demonstrated to be active for the treatment of relapsed ovarian cancer. However, in order to develop this agent commercially, we believe it is essential that we clearly differentiate it from topotecan (Hycamtin®) in terms of activity, safety and convenience. We have, therefore, initiated a head-to-head randomized Phase II trial versus topotecan in relapsed ovarian cancer and an open label Phase II trial in advanced small cell lung cancer. Data are expected from these studies during the coming year. Without significant differentiation from topotecan, it is unlikely that we will continue the development of OSI-211 for commercial reasons; and therefore, we would consider out-licensing the product for further development.

OSI-7836. OSI-7836 is a member of the nucleoside class of cytotoxic drugs of which gemcitabine (Gemzar®) is the market leader. In ongoing Phase I trials, the candidate has experienced toxicity issues, principally high-grade fatigue. If we are unable to overcome these issues with schedule changes, we expect to terminate this program after the first quarter of fiscal 2004. OSI-7836 would be a candidate for out-licensing for further development.

Pfizer Collaborative Cancer Programs

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

Our Drug Discovery and Development Capabilities

Drug Discovery

In fiscal 2003, we re-focused our pre-clinical research efforts into two areas in which we believe we can build a competitive presence in cancer drug discovery. These areas relate to two core biological processes important in both normal and cancer cell regulation, namely signal transduction pathways that either drive proliferation or prevent apoptosis (programmed cell death). The dysfunctional regulation of these two processes are key elements in the progression of normal cells to the cancerous state. Within these areas, we have focused our efforts on three key signaling axes described by the central signal transduction gene products that make up these pathways; they are the Ras-Raf-Mek-Erk axis, the PI-3K-PDK-PKB axis, and the

PKG-MEKK1-JNK1 axis. These three pathways are thought to be critical in driving either cancer cell proliferation (e.g. EGFR via the Ras-Erk axis) or in protecting cancer cells from undergoing apoptosis (e.g. 1GF-1R via the PKB axis).

Our approach to discovering drugs which target these axes is focused on the discovery and development of small molecule pharmaceutical products that, typically, would be taken either orally by a patient as a pill, capsule or suspension or intravenously as is common for many cancer products. Our drug discovery platform constitutes an integrated set of technologies and capabilities covering every major aspect of pre-clinical research and pre-clinical and clinical development. We have built a fully-integrated drug discovery platform in order to accelerate the process of identifying and optimizing high-quality, small molecule drug candidates. Our core technologies and capabilities include (i) gene transcription, signal transduction, protein kinases and other assay systems, (ii) automated high throughput screening, (iii) an extensive library of proprietary small molecule compounds, (iv) medicinal and automated combinatorial chemistry, (v) *in vivo* pharmacology, pharmacokinetics and pharmaceutical development capabilities, and (vi) core clinical project management and regulatory affairs units. We currently employ approximately 170 scientists in our pre-clinical research activities.

In order to enhance our capabilities in drug discovery we have developed multiple relationships with academic centers as well as with other biotechnology partners. For instance, in collaboration with Cold Spring Harbor Laboratories we are identifying and validating new targets for cancer drug discovery. This collaboration focuses 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. To help complement our medicinal chemistry efforts we have initiated collaborations (for example with Structural Genomix, Inc.) the goals of which are to use structure based design in the lead optimization phase of our active projects. During lead optimization, medicinal chemists synthesize new molecules and combinatorial libraries that are structurally related to the lead compound. Co-crystallization of the lead compound with the target protein enhances the subsequent efforts of the medicinal chemists designing improved compounds. 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 and toxicity. Target identification, validation, lead identification and lead optimization phases are expected to take 18-24 months.

To ensure that our lead compounds are active against the target of interest they are profiled in pharmacodynamic assays. This allows us to develop surrogate biomarkers of drug activity *in vivo* and may well enable and support our future clinical development. This will ensure that our lead compounds have retained their anticipated mechanism of action *in vivo*. Lead compounds are tested extensively in order to identify a drug candidate that has the desired drug-like pharmaceutical qualities, is biologically active and generally well-tolerated in animal models and can be patented as a novel pharmaceutical.

Drug Development

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 development strategy are addressed. This Phase typically takes up to one year. An investigational new drug, or IND, application is reviewed by the FDA or its foreign equivalent prior to the commencement of clinical studies. A drug is first assessed for its safety and pharmacokinetics. After these Phase I trials, drugs are tested for preliminary efficacy in Phase II trials to demonstrate initial activity and confirm safety in humans prior to the initiation of extensive Phase III trials designed to collect the safety and efficacy data necessary to support a filing of an NDA with the FDA or similar marketing application authorization overseas. We currently employ over 140 physicians and specialists who are responsible for generating pre-clinical data required for IND submission and managing clinical trials and the associated regulatory affairs effort to support submissions and interactions with the FDA and other regulatory agencies around the world.

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

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

Manufacturing and Supply

In connection with our acquisition of certain of the pre-clinical research operations of British Biotech in September 2001, we acquired a fully-integrated current Good Manufacturing Practices, or 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 non-cytotoxic products and to support our current and future pre-clinical and clinical development programs.

We currently rely on third-party manufacturers to manufacture our in-line products and 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 for the supply of commercial quantities of Tarceva™ tablets for sales within the United States. Under our collaboration agreement with Roche, Roche has elected to take responsibility for the supply of Tarceva™ tablets for sales outside of the United States. Tarceva™ 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. We contracted a third party manufacturer to formulate Tarceva™ into tablets. Additionally, we are working with an additional source for the tablet manufacture. All manufacturers are required to comply with cGMP. We have sufficient quantities of Tarceva™ tablets to conduct our ongoing clinical trials and we expect to have a fully validated supply chain in place in advance of the potential launch of Tarceva™. We currently use third parties to label, inventory and distribute the drug product. In addition, we are using third-party manufacturers to develop an intravenous formulation and an oral solution.

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

Under the terms of the agreement entered into with Serono in March 2003, we acquired the marketing and promotion rights to Novantrone® for oncology indications in the United States. Pursuant to that agreement, we do not have the obligation nor right to manufacture or distribute the product.

In connection with our purchase of certain oncology assets from Gilead in December 2001, we entered into a manufacturing agreement covering products acquired from Gilead. During the one-year transition period, Gilead manufactured and supplied us with the API for preparation of OSI-7904L and OSI-7836 drug products. We have transitioned the manufacture of the API to new manufacturers. Starting materials for OSI-7904L are manufactured by other third-party manufacturers. 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-7904L and OSI-211 at its manufacturing facility in San Dimas, California to support our ongoing clinical trial activities and, upon FDA approval, our commercial manufacturing needs for these two liposomal products.

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. We have entered into a Tripartite Agreement and separate agreements with both Genentech and Roche with respect to 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 goals of obtaining regulatory approval for commercial marketing and sale in the United States of products resulting from the collaboration, and, subsequently, supporting the commercialization of the product. Consistent with the development plan and with the approval of a joint steering committee, we 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 are triggered by the fulfillment of certain conditions; we believe that we have met these conditions and are in active discussions with Genentech regarding these rights. 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, that is, until the date that we and Genentech mutually agree to terminate the collaboration or until either party exercises early termination rights. The OSI/Genentech agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, since January 8, 2003, Genentech has had the right to terminate the OSI/Genentech agreement with six months prior written notice.

Under the OSI/Roche agreement, we granted to Roche a license to our intellectual property rights with respect to Tarceva™. Roche is collaborating with us and Genentech in the product development of Tarceva™ and is responsible for future marketing and commercialization of Tarceva™ outside of the United States in certain territories as defined in the agreement. The grant is a royalty-bearing, non-transferable (except under certain circumstances), non-sublicensable (except under certain circumstances), sole and exclusive license to use, sell, offer for sale and import products resulting from the development of Tarceva™ 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™, that is, until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva™ or, in countries where there is no valid patent covering Tarceva™, on the tenth anniversary of the first commercial sale of Tarceva™ in that country, or until either party exercises early termination rights. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material

breach of the agreement and bankruptcy. In addition, since July 31, 2003, Roche has had the right to terminate the agreement on a country-by-country basis with six months prior written notice. Since such time, we also have had the right to terminate the agreement on a county-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

Other Collaborations

We have several other product candidates 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.

As a result of our strategy to focus on oncology, we made the strategic decision to divest all non-oncology research programs and realign our internal research effort toward an oncology strategy focused on the discovery of novel anti-cancer drugs targeting defects in signal transduction and apoptosis that are necessary for the growth of many human tumors. We created a U.K. subsidiary for our diabetes and obesity programs, Prosidion Limited, in fiscal 2003. We transferred and/or licensed our diabetes assets to Prosidion. We have also transferred to Prosidion our existing diabetes teams comprised of approximately 25 employees. In October 2003, we committed $7.5 million in venture funding to Prosidion to support the organization through June 2004. We have hired a chief executive officer for Prosidion and established a separate board of directors comprised of senior OSI management and OSI directors. We may add additional outside directors as the venture progresses. We are currently seeking funding or strategic partners for the venture. If we are unable to obtain external funding for Prosidion, we will consider other alternatives to discontinue the diabetes program, including out-licensing our diabetes assets and reducing employee headcount.

Our Intellectual Property

Patents and other proprietary rights are vital to our business. Our policy is to protect our intellectual property rights through a variety of means, including applying for patents in the United States and other major industrialized countries. We also rely upon trade secrets and improvements, unpatented proprietary know-how and continuing technological innovations to develop and maintain our competitive position. In this regard, we seek restrictions in our agreements with third parties, including research institutions, with respect to the use and disclosure of our proprietary technology. We also enter into confidentiality agreements with our employees, consultants and scientific advisors.

Patents issued in the United States, 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, 2003, we held 88 U.S. patents, 151 foreign patents, 97 pending applications for U.S. patents, five of which have been allowed, and 205 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, we jointly hold, with the University of Arizona, 11 issued U.S. patents, three U.S. pending patent applications, 17 foreign patents, and 25 pending foreign patent applications. 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 patents and patent applications include two families of patents covering composition of matter for Tarceva™. They also include other development compounds being pursued by Pfizer (i.e., VEGFR, PDGFR and erbB2 inhibitors) as well as several families covering farnesyl transferase

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 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 (assigned to Vertex Pharmaceuticals Incorporated), Pharmacia Inc., R.W. Johnson Pharmaceutical Research Institute, Wyeth, BASF Corporation 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. 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 for 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-7904L and OSI-211 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-7904L and OSI-211.

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 fully-integrated pharmaceutical companies, as well as numerous smaller companies, which possess extensive drug discovery programs and are pursuing the same or similar technologies as those that comprise our technology platforms and are pursuing pharmaceutical products or therapies that are directly competitive with ours, including developing novel small molecule pharmaceuticals. Most of the major pharmaceutical organizations competing with us have greater capital resources, larger overall research and development staff and facilities and considerably more experience in drug development, obtaining regulatory approval and pharmaceutical product manufacturing and marketing.

With respect to our cancer drug discovery and development programs, other companies have potential drugs in clinical trials to treat diseases in the same areas for which we are seeking to discover and develop drug candidates. These competing drug candidates may be further advanced in clinical development than our potential products within our small molecule programs, and may result in effective, commercially successful products. Our lead drug candidate, Tarceva™, is currently in Phase III trials. At least three competitors, AstraZeneca, Bristol Myers Squibb Company/ImClone Systems Incorporated/Merck KGA, and Amgen/ Abgenix, Inc., also have substantial clinical development programs for the same target. AstraZeneca has received approval for its anti-EGFR, small molecule drug in the Unites States (accelerated approval, contingent studies required by FDA) and Japan. Regulatory filings for BMS/ImClone/Merck KGA's anti-EGFR antibody, Erbitux™, have recently been submitted both in the United States and Europe. In the United States, the biological license application for this antibody is for second-line treatment of colorectal cancer and

approval is expected in early 2004. In Europe, Merck KGA is seeking an indication as a single agent or in combination with irinotecan in metastatic colorectal cancer patients, with approval across the European Union expected in mid-2004; initial approvals have been granted in Switzerland.

With the acquisition of the co-promotion right for Novantrone® in the oncology arena in the United States and the marketing and distribution rights for Gelclair® in North America, we are facing competition in their respective areas of use. Novantrone® is mainly used for the treatment of pain associated with advanced HRPC, ANLL and Non Hodgkin's lymphoma (which is not an approved indication in the United States). A key competitor in HRPC is Taxotere®, a cytotoxic agent marketed by Aventis. Taxotere® is not approved for HRPC but it is used extensively in this setting and Phase III trials for HRPC are expected to be completed in early 2004. In ANLL, Novantrone® competes against a variety of generic products including idarubicin and daunorubicin. In non-Hodgkin's lymphoma, the reference standard is the CHOP regimen consisting of four generic agents: cyclophosphamide, doxorubicin, vincristine, and prednisone. In addition, Rituxan® (Genentech/IDEC) is used extensively in non-Hodgkin's lymphoma both as a single-agent and in combination with CHOP or other chemotherapies including Novantrone®. Gelclair® is a bioadherent oral gel for treatment of pain associated with the oral mucosa, such as chemotherapy-induced oral mucositis. Key competitors include a myriad of products often blended in the dispensing pharmacy, none specifically approved for this indication, such as Xylocaine®, Benadryl® Elixir, Carafate®, Orabase®, and over-the-counter and prescription analgesics.

Our next-generation cytotoxic drug candidates are designed to improve upon in the market products of similar mechanism. We must therefore clearly differentiate the activity or safety of our molecules if we are to successfully register the drugs and compete in the marketplace. The most advanced of these products is OSI-211, a topoisomerase-1 inhibitor, currently in Phase II trials for relapsed ovarian and small cell lung cancer. It is designed to improve upon Hycamtin® (GlaxoSmithKline), one of two agents in this class that are already marketed. Camptosar® (Pfizer) is the second such agent approved for colorectal cancer, but its use in small cell lung cancer is increasing. OSI-7904L, currently in Phase II trials is a TSI and is designed to compete with generic 5-FU, as well as Xeloda® (Roche), an oral TSI. OSI-7836, currently in Phase I trials, is a nucleoside analog, which was expected to compete with Gemzar® (Eli Lilly and Company) that is already on the market. Companies with related research and development activities also present significant competition for us. Aptosyn® and OSI-461 are both inhibitors of cGMP phosphodiesterases. Chemically, Aptosyn® is a sulfone derivative of an NSAID, sulindac, while OSI-461 is a more potent second generation follow-on candidate to Aptosyn®. 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(s);
- submission to the FDA of an NDA; and
- FDA review of the NDA or product license application in order to determine, among other things, whether the drug is safe and effective for its intended uses.

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

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

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

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

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

Among the conditions for NDA approval is the requirement that the prospective manufacturer's procedures conform to 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

We believe that our success is largely dependant upon our ability to attract and retain qualified personnel in the scientific and technical fields. As of October 31, 2003, we employed 480 persons worldwide (325 in the United States), of whom 174 were primarily involved in research activities and 147 in development activities, 42 in sales and marketing, with the remainder engaged in executive and administrative capacities. Although we believe that we are appropriately sized to focus on our mission 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.

Available Information

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 electronically with the Securities and Exchange Commission. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

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

CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

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

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

If we have setbacks in our Tarceva™ program, our stock price would most certainly decline.

Our registration plans for Tarceva™ are focused on a key Phase III study using Tarceva™ as a single agent in second/third-line NSCLC. We are conducting another Phase III study of Tarceva™ in pancreatic cancer in combination with chemotherapy and a Phase II study in glioblastoma. As a result of not meeting our primary endpoints in our two front-line Phase III studies of Tarceva™ plus chemotherapy, a positive outcome from the pancreatic study in combination with chemotherapy must now be considered high risk. If we do not receive any positive results from the on-going Phase III trials or from our glioblastoma Phase II program, we would need to conduct additional clinical trials to achieve Tarceva™ registration. Since Tarceva™ is our most advanced product candidate, a setback of this nature could almost certainly cause a decline 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 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™. On October 1, 2003, we announced that two of our front-line Phase III studies of Tarceva™ in NSCLC did not meet their primary endpoints. These studies tested the use of Tarceva™ in combination with conventional chemotherapy. Although they were expected to fail following similar results from a competitive compound a year ago, these studies exemplify the challenge of clinical development. 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 for oncology drugs 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 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 delay or prevent, respectively, us from commercializing and generating revenues from Tarceva™.

We have incurred losses since our inception, and we expect to incur losses over the next few 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, 2003, our accumulated deficit was $505.6 million. Our net losses were $181.4 million, $218.5 million, and $23.8 million for fiscal years 2003, 2002 and 2001, respectively. The net loss for fiscal 2003 included an in-process research and development charge of $31.5 million related to the acquisition of Cell Pathways, Inc. in June 2003. The net

loss for fiscal 2002 included an in-process research and development charge of $130.2 million related to the acquisition of certain assets from Gilead Sciences, Inc. in December 2001. Our losses have resulted principally from costs incurred in research and development, acquired in-process research and development and from selling, 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 research programs and the expansion of our commercial operations. 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 achieve profitability until approximately 24 months after a successful launch of Tarceva™.

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™ or produce data indicating that their products are as effective or more effective than Tarceva™, then our ability to compete for sales in this market may be a greater challenge.

If our competitors, some of which 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. On May 5, 2003, AstraZeneca plc received FDA approval for Iressa®, its anti-EGFR drug, as a monotherapy for the treatment of advanced NSCLC. Another competitor, Bristol Myers Squibb Company/ImClone Systems Incorporated, has initiated a biologics license application submission to treat colon cancer for their product, Erbitux™, and may reach the U.S. market ahead of Tarceva™. A third competitor, Amgen, Inc./Abgenix, Inc., has a product in Phase II trials. If these, or other competitors, succeed in developing drugs similar to Tarceva™ that are as effective or more effective than our product, our product may not gain widespread market acceptance.

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 can recover any of the expenses incurred to develop them.

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

Tarceva™ is being developed in an alliance with Genentech, Inc. and Roche. The development program is managed by the three parties under a global development committee. Genentech and Roche each managed one of the Phase III trials in NSCLC testing Tarceva™ in combination with cytotoxic chemotherapy. We are managing two Phase III trials in second/third-line NSCLC and pancreatic cancer. If Tarceva™ receives regulatory approval, Genentech will lead the marketing effort in the United States and Roche will market the drug in the rest of the world. We have entered into agreements with both Genentech and Roche with respect to the alliance. The term of the OSI/Genentech agreement continues until the date on which neither we nor Genentech is entitled to receive a share of the operating profits or losses on any products resulting from the

collaboration, that is, until the date that we and Genentech mutually agree to terminate the collaboration or until either party exercises early termination rights as described as follows. The OSI/Genentech agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, since January 8, 2003, Genentech has had the right to terminate the OSI/Genentech agreement with six months prior written notice. 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™, that is, until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva™ or, in countries where there is no valid patent covering Tarceva™, on the 10th anniversary of the first commercial sale of Tarceva™ in that country. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, since July 31, 2003, Roche has had the right to terminate the agreement on a country-by-country basis with six months prior written notice. After such time we also have had the right to terminate the agreement on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances. If we do not maintain a successful collaborative partnership with Genentech and Roche for the co-development and commercialization of Tarceva™, we may be forced to focus our efforts internally to commercialize Tarceva™. This situation would require a greater expenditure of financial resources and may cause a delay in launch and market penetration while we continue to 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, we may need to replace Roche's manufacturing role in markets outside of the United States.

Setbacks on the part of our competitors who are developing drugs in the HER1/EGFR field have historically caused volatility in our stock price and could do so in the future.

Two of our major competitors, AstraZeneca and ImClone, which are developing drugs in the HER1/EGFR field, that are similar to our most advanced clinical candidate, Tarceva™, have suffered setbacks with respect to their drug candidates over the last two years which have impacted our stock price by raising concerns regarding the HER1/EGFR class of targeted therapies. Additional setbacks, whether before or after FDA approval, on the part of our competitors could result in a further decrease in our stock price.

If any of our marketed products were to become the subject of problems, or if new, more effective treatments should be introduced, our sales revenues from such marketed products could decrease.

We currently market two products, Novantrone® and Gelclair®. If these marketed products become the subject of problems including, among others:

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

or if new, more effective treatments are introduced, our sales revenues from such products could decrease. For example, efficacy or safety concerns may arise, whether or not justified, that could lead to the recall or withdrawal of either or both products. In the event of a recall or withdraw of a product such as Novantrone®, our sales revenues would significantly decline.

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

In order to continue to generate sales of Novantrone® and Gelclair®, we will need to maintain a successful commercial infrastructure. If we are unsuccessful maintaining this infrastructure, we would need to enter into and successfully maintain additional commercialization agreements. This could result in our receipt of decreased revenues from sales of Novantrone® for oncology indications and Gelclair® and potential oncology products other than Tarceva™.

Congress has recently passed legislation that materially changes the Medicare reimbursement guidelines for intravenous and oral oncology products which may impact our sales revenues.

The formula by which Medicare reimbursement for intravenous oncology products is rendered to the oncologist was vigorously debated by Congress. As a result of the debates, Congress recently passed legislation that will lower the reimbursement to oncologists for intravenous oncology products like Novantrone® while providing increased reimbursement for oral drugs like Tarceva™ (if approved by the FDA) which are not currently covered by Medicare. The legislation is subject to the President's approval which is expected. These changes in Medicare reimbursement could have a negative impact on our sales revenues of Novantrone®.

If Serono S.A. or Helsinn Healthcare, S.A. do not fulfill their obligations of manufacturing and supplying Novantrone® and Gelclair®, respectively, we may not be able to continue the marketing and/or distribution of the product which could cause our revenues to decrease.

Under the terms of our agreements with Serono and Helsinn, we do not have the obligation nor the right to manufacture Novantrone® or Gelclair®. These obligations and rights are held solely by Serono and Helsinn. If either of the parties are delayed in and/or restricted from supplying the product, we would be directly affected. Any delay or restrictions would impede us from selling the product. Without the sales of Novantrone® and Gelclair®, our revenues would decrease.

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 commercial 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 our potential oncology products, including Tarceva™, may never 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 various stages of development and do not expect them to be commercially available for a number of years, if at all. All but nine of our product candidates are in pre-clinical development. The nine 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 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 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 our 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 the other regulatory agencies (i.e., the European Union Health Authorities and the Japanese Ministry of Health) in additional markets, which are material to us and our collaborative partners, may delay or deny the approval of our proposed products. None of our proposed 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 our manufacturer are subject to continuing regulatory oversight, 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 new drug application.

If our collaborative partners or other third party contractors give other products greater priority than our products or fail to perform their obligations under the agreements, 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 or compete effectively in the market. 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 commercialization, 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 commercialization, 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 commercialization, research and development or manufacturing arrangements on acceptable terms, if at all.

Our reliance on third parties such as manufacturers, clinical distributors, 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 engage manufacturers, clinical distributors, and/or CROs to manufacture and distribute the product candidate, to conduct and manage clinical studies and to assist us in guiding products through the FDA review and approval process. For example, we collaborate with the National Cancer Institute of Canada's Clinical Trial Group in connection with our Tarceva™ Phase III trials. Because we have engaged and intend to engage manufacturers, clinical distributors, 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 manufacturers, clinical distributors, 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.

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

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

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

As of September 30, 2003, we held 88 U.S. patents, 151 foreign patents, 97 pending applications for U.S. patents, five of which have been allowed, and 205 applications for foreign patents, two of which have been allowed. Moreover, we jointly own with Pfizer Inc. 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, we jointly hold, with the University of Arizona, 11 issued U.S. patents, three U.S. pending patent applications, 17 foreign patents, and 25 pending foreign patent applications. We intend to continue to seek patent protection for or maintain as trade secrets all of the commercially promising product candidates that we have discovered, developed or acquired. Our success depends, in part, on our ability and our collaborative partners' ability to obtain 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 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. If our pending patent applications are not approved for any reason or if we are unable to develop additional proprietary technologies that are patentable, the degree of future protection for our proprietary rights will remain uncertain. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents.

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. 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.

In a legal action to enforce our gene transcription patents or other patents, courts may find that the scope of our patents is not sufficiently broad enough to cover our products or competitors infringing on our products. Further, courts may find that our patents are invalid or unenforceable. This would lessen our ability to enforce or license our patents and would lessen our ability to prevent competitors from marketing similar products.

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

Our processes and potential products may conflict with patents that have been or may be granted to competitors, academic institutions or others. As the biotechnology and pharmaceutical industries expand and more patents are filed and issued, the risk increases that our product candidates may give rise to a declaration of interference by the U.S. Patent and Trademark Office, to administrative proceedings in foreign patent offices or to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal proceedings against us seeking substantial damages or seeking to enjoin us from testing, manufacturing or marketing our products. If any of these actions were successful, we may also be required to cease the infringing activity or obtain the requisite licenses or rights to use the technology that may not be available to us on acceptable terms, if at all. Any litigation, regardless of the outcome, could be extremely costly to us.

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.

As of September 30, 2003, our cash reserves, consisting of cash, cash equivalents, restricted short and long-term investments, and unrestricted short-term investments, aggregated approximately $404.1 million, following the completion and assimilation of the Cell Pathways and Novantrone® transactions. Additionally, we estimate our cash burn will be approximately $115 million in fiscal 2004, and we have established a goal of achieving profitability and positive cash flow within 24 months of a successful market launch of Tarceva™. 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 and debt securities, as well as from collaborative partners in order to further our growth. We may not be able to obtain adequate funding from the sale of our securities or from collaborative partners 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.

Our outstanding indebtedness increased substantially with the issuance of convertible senior subordinated notes in February 2002 and September 2003, and we may not be able to make the required payments on these notes when due.

As a result of the issuance of our 4% Convertible Senior Subordinated notes due 2009 in February 2002 and the issuance of our 3.25% Convertible Senior Subordinated Notes due 2023 in September 2003, our long-term debt represented by these notes was $310.0 million as of September 30, 2003. Our Convertible Senior Subordinated Notes due 2009 and 2023 significantly increased our interest expense and related debt service costs. Interest on these notes accrues at the rate of 4% and 3.25% per annum, respectively. This amounts to interest payments of $3.2 million due and payable on the 2002 notes semi-annually on February 1 and August 1 of each year and $2.4 million due and payable on the 2003 notes semi-annually on March 8 and September 8 of each year on the outstanding amount of the notes. Cumulative interest payments of $35.2 million are

scheduled to be paid between February 1, 2004 and February 1, 2009 on the 2009 notes and $97.5 million between March 8, 2004 and September 8, 2023 on the 2023 notes. This long-term debt may:

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

We currently are not generating sufficient cash flow to satisfy the annual debt service payments on 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, we will default on our 2002 notes and our 2003 notes, and we would face liquidity problems as a result.

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

When the stock prices of companies in the Nasdaq Biotechnology Index fall, our stock price will most likely fall as well. The 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. From October 1, 2000 through September 30, 2001, the range of our stock price was between $86.38 and $30.19, and the range of the Nasdaq Biotechnology Index was between $1,323.41 and $608.24. From October 1, 2001 through September 30, 2002, the range of our stock price was between $50.94 and $11.50, and the range of the Nasdaq Biotechnology Index was between $978.42 and $397.36. From October 1, 2002 through September 30, 2003, the range of our stock price was between $38.34 and $12.84, and the range of the Nasdaq Biotechnology Index was between $801.40 and $442.09. 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.

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

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

We have had a shareholder rights plan, commonly referred to as a "poison pill," since January 1999. The purpose of the shareholder rights plan is to protect stockholders against unsolicited attempts to acquire control of us that do not offer a fair price to our stockholders as determined by our board of directors. Under the plan,

the acquisition of 17.5% or more of our outstanding common stock by any person or group, unless approved by our board of directors, will trigger the right by our stockholders to acquire additional shares of our common stock (and in certain cases the stock of the potential acquiror) at a bargain purchase price, thus significantly increasing the acquisition cost to a potential acquiror. The shareholder rights plan may have the effect of dissuading a potential hostile acquiror from making an offer for our common stock at a price that represents a premium to the then current trading price. Our certificate of incorporation and by-laws contain certain additional anti-takeover protective devices. For example,

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

An issuance of preferred stock with dividend and liquidation rights senior to the common stock and convertible into a large number of shares of common stock could prevent a potential acquiror from gaining effective economic or voting control. Further, we are subject to Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, restricts certain transactions and business combinations between a corporation and a stockholder owning 15% or more of the corporation's outstanding voting stock for a period of three years from the date the stockholder becomes a 15% stockholder. In addition to discouraging a third party from acquiring control of us, the foregoing provisions could impair the ability of existing stockholders to remove and replace our management and/or our board of directors.

ITEM 2. PROPERTIES

We currently lease three facilities in New York, one located at 58 South Service Road, Melville, New York, consisting of approximately 37,000 square feet, one located at 106 Charles Lindbergh Boulevard, Uniondale, New York, consisting of approximately 30,000 square feet, and one located at One 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 Farmingdale facility houses our U.S. drug discovery and pre-clinical laboratories. In August 2003, we consolidated our employees from the Uniondale facility into the Farmingdale facility. We are currently in the process of attempting to either assign or sublease our rights under the lease agreement for the Uniondale facility.

We currently lease three facilities in Colorado, one located at 2860 Wilderness Place, Boulder, Colorado, consisting of approximately 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. We are currently in the process of attempting to either assign or sublease our rights under the lease agreement for the facility at 2900 Center Green Court South.

In June 2003, in connection with our acquisition of Cell Pathways, Inc. we acquired a lease to a facility in Horsham, Pennsylvania, consisting of approximately 40,000 square feet. We are currently in the process of attempting to either assign or sublease our rights under the lease agreement for this facility.

Our subsidiary, OSI Pharmaceuticals (UK) Limited, leases two facilities, one located at Windrush Court, Watlington Road, Oxford, England, consisting of approximately 88,000 square feet, and another located at Isis House, Watlington Road, Oxford, England, consisting of approximately 34,000 square feet. The Oxford facilities house research and development laboratories and administrative offices as well as our Prosidion Limited subsidiary. We ceased operations at our Aston Science Park, Birmingham, England facility in March 2002 and have consolidated the Birmingham operations into the Oxford facilities. In March 2003 we entered into a surrender agreement whereby the landlord released us of our obligations under the lease at the Aston Science Park, Birmingham, England facility in consideration for a payment of approximately $662,000.

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 2003.

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, 2001 through September 30, 2003 as reported on the NASDAQ National Market:

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

2002 FISCAL YEAR	HIGH	LOW
First Quarter	$50.94	$31.91
Second Quarter	49.05	35.11
Third Quarter	39.45	20.52
Fourth Quarter	33.81	11.50

Holders and Dividends

As of November 3, 2003, there were approximately 997 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.

Recent Sales of Unregistered Securities

In September, we issued $150 million aggregate principal amount of 3.25% Convertible Senior Subordinated Notes due 2023 to Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Morgan Stanley & Co., Incorporated, the initial purchasers of the notes, for resale in transactions exempt from the registration requirements of the Securities Act of 1933, as amended, to persons reasonably believed by the initial purchasers to be "qualified institutional buyers" as defined in Rule 144A under the Securities Act. The initial purchasers' discount was approximately $4.9 million. We used approximately $19.0 million of the net proceeds to repurchase 503,800 shares of our common stock. We also used approximately $14.2 million to acquire U.S. government securities that we pledged to the trustee as security for the notes sufficient to pay the first six interest payments on the notes. We intend to use the remainder of the net proceeds to continue the development of our oncology franchise, which may include additional product or corporate acquisitions, and for general corporate purposes. Interest on the notes accrue at a rate of 3.25% per year and will mature in 2023. The notes are convertible into shares of our common stock at any time on or prior to maturity, at a conversion price of $50.02 per share, subject to normal and customary adjustments in certain circumstances. We will file a registration statement to enable the selling securityholders to sell their notes and the shares issuable upon conversion of the notes.

Securities Authorized for Issuance Under Equity Compensation Plans

Plan category	Equity Compensation Plan Information as of September 30, 2003 Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders(a)	4,525,380	$24.83	2,989,191(d)
Equity compensation plans not approved by security holders(b)	766,587(c)	$46.81	—
Total	5,291,967	$28.01	2,989,191

(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 Pharmaceuticals (UK) Limited, and options granted to outside directors.

(d) Includes 807,736 shares reserved for issuance under the 1993 Employee Stock Purchase Plan, the 1995 Employee Stock Purchase Plan, the stock purchase plan for employees of OSI-UK and the Stock Purchase Plan for Non-Employee Directors (see notes 11(d) and 11(e) to the accompanying consolidated financial statements).

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

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth our selected consolidated financial data as of and for each of the years in the five-year period ended September 30, 2003. 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)				
	2003(a)	2002(b)	2001(c)	2000(d)	1999(e)
Consolidated Statement of Operations Data:					
Revenues	$ 32,369	$ 21,816	$ 26,022	$ 28,652	$ 22,652
Expenses:					
Cost of product sales	157	—	—	—	—
Research and development	102,642	102,202	56,038	39,622	24,190
Acquired in-process research and development	31,451	130,200	—	—	806
Selling, general and administrative	70,532	28,146	16,033	11,773	10,432
Amortization of intangibles	9,300	1,255	742	870	1,469
Loss from operations	$(181,713)	$(239,987)	$(46,791)	$(23,613)	$(14,245)
Other income — net	356	7,904	25,661	3,519	1,156
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	—	12,604	—	—	—
Loss before cumulative effect of accounting change	$(181,357)	$(218,479)	$(21,130)	$(16,348)	$ (9,798)
Cumulative effect of the change in accounting for the recognition of upfront fees	—	—	(2,625)	—	—
Net loss	$(181,357)	$(218,479)	$(23,755)	$(16,348)	$ (9,798)
Basic and diluted net loss per common share:					
Loss before cumulative effect of change in accounting policy	$ (4.87)	$ (6.07)	$ (0.62)	$ (0.67)	$ (0.46)
Cumulative effect of change in accounting policy	—	—	$ (0.08)	—	—
Net loss	$ (4.87)	$ (6.07)	$ (0.70)	$ (0.67)	$ (0.46)
Weighted average number of shares of common stock outstanding	37,249	35,978	33,852	24,531	21,451

	AS OF SEPTEMBER 30, (In thousands)				
	2003(a)	2002(b)	2001(c)	2000(d)	1999(e)
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investment securities (unrestricted and restricted)	$404,147	$476,277	$551,479	$85,065	$18,862
Receivables	11,654	6,981	6,633	1,049	5,194
Working capital	379,598	445,596	533,761	80,467	14,943
Total assets	591,502	579,044	591,689	99,776	47,031
Long-term liabilities	338,592	169,774	14,387	3,082	3,466
Stockholders' equity	218,057	379,108	549,831	89,882	33,365

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

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

(c) The fiscal 2001 consolidated financial statements include a cumulative effect of the change in accounting principle of $2.6 million relating to the adoption of SAB No. 101; the acquisition of certain assets from British Biotech plc for $13.9 million; $25 million in upfront fees received upon the execution of collaboration agreements with Genentech, Inc. and Roche; net proceeds of approximately $404 million from a public offering of common stock in November 2000; the sale of newly-issued shares of common stock to Genentech and Roche for an aggregate purchase price of $35 million each; and a charge to operations of $5.1 million for the estimated cost of closing our Birmingham, England and Tarrytown, New York facilities. (See notes 1(b), 3(d), 5(a), 11(f), 11(g), 17(a) and 17(b) to the accompanying consolidated financial statements.)

(d) The fiscal 2000 consolidated financial statements include a $3.5 million technology access fee received upon the execution of a collaborative research and license agreement with Tanabe Seiyaku Co., Ltd.; non-cash compensation charges of approximately $6.8 million and deferred compensation of approximately $8.8 million associated with options issued to an employee and consultants; net proceeds of approximately $53 million from a private placement of common stock; a $3.7 million gain resulting from the sale of our diagnostics business, including the assets of our wholly-owned subsidiary, OSDI, Inc., to The Bayer Corporation; and 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. (See notes 5(c), 11(a) and 18 to the accompanying consolidated financial statements.)

(e) The fiscal 1999 consolidated financial statements include the acquisition of Cadus' research business for $2.2 million in cash, including a $806,000 charge to operations for in-process research and development 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.

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 novel mechanism based, targeted therapies in the areas of signal transduction and apoptosis and next-generation cytotoxic chemotherapy agents. We also market two products: Novantrone® and Gelclair®. We acquired the rights to market and promote Novantrone® (mitoxantrone concentrate for injection) for approved oncology indications in the United States and to market and distribute Gelclair® Bioadherent Oral Gel in North America during fiscal 2003.

Our most prominent 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 including lung and pancreatic cancers. The HER1/EGFR gene is also amplified in certain tumors including glioblastoma multiforme, an aggressive form of brain cancer. 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, we are developing Tarceva™ in a global 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 the drug 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 I and Phase II trials in non-small cell lung cancer, or NSCLC, bronchioloalveolar cell carcinoma, or BAC (a form of lung cancer), glioblastoma multiforme, head and neck cancer and ovarian cancer. Based upon these data, the alliance embarked upon a comprehensive global development plan in 2001 designed to both register Tarceva™ and maintain a competitive position against other EGFR inhibitors. In October 2003, we announced that two Tarceva™ Phase III clinical trials for front-line NSCLC (in combination with conventional chemotherapy versus chemotherapy alone) did not meet their primary endpoints of improving overall survival. We had considered these trials high risk as a result of a competitor's previously announced failure of its EGFR inhibitor in this setting which had demonstrated that combining an EGFR inhibitor concomitantly with conventional chemotherapy drug regimens did not result in improved patient benefit. Tarceva™ is currently in a fully enrolled 730 patient Phase III clinical trial for second/third-line NSCLC patients, which is our primary registration study. This study compares the use of Tarceva™ as a monotherapy versus placebo in lung cancer patients who have failed conventional chemotherapy treatments. The study is designed to detect a survival advantage as its primary endpoint with secondary endpoints that include symptom relief and improvement of quality of life. Based on encouraging data from a Phase I study in glioblastoma, our partner, Genentech, initiated a Phase II program for this indication in August 2003. Tarceva™ is also in a Phase III trial for pancreatic cancer where it is being tested in combination with gemcitabine versus gemcitabine plus placebo. We expect top-line data for the ongoing Phase III trials and Phase II glioblastoma trial during 2004. We estimate the approval of Tarceva™ by the U.S. Food and Drug Administration in the fourth quarter of calendar 2004 if the second/third-line NSCLC study successfully meets its endpoint.

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 direct 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:

- support and enable the successful development, registration and commercialization of Tarceva™ by reducing program execution and registration risk and by maximizing Tarceva™'s differentiation and competitive positioning; and

- establish a first-class oncology franchise around Tarceva™ by assembling, through mergers, acquisitions and internal growth, a full complement of capabilities and technology and a diversified risk balanced portfolio and pipeline of drug candidates.

Behind Tarceva™, we have multiple drug candidates in clinical development. OSI-7904L, the most promising of our next generation cytotoxic chemotherapy candidates, is a liposomal formulation of a thymidylate synthase inhibitor. It is being developed as a potential competitor to 5-fluorouracil, or 5-FU and capecitabine (Xeloda®). OSI-7904L is in a Phase II program which includes a Phase II trial in gastric and gastric esophageal junction cancers and combination Phase I trials with cisplatin (Platinol®) and oxaliplatin (Eloxatin™). Aptosyn® (exisulind) was added to our pipeline with the acquisition of Cell Pathways, Inc. in June 2003 and is currently in a Phase III trial in combination with docetaxel (Taxotere®) for the treatment of advanced NSCLC. Although Cell Pathways had advanced Aptosyn® to Phase III trials, we consider it to be a higher risk prototype drug candidate arising from the apoptosis platform acquired from Cell Pathways. We believe OSI-461 (formerly CP461), the second drug candidate acquired from Cell Pathways to be a more promising second-generation molecule that is currently being evaluated in a dose ranging Phase I study and a series of exploratory Phase II studies in chronic lymphocytic leukemia, renal cell carcinoma and prostate cancer. OSI-211 and OSI-7836 are two additional next generation cytotoxic agents currently undergoing Phase II and Phase I trials, respectively. Final data from the on-going Phase I and Phase II studies is expected from both programs during the coming year. We currently view the continued development of these two candidates beyond these studies to be unlikely. Three molecules, CP-547,632 (targeting the vascular endothelial growth factor receptor, or VEGFR, gene), CP-724,714 (targeting the HER2 gene) and CP-868,596 (targeting the platelet derived growth factor receptor, or PDGFR, gene) that were discovered as part of our historical alliance with Pfizer Inc. and are currently in clinical trials conducted by Pfizer. We will receive royalty payments on the Pfizer candidates if they are successfully commercialized.

Key Transactions in Fiscal 2003

We have carried out three major transactions in fiscal 2003 in keeping with our strategy of building an oncology franchise around Tarceva™, maintaining a strong cash position as we do so and assembling a commercial operation in the United States ahead of Tarceva™'s projected launch.

On March 11, 2003, we entered into an agreement to market and promote the drug Novantrone® for approved oncology indications in the United States pursuant to the terms of a Co-Promotion Agreement with Ares Tradings, S.A., an affiliate of Serono S.A. In consideration for exclusive marketing and promotion rights, we paid $45.0 million in cash. In consideration for certain transition services provided by Serono during a four-month transition period starting on the effective date of the agreement, we also paid a one-time fee of $10.0 million. Under the terms of the agreement, we pay quarterly maintenance fees to Serono until the later of the expiration of the last valid patent claim or the first generic date. We receive commissions on net sales of Novantrone® in the United States for oncology indications. These commission rates increase upon the achievement of certain annual sales goals for Novantrone® in oncology indications. Novantrone® is approved by the FDA for the treatment of acute nonlymphocytic leukemia, which includes myelogenous, promyelocytic, monocytic and erythroid acute leukemias, and the relief of pain associated with advanced hormone-refractory prostate cancer. The drug is also approved for certain advanced forms of multiple sclerosis. Serono will continue to market Novantrone® in the multiple sclerosis indications and will record all U.S. sales in all indications. We initiated our sales activity for Novantrone® during the third quarter of fiscal 2003.

On June 12, 2003, we completed our acquisition of Cell Pathways. Cell Pathways was a development stage biotechnology company focused on the research and development of products to treat and prevent cancer, and the future commercialization of such products. Cell Pathways also marketed and sold Gelclair®, the manufacturing rights and obligations of which were held by Sinclair Pharmaceuticals Ltd. of the United Kingdom and subsequently licensed to Helsinn Healthcare S.A. in July 2003. The assets purchased and liabilities assumed by us included: (a) two drug candidates in clinical development: Aptosyn® and OSI-461 and the related technology platform and patent estate; (b) exclusive distribution rights to Gelclair®, a marketed oncology device; (c) inventory; (d) rights to Cell Pathways' leased facility in Horsham, Pennsylvania, as well as leasehold improvements and certain equipment; and (e) certain other assets and liabilities.

As consideration for the merger, each share of Cell Pathways common stock was exchanged for (i) 0.0567 shares of OSI common stock and (ii) a contingent value right to receive 0.04 shares of OSI common stock. The contingent value right is triggered in the event a new drug application is accepted for filing with the U.S. Food and Drug Administration by June 12, 2008 for either of the two newly acquired clinical candidates, Aptosyn® or OSI-461. Based on the exchange ratio of 0.0567, we issued approximately 2.2 million shares of OSI common stock to Cell Pathways' stockholders in connection with the merger.

On September 8, 2003, we issued $135.0 million aggregate principal amount of convertible senior subordinated notes in a private placement for net proceeds of $130.3 million. On September 17, 2003, the bankers associated with this convertible debt offering exercised an option to purchase an additional $15.0 million of notes, for additional net proceeds of $14.5 million. The notes bear interest at 3.25% per annum, payable semi-annually, and mature on September 8, 2023. The notes are convertible into shares of our common stock at a conversion price of $50.02 per share. We used $19.0 million of the net proceeds for the purchase of 503,800 shares of our common stock and $14.2 million to acquire U.S. government securities that were pledged to the trustee as security for the notes in an amount sufficient to pay the first six interest payments on the notes. We are planning to use the remainder of the proceeds from the sale of the notes for the continued development of our oncology franchise which may include additional product or corporate acquisitions and general corporate purposes.

To support Novantrone®, we have built a core commercial operation comprising of approximately 60 sales, marketing, medical affairs, commercial planning and other support personnel including an approximately 30 person sales force. We believe that the tangible and intangible benefits of this commercial capability are significant in that it allows us to pursue additional in-licensing and co-promotion arrangements for other marketed products, enables us to directly market our future pipeline products in the United States, and further validates OSI as a quality development and commercialization partner for oncology development candidates. In addition, it allows us to pursue our co-promotion rights for Tarceva™ in the United States with our partner, Genentech.

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 revenues 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

Sales commissions represent the commissions earned on sales of Novantrone® for oncology uses pursuant to the Co-Promotion Agreement with Serono. Serono will continue to market Novantrone® for multiple sclerosis indications and will record all U.S. sales for all indications, including oncology indications. Sales commissions from Novantrone® on net oncology sales are recognized in the period the sales occur based on the estimated split between oncology sales and multiple sclerosis sales of Novantrone®, as determined on a quarterly basis by an external third party. The split between oncology and multiple sclerosis sales is subject to further adjustment based on final review by the external party, in the subsequent quarter. Management does not believe these adjustments, if any, will be significant to the consolidated financial statements.

Product sales represent revenues earned on sales of Gelclair®. The marketing and distribution rights to Gelclair® were acquired in our acquisition of Cell Pathways effective June 12, 2003. In accordance with SFAS

No. 48, "Revenue Recognition When Right of Return Exists," given the limited sales history of Gelclair®, we at this time defer the recognition of revenue on product shipments of Gelclair® to wholesale customers until such time as the product is sold from the wholesale customer to the retail and non-retail outlets. For each reporting period, we monitor shipments from wholesale customers to pharmacies and hospitals and wholesale customer reorder history based on data from an external third party.

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. Our most significant application of this policy, to date, is the $25.0 million in upfront fees received from Genentech and Roche in January 2001, which were originally being recognized evenly over the expected three-year term of our required research and development efforts under the terms of the agreement. 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 from three years to four years to reflect the revised estimated timing of our research and development commitment for Tarceva™ under the alliance. The revision was a result of the review of the current research data available, current developments in the HER1/EGFR targeted therapy market and the involved parties' revised projections for the clinical development plan. As a result of this revision, we recorded revenues of $5.0 million for fiscal 2003, compared to $8.3 million had the upfront fees continued to be recognized over the 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.

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.

Accounting for Goodwill and Other Intangible Assets

Effective October 1, 2002, we fully adopted SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 requires that goodwill and certain other intangibles with indefinite useful lives, are not amortized into results of operations but instead are reviewed for impairment at least annually and written down, and charged to results of operations in periods in which the recorded value of goodwill and certain other intangibles is more than their implied fair value. We completed our impairment review of goodwill during the first quarter of fiscal 2003 and determined that no impairment charge was required upon adoption. In addition, no indications of impairment were identified during the fiscal year ended September 2003.

Our identifiable intangible assets are subject to amortization. We reassessed the useful life of our intangible assets upon adoption of SFAS No. 142 to make any necessary amortization period adjustments to our then existing intangible assets. No adjustments resulted from this assessment. SFAS No. 142 requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives and reviewed for impairment in accordance with SFAS No. 121, "Accounting for the Impairment of Long-Lived Asset to be Disposed Of. "Under SFAS No. 121, intangible and other long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. As a result of our acquisition of the exclusive rights to market and promote Novantrone® for the approved oncology indications in the United States, we recorded an identifiable intangible asset with an estimated useful life through the expiration of the Novantrone® patent in April 2006. In connection with our

acquisition of Cell Pathways, we assumed the exclusive rights to market and distribute Gelclair® in North America which Cell Pathways had acquired from Sinclair in January 2002 for a period of 10 years. As a result, we recorded an identifiable intangible asset which is being amortized over eight and a half years, the remaining term of the agreement.

Accounting for the Impairment of Long-Lived Assets

On October 1, 2002, we adopted the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 requires, among other things, that long-lived assets be measured at the lower of carrying amount or fair value, less cost to sell, whether reported in continuing operations or in discontinued operations. Intangibles with determinable lives 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 intangibles with determinable lives and other long-lived assets are impaired which may result in an adverse impact on our financial condition and results of operations. The adoption of SFAS No. 144 did not have an impact on our consolidated financial statements as of and for the fiscal year ended September 30, 2003.

Comparison of Fiscal 2003 and Fiscal 2002

Results of Operations

Our fiscal 2003 net loss of $181.4 million decreased $37.1 million compared to our fiscal 2002 net loss of $218.5 million. The fiscal 2003 loss included an in-process R&D charge of $31.5 million in connection with the acquisition of Cell Pathways. The fiscal 2002 loss included an in-process R&D charge of $130.2 million in connection with the acquisition of Gilead Sciences, Inc.'s oncology assets. The increase in net loss excluding the in-process R&D charges was in part related to a one-time fee and quarterly maintenance fees expended in connection with the Novantrone® licensing agreement with Serono, fees associated with the Celgene Corporation deal to acquire full North American marketing rights to Gelclair®, the costs of scaling up and recruiting a commercial organization and increased amortization expense.

Revenues

Total revenues for fiscal 2003 were $32.4 million compared to revenues of $21.8 million for fiscal 2002. The increase in revenues was primarily due to Novantrone® sales commissions. On March 11, 2003, we began recording Novantrone® sales commissions, upon the execution of the Co-Promotion Agreement with Serono. Total sales commissions for fiscal 2003 were $16.3 million. We launched our sales efforts for Novantrone® during the third quarter of fiscal 2003. We project that our total fiscal 2004 sales commissions on Novantrone® oncology sales will be in excess of $30 million. However, Congress has recently passed legislation, subject to the President's approval which is expected, that materially changes the Medicare reimbursement guidelines for intravenous and oral oncology products which may impact the sales revenues of all intravenous chemotherapy agents. We began recognizing Gelclair® product sales on June 12, 2003, upon the closing of our acquisition of Cell Pathways. Total product sales for the period June 12, 2003 to September 30, 2003 were $437,000. We launched our sales effort for this product in October 2003. We estimate that our total fiscal 2004 product sales of Gelclair® will be between $3.0 million to $4.0 million.

License and other revenues decreased $3.8 million or 38% for fiscal 2003 compared to fiscal 2002. This decrease was primarily due to the decrease in the amount of revenue recognized relating to the $25.0 million upfront fees received from Genentech and Roche (see note 5(a) to the accompanying consolidated financial statements). In accordance with the provisions of SAB No. 101, we were recognizing the $25.0 million received from Genentech and Roche evenly over the expected three-year development phase of our agreement. In the fourth quarter of fiscal 2002, we changed the expected term of the agreement from three years to four years to reflect the revised estimated timing of our research and development commitment for

Tarceva™ under the alliance. The revision was a result of the review of the current research data available, current developments in the HER1/EGFR targeted therapy market and the involved parties' revised projections for the clinical development plan. In accordance with Accounting Principles Board Opinion No. 20, "Accounting Changes," the remaining unearned revenue is being recognized prospectively over the revised term. As a result, we recorded revenues of $5.0 million during fiscal 2003 compared to revenues of $7.5 million during fiscal 2002. The decrease in fiscal 2003 was also due to a decrease in revenues of $923,000 related to certain administrative services provided to British Biotech plc and Gilead during the transition periods following the acquisitions of certain assets of each company in fiscal 2002.

Total collaborative program revenues decreased $2.4 million or 20% for fiscal 2003 compared to fiscal 2002. The decrease was primarily due to the phase-down of our collaboration in cosmeceuticals with Anaderm Research Corporation. In July 2002, we entered into an agreement with Pfizer to accelerate the phase-down period of the collaboration with Anaderm so that it would terminate no later than April 23, 2003. In consideration for the work performed by us during the accelerated phase-down period, we received $4.5 million in September 2002 and $3.5 million in March 2003 upon the successful completion of the transition period. The $4.5 million was recognized as revenue ratably over the term of the transition period and the $3.5 million was recognized during the second quarter of fiscal 2003 upon the successful completion of the transition. The decrease for the year was also due to a decrease in activity related to our collaboration in diabetes with Tanabe Seiyaku Co., Ltd., which expired in October 2003 and was not renewed. As a result of our strategic decision to divest all non-oncology research programs, as well as the completion of the Anaderm and Tanabe collaborations in fiscal 2003, we no longer expect collaborative revenues from research alliances going forward.

Expenses

Total operating expenses of $214.1 million decreased $47.7 million or 18% for fiscal 2003 compared to operating expenses of $261.8 million for fiscal 2002. Excluding the acquired in-process R&D charges of $31.5 million and $130.2 million recorded in fiscal 2003 and fiscal 2002, respectively, operating expenses increased $51.0 million or 39% for fiscal 2003. These in-process R&D charges related to the acquisition of Cell Pathways in June 2003 and the acquisition of certain assets from Gilead in December 2001. We do not deem these charges to be indicative of the day-to-day operations of our company. Operating expenses recognized in fiscal 2003 and 2002 primarily included (i) research and development expenses, which included expenses related to the development of our lead clinical candidate, Tarceva™ and our other clinical candidates, and proprietary and collaborative-based research; (ii) in-process R&D charges related to the acquisition of Cell Pathways in June 2003 and the acquisition of oncology assets acquired from Gilead in December 2001; (iii) selling, general and administrative expenses; and (iv) amortization of intangibles.

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

The largest component of our total expenses, excluding the in-process R&D charges, is our ongoing investments in research and development, and particularly, the clinical development of our product pipeline. We currently have multiple drug candidates in clinical development including our most prominent candidate, Tarceva™, which is currently in Phase III trials for NSCLC and pancreatic cancer, Phase II trials for glioblastoma, and various other Phase I and II trials. The other drug candidates are in various stages of clinical development. Aptosyn® was added to our pipeline with the acquisition of Cell Pathways and is currently in Phase III trials. OSI-461, which was acquired along with Aptosyn® in connection with our acquisition of Cell Pathways, is a second-generation molecule that is being evaluated in chronic lymphocytic leukemia, renal cell carcinoma and prostate cancer. Three candidates (OSI-7904L, OSI-211 and OSI-7836) are next generation cytotoxic chemotherapy agents, which we are developing. Three other candidates (CP-547,632, CP-724,714 and CP-868,596) are gene-targeted therapies currently being developed by Pfizer and require no further research and development investment by us. We consider the active management and development of our clinical pipeline crucial to the long-term approval process. We manage our overall research, development and in-licensing efforts in a manner designed to generate a constant flow of clinical candidates into development to

offset both the advancement of products to the market and the anticipated attrition rate of drug candidates that fail in clinical trials or are terminated for business reasons. The table below summarizes the typical duration of each phase of clinical development and the typical cumulative probabilities of success for approval of drug candidates entering clinical development. The numbers are based upon industry survey data for small molecule drugs:

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

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

Research and development expenses marginally increased by $440,000 in fiscal 2003 compared to fiscal 2002. Increases in costs associated with the clinical development of Tarceva™ and transition costs associated with the assimilation of Cell Pathways were offset by a shift from non-oncology and collaborative programs to oncology programs. Also included in research and development expenses for fiscal 2003 was a severance charge of $694,000. This charge related to a reduction in our headcount in October 2002 as we refocused our business on oncology and away from services that we had historically provided to our former collaborative partners.

Our most advanced development program is for Tarceva™. In January 2001, we entered into the alliance with Genentech and Roche for the global development and commercialization of Tarceva™. The significant perceived market potential for Tarceva™ has resulted in the alliance partnership committing to an unusually large and comprehensive global development plan for the candidate. The global development plan comprises of major Phase III clinical trials in lung and pancreatic cancers and a large number of earlier stage trials in a variety of disease settings, including glioblastoma. In addition, numerous collaborative and investigator sponsored studies are ongoing in a number of other disease settings including bronchioloalveolar cell-carcinoma and gynecological malignancies. The alliance partners have committed to invest a combined $300 million in the global development plan to be shared equally by the three parties. Additional research and development investments can be made by the parties outside of the global development plan with the consent of the other parties. We estimate that we will invest an additional $10-$15 million in Tarceva™ research and development outside of the global development plan prior to the drug's targeted FDA approval in the fourth quarter of calendar 2004. As of September 30 , 2003, we have invested in excess of $75 million, representing our share of the costs incurred to date in the tripartite global development plan and additional investments outside the plan. Our research and development expenses for Tarceva™ incurred for fiscal 2003 were $35.9 million. We anticipate investing a majority of the remaining $35-$40 million we have provisionally budgeted for this program over the next two years. Should Tarceva™ be successfully registered and launched, we would anticipate continued research and development investment in the product to support its commercial growth. For our second Phase III clinical candidate, Aptosyn®, we expect the cost to complete the Phase III trials to be between $4.0 and $5.0 million as of September 30, 2003.

In connection with the acquisition of Cell Pathways in June 2003, we recorded an in-process R&D charge of $31.5 million, representing the estimated fair value of the acquired in-process technology that had not yet reached technological feasibility and had no alternative future use (see note 3(a) to the accompanying consolidated financial statements). The in-process R&D charge was assigned to the two development projects and their related technology platform and patent estates for Aptosyn® ($3.7 million) and OSI-461 ($27.8 million), based on their value on the date of the acquisition. In determining the value of the in-process R&D, the assumed commercialization dates for these products ranged from 2005 to 2006. Significant assumptions and estimates used in the valuation of in-process R&D included: the stage of development for each of the two projects; future revenues; growth rates for each product; product sales cycles; the estimated life of a product's underlying technology; future operating expenses; probability adjustments to reflect the risk of developing the acquired technology into commercially viable products; and a discount rate of 25% to reflect present value.

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

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

For each project, we need to successfully complete a series of clinical trials and to receive FDA or other regulatory approvals prior to commercialization. There can be no assurance that any of these candidates will ever reach feasibility or develop into products that can be marketed profitably, nor can there be any assurance that 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 candidates, we may discontinue such further development of certain or all of these candidates.

Selling, general and administrative expenses increased $42.4 million or 151% for fiscal 2003 compared to fiscal 2002. The increase was due to (i) additional management and personnel relating to the establishment of commercial operations to support Gelclair® and Novantrone®; (ii) subcontracting expenses relating to our short-term transitional arrangement with a contract sales organization comprising a core of sales representatives as we build our commercial operations; (iii) increased commercialization and marketing costs relating to Tarceva™ which are shared with Genentech in accordance with the terms of our collaboration with Genentech; (iv) expenses for maintenance fees and transition support services provided by Serono relating to Novantrone® sales in oncology indications; and (v) expenses associated with the full recovery of rights to market and distribute Gelclair® from Celgene, as well as transition support services provided by Celgene. Included in selling, general and administrative expenses for fiscal 2003 is a severance charge of $249,000 relating to a reduction in our headcount in October 2002. We expect selling, general and administrative costs to increase as we expand our commercial operations which include a sales force and an associated marketing and sales management infrastructure. The sales and marketing infrastructure is comprised of approximately 60 sales, marketing, medical affairs, commercial planning and support personnel, including an approximately 30 person sales force.

Amortization of intangibles increased $8.0 million or 641% for fiscal 2003 compared to fiscal 2002. The increase primarily related to $8.1 million in amortization expense related to the exclusive rights to market and promote the drug Novantrone® for approved oncology indications in the United States. Also included in amortization for fiscal 2003 is $984,000 in amortization expense related to the exclusive rights to market and distribute Gelclair® in North America. Offsetting these increases was a $1.0 million decrease in amortization expense from fiscal 2002 attributable to the full adoption of SFAS No. 142 on October 1, 2002, whereby we ceased amortizing the assembled workforce acquired from British Biotech and reclassified the balance of $2.1 million to goodwill.

Other Income and Expense

Net investment income decreased $6.9 million or 47% for fiscal 2003 compared to fiscal 2002. The decrease was primarily attributable to a decrease in the average rate of return on our investments and to less funds available for investment during the respective periods. Interest expense increased $1.5 million or 28% for fiscal 2003 compared to fiscal 2002. The increase was primarily due to the interest expense incurred on the convertible senior subordinated notes. In February 2002, we issued $200.0 million aggregate principal amount of convertible senior subordinated notes, which bear interest at 4% per annum, are payable semi-annually, and mature in February 2009. In August and September 2002, we retired a total of $40.0 million in principal amount of these notes. In September 2003, we issued $150.0 million aggregate principal amount of convertible senior subordinated notes, which bear interest at 3.25% per annum, are payable semi-annually, and mature in September 2023. For fiscal 2003, other expense-net was $737,000 compared to other expense-net of $1.6 million for fiscal 2002. Included in fiscal 2003 was the amortization of debt issuance costs of $834,000, offset by realized gains from the sale of investments of $347,000. 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-held healthcare information company (see note 4(b) to the accompanying consolidated financial statements). With respect to the early retirement of the convertible senior subordinated notes in August and September 2002, we recognized a net gain of $12.6 million in fiscal 2002 representing the difference between the purchase price of $26.2 million and the aggregate principal of $40.0 million and related accrued interest less the writedown of $1.3 million of related debt issuance costs (see note 10(b) to the accompanying consolidated financial statements). Also in fiscal 2002, we recognized 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 18 to the accompanying consolidated financial statements).

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 in-process R&D charge of $130.2 million in connection with the acquisition of Gilead's oncology assets. The increase in the net loss, excluding the in-process R&D charge, is primarily due to an increase in development costs associated with Tarceva™ and our three next generation cytotoxic chemotherapy agents 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 for fiscal 2002 were $21.8 million compared to revenues of $26.0 million for fiscal 2001. License and other revenues increased $1.8 million or 22% for fiscal 2002 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. The increase was also related to certain administrative services provided to provided to British Biotech and Gilead during the transition periods following the acquisitions of certain assets of each company in fiscal 2002.

Total collaborative program revenues decreased $6.0 million in fiscal 2002 or 33% compared to fiscal 2001. This decrease was 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 would 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 $3.5 million in March 2003 upon the successful completion of the transition period. The $4.5 million was recognized as revenue ratably over the expected term of the transition period and the $3.5 million was recognized during the second quarter of fiscal 2003 upon the successful completion of the transition. For fiscal 2002, we recognized $1.8 million of revenue related to the phase-down.

Expenses

Total 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 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.

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 150,000 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 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(b) to the accompanying consolidated financial statements). 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-7904L (Phase I), OSI-211 (Phase II) and OSI-7836 (Phase I). Value was assigned to each program ($13.4 million to OSI-7904L; $19.9 million to OSI-211; $96.9 million to OSI-7836) based on the assessment of estimated value at the date of acquisition.

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 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 $12.1 million or 76% 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.

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 10(b) 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 10(b) 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 18 to the accompanying consolidated financial statements).

Liquidity and Capital Resources

At September 30, 2003, working capital, representing primarily cash, cash equivalents, and restricted and unrestricted short-term investments, aggregated $379.6 million compared to $445.6 million at September 30, 2002. This decrease of $66.0 million is primarily due to the payment for the exclusive rights to market and promote Novantrone® and related fees totaling $46.0 million, the purchase of our common stock in September 2003, the transition services fees and maintenance fees paid to Serono, as well as net operating cash burn for the period. This decrease was offset by the net proceeds of $145.1 million from the issuance of the convertible senior subordinated notes in September 2003, offset by the long-term portion of restricted investment securities purchased, sales commissions earned on Novantrone® sales for oncology uses in the United States, and cash proceeds from the exercise of options.

On September 8, 2003, we issued $135.0 million aggregate principal amount of convertible senior subordinated notes in a private placement for net proceeds of $130.3 million. On September 17, 2003, the bankers associated with this convertible debt offering exercised an option to purchase an additional $15.0 million of notes, for an additional net proceeds of $14.5 million. The notes bear interest at 3.25% per annum, payable semi-annually, and mature on September 8, 2023. The notes are convertible into shares of our common stock at a conversion price of $50.02 per share, subject to normal and customary adjustments such as stock dividends. We may redeem the notes, in whole or in part, at any time after September 8, 2008 for a price equal to 100% of the principal amount of the notes to be redeemed, plus any accrued and unpaid interest. If we redeem the notes, the purchase price must be paid in cash. The holders of the notes have the right to require us to purchase all of the notes, or a portion thereof, on September 8, 2008, September 8, 2013 and September 8, 2018. Upon a change of 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. Upon the election by the holders of the right to require us to purchase the notes or upon a change in control, we may elect to pay the purchase price in common stock instead of cash. The number of shares of common stock a holder will receive will equal the purchase price divided by 95% of the average of the closing prices of our common stock for the five-trading day period ending on the third business day prior to the purchase date. 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 related debt issuance costs of $5.2 million were deferred and are being amortized on a straight-line basis over the term of the notes. In connection with the issuance of the notes, we used $19.0 million of the net proceeds for the purchase of 503,800 shares of our common stock. With respect to the notes, we pledged $14.2 million of U.S. government

securities with maturities at various dates through August 2006. Upon maturity, the proceeds of these restricted investment securities will be sufficient to pay the first six scheduled interest payments on the notes when due. We consider these 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, 2003 were $14.3 million and $14.2 million, respectively.

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 $192.9 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. Upon a change of control, 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 purchase price divided by 95% of the average of the closing prices of our common stock for the five-trading day period ending on the third business day prior to the purchase date. 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.

If all or any portion of the notes issued in September 2003 and February 2002 have not been converted into common stock prior to their maturity dates, we will be required to pay, in cash, the outstanding principal amounts of the notes plus any accrued and unpaid interest. This could have a significant impact on our liquidity depending on our cash position at time of maturity. If we do not have sufficient cash to repay the debt, we may need to borrow additional funds or sell additional equity in order to meet out debt obligations.

We expect to incur continued losses over the next few years as we continue our investment in Tarceva™ and other product candidates in our pipeline as well as our research programs and our commercial operations. The major expenses associated with the broad-based Phase III development program for Tarceva™ were incurred in fiscal 2003. We estimate that our fiscal 2004 cash burn will be approximately $115 million. We have established a goal of achieving profitability and positive cash flow within 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. In addition, as we continue to pursue strategic in-licensing and acquisition opportunities that would bring additional products and clinical development candidates to our cancer pipeline, we will be required to use our available cash and/or equity securities. To achieve profitability, we, alone or with others, must successfully develop and commercialize our technologies and products, conduct pre-clinical studies and clinical trials, secure required regulatory approvals and obtain adequate assistance to

successfully manufacture, introduce and market such technologies and products. 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, 2003 and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	2004	2005	2006	2007	2008	2009 & Thereafter	Total
Contractual Obligations:							
Senior convertible debt(a)	$11,275	$11,275	$11,275	$11,275	$11,275	$386,325	$442,700
Operating leases	8,095	8,080	6,772	5,476	6,327	52,106	86,856
Capital commitments	624	—	—	—	—	—	624
Loans and capital leases payable(b)	70	8	—	—	—	—	78
Total contractual obligations	$20,064	$19,363	$18,047	$16,751	$17,602	$438,431	$530,258

(a) Includes interest payments at a rate of 4% per annum and 3.25% per annum relating to convertible senior subordinated notes issued in February 2002 and September 2003, respectively.

(b) Includes interest payments.

Other significant commitments and contingencies include the following:

- We are committed to share equally with Genentech and Roche a combined $300 million in certain global development costs for Tarceva™. As of September 30, 2003, we have spent approximately 75% of our commitment under the agreement. We are also committed to share certain commercialization costs relating to Tarceva™ with Genentech.
- In connection with our agreement with Serono to market and promote Novantrone® in approved oncology indications, we are required to pay quarterly maintenance fees to Serono until the later of the expiration of the last valid patent claim or the first generic date, as defined in the agreement, or unless the agreement is earlier terminated.
- In connection with the exclusive distribution agreement to market and distribute Gelclair® in North America, we are committed to additional inventory purchases of $3.0 million and $5.0 million in 2003 and 2004, respectively, and annual marketing expenditures of $750,000, $500,000 and $250,000 for 2003 through 2006, 2007 through 2008 and 2009 through 2011, respectively. In addition, we are obligated to spend $1.3 million annually for direct sales force efforts. We could be responsible for milestone payments totaling $3.0 million related to achievement of certain sales, patent and clinical trial milestones.
- Under agreements with external CROs we will continue to incur expenses relating to the progress of Tarceva™ and other candidate 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 termination agreement with Celgene, we are required to make a payment to Celgene on the first anniversary of the effective date provided that the transition services, as defined in the agreement, have been provided to us. The agreement also provides for a milestone payment to Celgene upon the achievement of a specified amount of net sales of Gelclair®.

- We have outstanding letters of credit issued by a commercial bank. One is an irrevocable letter of credit related to our Oxford, England facility and expires annually with a final expiration date of September 27, 2007. The amount under this letter of credit is $2.3 million of which the full amount was available on September 30, 2003. Another is an irrevocable letter of credit related to our Horsham, Pennsylvania facility, whose lease we assumed through the acquisition of Cell Pathways. The letter expires annually with a final expiration date of September 22, 2008. The amount under this letter of credit is $400,000 of which the full amount was available on September 30, 2003.

- In May 2003, we entered into a contract with a third-party contract sales organization for the outsourcing of sales representatives and other sales force infrastructure. The remaining commitment is approximately $1.6 million as of September 30, 2003.

- 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 $3.1 million at September 30, 2003.

- In connection with the acquisition of Cell Pathways in June 2003, we provided additional consideration in the form of five-year contingent value rights through which each share of Cell Pathways' common stock will be eligible for an additional 0.04 share of OSI common stock in the event of a filing of a new drug application by June 12, 2008 for either of the two clinical candidates acquired from Cell Pathways, OSI-461 or Aptosyn®.

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

- Under certain license agreements, we are required to pay license fees for the use of technologies and products in our research and development activities.

Recent Accounting Pronouncements

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure." SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation as originally provided by SFAS No. 123 "Accounting for Stock-Based Compensation." Additionally, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosure in both the annual and interim financial statements about the method of accounting for stock-based compensation and the effect of the method used on reported results. The transitional requirements of SFAS No. 148 are effective for all financial statements for fiscal years ending after December 15, 2002. We adopted the disclosure portion of this statement beginning in the fiscal quarter ended March 31, 2003. The application of the disclosure portion of this standard will have no impact on our consolidated financial position or results of operations. On April 22, 2003, FASB determined that stock-based compensation should be recognized as a cost in the financial statements and that such cost be measured according to the fair value of the stock options. The FASB has not as yet determined the methodology for calculating fair value and plans to issue an exposure draft and final statement in 2004. We will continue to monitor communications on this subject from the FASB in order to determine the impact on our consolidated financial statements.

Forward Looking Statements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

Our cash flow and earnings are subject to fluctuations due to changes in interest rates in our investment portfolio of debt securities, to the fair value of equity instruments held and to foreign currency exchange rates. We maintain an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a component of accumulated other comprehensive income (loss) included in stockholders' equity. With respect to the convertible senior subordinated notes issued in September 2003 and February 2002, we pledged $14.2 million and $22.9 million, respectively, of U.S. government securities (restricted investment securities) with maturities at various dates through August 2006 and November 2004, respectively. 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 10 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. We have not used or held derivative financial instruments in our investment portfolio.

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. 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 13(d) to the accompanying consolidated financial statements. We did not have any forward foreign exchange contracts as of September 30, 2003.

At September 30, 2003, we maintained a portion of our cash and cash equivalents in financial instruments with original maturities of three months or less. We also maintained an investment portfolio principally comprised of government and government agency obligations and corporate obligations that are subject to interest rate risk and will decline in value if interest rates increase. A hypothetical 10% change in interest rates during the year ended September 30, 2003 would have resulted in approximately a $781,000 change in our net loss.

Our long-term debt totaled $310.0 million at September 30, 2003 and was primarily comprised of the convertible senior subordinated notes we issued in September 2003 and February 2002 which bear interest at a fixed rate of 3.25% and 4%, respectively.

Underlying market risk exists related to an increase in our stock price or an increase in interest rates which may make the conversion of the convertible senior subordinated notes to common stock beneficial to the convertible senior subordinated notes holders. Conversion of the convertible senior subordinated notes would have a dilutive effect on any future earnings and book value per common share.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements:

	Page Number
Independent Auditors' Report	50
Consolidated Balance Sheets — September 30, 2003 and 2002	51
Consolidated Statements of Operations — Years ended September 30, 2003, 2002 and 2001	52
Consolidated Statements of Stockholders' Equity — Years ended September 30, 2003, 2002 and 2001	53
Consolidated Statements of Cash Flows — Years ended September 30, 2003, 2002 and 2001	54
Notes to Consolidated Financial Statements	55

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, 2003 and 2002, 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, 2003. 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, 2003 and 2002, and the results of their operations and their cash flows for each of the years in the three-year period ended September 30, 2003, in conformity with accounting principles generally accepted in the United States of America.

As discussed in notes 1(j) and 8 to the consolidated financial statements, the Company fully adopted the provisions of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets" in 2003 and adopted provisions of SFAS No. 141, "Business Combinations" and SFAS No. 142, for acquisitions consummated on or after July 1, 2001.

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

/s/ KPMG LLP

Melville, New York
November 17, 2003

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
September 30, 2003 and 2002
(In thousands except per share data)

	September 30, 2003	September 30, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 202,519	$ 152,578
Investment securities	174,057	304,388
Restricted investment securities — short-term	12,758	7,938
Receivables, including amounts due from related parties of $74 and $3,000 at September 30, 2003 and 2002, respectively	10,121	3,253
Inventory	3,616	—
Interest receivable	1,533	3,728
Prepaid expenses and other current assets	9,847	3,873
Total current assets	414,451	475,758
Restricted investment securities — long-term	14,813	11,373
Property, equipment and leasehold improvements — net	44,977	46,175
Debt issuance costs — net	9,488	5,145
Goodwill	38,810	38,648
Other intangible assets — net	66,145	458
Other assets	2,818	1,487
	$ 591,502	$ 579,044
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including amounts due to related parties of $6,875 and $2,190 at September 30, 2003 and 2002, respectively	$ 29,013	$ 21,022
Unearned revenue — current; including amounts received in advance from related parties of $5,000 and $7,687 as of September 30, 2003 and 2002, respectively	5,779	8,613
Loans and capital leases payable — current	61	527
Total current liabilities	34,853	30,162
Other liabilities:		
Deferred rent expense — long term	2,179	1,040
Unearned revenue — long-term, including amounts received in advance from related parties of $1,250 and $6,250 as of September 30, 2003 and 2002, respectively	1,250	6,250
Convertible senior subordinated notes, and loans and capital leases payable — long-term	310,008	160,014
Contingent value rights	22,047	—
Accrued postretirement benefit cost	3,108	2,470
Total liabilities	373,445	199,936
Stockholders' equity:		
Preferred stock, $.01 par value; 5,000 shares authorized; no shares issued at September 30, 2003 and 2002	—	—
Common stock, $.01 par value; 200,000 shares authorized, 40,298 and 37,335 shares issued at September 30, 2003 and 2002, respectively	403	373
Additional paid-in capital	747,737	708,435
Deferred compensation	(216)	(49)
Accumulated deficit	(505,580)	(324,223)
Accumulated other comprehensive income	1,164	1,005
	243,508	385,541
Less: treasury stock, at cost; 1,443 and 940 shares at September 30, 2003 and 2002, respectively	(25,451)	(6,433)
Total stockholders' equity	218,057	379,108
Commitments and Contingencies		
	$ 591,502	$ 579,044

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,		
	2003	2002	2001
Revenues:			
Sales commissions	$ 16,289	$ —	$ —
Product sales	437	—	—
License and other revenues, including $5,000, $7,500 and $6,250 from related parties in 2003, 2002 and 2001, respectively	6,088	9,840	8,038
Collaborative program revenues, including $6,187, $7,824, and $12,163 from related parties in 2003, 2002 and 2001, respectively	9,555	11,976	17,984
	32,369	21,816	26,022
Expenses:			
Cost of products sales	157	—	—
Research and development	102,642	102,202	56,038
Acquired in-process research and development (notes 3(a) and 3(b))	31,451	130,200	—
Selling, general and administrative	70,532	28,146	16,033
Amortization of intangibles	9,300	1,255	742
	214,082	261,803	72,813
Loss from operations	(181,713)	(239,987)	(46,791)
Other income (expense):			
Investment income — net	7,808	14,729	25,910
Interest expense	(6,715)	(5,235)	(21)
Other expense — net	(737)	(1,590)	(228)
Gain on early retirement of convertible senior subordinated notes — net	—	12,604	—
Gain on sale of diagnostics business	—	1,000	—
Loss before cumulative effect of accounting change	(181,357)	(218,479)	(21,130)
Cumulative effect of the change in accounting for the recognition of upfront fees	—	—	(2,625)
Net loss	$(181,357)	$(218,479)	$(23,755)
Basic and diluted net loss per common share:			
Loss before cumulative effect of change in accounting policy	$ (4.87)	$ (6.07)	$ (0.62)
Cumulative effect of change in accounting policy	$ —	$ —	$ (0.08)
Net loss	$ (4.87)	$ (6.07)	$ (0.70)
Weighted average shares of common stock outstanding	37,249	35,978	33,852
Proforma information assuming new revenue recognition policy had been applied retroactively:			
Net loss			$(21,130)
Basic and diluted net loss per common share			$ (0.62)

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended September 30, 2003, 2002 and 2001
(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, 2000	28,282	$283	$187,731	$(8,767)	$ (81,989)	$ (944)	$ (6,433)	$ 89,881
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	35,901	359	664,095	(3,922)	(105,744)	1,476	(6,433)	549,831
Comprehensive income (loss):								
Net loss	—	—	—	—	(218,479)	—	—	(218,479)
Unrealized holding loss on investment securities, net of reclassification adjustment	—	—	—	—	—	(1,166)	—	(1,166)
Translation adjustment	—	—	—	—	—	695	—	695
Total comprehensive loss								(218,950)
Options exercised	432	4	5,676	—	—	—	—	5,680
Warrants exercised	11	—	375	—	—	—	—	375
Issuance of common stock for employee purchase plan and other	66	1	1,074	—	—	—	—	1,075
Change in deferred compensation	—	—	(349)	349	—	—	—	—
Amortization of deferred compensation	—	—	—	1,097	—	—	—	1,097
Reversal of deferred compensation	—	—	(2,427)	2,427	—	—	—	—
Issuance of common stock, in connection with acquisition of Gilead oncology assets	925	9	39,991	—	—	—	—	40,000
Balance at September 30, 2002	37,335	373	708,435	(49)	(324,223)	1,005	(6,433)	379,108
Comprehensive income (loss):								
Net loss	—	—	—	—	(181,357)	—	—	(181,357)
Unrealized holding loss on investment securities, net of reclassification adjustment	—	—	—	—	—	(991)	—	(991)
Translation adjustment	—	—	—	—	—	1,150	—	1,150
Total comprehensive loss	—	—	—	—	—	—	—	(181,198)
Options exercised	636	6	6,773	—	—	—	—	6,779
Warrants issued	—	—	146	—	—	—	—	146
Issuance of common stock for directors' annual retainer	31	—	487	(487)	—	—	—	—
Issuance of common stock for employee purchase plan and other	42	1	803	—	—	—	—	804
Issuance of common stock in connection with acquisition of Cell Pathways	2,246	23	31,223	—	—	—	—	31,246
Issuance of common stock to consultant	8	—	286	—	—	—	—	286
Registration costs in connection with acquisition of Cell Pathways	—	—	(416)	—	—	—	—	(416)
Amortization of deferred compensation	—	—	—	320	—	—	—	320
Purchase of treasury stock	—	—	—	—	—	—	(19,018)	(19,018)
Balance at September 30, 2003	40,298	$403	$747,737	$ (216)	$(505,580)	$ 1,164	$(25,451)	$ 218,057

See accompanying notes to consolidated financial statements.

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

	Years ended September 30,		
	2003	2002	2001
Cash flow from operating activities:			
Net loss	$(181,357)	$(218,479)	$ (23,755)
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)	—
Loss (gain) on sale of investments	(347)	143	(278)
Loss on sale and disposals of equipment	86	359	115
Depreciation and amortization	21,434	11,102	6,004
In-process research and development charge	31,451	130,200	—
Non-cash compensation charges	862	1,606	3,286
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:			
Receivables	(4,634)	(520)	(5,586)
Inventory	(514)	—	—
Prepaid expenses and other current assets	(5,505)	(686)	(1,325)
Other assets	1,077	304	37
Accounts payable and accrued expenses	(2,034)	2,250	11,648
Unearned revenue	(8,941)	(6,312)	17,526
Accrued postretirement benefit cost	638	390	194
Net cash (used in) provided by operating activities	(147,784)	(92,569)	10,491
Cash flows from investing activities:			
Payments for acquisitions, net of cash acquired	(193)	(135,742)	(13,869)
Payments for acquisition of Novantrone® marketing rights	(46,009)	—	—
Net proceeds from sale of diagnostic business	—	1,000	—
Purchases of investments (restricted and unrestricted)	(412,944)	(400,951)	(535,099)
Maturities and sales of investments (restricted and unrestricted)	534,332	402,318	248,458
Net additions to property, equipment and leasehold improvements	(8,486)	(18,181)	(10,590)
Additions to compound library assets	(1,158)	(92)	—
Investments in privately-owned companies	(380)	(870)	(420)
Net cash provided by (used in) investing activities	65,162	(152,518)	(311,520)
Cash flows from financing activities:			
Net proceeds from the issuance of common stock	—	—	474,181
Proceeds from the exercise of stock options, stock warrants, employee purchase plan, and other	7,327	6,247	3,819
Proceeds from the issuance of convertible senior subordinated notes	150,000	200,000	—
Retirement of convertible senior subordinated notes	—	(26,098)	—
Debt issuance costs	(5,177)	(7,084)	—
Payments on loans and capital leases payable	(546)	(268)	(149)
Purchase of treasury stock	(19,018)	—	—
Net cash provided by financing activities	132,586	172,797	477,851
Net increase (decrease) in cash and cash equivalents	49,964	(72,290)	176,822
Effect of exchange rate changes on cash and cash equivalents	(23)	(282)	(65)
Cash and cash equivalents at beginning of year	152,578	225,150	48,393
Cash and cash equivalents at end of year	$ 202,519	$ 152,578	$ 225,150
Non-cash activities:			
Issuance of common stock in satisfaction of deferred acquisition costs	$ —	$ 375	$ —
Issuance of common stock in connection with acquisition	$ 31,245	$ 40,000	$ —
Issuance of contingent value rights in connection with acquisition	$ 22,047	$ —	$ —
Assumption of warrants in connection with acquisition	$ 146	$ —	$ —
Issuance of common stock to employees	$ 92	$ 450	$ —
Issuance of common stock to directors	$ 488	$ —	$ —
Issuance of common stock to consultant (former Cell Pathways employee)	$ 286	$ —	$ —
Acceleration of an employee's stock options	$ 164	$ —	$ —
Cash paid for interest	$ 6,418	$ 4,035	$ 21

See accompanying notes to consolidated financial statements.

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

(1) Summary of Significant Accounting Policies

(a) Principles of Consolidation

Our consolidated financial statements include the accounts of OSI Pharmaceuticals, Inc., and our wholly-owned subsidiaries, OSI Pharmaceuticals (UK) Limited ("OSI-UK"), MYCOsearch, Inc., OSDI, Inc. ("OSDI"), and Applied bioTechnology, Inc. During fiscal 2003, we created a UK subsidiary, Prosidion Limited ("Prosidion") into which we transferred our diabetes and obesity research programs. As of September 30, 2003, we held an approximately 80% ownership interest in Prosidion. All intercompany balances and transactions have been eliminated in consolidation. We operate in one segment. We are focused on the discovery, development and commercialization of high-quality oncology products that both extend life and improve the quality-of-life for cancer patients worldwide.

(b) Revenue Recognition

Sales commissions represent commissions earned on the sales of the drug, Novantrone® (mitoxantrone for injection concentrate), in the United States for oncology indications pursuant to a Co-Promotion Agreement dated March 11, 2003 with Ares Trading S.A. ("Ares Trading"), an affiliate of Serono S.A. ("Serono") (see note 2). Serono will continue to market Novantrone® in multiple sclerosis indications and will record all U.S. sales for all indications including oncology indications. Sales commissions from Novantrone® on net oncology sales are recognized in the period the sales occur based on the estimated split between oncology sales and multiple sclerosis sales of Novantrone®, as determined on a quarterly basis by an external third party. The split between oncology and multiple sclerosis sales is subject to further adjustment based on final review by the external party, in the subsequent quarter. Management does not believe these adjustments, if any, will be significant to the consolidated financial statements.

Product sales represent sales of Gelclair® Bioadherent Oral Gel ("Gelclair®") in accordance with an exclusive distribution agreement with Sinclair Pharmaceuticals, Ltd. ("Sinclair") to market and distribute Gelclair® in North America. We acquired the rights under this agreement on June 12, 2003 in connection with the acquisition of Cell Pathways, Inc. ("Cell Pathways") (see note 3(a)). Sinclair licensed its worldwide rights to Gelclair® to Helsinn Healthcare S.A. ("Helsinn") in July 2003. In accordance with SFAS No. 48, "Revenue Recognition When Right of Return Exists," given the limited sales history of Gelclair®, we at this time defer the recognition of revenue on product shipments of Gelclair® to wholesale customers until such time as the product is sold from the wholesale customer to the retail and non-retail outlets. For each reporting period, we monitor shipments from wholesale customers to pharmacies and hospitals, and wholesale customer reorder history based on data from an external third party. The related cost of the product shipped to wholesale customers that has not been recognized as revenue has been reflected as inventory subject to return (see note 1(l)). The unearned revenue related to shipments of Gelclair® to wholesale customers was $779,000 as of September 30, 2003 and is included in unearned revenue-current on the accompanying consolidated balance sheet.

We account for upfront nonrefundable technology access and other upfront fees over the term of the related research and development 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. We received a total of $25.0 million in upfront fees from Genentech, Inc. ("Genentech") and Roche ("Roche") in January 2001 which was originally being recognized on a straight-line basis evenly over the expected three-year term of our required research and development efforts under the terms of a Tripartite Agreement with Genentech and Roche. In the fourth quarter of fiscal 2002, the expected

term was changed to four years to reflect our revised estimate of the term of the continued involvement in the research and development efforts under the agreement (see note 5(a)). In accordance with Accounting Principle Board Opinion No. 20, "Accounting Changes," the remaining unearned revenue is being recognized prospectively over the revised term. We recorded revenues relating to these upfront fees of $5.0 million, $7.5 million and $6.3 million for fiscal 2003, 2002, and 2001, respectively, which is included in license and other revenues in the accompanying consolidated statements of operations.

For the year ended September 30, 2000, we recognized as revenue the full $3.5 million technology access fee received from Tanabe Seiyaku Co., Ltd. ("Tanabe") related to a four-year term collaboration (see note 5(c)). Our 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).

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

(c) Research and Development Costs

Research and development 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 2003, 2002 and 2001, R&D activities included $99.8 million, $95.1 million, and $44.6 million, respectively, of proprietary R&D. Proprietary R&D includes our proportionate share of development expenses related to the Tripartite Agreement with Genentech and Roche (see note 5(a)), and R&D activities funded by government research grants and other independent R&D programs. The balance of R&D represents expenses under our collaborative agreements.

(d) Acquired In-Process Research and Development

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

(e) Accounting for Stock-Based Compensation

We follow the provisions of SFAS No. 123, "Accounting for Stock-Based Compensation." The provisions of SFAS No. 123 allow us to either expense the estimated fair value of stock options or to continue to follow the intrinsic value method set forth in Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees," but disclose the pro forma effect on net income (loss) had the fair value of the options been expensed. We have elected to continue to apply APB No. 25 in accounting for stock options issued to employees.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure." SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation as originally provided by SFAS No. 123. Additionally, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require

prominent disclosure in both the annual and interim financial statements about the method of accounting for stock-based compensation and the effect of the method used on reported results. The transitional requirements of SFAS No. 148 are effective for all financial statements for fiscal years ending after December 15, 2002. We adopted the disclosure portion of this statement beginning in the fiscal quarter ended March 31, 2003. The application of the disclosure portion of this standard will have no impact on our consolidated financial position or results of operations.

Stock option grants are generally set at the closing price of our common stock on the date of grant and the related number of shares granted are fixed at that point in time, except for one grant (see note 11(a)). Therefore under the principles of APB Opinion No. 25, we do not recognize compensation expense associated with the grant of stock options. SFAS No. 123 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 we had accounted for our employee stock options and shares sold under our stock purchase plan under the fair value method of SFAS No. 123.

The fair value of the options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions for fiscal 2003, 2002 and 2001, respectively: risk-free interest rates of 1.76%, 3.86% and 3.28%; dividend yields of 0%; volatility factors of the expected market price of our common stock of 81.63%, 77.19% and 81.9%; expected life of the employees' options of 3.0 years, 3.0 years, and 3.0 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 $14.82, $17.19 and $25.29 per share for stock options granted in fiscal 2003, 2002 and 2001, respectively.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized over the options' vesting periods. Our pro forma information for fiscal 2003, 2002 and 2001 is as follows (in thousands, except per share information):

	Years Ended September 30,		
	2003	2002	2001
Net loss	$(181,357)	$(218,479)	$(23,755)
Compensation cost determined under fair value method	(19,828)	(17,105)	(10,468)
Pro forma net loss	$(201,185)	$(235,584)	$(34,223)
Basic and diluted loss per common share:			
Net loss	$ (4.87)	$ (6.07)	$ (0.70)
Compensation cost	(0.53)	(0.48)	(0.31)
Pro forma net loss	$ (5.40)	$ (6.55)	$ (1.01)

(f) Net Loss Per Share

Basic and diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. If fiscal 2003 and fiscal 2002 had resulted in net income and had the common share equivalents for the 4% convertible senior subordinated notes (3,200,000 shares) issued in February 2002 and the 3.25% convertible senior subordinated notes (2,998,800 shares) issued in September 2003 been dilutive, interest expense related to the notes would have been added back to net income (loss) to calculate diluted earnings per share. The related interest expense for fiscal 2003 and fiscal 2002 totaled $6.7 million and $5.2 million, respectively.

Common share equivalents (the convertible senior subordinated notes, stock options and warrants) and contingent shares pursuant to the contingent value rights are not included since their effect would be anti-dilutive. Such common share equivalents (convertible senior subordinated notes, stock options and warrants) and contingent shares amounted to 5,016,096 and 1,584,973, respectively, for fiscal 2003. Such common share equivalents (convertible senior subordinated notes and stock options) amounted to 4,894,588 for fiscal 2002. Such common share equivalents (stock options and warrants) amounted to 2,105,676 for fiscal 2001.

(g) Comprehensive Income (Loss)

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

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

	2003	2002
Cumulative foreign currency translation adjustment	$ 830	$ (320)
Unrealized gains on available-for-sale securities	334	1,325
Accumulated other comprehensive income	$1,164	$1,005

(h) Cash and Cash Equivalents

We include as cash equivalents reverse repurchase agreements, treasury bills, commercial paper and time deposits with original maturities of three months or less. Such cash equivalents amounted to $192.8 million and $142.8 million as of September 30, 2003 and 2002, respectively.

(i) Investments

Investment securities at September 30, 2003 and 2002 consist of U.S. Treasury obligations, municipal obligations and corporate debt and equity securities. We classify our investments as available-for-sale securities, as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are recorded at their fair value. Unrealized holding gains and losses, net of the related tax effect, if any, on available-for-sale securities are excluded from earnings and are reported in accumulated other comprehensive income (loss), a separate component of stockholders' equity, until realized. The specific identification basis is utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities.

A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary results in a reduction in carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Dividend and interest income are recognized when earned.

In September 2003, in connection with the issuance of convertible senior subordinated notes (see note 10(a)), we pledged $14.2 million of U.S. government securities (restricted investment securities) with maturities at various dates through August 2006. In February 2002, in connection with the issuance of convertible senior subordinated notes (see note 10(b)), 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 respective convertible senior subordinated notes when due. We consider our restricted investment securities to be held-to-maturity, as defined by SFAS No. 115. These securities are

reported at their amortized cost, which includes the direct costs to acquire the securities, plus the amortization of any discount or premium, and accrued interest earned on the securities.

With respect to our facility leases at Horsham, Pennsylvania and Oxford, England, which were assumed in connection with our acquisition of Cell Pathways and our acquisition of certain assets of British Biotech plc ("British Biotech"), respectively (see notes 3(a) and 3(d)), we have outstanding letters of credit issued by a commercial bank. The irrevocable letter of credit for our Oxford, England facility expires annually on September 27th with a final expiration date of September 27, 2007. The amount under this letter of credit is $2.3 million of which the full amount was available on September 30, 2003. The collateral for these letters of credit are maintained in a restricted investment account. Included in cash and cash equivalents and investments securities as of September 30, 2003 is $35,000 and $3.4 million, respectively, relating to restricted cash and investments to secure these letters of credit. Included in cash and cash equivalents and investments securities as of September 30, 2002 is $1.0 million and $2.0 million, respectively, relating to restricted cash and investments to secure the letter of credit for the Oxford lease.

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

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

(j) Goodwill and Intangible Assets

In July 2001, the FASB 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. The provisions of SFAS No. 141 and No. 142 were adopted for acquisitions consummated on or after July 1, 2001. Effective October 1, 2002, we fully adopted SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 requires that goodwill and intangible assets determined to have indefinite lives no longer be amortized but instead be tested for impairment at least annually and whenever events or circumstances occur that indicate impairment might have occurred. SFAS No. 142 also requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives and reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable (see note 8).

As a result of our R&D programs, including programs funded pursuant to R&D funding agreements (see note 5), we have applied for a number of patents in the United States and abroad. Costs incurred in connection with patent applications for our R&D programs have been expensed as incurred.

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

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

lowest level for which identifiable cash flows exist. If impairment has occurred, we recognize a loss for the difference between the carrying amount and the fair value of the asset. Fair value is the amount at which the asset could be bought or sold in a current transaction between a willing buyer and seller other than in a forced or liquidation sale and can be measured as the asset's quoted market price in an active market or, where an active market for the asset does not exist, our best estimate of fair value based on discounted cash flow analysis. Assets to be disposed of by sale are measured at the lower of carrying amount or fair value less estimated costs to sell.

(l) Inventory

Inventory is comprised solely of Gelclair® and is stated at the lower of cost or market, as determined using the first-in, first-out method. Inventory at September 30, 2003 and September 30, 2002, consisted of the following (in thousands):

	September 30,	
	2003	2002
Finished goods on hand	$3,358	$ —
Inventory subject to return	258	—
	$3,616	$ —

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

(m) Depreciation and Amortization

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

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

(n) Computer Software Costs

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

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

We record accruals for estimated clinical study costs. Clinical study costs represent costs incurred by clinical research organizations ("CROs") and clinical sites. These costs are recorded as a component of R&D expenses. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may or may not match the estimated costs for a given accounting period. Actual results could differ from those estimates under different assumptions. The accrued CRO and site costs as of September 30, 2003 and 2002 were $5.0 million and $3.1 million, respectively.

(p) Foreign Currency Translation

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

(q) Income Taxes

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

(r) Use of Estimates

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

(s) Reclassifications

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

(2) Co-Promotion Agreement

On March 11, 2003, we entered into the Co-Promotion Agreement with an affiliate of Serono, Ares Trading, to market and promote Novantrone® for approved oncology indications in the United States through December 2017. In consideration for these exclusive rights, we paid $45.0 million in cash. This payment and related professional fees are included in other intangible assets in the accompanying consolidated balance sheet as of September 30, 2003 and are being amortized on a straight-line basis through expiration of the Novantrone® patent in April 2006. In consideration for certain transition services required to be provided by Serono, we also paid a fee of $10.0 million, which was recognized over the four-month transition period from the effective date of the agreement and is included in selling, general and administrative expenses in the accompanying statement of operations for fiscal 2003. Under the terms of the agreement, we are also required to pay quarterly maintenance fees to Serono until the later of the expiration of the last valid patent claim or the first generic date, as defined in the agreement. Such maintenance fees will be expensed as incurred. We receive commissions on net sales of Novantrone® in the United States for oncology indications. Sales commissions for the period March 11, 2003 to September 30, 2003 were $16.3 million.

(3) Acquisitions

(a) Cell Pathways

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

July 14, 2003. Cell Pathways was a development stage biotechnology company focused on the research and development of products to treat and prevent cancer, and the future commercialization of such products.

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

Gelclair® is a bioadherent oral gel that provides relief for the treatment of pain associated with oral mucositis, a debilitating side effect often seen in patients undergoing chemotherapy or radiation treatment. In January 2002, Cell Pathways entered into a ten-year exclusive distribution agreement with Sinclair to market and distribute Gelclair® in North America (United States, Canada and Mexico). Sinclair licensed its worldwide rights to Gelclair® to Helsinn in July 2003. Cell Pathways entered into a four-year marketing agreement with John O. Butler Company ("Butler"), under which Butler markets Gelclair® to the dental market within the United States and will market in Canada if and when Gelclair® is approved for marketing in Canada. In October 2002, Cell Pathways entered into a three-year agreement with Celgene Corporation ("Celgene") for the promotion of Gelclair®, primarily in the U.S. oncology market. On June 12, 2003, we entered into an agreement with Celgene by which we recovered full rights to market and distribute Gelclair®in the oncology setting in North America. This agreement required us to make a payment to Celgene, which was expensed in the fourth quarter of fiscal 2003, upon the return of certain sales and marketing data. The agreement also requires us to make a payment to Celgene upon the first anniversary of the effective date provided the transition services, as defined in the agreement, have been provided to us. The transition services are being expensed ratably over the transition period, which is expected to be completed by December 2003. The agreement also provides for a milestone payment to Celgene upon the achievement of a specified amount of net sales of Gelclair®.

As consideration for the merger, each share of Cell Pathways common stock was exchanged for (i) 0.0567 shares of our common stock and (ii) a contingent value right to receive 0.04 shares of our common stock in the event a new drug application is accepted for filing with the U.S. Food and Drug Administration by June 12, 2008 for either of the two newly acquired clinical candidates, Aptosyn® or OSI-461. Based on the exchange ratio of 0.0567, approximately 2.2 million shares of our common stock were issued to Cell Pathways' stockholders in connection with the merger. The 2.2 million common shares were valued at $31.2 million which was based on the average five-day closing price of our common stock around the date of the announcement of the merger which occurred on February 10, 2003. Any outstanding options that were not exercised prior to the effective date of the merger were, in accordance with their terms, terminated. We assumed approximately 44,000 outstanding and unexercised warrants to purchase shares of Cell Pathways common stock under the same terms and conditions as the original Cell Pathways' warrants except that the exercise price of the warrants and the number of shares of our common stock for which the warrants are exercisable were adjusted based on the exchange ratio described above.

The acquisition was accounted for under the purchase method of accounting. The results of operations of Cell Pathways have been included in the consolidated statements of operations commencing as of June 12, 2003. The purchase price was allocated to the acquired assets and assumed liabilities based on the fair values as of the date of the acquisition. The excess of the fair value of the net identifiable assets acquired over the

purchase price paid represented negative goodwill of approximately $49.2 million. Since a portion of the negative goodwill is a result of not recognizing contingent consideration (i.e., the contingent value rights), the maximum value of the contingent value rights at the date of the acquisition has been recorded as if it were a liability, thereby reducing the negative goodwill. The value of the contingent value rights of $22.0 million was based on the average five day closing price of our common stock around the date of the announcement of the merger which occurred on February 10, 2003. The remaining negative goodwill of $27.0 million was allocated proportionately to reduce the value of the non-current assets acquired and the in-process research and development which was charged to operations.

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

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

During the fourth quarter of fiscal 2003, we recorded a net adjustment of $311,000 to the preliminary purchase price allocation for the amount of deferred revenue and inventory acquired in the transaction. This adjustment affected the allocation of the purchase price between the inventory, deferred revenue, in-process R&D and the Gelclair® rights.

The value assigned to the acquired in-process R&D was determined by identifying those acquired in-process research projects for which: (a) technological feasibility had not been established at the acquisition date, (b) there was no alternative future use, and (c) the fair value was estimable based on reasonable assumptions. The acquired in-process R&D was valued at $31.5 million after the allocation of the negative goodwill, expensed on the acquisition date, and included in the accompanying consolidated statements of operations for the year ended September 30, 2003. The portion of the purchase price assigned to the acquired in-process R&D was allocated to the following two clinical candidates: Apotsyn® ($3.7 million), currently in a Phase III trial in combination with Taxotere® for the treatment of advanced non-small cell lung cancer ("NSCLC"), and OSI-461 ($27.8 million), a more potent, second-generation molecule that is currently being evaluated in dose ranging Phase I studies and a series of exploratory Phase II studies in chronic lymphocytic leukemia, renal cell carcinoma and prostate cancer. In addition, OSI-461 is being evaluated in a Phase II study for inflammatory bowel disease where there has been encouraging initial indications of activity in the form of symptom improvement and a remission.

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

such projects were based on management's estimates of revenues and operating profits related to such projects. The value of the in-process R&D was based on the income approach that focuses on the income-producing capability of the assets. The underlying premise of this approach is that the value of an asset can be measured by the present worth of the net economic benefit (cash receipts less cash outlays) to be received over the life of the asset. Significant assumptions and estimates used in the valuation of in-process R&D included: the stage of development for each of the two projects; future revenues; growth rates for each product; product sales cycles; the estimated life of a product's underlying technology; future operating expenses; probability adjustments to reflect the risk of developing the acquired technology into commercially viable products; and a discount rate of 25% to reflect present value.

(b) Gilead's Oncology Assets

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

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

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

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

The value of the acquired in-process R&D was determined by estimating the projected net cash flows related to products under development, based upon the future revenues to be earned upon commercialization of such products. In determining the value of the in-process R&D, the assumed commercialization dates for these products ranged from 2004 to 2008. Given the risks associated with the development of new drugs, the revenue and expense forecasts were probability-adjusted to reflect the risk of advancement through the approval process. The risk adjustments applied were based on each compound's stage of development at the time of assessment and the historical probability of successful advancement for compounds at that stage. These modeled cash flows were discounted back to their net present value. The projected net cash flows from such projects were based on management's estimates of revenues and operating profits related to such projects. The in-process R&D was valued based on the income approach that focuses on the income-producing capability of the assets. The underlying premise of this approach is that the value of an asset can be measured by the present worth of the net economic benefit (cash receipts less cash outlays) to be received over the life of the asset. Significant assumptions and estimates used in the valuation of in-process R&D included: the stage of development for each of the three projects; future revenues; growth rates for each product; product sales cycles; the estimated life of a product's underlying technology; future operating expenses; probability adjustments to reflect the risk of developing the acquired technology into commercially viable products; and a discount rate of 18% to reflect present value.

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

(c) Unaudited Pro Forma Financial Information

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

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

The unaudited pro forma financial information has been prepared for comparative purposes only. The pro forma information includes the historical unaudited results of Cell Pathways and certain assets from Gilead for

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

(d) British Biotech Assets

On September 28, 2001, we acquired certain assets from British Biotech 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	635
Total assets acquired	$13,869

We 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, we acquired a non-exclusive license to compound libraries and we 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 libraries will be used. Also in connection with the acquisition, we acquired 58 employees of which 42 were in research and development, two were in information technology and the remainder were in administrative positions.

(4) Investments

(a) Investment Securities

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

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

2003	Cost	Gross Unrealized Gains	Fair Value
U.S. Treasury securities and obligations of U.S. Government agencies	$144,026	$136	$144,162
Corporate debt securities	29,690	205	29,895
Total	$173,716	$341	$174,057

2002	Cost	Gross Unrealized Gains	Fair Value
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	88,507	859	89,366
Total	$303,016	$1,372	$304,388

Government and corporate debt securities include interests in mutual funds with a cost basis and fair market value of $1.6 million as of September 30, 2003 and a cost basis and fair market value of $15.4 million and $15.7 million respectively, as of September 30, 2002. Net realized gains (losses) on sales of investments during fiscal 2003, 2002 and 2001 were $347,000, $(143,000), and $278,000, respectively.

Maturities of securities classified as available-for-sale were as follows at September 30, 2003 (in thousands):

	Cost	Fair Value
2004	$ 19,268	$ 19,381
2005	13,663	13,758
2006	137,000	137,199
2007	714	698
2008	194	192
2009 and thereafter	1,250	1,209
	$172,089	$172,437

(b) Other Investments

In July 1997, we, together with Cold Spring Harbor Laboratory and Roche, formed Helicon Therapeutics, Inc. ("Helicon"), a Delaware corporation. In exchange for approximately 30% of Helicon's outstanding capital stock, we contributed to Helicon molecular screening services which were completed in fiscal 1998 and a nonexclusive license with respect to certain screening technology. As of September 30, 2003, we owned approximately 5.68% of Helicon common stock. As of September 30, 2003 and 2002, our investment in Helicon was fully reserved.

We have an investment in a venture capital fund limited partnership that is focused on emerging companies that are developing therapeutics to treat cancer and other diseases. We account for our investment under the cost method of accounting. As of September 30, 2003 and 2002, our investment in the limited partnership was $1.2 million and $790,000, respectively, representing a 1.96% ownership interest, and is included in other assets in the accompanying consolidated balance sheets.

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

consolidated statement of operations for the year ended September 30, 2002. The remaining portion of the prepaid balance was expensed in fiscal 2003.

(5) Product Development Contracts

(a) Roche and Genentech

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

We received upfront fees of $25 million related to this alliance, which was being recognized evenly over the expected term of our required R&D efforts under these agreements. We are also entitled to up to $92 million upon the achievement of certain milestones under the terms of the alliance. As discussed in note 11(g), concurrent with the execution of the alliance agreements, Genentech and Roche each purchased 462,570 newly-issued shares of our common stock for $35 million ($75.66 per share).

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. Any reimbursement from or additional payments to Genentech or Roche for R&D costs under the cost sharing arrangement of the Tripartite Agreement are recorded as an increase or decrease to R&D expenses in the accompanying consolidated statements of operations.

Under the OSI/Genentech agreement, we agreed to collaborate in the product development of Tarceva™ with the goals of obtaining regulatory approval for commercial marketing and sale in the United States of products resulting from the collaboration and, subsequently, supporting the commercialization of these products. 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 are triggered by the fulfillment of certain conditions; we believe that we have met these conditions and we are in active discussions with Genentech regarding these rights. 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, that is, until the date that we and Genentech mutually agree to terminate the collaboration or until either party exercises early termination rights as described as follows. The OSI/Genentech agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, since January 8, 2003, Genentech has had the right to terminate the OSI/Genentech agreement with six months prior written notice.

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™, that is until the date of expiration or revocation or complete rejection of the last to expire patent covering Tarceva™ or, in countries where there is no valid patent covering Tarceva™, on the tenth anniversary of the first commercial sale of Tarceva™ in that country. The OSI/Roche agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, since July 31, 2003, Roche has had the right to terminate the agreement on a country-by-country basis with six months prior written notice. After such time, we also have had the right to terminate the agreement on a country-by-country basis if Roche has not launched or marketed a product in such country under certain circumstances.

(b) Anaderm

On April 23, 1996, we formed Anaderm Research Corporation ("Anaderm") with Pfizer Inc. ("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 received an $8 million wind-down fee in consideration for transferring all research being performed by us to Anaderm. Of such amount, we received $4.5 million in September 2002 and received $3.5 million in March 2003 after completion of the transfer. The $4.5 million was recognized as revenue ratably over the expected term of the transition period and the $3.5 million was recognized upon the successful completion of the transition. For the years ended September 30, 2003 and 2002, we recognized $6.2 million and $1.8 million, respectively, of collaborative program revenues relating to the phase-down.

(c) Tanabe

Effective as of October 1, 1999, we entered into a Collaborative Research and License Agreement with Tanabe focused on discovering and developing novel pharmaceutical products to treat diabetes. The contract period under this agreement expired on October 1, 2003 and was not renewed. Tanabe continues to maintain responsibility for further development and marketing of a lead compound in exchange for milestone and royalty payments to us.

(d) Vanderbilt

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

We provided funding to Vanderbilt to conduct the OSI/Vanderbilt research program. A portion of this funding came from Tanabe's funding of the OSI/Tanabe research program. 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.

(e) Pfizer

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

In June 2000, we gained full development and marketing rights to Tarceva™ in order to allow Pfizer to meet certain requirements of the U.S. Federal Trade Commission arising from the FTC's review of Pfizer's merger with the Warner-Lambert Company. Under terms of the agreement with Pfizer, which became effective upon issuance and publication of the FTC's order on June 19, 2000, we received a royalty-free license to all rights for the further development and commercialization of Tarceva™. The terms of the agreement did not require us to make any payments to Pfizer for the license. In January 2001, we entered into a co-development and marketing partnership with Genentech and Roche for Tarceva™ (see note 5(a)).

(f) Other

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

Total collaborative program revenues under our collaborative research agreements are as follows (in thousands):

	Years Ended September 30,		
	2003	2002	2001
Related Parties:			
Anaderm	$6,187	$ 7,649	$10,244
Pfizer	—	—	1,909
Other	—	175	10
Total related parties	6,187	7,824	12,163
Tanabe	3,368	4,077	4,335
Sankyo	—	75	1,007
Solvay	—	—	479
Total	$9,555	$11,976	$17,984

(6) License Agreements

We have entered into various license agreements with third parties to grant the use of our proprietary assets. These licenses include the use of our patented gene transcription estate 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 our license fees, annual fees, and milestones and royalties based on the development and sale of products derived from the licensed patents. Generally, the duration of each license is to be coextensive with the life of the last to expire of the underlying patents.

(7) Property, Equipment and Leasehold Improvements

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

	Estimated Life (Years)	September 30,	
		2003	2002
Laboratory equipment	5-15	$28,446	$25,639
Office furniture & equipment and computer equipment	3-10	13,297	12,536
Capitalized software	3	3,410	2,718
Leasehold improvements	Life of lease	34,503	29,146
		79,656	70,039
Less: accumulated depreciation and amortization		34,679	23,864
Property, equipment and leasehold improvements — net		$44,977	$46,175

We capitalized $3.4 million and $2.7 million of computer software costs as of September 30, 2003 and 2002, respectively, of which $2.0 million and $980,000 was amortized as of September 30, 2003 and 2002, respectively.

(8) Intangible Assets

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

	September 30, 2003	September 30, 2002
Goodwill	$38,810	$38,648
Other Intangible Assets:		
Novantrone® rights	$46,009	$ —
Gelclair® rights	28,957	—
License to compound libraries	740	687
	75,706	687
Less accumulated amortization	9,561	229
Other intangible assets — net	$66,145	$ 458

As of September 30, 2002, our intangible assets were $39.1 million, consisting of $36.5 million of goodwill, $2.1 million of acquired workforce, and $458,000 for a license to compound libraries. In accordance with SFAS No. 142, the goodwill has not been amortized as it was acquired in connection with the acquisition of certain oncology assets from Gilead, which occurred after July 1, 2001. Upon full adoption of SFAS No. 142, acquired workforce no longer meets the definition of an identifiable intangible asset. As a result, the net balance of $2.1 million as of September 30, 2002 was reclassified to goodwill. The carrying amount of goodwill as of September 30, 2003, inclusive of the acquired workforce, was $38.8 million, which includes a $162,000 effect from foreign currency exchange rate fluctuations during fiscal 2003.

As of September 30, 2003, our identifiable other intangible assets were $66.1 million, net of accumulated amortization, consisting primarily of $37.9 million for the rights to market and promote Novantrone® and net $28.0 million for the rights to market and distribute Gelclair®. As a result of our acquisition from Serono in March 2003 of the exclusive rights to market and promote the drug Novantrone® for the approved oncology indications in the United States, we recorded an intangible asset of $46.0 million, which is being amortized over the remaining 37-month life of the underlying patent (see note 2). In connection with the acquisition of Cell Pathways, we assumed the exclusive rights to market and distribute Gelclair® in North America which Cell Pathways had acquired from Sinclair in January 2002 for a period of ten years. We recorded an identifiable intangible asset of $29.0 million which is being amortized over eight and a half years, the remaining term of the agreement. These identifiable intangible assets are subject to amortization. We reassessed the useful life of the license to compound libraries upon the adoption of SFAS No. 142 to make any necessary amortization period adjustments. No adjustments resulted from this assessment. Amortization expense for these intangible assets for the years ended September 30, 2003 and 2002, was $9.3 million and $216,000, respectively. Amortization expense is estimated to be $18.5 million in fiscal 2004, $18.3 million in fiscal 2005, $11.5 million in fiscal 2006, $3.4 million in fiscal 2007 and $3.4 million in fiscal 2008.

Under the non-amortization approach, goodwill and intangible assets with indefinite lives are not amortized into results of operations but instead are reviewed for impairment, written down, and charged to results of operations in periods in which the recorded value of goodwill and certain other intangibles is more than their implied fair value. We completed our impairment review of goodwill during the first quarter of fiscal 2003 and determined that no impairment charge was required upon adoption. A reconciliation of previously

reported net loss and net loss per share for fiscal 2003, 2002 and 2001 to the amounts adjusted for the exclusion of acquired workforce and goodwill amortization is as follows (in thousands except per share data):

	2003	2002	2001
Net loss	$(181,357)	$(218,479)	$(23,755)
Goodwill amortization	—	—	694
Acquired workforce amortization	—	1,039	48
Adjusted net loss	$(181,357)	$(217,440)	$(23,013)
Reported basic and diluted net loss per share	$ (4.87)	$ (6.07)	$ (0.70)
Goodwill amortization per share	—	—	.02
Acquired workforce amortization per share	—	.03	—
Adjusted basic and diluted net loss per share	$ (4.87)	$ (6.04)	$ (0.68)

Goodwill amortization in fiscal 2001 represented amortization of goodwill from the acquisition of Aston Molecules Ltd., which was fully amortized as of September 30, 2001.

(9) Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses at September 30, 2003 and 2002 are comprised of (in thousands):

	September 30,	
	2003	2002
Accounts payable	$ 4,106	$ 1,949
Accrued payroll and employee benefits	2,054	2,050
Accrued incentive compensation	2,700	2,300
Accrued facility closing costs	—	1,630
Accrued interest	1,364	1,067
Accrued clinical research organization and site costs	4,977	3,061
Accrued commercial cost due to Genentech	5,812	1,731
Other accrued expenses	8,000	7,234
	$29,013	$21,022

(10) Convertible Senior Subordinated Notes

(a) 3.25% Convertible Senior Subordinated Notes

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

2003 Notes have the right to require us to purchase all of the 2003 Notes, or a portion thereof, on September 8, 2008, September 8, 2013 and September 8, 2018 for a price equal to 100% of the principal amount of the 2003 Notes plus any accrued and unpaid interest. Upon a change in control, as defined in the indenture governing the 2003 Notes, the holders of the 2003 Notes will have the right to require us to purchase all of the 2003 Notes, or a portion thereof, not previously called for redemption at a purchase price equal to 100% of the principal amount of the 2003 Notes purchased, plus accrued and unpaid interest. Upon the election, by the holders, of the right to require us to purchase the 2003 Notes or upon a change of control, we may elect to pay the purchase price in common stock instead of cash. The number of shares of common stock a holder will receive will equal the purchase price divided by 95% of the average of the closing prices of our common stock for the five-trading day period ending on the third business day prior to the purchase date. The related debt issuance costs of $5.2 million were deferred and are being amortized on a straight-line basis over the 20-year term of the 2003 Notes.

With respect to the 2003 Notes, we pledged $14.2 million of U.S. government securities ("Restricted Investment Securities") with maturities at various dates through August 2006. Upon maturity, the proceeds of the Restricted Investment Securities will be sufficient to pay the first six scheduled interest payments on the 2003 Notes when due. The aggregate fair value and amortized cost of the Restricted Investment Securities at September 30, 2003 were $14.3 million and $14.2 million, respectively.

At September 30, 2003, the fair value of the outstanding 2003 Notes was approximately $147.7 million based on their quoted market value. In connection with the issuance of the 2003 Notes, we used $19.0 million of the net proceeds for the purchase of 503,800 shares of our common stock (see note 11(i)).

(b) 4.00% Convertible Senior Subordinated Notes

On February 1, 2002, we issued $200.0 million aggregate principal amount of convertible senior subordinated notes (the "2002 Notes") in a private placement for net proceeds to us of $192.9 million. The 2002 Notes bear interest at 4% per annum, payable semi-annually, and mature on February 1, 2009. The 2002 Notes are convertible into shares of our common stock at a conversion price of $50 per share, subject to normal and customary adjustments such as stock dividends. We may redeem the 2002 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 ("Provisional Redemption"). Upon any such Provisional 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 2002 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 2002 Notes, the holders of the 2002 Notes will have the right to require us to repurchase all of the 2002 Notes, or a portion thereof, not previously called for redemption at a purchase price equal to 100% of the principal amount of the 2002 Notes purchased, plus accrued and unpaid interest. We may elect to pay the purchase price in common stock instead of cash. The number of shares of common stock a holder will receive will equal the 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. The related debt issuance costs of $7.1 million were deferred and are being amortized on a straight-line basis over the seven-year term of the 2002 Notes.

With respect to the 2002 Notes, we pledged $22.9 million of 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 2002 Notes when due. The aggregate fair value and amortized cost of the Restricted Investment Securities were $13.5 million and $13.4 million, respectively, at September 30, 2003 and $19.6 million and $19.3 million, respectively, at September 30, 2002.

In August and September 2002, we retired a total of $40.0 million in principal amount of the 2002 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 2002 Notes retired and accrued interest, resulted in a net gain on the early retirement of the 2002 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. We early adopted SFAS No. 145, "Recission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections" in fiscal 2002 and as a result, we 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, 2003, the fair value of the outstanding 2002 Notes was approximately $154.3 million based on their quoted market value.

(11) Stockholders' Equity

(a) Stock Option Plans

We have established eight stock option plans for our employees, officers, directors and consultants, including the 2001 Incentive and Non-Qualified Stock Option Plan and the stock option plan adopted upon the acquisitions of Gilead's oncology assets in December 2001 (see note 3(b)). The plans are administered by the Compensation Committee of the Board of Directors, which may grant either non-qualified or incentive stock options. The Committee determines the exercise price and vesting schedule at the time the option is granted. Options vest over various periods and expire no later than 10 years from date of grant. The total authorized shares under these plans is 12,565,249.

Our Board of Directors adopted the 2001 Incentive and Non-Qualified Stock Option Plan (the "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 we may grant incentive stock options and non-qualified stock options to purchase up to 4,000,000 shares. Participation in the plan is limited to our directors, officers, employees and consultants of our parent or subsidiaries. The plan also continues the automatic, formula-based grants of non-qualified stock options to directors who are not our employees. On December 11, 2002, our Board of Directors approved an amendment to the Stock Option Plan that only affected the automatic, formula-based grants of non-qualified stock options to directors who are not our employees. Under the amended formula, each individual who becomes a director on or after January 1, 2003 will receive an initial option to purchase 50,000 shares of common stock upon his or her election to the Board. Persons elected to the Board after June 13, 2001 but prior to January 1, 2003 were entitled to an initial grant of an option to purchase 30,000 shares of common stock upon their initial election. All persons elected to the Board after June 13, 2001 receive annual grants of options to purchase 7,500 shares upon reelection to the Board. Persons elected to the Board prior to June 13, 2001 will continue to be eligible, upon reelection to the Board, for annual grants of options to purchase shares of common stock in an amount which depends upon the number of years of service as a director (20,000 shares reducing to 7,500 shares).

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 during 2003, 2002 and 2001:

	Shares (In thousands)	Exercise Price		
		Low	High	Weighted Average
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	(55)	4.25	51.80	29.03
Balance at September 30, 2001 — Unexercised	3,758	$ 3.25	$60.06	$23.20
Granted	1,817	13.09	47.68	33.02
Exercised	(432)	3.25	23.25	13.16
Forfeited	(533)	3.50	60.06	41.73
Balance at September 30, 2002 — Unexercised	4,610	$ 3.25	$60.06	$26.00
Granted	1,665	15.02	37.16	28.10
Exercised	(642)	3.25	31.85	10.60
Forfeited	(341)	21.55	51.80	33.57
Balance at September 30, 2003 — Unexercised	5,292	$ 3.25	$60.06	$28.01

At September 30, 2003, we have reserved 7,743,422 shares of our authorized common stock for all shares issuable under options. At September 30, 2003, 2002 and 2001, the number of options exercisable were 2,757,136, 2,291,689, and 2,147,374, respectively.

Information regarding stock options outstanding as of September 30, 2003, is as follows:

	Options Outstanding			Options Exercisable	
Price Range	Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Shares (in thousands)	Weighted Average Exercise Price
$ 0.00 - $10.00	919	$ 6.29	3.7	919	$ 6.29
$10.01 - $20.00	351	16.02	8.7	78	15.78
$20.01 - $30.00	1,341	22.48	7.9	738	22.40
$30.01 - $40.00	1,342	31.64	9.5	114	35.66
$40.01 - $50.00	865	44.71	8.2	514	44.80
$50.01 - $60.00	356	51.80	6.5	283	51.80
$60.01 - $70.00	118	60.06	7.2	111	60.06

On August 17, 2000, our Board of Directors granted non-qualified options to purchase up to 250,000 shares of common stock 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 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 150,000 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.

In fiscal 2002 and 2001, we granted options to certain non-employees to purchase 8,500 and 127,000 shares of common stock, respectively. Such options vest over a three-year period, based upon future service requirements. We recorded net deferred compensation of $1,000 and $49,000 based on the fair value of such options as of September 30, 2003 and 2002, respectively, as determined using a Black-Scholes option pricing model (see note 1(e) 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. We recorded compensation expense in fiscal 2003 of $47,000 for options granted in fiscal 2002 and 2001. We recorded compensation expense in fiscal 2002 of $612,000 for options granted in fiscal 2002, 2001 and 2000. We recorded compensation expense in fiscal 2001 of $1.8 million for options granted in fiscal 2001, 2000 and 1999.

(b) Shareholder Rights Plan

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

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

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

(c) Authorized Common and Preferred Stock

We have 200,000,000 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 our Board of Directors.

(d) Employee Stock Purchase Plan

We have an Employee Stock Purchase Plan under which eligible employees may contribute up to 10% of their base earnings toward the quarterly purchase of our common stock. The employee's purchase price is derived from a formula based on the fair market value of the common stock. No compensation expense is recorded in connection with the plan. During fiscal 2003, 2002 and 2001, 26,442, 19,046 and 3,350 shares were issued with 118, 163 and 57 employees participating in the plan, respectively. At September 30, 2003, we had 582,262 shares of our authorized common stock reserved in connection with this plan.

We sponsor a stock purchase plan for employees of OSI-UK, our wholly-owned subsidiary. Under the terms of the plan, eligible employees may contribute between £5 and £250 of their base earnings, in 36 monthly installments towards the purchase of our common stock. The employee's purchase price is determined at the beginning of the 36-month period and compensation expense is recorded over the 36-month period. During fiscal 2003, the maximum shares that may be issued under this plan was increased from 100,000 shares to 200,000 shares. As of September 30, 2003, there were 50 employees, 85 employees, and eight employees in the 2003, 2002 and 2001 stock purchase plans, respectively. At September 30, 2003, we had 156,070 shares of our common stock reserved in connection with this plan.

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

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

On December 11, 2002, our Board of Directors approved an amendment to the Stock Purchase Plan. Pursuant to the amended Stock Purchase Plan, fifty-percent of the annual retainer fee earned by each non-employee director will be paid to the director in the form of a restricted stock award. The restricted stock award will be made as of each annual stockholder meeting at which directors are elected beginning with the Annual Meeting of Stockholders which occurred on March 19, 2003. Annual restricted stock awards will vest in monthly installments over the one-year term for which the award is made. In the event a director's membership on the Board terminates prior to the end of such one-year term, any unvested portion of the director's restricted stock award will be forfeited. Shares of restricted stock awarded annually may not be sold or transferred by the director until the first anniversary of the date of grant of such award. Non-employee directors may elect to receive the remaining fifty-percent of the director's annual retainer in the form of shares of common stock under the Stock Purchase Plan as well. At September 30, 2003, we had 69,405 shares of our common stock reserved in connection with this plan.

(f) Public Offering

On November 6, 2000, we 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), we 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 our 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, we issued 924,984 shares of common stock valued at $40.0 million (see note 3(b)).

(i) Convertible Notes

On September 8, 2003, we issued $135.0 million aggregate principal amount of convertible senior subordinated notes in a private placement for net proceeds to us of $130.3 million. On September 17, 2003, the bankers associated with this convertible debt offering exercised an option to purchase an additional $15.0 million of 2003 Notes, for an additional net proceeds to us of $14.5 million. The 2003 Notes are convertible into shares of our common stock at a conversion price of $50.02 per share, subject to normal and customary adjustments such as stock dividends or other dilutive transactions (see note 10(a)). In connection with the issuance of the 2003 Notes, we used $19.0 million of the net proceeds for the purchase of 503,800 shares of our common stock.

On February 1, 2002, we issued $200.0 million aggregate principal amount of the notes in a private placement. In August and September 2002, we retired a total of $40.0 million in principal amount of the 2002 Notes for an aggregate purchase price of approximately $26.2 million. The 2002 Notes are convertible into shares of our common stock at a conversion price of $50 per share, subject to normal and customary adjustments such as stock dividends or other dilutive transactions (see note 10(b)).

(12) Income Taxes

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

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

	September 30, 2003	September 30, 2002
Deferred tax assets:		
Net operating loss carry forwards	$ 213,358	$ 95,713
Research and development tax credit carry forwards	12,610	6,203
Intangible assets	1,292	—
Unearned revenue	2,952	5,460
Purchased research and experimental expenditures	48,000	51,642
Capitalized research and experimental expenditures	16,764	—
Capitalized start-up costs	9,586	—
Other	9,396	9,112
	313,958	168,130
Valuation allowance	(300,159)	(167,970)
	13,799	160
Deferred tax liability:		
Gelclair® rights	(11,805)	—
Intangible assets	—	(160)
UK accelerated depreciation allowance	(1,994)	—
	(13,799)	(160)
	$ —	$ —

Included in our deferred tax assets at September 30, 2003 are approximately $32 million of net operating loss carry forwards and $29 million of other temporary differences and research and development tax credit carry forwards acquired from Cell Pathways that may be subject to significant limitation under Section 382 of the Internal Revenue Code. Accordingly, all or a portion of the benefit of these deferred tax assets may not be available to us in the future. As of September 30, 2003, we have available federal net operating loss carry forwards of approximately $529 million (of which approximately $95 million relates to net operating loss carry forwards acquired from Cell Pathways) which will expire in various years from 2004 to 2023 and may be subject to certain annual limitations. Our research and development tax credit carry forwards expire in various years from 2006 to 2023.

Of the $300 million valuation allowance at September 30, 2003, $93 million relates to deductions for employee stock options for which the tax benefit will be credited to additional paid in capital if realized.

(13) Commitments and Contingencies

(a) Lease Commitments

We lease office, operating and laboratory space under various lease agreements.

Rent expense was $7.4 million, $6.2 million and $2.1 million for fiscal 2003, 2002 and 2001, respectively. The rent expense for fiscal 2003 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), the Melville, New York facility lease (commenced in June 2001), the Uniondale, New York facility lease (commenced in July 1991) and the Horsham, Pennsylvania facility lease (acquired in June 2003). This was offset by the termination of the Tarrytown, New York lease (August 2002). From April 2002 through April 2003, rental payments for the Birmingham, England facility were charged against the closing cost accrual (see note 17(a)).

The following is a schedule of future minimum rental payments for the next five fiscal years and thereafter required as of September 30, 2003, assuming expiration of the leases for the Boulder facilities in October 2006, the Uniondale facility in June 2006, the Horsham facility in June 2008, the Melville facility in December 2009, the two Oxford, England facilities in August 2009 and March 2021, respectively, and the Farmingdale facility in May 2022. Also included in the amounts below are commitments for equipment under various operating leases (in thousands).

2004	$ 8,095
2005	8,080
2006	6,772
2007	5,476
2008	6,327
2009 and thereafter	52,106
	$86,856

As of September 30, 2003, we have entered into capital commitments of $624,000 relating to the purchase of laboratory equipment and compound libraries.

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

(b) Contingencies

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

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

(c) Borrowings

As of September 30, 2003, we 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 3/4. There were no amounts outstanding under the line of credit as of September 30, 2003 or 2002.

In connection with the acquisition of certain assets from Gilead in December 2001 (see note 3(b)), we assumed certain liabilities from Gilead including loans utilized to finance equipment. The loans had fixed interest rates ranging from 11.50% to 11.90% and were fully repaid in the third quarter of fiscal 2003. In connection with the acquisition of Cell Pathways in June 2003 (see note 3(a)), we assumed certain liabilities from Cell Pathways including two capital leases to finance equipment. The leases have fixed interest rates of 8.20% and 11.00%, respectively, and are due in full by March 2005. Our wholly-owned subsidiary, OSI-UK, also maintains certain loans to finance equipment. The loans have interest rates ranging from 11.64% to 15.17% and are due in full by October 2003. The loan balance as of September 30, 2003 was $15,000.

(14) Related Party Transactions

One director is a partner in a law firm which represents us on our patent and license matters. Fees paid to this firm in fiscal 2003, 2002 and 2001 were approximately $579,000, $504,000, and $546,000, respectively. One director is a controlling member of Mehta Partners LLC ("Mehta") with which we had a strategic and financial services arrangement that expired in December 2002. In fiscal 2002 and 2001, we paid Mehta $175,000 per annum for consulting services received. In addition, we have compensated other directors for services performed pursuant to consultant arrangements. In fiscal 2003, 2002 and 2001, consulting fees in the amounts of $150,000, $153,000 and $151,000, respectively, were paid by us pursuant to these arrangements. A director is an officer of Cold Spring Harbor Laboratory which was a founder of Helicon. In fiscal 2003, we entered into a research agreement with Cold Spring Harbor Laboratory. One of our former executive officers was vice president of Helicon through November 2002 and vice president of Anaderm through November 2001. A director was the chief executive officer of Helicon through December 1999. We have a fully reserved investment in Helicon (note 4(b)). A director is on the faculty of Vanderbilt with which we had a collaborative research agreement through September 30, 2003, and also has a consulting agreement with our subsidiary, Prosidion, and is a shareholder of Prosidion. A director is a non-executive director of Genentech and is an advisor to Roche, both entities with which we have collaboration agreements.

One of our officers and one of our vice presidents have outstanding loans with us aggregating $200,000 with a carrying amount of $174,000 as of September 30, 2003. We assumed these loans in connection with the acquisition of certain assets from Gilead on December 21, 2001.

(15) Employee Savings and Investment Plan

We sponsor an Employee Savings and Investment Plan under Section 401(k) of the Internal Revenue Code. The plan allows our U.S. employees to defer from 2% to 20% of their income on a pre-tax basis through contributions into designated investment funds. For each dollar the employee invests, up to 6% of his or her earnings, we will contribute an additional 50 cents into the funds. For fiscal 2003, 2002 and 2001, our expenses related to the plan were approximately $543,000, $502,000 and $350,000, respectively.

We also sponsor four pension plans covering the employees of OSI-UK. The Group Personal Pension Plan allows employees to contribute up to 31% (depending on their age) of their income on a post-tax basis into designated investment funds. The tax paid on the contribution is then recovered from the Inland Revenue. We will contribute from 4% to 9% depending on the employees' contributions. The British Biotech Pension Scheme covers employees retained from the acquisition of certain assets from British Biotech (see note 3(d)), as well as certain former employees of British Biotech hired by us subsequent to the acquisition. The plan allows the employees to defer up to 15% of their income on a pre-tax basis through contributions into designated pension funds. For each pound the employee invests, we will contribute up to 9% into the funds. We also sponsor a personal pension plan for one employee and a Flexible Executive Pension Plan covering two senior employees. The Flexible Executive Pension Plan allows the employees to defer up to 15% of their income on a pre-tax basis through contributions into designated pension funds. For each pound the employee

invests, we will contribute up to 9% into the funds. For fiscal 2003, 2002, and 2001, our expenses related to the plans were $714,000, $602,000 and $186,000, respectively.

(16) Employee Postretirement Plan

On November 10, 1992, we adopted a plan which provides postretirement medical and life insurance benefits to eligible employees, board members and qualified dependents. Eligibility is determined based on age and service requirements. These benefits are subject to deductibles, co-payment provisions and other limitations.

We follow SFAS No. 106, "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 2003, 2002 and 2001 includes the following components (in thousands):

	2003	2002	2001
Service cost for benefits earned during the period	$430	$255	$159
Interest cost on accumulated postretirement benefit obligation	235	189	156
Amortization of initial benefits attributed to past service	6	6	6
Amortization of loss	29	—	—
Net postretirement benefit cost	$700	$450	$321

The accrued postretirement benefit cost at September 30, 2003 and 2002 was as follows (in thousands):

	2003	2002
Accumulated postretirement benefit obligation	$4,425	$3,508
Unrecognized cumulative net loss	(1,214)	(930)
Unrecognized transition obligation	(103)	(108)
Accrued postretirement benefit cost	$3,108	$2,470

The changes in the accumulated postretirement benefit obligation during fiscals 2003 and 2002 were as follows (in thousands):

	2003	2002
Balance at beginning of year	$3,508	$2,246
Benefit payments	(60)	(60)
(Gain)/loss experience	312	878
Service cost	430	255
Interest cost	235	189
Balance at end of year	$4,425	$3,508

The accumulated postretirement benefit obligation was determined using a discount rate of 6% and 6.75% in 2003 and 2002, 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. This assumption was not changed in fiscal 2003. 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, 2003 by approximately $975,000 and the fiscal 2004 net postretirement service and interest cost by approximately $247,000. Benefits paid during fiscal 2003, 2002 and 2001 were $60,000, $60,000 and $127,000, respectively.

(17) Consolidation of Facilities

(a) Birmingham

During the fourth quarter of fiscal 2001, we announced the decision to consolidate our Birmingham, England facility with the newly acquired Oxford, England facility as a result of the acquisition of the British Biotech assets (see note 3(d)). The operations at the facility ceased on March 31, 2002 and we completed closing down the facility in April 2003. Fifty research and administrative employees relocated to the Oxford facilities. Under the plan for consolidating this facility, we had anticipated that 28 research and administrative employees would not relocate but would receive a severance package based on the number of years of service. As of the cessation of operations, 32 employees did not relocate and received the severance package.

The estimated cost of closing this facility as of September 30, 2001 was $4.3 million and was included 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 consisted of non-cancelable lease exit costs for the period April 2002 through February 2004 of $2.0 million, write down of equipment and leaseholds which are not being relocated of $2.1 million, and severance costs of $190,000.

During fiscal 2002, we 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, we have 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. We 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. We also wrote-off approximately $2.3 million of leasehold improvements and furniture and equipment which were not relocated to the Oxford facility. We 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. In March 2003, we entered into a surrender agreement whereby the landlord released us of our obligations under the remaining facility leases in consideration for a payment of approximately $662,000. This payment was made in April 2003. As a result of the terms of the surrender agreement, we recorded an adjustment to reduce the restructuring reserve by $180,000 during the second quarter of fiscal 2003. As of September 30, 2003, the plan was completed and no liability remains. The consolidation activity for the fiscal year ended September 30, 2003 was as follows (in thousands):

	Lease Exit Costs
Balance at September 30, 2002	$ 1,630
Cash paid	(1,477)
Changes in estimates	(193)
Foreign currency translation adjustments	40
Balance at September 30, 2003	$ —

(b) Tarrytown

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

The estimated cost of closing this facility as of September 30, 2001 was $775,000, and has been included 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 consisted of write down of equipment and leaseholds, which were not relocated, of $384,000, and severance costs of $391,000.

During fiscal 2002, we 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. We 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. We 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, the plan was completed and no liability remains.

(18) Sale of Diagnostics Business

On November 30, 1999, we sold assets of our diagnostics business to Bayer including the assets of our 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, we and OSDI entered into certain agreements with Bayer including an Assignment and Assumption of Lease with respect to the OSDI facility located in Cambridge. We recorded a gain on the sale of approximately $3.7 million during fiscal 2000. Under the terms of the agreement, we received $9.2 million up-front from Bayer with additional contingent payments of $1.0 million made to us, and recorded as a gain, in December 2001.

(19) Quarterly Financial Data (unaudited)

The tables below summarize our unaudited quarterly operating results for fiscal 2003 and 2002.

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

	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)

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

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

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

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

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

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

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

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

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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