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PUBLIC DOCUMENT COUNT: 4
CONFORMED PERIOD OF REPORT: 19980930
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COMPANY DATA:
COMPANY CONFORMED NAME: OSI PHARMACEUTICALS INC
CENTRAL INDEX KEY: 0000729922
STANDARD INDUSTRIAL CLASSIFICATION: IN VITRO & IN VIVO DIAGNOSTIC SUBSTANCES [2835]
IRS NUMBER: 133159796
STATE OF INCORPORATION: DE
FISCAL YEAR END: 0930

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BUSINESS ADDRESS:
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CITY: UNIONDALE
STATE: NY
ZIP: 11553
BUSINESS PHONE: 5162220023

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FORMER COMPANY:
FORMER CONFORMED NAME: ONCOGENE SCIENCE INC
DATE OF NAME CHANGE: 19920703
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FORM 10-K
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

---

(MARK ONE)
[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 1998
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)

<TABLE>
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| DELAWARE | 13-3159796 |
|---|---|
| (STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION) | (I.R.S. EMPLOYER IDENTIFICATION NO.) |
| 106 CHARLES LINDBERGH BLVD., UNIONDALE, N.Y. (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) | 11553 (ZIP CODE) |

</TABLE>

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (516) 222-0023

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:

<TABLE>
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| TITLE OF EACH CLASS | NAME OF EACH EXCHANGE ON WHICH REGISTERED |
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| NONE | NONE |

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SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT:

COMMON STOCK, PAR VALUE $.01 PER SHARE
(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 [X] 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 November 30, 1998, the aggregate market value of the Registrant's voting stock held by non-affiliates was $58,502,216. 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 November 30, 1998 were excluded. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant, or that such person is controlled by or under common control with the Registrant.

As of November 30, 1998, there were 22,308,833 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 1999 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K.

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- ----------
<PAGE> 2

PART I

ITEM 1. BUSINESS

OSI Pharmaceuticals, Inc. ("OSI" or the "Company") discovers and develops novel, small-molecule pharmaceutical products for commercialization by the pharmaceutical industry. The Company has innovated, assembled, and reduced to practice a constellation of drug discovery and development technologies and other assets that enable it to conduct the full range of drug discovery and early development activities, from the identification of an attractive biological target for drug discovery to the development of a drug candidate in human clinical efficacy studies. These capabilities provide OSI with a sound base from which to grow and a variety of commercialization opportunities that can be used to fuel growth.

The Company conducts its drug discovery and development programs independently and through funded collaborations with major pharmaceutical companies. The Company's major corporate partners include Pfizer Inc. ("Pfizer"), The Bayer Corporation ("Bayer"), Sankyo Company, Ltd. ("Sankyo") and Hoechst Marion Roussel, Inc. ("HMRI"). Independently and in collaboration with its various partners, the Company is involved in the discovery and development of drugs for 38 targets. These drug discovery efforts are primarily focused in the areas of cancer, cosmeceuticals, anti-infectives and diabetes. The Company's research and development capabilities together with its ongoing discovery and development programs have positioned it as a leader in the field of drug discovery and development. The Company was incorporated in 1983. Its NASDAQ stock symbol is OSIP.

BACKGROUND

Historically, drug discovery has been an expensive process of attrition. In the pharmaceutical industry, only about 1-in-16 research and development programs involving compounds screened against specific targets actually results in a successful drug. On average, it costs more than $300 million in research and development (including failures) to bring a drug from initial lead

identification to market.

During the 1990s, the rising cost of health care and changes in health care management policies have fundamentally altered the pharmaceutical landscape, putting increasing competitive pressure on the pharmaceutical industry. This has resulted in a series of major pharmaceutical company mergers, as organizations strive to enhance market share and improve profit margins.

At the same time, these new pressures have led to a growing emphasis on product pipeline enhancement through the cost-effective discovery and development of novel classes of pharmaceuticals that will meet large, unmet medical needs, can more rapidly be brought to the marketplace, and have the potential to command premium prices. Advances in molecular biology, automation, and computing and the understanding of the human genome have revolutionized the ways in which drug discovery is conducted, creating the potential for accelerated discovery and development of new generations of drugs.

Pharmaceutical companies have typically formed collaborations with biotechnology companies in order to access these types of technologies in pursuit of novel drug development. OSI believes that the competitive pressures described above have caused pharmaceutical companies to greatly reduce the royalty rates they are willing to pay to biotechnology companies for technological contributions to their product development efforts. On the other hand, the Company believes that such pressures are making pharmaceutical companies more willing to pay premiums for high quality drug candidates that have already undergone some degree of optimization and clinical development.

STRATEGY

OSI's mission is the discovery and early development of novel pharmaceutical products that improve the human condition. The Company's strategy is to build and sustain a pipeline of pharmaceutical product





opportunities for commercialization by its pharmaceutical company partners. The Company's plan for accomplishing its mission and strategy consists of the following elements:

Exploit Full Range of Discovery and Early Development Capabilities. OSI has built a fully integrated drug discovery technology platform. This platform includes every major aspect of drug discovery and development, from the identification of a validated drug discovery target to the emergence of a drug candidate. The integrated management of these technologies is designed to accelerate the process of identifying and optimizing high quality, small molecule drug candidates for clinical development and then to progress such candidates through Phase II clinical trials. OSI believes it will be able to rapidly and effectively deliver high quality drug candidates in early Phase II clinical trials and that this will position the Company to recognize enhanced payments, milestones, royalties, and success fees on OSI funded discovery programs. The Company seeks to achieve risk diversification as well as breadth and depth in its product pipeline through fully funded, royalty bearing, discovery alliances with major pharmaceutical company partners.

Focus Resources on Selected Disease Areas. In order to more rapidly progress product development opportunities to a clinical stage, the Company intends to focus its growing resources and energies on a smaller number of targets in fewer disease areas to provide the critical mass and disease area expertise to effectively move these programs forward. The Company has begun to focus primarily on the areas of cancer, cosmeceuticals, anti-infectives and

diabetes. OSI has major collaborations in cancer and cosmeceuticals. The Company has terminated its existing co-ventures in the area of anti-infectives and plans to pursue discovery and early development in this area and selected cancer targets as proprietary programs. Generally, the Company's objectives with respect to its proprietary programs are to identify lead compounds, advance them through pre-clinical development, and manage clinical development through early stage clinical trials. If such efforts are successful, the Company expects to partner with pharmaceutical companies for clinical and commercial development of these proprietary products. With respect to the diabetes program, the Company is currently seeking a funding partner.

Commercialize Certain Technology Assets. OSI is seeking to generate a revenue stream by licensing pharmaceutical and biotechnology companies to practice under its gene transcription patent estate. For example, in May 1998 OSI and Aurora Biosciences Corp. ("Aurora") entered into a license agreement covering OSI's gene transcription patent estate. Under the terms of the agreement, OSI received Aurora common stock and cash for Aurora's non-exclusive license and certain sub-licensing rights to OSI's Methods of Modulation patent, for which the U.S. Patent Office has issued claims. OSI will also receive revenues from any sub-licenses granted by Aurora to its pharmaceutical partners to develop small molecule gene transcription modulators encompassed by the Methods of Modulation claims. The Company is currently in discussions with several other parties concerning licenses to its gene transcription patent estate. Additionally, under its collaborative agreement with Bayer for the development of serum-based diagnostic products, the Company has retained rights to sell certain types of these products. The Company, through its wholly owned subsidiary, Oncogene Science Diagnostics, Inc. ("OSDI"), is actively selling cancer diagnostic tests to the clinical research market and has initiated plans to expand sales of these products in this market.

## PRODUCT DEVELOPMENT AND RESEARCH PROGRAMS

OSI utilizes its broad-based drug discovery capability in multiple drug discovery programs encompassing a variety of major human diseases. The Company's major areas of focus in research and development ("R&D") are as follows:

### Cancer

During the 1980s, cancer researchers developed a sophisticated understanding of the role played by certain genes in the transformation of normal cells into a cancerous state, and thus were able to identify novel targets for drug intervention. As the decade of the 1990s comes to a close, this new knowledge of the molecular basis of cancer has started to move from the laboratory into the clinical arena, promising new hope for patients with many types of cancers, including breast, colon, head and neck, and ovarian. In the next decade, novel anticancer therapies and diagnostic tools are expected to be commercialized, creating a new



paradigm for cancer treatment, with the potential that cancer can either be cured or managed safely over the long term. OSI, through its pharmaceutical collaboration with Pfizer and diagnostic alliances with Bayer and Fujirebio, Inc. ("Fujirebio"), is positioned at the forefront of this unfolding revolution in the diagnosis and treatment of cancer.

With its collaborative partner Pfizer, OSI has focused since 1986 on the discovery and development of novel classes of orally active, molecularly targeted, small molecule anticancer drugs based on oncogenes and tumor suppressor genes and the fundamental mechanisms underlying tumor growth. The

first of these programs to yield a clinical candidate, CP-358,774, which targets a variety of cancers including ovarian, pancreatic, non-small cell lung and head and neck, achieved a significant milestone with the completion of Phase I safety trials and the initiation of Phase II clinical trials in the United States in cancer patients. CP-358,774 is a potent, selective and orally active inhibitor of the epidermal growth factor receptor, a key oncogene in these cancers. In addition, two other compounds, CP-564,959 and CP-609,754, have been identified and are in advanced stages of pre-clinical development. Nine other targets are in active R&D at OSI. CP-564,959 is being developed as an orally available, potent and selective inhibitor of a key protein tyrosine kinase receptor involved in blood vessel growth or angiogenesis. Angiogenesis is induced by solid tumors which require nutrients that will enable growth. The Company believes that the ability to safely and effectively inhibit this process represents one of the most exciting areas of cancer drug development. CP-609,754 is an orally active inhibitor of the ras oncogene, which is another important target involved in many major tumors including colon and bladder. The types of novel anticancer drugs being developed in the OSI/Pfizer collaboration are expected to be safer and more effective than standard chemotherapeutic agents.

In addition to its cancer therapeutics programs, OSI is also a leader in the development of novel cancer diagnostic products based on oncogenes, tumor suppressor genes, and other gene targets whose proteins are directly involved in tumor growth or metastasis. These new diagnostic products are expected to help guide oncologists in the confirmation, monitoring, staging, screening or prognosis of cancer and may enable reference labs and physicians to select more effective types of treatment, to more easily monitor patients during therapy, or to diagnose cancer at an earlier stage.

Through OSDI, the Company is launching its HER-2/neu serum based diagnostic product. The OSDI tests are currently being sold directly by OSDI into the clinical research market. Through the partnership with Bayer, the HER-2/neu immunoassay is being formatted on the Bayer Immuno-1 automated clinical analyzer. The Company expects that in 1999 Bayer and OSDI will seek Food and Drug Administration ("FDA") approval for both the automated and manual HER-2/neu serum test.

In addition to its HER-2/neu diagnostic product, OSDI is in advanced development of a test to quantitate complexed Prostate Specific Antigen ("c-PSA") in serum. The Company believes the measurement of c-PSA represents a significant advancement over current PSA tests. Current clinical tests measure total PSA, free PSA or the free-to-total PSA ratio. The Company's collaborative studies with Bayer have demonstrated the improved specificity of the c-PSA assay. The c-PSA assay is a direct measure of the amount of c-PSA present in the serum. c-PSA is the component of serum PSA that increases with the progression of prostate cancer. These new assays will provide oncologists with essential information necessary to determine which patients will respond best to the newly developed therapies directed at oncogenes and tumor suppressor genes.

Cosmeceuticals

Every year, consumers in the United States, Europe, and Asia spend billions of dollars on cosmetic products and services that promise to provide a youthful, healthy, or culturally desirable appearance. Some of these products are marketed on the basis of ostensible pharmaceutical effects, such as the reduction of skin wrinkles and pigmentation or the promotion of hair growth. The Company believes that most of these products are not optimally effective and may have undesirable side effects.

In 1996, OSI entered into a joint venture with Pfizer (the majority owner) and New York University ("NYU") in Anaderm Research Corp. ("Anaderm"), a virtual company dedicated to the application of modern tools to the discovery and

development of safe, effective, pharmacologically active agents for certain





cosmetic and quality-of-life indications, such as skin pigmentation, hair loss and wrinkling. This program has made significant progress, with certain compounds in the skin pigmentation program already in advanced pre-clinical development.

To date, all of the targets encompassed in the Anaderm program are in active R&D, and the program is undergoing expansion in R&D activities. OSI, which owns a minority equity stake in Anaderm, provides most of the discovery and early development capabilities for the programs, which are fully funded by Anaderm. The Company believes that its participation in Anaderm represents a major validation of its drug discovery and development capabilities.

Anti-infectives

During the 1990s, the overuse and misuse of antibiotics has resulted in the emergence of antibiotic-resistant microorganisms that represent a growing health care threat. Already, many of the most effective and widely prescribed antibiotic drugs used to treat common infections have been rendered useless for certain drug resistant infections. Within the health care and pharmaceutical industries, there is a renewed sense of urgency to develop and commercialize novel drugs for the effective treatment of many viral and fungal diseases, markets which represent billions of dollars in annual sales.

During 1996 and 1997, OSI entered into co-venture arrangements with BioChem Pharma (International) Inc. ("BioChem Pharma") in anti-virals and Sepracor, Inc. ("Sepracor") in anti-bacterials. Both ventures were successful in seeding core drug discovery capabilities in anti-infectives that were of mutual benefit to both OSI and its co-venture partners. Both programs were also successful in discovering early leads. During 1998, the Company made the decision that it could most effectively capitalize on its integrated drug discovery platform by seeking sole management of its proprietary (OSI funded) discovery programs as opposed to co-venture agreements. In March 1998, an agreement was reached with Sepracor to terminate the OSI/Sepracor co-venture. OSI will receive royalties on the successful development of products arising from the co-venture. The Company expects the OSI/BioChem Pharma co-venture to be terminated in the near future.

During 1998, anti-infectives became the major lead-seeking effort for OSI's proprietary drug discovery program. The Company believes that anti-infectives are an area well suited for drug discovery at OSI. The discovery and development pathways involved in anti-infectives have well defined end points and relatively short timelines for pre-clinical and clinical development. In addition, the Company believes its natural products fungal library is a unique source for novel anti-bacterial and anti-fungal agents. In an effort to focus the Company's resources in the anti-infectives area, a number of anti-infectives targets, including Methicillin Resistant Staphylococcus Aureas ("MRSA"), will be pursued by OSI for its own account using its own R&D resources.





TABLE I. CURRENT PRODUCT DEVELOPMENT AND RESEARCH PROGRAMS

The following table summarizes OSI's current product development and research programs as of December 1, 1998. The table is qualified in its entirety by reference to the more detailed descriptions elsewhere in this report.

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<CAPTION>

| | | | PRE-CLINICAL | | | |
|---|---|---|---|---|---|---|
| CLINICAL | DRUG DISCOVERY PROGRAM | NUMBER OF TARGETS | LEAD SEEKING(A) | LEAD OPTIMI-ZATION(B) | LEAD DEVELOP-MENT(C) | - |
| PHASE I(D) PHASE II(E) DISEASE FIELD | | | | | | |
| <S> | <C> | <C> | <C> | <C> | <C> | |
| <C> <C> | | | | | | |
| CANCER..... | PFIZER | 13 | 6 | 4 | 2 | |
| 1 | | | | | | |
| COSMECEUTICALS..... | ANADERM | 5 | 3 | 1 | 1 | |
| ANTI-INFECTIVES: | | | | | | |
| INFLUENZA..... | SANKYO | 4 | 4 | | | |
| HIV..... | OSI | 1 | 1 | | | |
| MRSA..... | OSI | 1 | 1 | | | |
| OTHER: | | | | | | |
| TGF-BETA 3..... | NOVARTIS | 1 | | | 1 | |
| VARIOUS DISEASES..... | HMRI | 10 | 8 | 2 | | |
| LONG TERM MEMORY..... | HELICON | 1 | 1 | | | |
| SICKLE CELL..... | OSI | 1 | | 1 | | |
| DIABETES..... | OSI | 1 | 1 | | | |
| | | -- | -- | -- | -- | |
| -- -- | | | | | | |
| TOTAL..... | | 38 | 25 | 8 | 4 | |
| 0 1 | | | | | | |
| | | == | == | == | == | |
| == == | | | | | | |

</TABLE>

- ---

(a) For most of the Company's programs in the "Lead Seeking" phase, the target proteins are either undergoing high throughput screening or lead compounds identified in these screens are being evaluated. Multiple lead compounds may exist for any target protein. These lead compounds may be at different stages of development, as indicated in the table above.

(b) In the "Lead Optimization" phase, the Company or its collaborative partners optimize lead compounds and conduct laboratory pharmacology and exploratory toxicology testing.

(c) In the "Lead Development" phase, the Company or its collaborators conduct formal pre-clinical toxicology testing on a development candidate and prepare a regulatory dossier.

(d) "Phase I" clinical trials consist of small scale safety trials typically in healthy human volunteers.

(e) "Phase II" clinical trials entail testing of compounds in humans for safety and efficacy in a limited patient population.

OSI'S TECHNOLOGY PLATFORM

OSI's technology platform constitutes an integrated set of drug discovery technologies covering every aspect of pre-clinical drug development. This platform includes a variety of cell-free and live-cell assays, high throughput

robotic screening, diverse compound libraries and combinatorial, medicinal and natural products chemistry capabilities, together with significant pre-clinical expertise in pharmaceutics, pharmacokinetics and molecular biology. The Company's technologies are designed to accelerate the process of identifying and optimizing high quality, small molecule drug candidates for clinical development. The Company pioneered the development of (i) genetically engineered live-cell assays targeting gene transcription and (ii) robotic high throughput screening. The Company has, through acquisition and internal technology development, added extensively to these core capabilities. The addition of large diverse libraries of small molecules and a broadened expertise in assay biology and medicinal, combinatorial and pharmaceutical chemistry capabilities have created a comprehensive drug discovery platform enabling the Company to progress leads discovered against novel targets all the way through the discovery and pre-clinical development stages. The Company's technology platform is widely applicable to the identification and optimization of small molecule drug candidates to treat many different diseases. Utilizing its technology platform, the Company has been able to





identify and optimize lead compounds that are potent and selective, possess minimal or no cellular toxicity, have activity in live-cells and animal models, and have progressed to clinical trials in humans.

Assay Biology

The Company has specialized in the development of drug screens that utilize genetically engineered human cells to identify compounds that affect transcription of target genes. These assay systems, which employ reporter gene technology, can be utilized to discover drugs that affect the expression of proteins encoded by the target genes. There are multiple sites within a cell where a drug can act to exert a specific effect. This broadly enabling technology allows the Company to discover compounds that exert their effects on receptors, signal transduction proteins, transcription factors and other sites. The Company's seminal contribution to the development of this technology was recognized by the issuance of U.S. Patent No. 5,665,543 in September 1997, which claims a method of identifying compounds that specifically modulate expression of target genes using cells engineered to include reporter genes, and U.S. Patent No. 5,776,502, which covers the use of small molecules to modulate gene transcription in vivo. This technology is used in the biotechnology and pharmaceutical industry, and the Company believes that the claims covered by this patent estate can be licensed for certain monetary and technology considerations. Over the last several years the Company broadened its assay expertise extensively. Currently, the Company is able to conduct screens on a wide variety of different assay platforms, including enzyme assays, immunoassays, scintillation proximity assays, protein-protein interaction assays and receptor-ligand screens. The Company believes this breadth of expertise enables it to select the most appropriate assay with which to pursue drug discovery against a novel biological target.

High Throughput Robotic Screening

OSI has been a pioneer and remains a leader in high throughput screening. The Company has developed software and automation that enable it to manage large compound libraries and prepare test substances for screening. The Company has developed proprietary hardware and software systems to automate the entire drug screening process, from the addition of the test substances to assay systems to the analysis of the data generated from the tests. In its proprietary robotic screening facility, the Company can analyze up to 300,000 different test samples each week, depending on the complexity of the assays. The Company's robotic

systems are not limited to any particular assay format and can be rapidly reconfigured to run a wide variety of assays.

Diverse Compound Libraries

Access to large libraries of diverse, small molecule compounds is a key asset in the Company's drug discovery efforts. Leads discovered from these libraries become the proprietary starting materials from which drugs are optimized. The Company manages over 1.5 million compounds in its compound libraries facility from its own and several of its partners' compound libraries for high throughput screening. The Company's proprietary libraries include its natural products library derived from its unique collection of over 70,000 fungal organisms, its focused libraries of small molecule compounds derived from its high-speed combinatorial analoging, and The Dow Chemical Company's ("Dow") library of approximately 140,000 small-molecule compounds. In March 1997, the Company acquired from Dow an exclusive worldwide license to this library for the purposes of discovery and development of small molecular weight pharmaceuticals and cosmeceuticals. The duration of this license is coextensive with the life of the last to expire of the patents related to the licensed compounds (or 20 years if no patents are filed). In exchange for these rights, the Company issued to Dow 352,162 shares of its common stock, $.01 par value ("Common Stock"). The Company will also pay royalties to Dow from sales of products derived from a small subset of Dow's compound library that is covered by existing Dow patents or proprietary technology. In addition, certain collaborative partners have made their compound libraries available for additional research by the Company outside of their existing collaborative programs. For any compound from the Company's collaborative partners' libraries that emerges as a lead in a proprietary program, the partner typically will have the right of first refusal to develop the compound or terminate its further development or to allow the Company to commercialize the compound independently or with a third party in exchange for royalty payments from the Company on product sales.





Natural Products Discovery

The Company has an extensive program to discover novel and active natural product compounds found in fungal fermentation extracts. Fungi are a known source of pharmaceuticals, including penicillin, cephalosporin, lovastatin, prevastatin and cyclosporin A. Through its MYCOsearch, Inc. subsidiary ("MYCOsearch"), the Company owns a unique and diverse collection of approximately 70,000 fungal organisms. In the MYCOsearch Natural Products Discovery Center in North Carolina, the Company has implemented automated microfermentation technology through which it has generated approximately 110,000 extracts for high throughput screening. This operation is expected to add between 50,000 and 100,000 new extracts to the Company's natural products library annually. The Company has invested substantial resources in implementing a fully integrated fermentation biology and natural products chemistry capability to provide the infrastructure and expertise necessary to isolate and identify active natural product compounds that may be present in fungal abstracts.

Chemistry and Lead Optimization

The pharmaceutical properties of a lead compound must be optimized before clinical development of that compound begins. In 1996 the Company acquired Aston Molecules Ltd. ("Aston"), a private British company with expertise in medicinal and combinatorial chemistry and pharmaceutical development, which are critical elements in the lead optimization and development process. The Company's Aston subsidiary has expertise in pharmacokinetics and pharmaceutical chemistry and

the management and generation of Good Manufacturing Practices ("GMP") accredited data required for regulatory dossier submissions to agencies such as the FDA. Thus, the Company is able to support the development of a drug candidate for clinical testing. The Company has invested significant resources in expanding this capability and in technological enhancements in this area. The Company also has a strategic alliance with Xenometrix, Inc. which is aimed at the development of automated live-cell assays that will allow the Company to profile genes that might be early indicators of the toxicological liability of a lead compound. In addition, the Company is implementing approaches that allow it to generate information on the metabolic liability of lead compounds together with their physical and chemical properties. The Company is in the process of establishing this integrated platform of automated and semi-automated technologies in an effort to support decision making regarding the quality of lead candidates earlier in the drug discovery process.

MAJOR COLLABORATIVE PROGRAMS

OSI pursues collaborations with pharmaceutical companies to combine the Company's drug discovery and development capabilities with the collaborators' development and financial resources. The Company's collaborations provide for its partners to fund the Company's collaborative research programs and to pay royalties on sales of any resulting products. Certain collaborative programs involve milestone payments by the Company's partners. The collaborative partners generally retain manufacturing and marketing rights worldwide. Generally, each collaborative research agreement prohibits the Company from pursuing with any third party drug discovery research relating to the drug targets being covered by research under the collaboration.

Pfizer Inc.

In April 1986, Pfizer and the Company entered into a collaborative research agreement and several other related agreements. During the first five years of the collaboration, the Company and Pfizer focused principally on understanding the molecular biology of oncogenes. In 1991, Pfizer and the Company renewed the collaboration for a second five-year term and expanded the resources and scope of the collaboration to focus on the discovery and development of cancer therapeutic products based on mechanisms-of-action that target oncogenes and anti-oncogenes and fundamental mechanisms underlying tumor growth. Oncogenes play a key role in the conversion of normal cells to a cancerous state and can cause cancer when they mutate or over express. Anti-oncogenes, or tumor suppressor genes, encode proteins that generally function to block the proliferative growth of particular cell types. A loss of function of certain tumor suppressor genes can result in uncontrolled cell growth. Tumor induced angiogenesis is a process whereby solid tumors develop the blood



supply necessary to sustain tumor growth. Effective April 1, 1996, the Company and Pfizer renewed their collaboration for a new five-year term by entering into new collaborative research and license agreements.

All patent rights and patentable inventions derived from the research under this collaboration are owned jointly by the Company and Pfizer. The Company has granted Pfizer an exclusive, worldwide license to make, use, and sell the therapeutic products resulting from this collaboration in exchange for royalty payments. This license terminates on the date of the last to expire of the Company's relevant patent rights.

Pfizer is responsible for the clinical development, regulatory approval, manufacturing and marketing of any products derived from the collaborative

research program. However, the collaborative research agreement does not obligate Pfizer to pursue these activities. Generally, the Company and Pfizer are prohibited during the term of the contract from independently pursuing or sponsoring research aimed at the compounds or products against specific targets in the program, except that the Company may conduct research with respect to human diagnostic products within the area of its collaborative research with Pfizer. The collaborative research agreement will expire on April 1, 2001. However, it may be terminated earlier by either party upon the occurrence of certain defaults by the other party. Any termination of the collaboration resulting from a Pfizer default will cause a termination of Pfizer's license rights. Pfizer will retain its license rights if it terminates the agreement in response to a default by the Company. In addition, between July 1 and September 30, 1999, Pfizer may terminate the collaborative research agreement, with or without cause, effective March 31, 2000. In the event of such early termination, Pfizer will retain its license rights.

From 1986 to September 1998, Pfizer paid an aggregate amount of $40.1 million to the Company in research funding. In 1986, Pfizer purchased 587,500 shares of the Company's Common Stock, which constitutes approximately 2.7% of the Company's outstanding Common Stock, for an aggregate purchase price of $3,525,000. Under the current collaborative research agreement, Pfizer has committed to provide research funding to the Company in an aggregate amount of approximately $18.8 million. Pursuant to a schedule set forth in the collaborative research agreement, Pfizer will make annual research funding payments to the Company, which will gradually increase from a maximum of approximately $3.5 million in the first year of the five-year term to approximately $4 million in the fifth year.

The Bayer Corporation

The Company is engaged in the development of a series of cancer diagnostic tests based on oncogenes, tumor suppressor genes and other gene targets whose proteins are directly involved in tumor growth or metastasis. These tests utilize immunoassays and monoclonal antibodies to detect these cancer markers in serum and urine. These tests are designed to aid oncologists in the confirmation, monitoring, staging, screening or prognosis of human cancer. These tests may enable reference labs and physicians to select more effective types of treatment, more easily monitor patients during therapy, or diagnose cancer at an earlier stage. The current focus of the Company's diagnostic development program is on breast and colon cancer, but the Company believes that many of the cancer markers in its program may have clinical utility for other human tumors, such as lung, prostate, ovarian and stomach cancer. None of these diagnostic tests have completed clinical development or received FDA clearance to be marketed in the United States.

The Company entered into a Collaborative Research and License Agreement with Bayer, effective January 1, 1997, for the development of serum-based cancer diagnostic products. Under this agreement, the Company has granted to Bayer licenses to manufacture, use and sell clinical diagnostic products based on the Company's cancer diagnostic technology for the automated analyzer market in exchange for royalties on net sales. Bayer will own all technology, and has the exclusive right to commercialize automated clinical diagnostic products derived from the collaboration. OSI has retained rights and is actively selling non-automated, or manual, versions of these tests to the clinical research market and has retained the right to commercialize the manual versions in the clinical diagnostic market. Bayer's license is perpetual with respect to non-patented technology and will terminate with respect to patented technology upon the expiration of the last to expire of the Company's patents. Bayer will provide funding for the Company's research under the

collaboration in the amount of $1.5 million for each of the first two years, and $1 million for each subsequent year. The Company will be required to provide up to $500,000 in annual funding for the collaboration to the extent the Company derives net revenues from out-licensing any cancer diagnostics technology or the sale of any clinical diagnostic or clinical research products. The agreement will terminate on December 31, 2002. Bayer has the right to terminate the agreement at any time upon 12 months notice.

Fujirebio, Inc.

The Company, through OSDI, entered into a Research Collaboration and License Agreement with Fujirebio effective April 1, 1998, creating a collaborative program focused on discovering and developing certain proprietary cancer assays and commercializing cancer diagnostic products. Under the agreement, Fujirebio is to fund the Company's research and development of cancer assays over a four-year term. The Company is to provide Fujirebio with antibodies, antigens and other substances necessary to manufacture the diagnostic products derived from the collaboration. Further, the Company has granted to Fujirebio a non-exclusive license to, among other things, develop, manufacture and sell the products developed pursuant to the collaboration in Japan in exchange for license fees and royalties on product sales. The duration of the license is to be coextensive with the lives of the patents related to the licensed products. Each of the parties has rights and obligations to prosecute and maintain patent rights related to specified areas of the research under the agreement. The agreement is subject to early termination by either party in the event of certain defaults.

Anaderm Research Corp.

On April 23, 1996, in connection with the formation of Anaderm, the Company entered into a Stockholders' Agreement (the "Stockholders' Agreement") among the Company, Pfizer, Anaderm, NYU and certain NYU faculty members (the "Faculty Members"), and a Collaborative Research Agreement (the "Research Agreement") among the Company, Pfizer and Anaderm for the discovery and development of novel compounds to treat conditions such as baldness, wrinkles and pigmentation disorders. Anaderm has issued common stock to Pfizer and the Company and options to purchase common stock to NYU and the Faculty Members. NYU and the Faculty Members have exercised their options fully, and Pfizer holds 82%, the Company holds 14%, and NYU and the Faculty Members collectively hold 4%, of Anaderm's common stock. In exchange for its 14% of the outstanding shares of Anaderm's common stock, the Company provided formatting for high throughput screens and conducted compound screening for 18 months at its own expense under the Research Agreement.

The term of the Research Agreement is three years. During the initial phase of the agreement (the first 18 months), the Company was required to provide at its own cost formatting for high throughput screens and perform screening of its own compounds and those compounds provided by Pfizer. Upon the termination of the initial phase, the Board of Directors of Anaderm made a determination that the initial phase was successfully completed. With Pfizer's approval, the funded phase commenced as of October 1, 1997 and will continue for the term of the Research Agreement. During this phase, Anaderm will make payments to the Company equal to its research costs, including overhead, plus 10%. Anaderm or Pfizer will pay royalties to the Company on the sales of products resulting from this collaboration.

In December 1997, the Company and Pfizer entered into an agreement for a second round of equity financing for Anaderm. The agreement called for an equity contribution of $14 million, of which the Company will contribute $2 million in

drug discovery resources, including assay biology, high throughput screening, lead optimization and chemistry, through 1999. Pfizer will contribute $12 million, approximately $7 million of which will be used to support the Company in its ongoing drug discovery activities. Through September 1998, the Company had contributed $770,000 of its $2 million contribution in resources.

Sankyo Company, Ltd.

Effective as of February 12, 1997, the Company entered into a Collaborative Research and License Agreement with Sankyo to be conducted in partnership with MRC Collaborative Center ("MRC CC"),





London, U.K. The collaboration is focused on discovering and developing novel pharmaceutical products to treat influenza.

Under the terms of the agreement, a research committee was formed consisting of three representatives from Sankyo, two representatives from the Company and one representative from MRC CC. The committee monitors the progress of the research program and directs the objectives, tasks and required activities of the collaboration. The Company is responsible for conducting research as directed by the research committee, including, without limitation, compound screening in exchange for research funding from Sankyo. Sankyo has the responsibility and the exclusive right to conduct pre-clinical and clinical development of all candidate compounds in exchange for milestone payments to the Company.

The Company and MRC CC have granted to Sankyo exclusive, worldwide licenses to, among other things, use, manufacture and sell all products resulting from the collaboration. In exchange for these licenses, Sankyo will pay to the Company and MRC CC license fees and royalties on product sales. The duration of the licenses is coextensive with the lives of the patents related to the licensed compound. If Sankyo discontinues development of all candidate compounds, the Company will have the sole and exclusive right to develop, use, manufacture and sell all products resulting from the collaboration, and it will pay royalties to Sankyo. Each of the parties has rights and obligations to prosecute and maintain patent rights related to specified areas of the research under the agreement.

Generally, the Company, Sankyo and MRC CC are prohibited during the term of the contract from pursuing or sponsoring research and development of compounds and products in the anti-influenza area other than pursuant to the agreement. The agreement is for a term of three years, with the option to extend for an additional one or two year period upon conditions and terms acceptable to the Company, Sankyo and MRC CC. The agreement is subject to early termination in the event of certain defaults by the parties.

Hoechst Marion Roussel, Inc.

Pursuant to the Amended Collaborative Research and License Agreement effective April 1, 1997, the Company and HMRI are conducting joint research and development activities, which focus specifically on OSI's expertise in live-cell assay technology. OSI conducts the lead seeking (screening) phase of the drug discovery process against a variety of targets in various disease areas. HMRI is responsible for all lead optimization and development activities. The Company has identified several compounds, which HMRI is optimizing for further development. The most advanced of these compounds are in lead optimization for individual targets in atherosclerosis and arthritis.

Under this collaboration, a research committee, with equal representation from OSI and HMRI, meets at least three times a year to evaluate the progress of the research program, make priority and program decisions, and prepare research plans identifying the drug targets to be pursued. New targets are added to the program on an ongoing basis by mutual agreement. The Company is responsible for achieving objectives outlined in the annual research plans. HMRI is responsible for assisting the Company in the pursuit of such objectives, including advancing the pharmacological assessment of compounds identified by the Company, determining the chemical structure of the selected compounds, identifying and selecting development candidates, pursuing clinical development and regulatory approval, and developing manufacturing methods and pharmaceutical formulations for the selected candidates. HMRI is responsible for funding the costs of the Company's discovery efforts. As of September 30, 1998, the Company had received or accrued an aggregate of $20.4 million in research funding from HMRI and its predecessors.

The Company has granted to HMRI an exclusive, worldwide license (and rights to acquire additional licenses) with respect to, among other things, the use, manufacture and sale of products resulting from OSI's lead seeking efforts against these individual drug targets. In exchange for these licenses, HMRI will pay royalties to the Company on sales of such products. The Company and HMRI have mutually exclusive rights and obligations to prosecute and maintain certain patent rights related to various specified areas of the research.





Generally, the Company is prohibited during the term of the collaboration from pursuing or sponsoring research independent of HMRI if it relates to the identified targets in the areas of collaboration with HMRI without the approval of the research committee. HMRI is generally prohibited from using the gene transcription method independent of OSI to discover novel human therapeutic products without the approval of the research committee. The agreement expires on the later of March 31, 2002 or the last to expire of any obligations of HMRI to pay royalties. The collaborative research agreement may be terminated early by either party upon the occurrence of certain defaults by the other party. Any termination by the Company resulting from an HMRI default will cause a termination of certain of HMRI's license rights. HMRI will retain its license rights if it terminates the agreement in response to a default by the Company. HMRI holds 1,590,909 shares of Common Stock of the Company, which includes a warrant to purchase 500,000 shares of the Company's Common Stock for $5.50 per share. This warrant expires in December 1999.

Effective as of January 1, 1997, the Company entered into a Collaborative Research and License Agreement with HMRI to develop orally active, small molecule inducers of erythropoietin gene expression for the treatment of anemia due to chronic renal failure and anemia associated with chemotherapy for AIDS and cancer. This collaboration identified active lead compounds that were advanced to a pre-clinical development stage. This research effort, however, did not achieve sufficient data to warrant further development. Consequently, in October 1998, this program was terminated.

Helicon Therapeutics, Inc.

In July 1997, the Company, Cold Spring Harbor Laboratory and Hoffman-La Roche Inc. ("Roche") formed Helicon Therapeutics, Inc., a new Delaware corporation ("Helicon"). In exchange for approximately 30% of Helicon's outstanding capital stock, the Company contributed to Helicon molecular screening services and a nonexclusive license with respect to certain screening technology. Cold Spring Harbor Laboratory contributed a royalty-free license to commercialize certain technology relating to genes associated with long-term

memory in exchange for a portion of Helicon's outstanding capital stock. Roche contributed cash for a portion of Helicon's outstanding capital stock. Certain individuals associated with Cold Spring Harbor Laboratory hold the remaining outstanding capital stock of Helicon.

The parties have entered into various collaborative research and license agreements pursuant to which they will jointly pursue the discovery, development and commercialization of novel drugs for the treatment of long-term memory disorders and other central nervous system dysfunctions. The initial term of the collaborative program is three years, commencing as of July 1, 1997, subject to extension for successive one-year periods upon agreement of the parties. Roche, however, will have the right to terminate the program at the end of the second year, or otherwise if certain milestones identified by the research committee are not achieved. The Company and Cold Spring Harbor Laboratory are to conduct research under the program, which is being funded by Helicon (except for the molecular screening services the Company is contributing to Helicon). Helicon is to receive funding from Roche for the first two years of the program. If the program is not previously terminated, Roche is to continue to provide funding for the third year of the program, with the actual amount to be determined by a research committee established to oversee the collaborative program. Roche is obligated to use reasonably diligent efforts to commercialize products derived from the program.

Helicon has granted to Roche a worldwide license to commercialize pharmaceutical products resulting from the collaborative program in exchange for certain milestone payments and royalties on Roche's sales of such products. Each of Helicon, the Company, Cold Spring Harbor Laboratory and Roche have various rights and obligations to prosecute and maintain patent rights related to specified developments and areas of the research under the collaborative program. Helicon is prohibited from independently conducting or sponsoring research related to the objectives of this collaborative program.

Novartis Pharma AG

The Company entered into an agreement with Novartis Pharma AG ("Novartis") in April 1995 for the development of TGF-Beta 3 for various indications. TGF-Beta 3 is a naturally occurring human growth factor, first isolated by the Company, that exerts either stimulatory or inhibitory effects depending upon the particular



cell type to which it is applied. This agreement granted to Novartis an exclusive, worldwide license to use and sell TGF-Beta 3 products for wound healing and oral mucositis, as well as certain other indications, in exchange for royalty payments to the Company on the sale of TGF-Beta 3 products.

During 1998, Phase II clinical trials being conducted by Novartis for both wound healing and oral mucositis failed to achieve their primary clinical end points. Consequently, no further clinical development of TGF-Beta 3 by Novartis for either wound healing or oral mucositis is anticipated. Novartis has an option through April 1999 (which it has not yet exercised) to obtain exclusive rights to all other indications for TGF-Beta 3 by making a $10 million payment in exchange for the Company's Common Stock at the higher of $5.50 per share or the then current market price. Novartis is currently conducting pre-clinical evaluation of TGF-Beta 3 for bone repair. Novartis and the Company are currently renegotiating this agreement to allow for the continued development of TGF-Beta 3 for this and other indications. The Company's agreement with Novartis ends upon the expiration of the last of the Company's patents relating to TGF-Beta 3.

PROPRIETARY DRUG DISCOVERY AND DEVELOPMENT

In addition to its proprietary program in anti-infectives, the Company is pursuing proprietary discovery and development activities in the following areas:

Sickle Cell Anemia and B-thalassemia

Currently, the Company's proprietary discovery and development efforts are focused principally in sickle cell anemia and B-thalassemia that are caused by genetic mutations which result in the mutation, absence or decrease in the adult chain of hemoglobin (the protein in red blood cells that binds oxygen). Currently available treatments for both of these diseases are inadequate and expensive. The cost of treating each sickle cell patient in the United States has been estimated to be in excess of $60,000 annually. Regular blood transfusions are the mainstay of current therapy for thalassemia. The Company's approach to address sickle cell anemia and thalassemia is to discover a small molecule compound that increases expression of the fetal hemoglobin ("HbF") gene to compensate for defects in the adult chain of hemoglobin. The Company has identified lead compounds that induce the production of HbF and has initiated pre-clinical developments.

Diabetes

The Company has assembled a comprehensive drug discovery capability in diabetes that it believes can provide a unique opportunity for a major pharmaceutical company to form a strategic partnership with the Company. In April 1998, the Company entered into a collaborative agreement with the Vanderbilt University Diabetes Center ("Vanderbilt") to discover and develop novel, small molecule drugs for the treatment of non-insulin dependent diabetes mellitus of Type II diabetes.

Type II diabetes affects a significant proportion of the population, 100 million people worldwide by some estimates. In the United States, over 10 million patients have symptoms associated with Type II diabetes, with approximately 500,000 new cases diagnosed each year. An estimated 20 million Americans have impaired glucose tolerance, one of the earliest manifestations of insulin resistance, which is believed to precede development of Type II diabetes. Serious complications associated with Type II diabetes cost the U.S. economy more that $90 billion annually. An orally active, well tolerated, efficacious drug to modulate blood glucose levels will benefit significant numbers of diabetic patients, or those designated to develop the disease.

The Company believes that the innovative alliance between the Company and Vanderbilt provides a comprehensive drug discovery and early clinical testing capability in the field of diabetes. The Company is actively seeking a pharmaceutical company to form a funded collaboration in this disease area.

INTELLECTUAL PROPERTY

The Company believes that patents and other proprietary rights are vital to its business. The Company's policy is to protect its intellectual property rights in technology developed by its scientific staff by a variety of means, including applying for patents in the United States and other major industrialized countries. The



Company also relies upon trade secrets and improvements, unpatented proprietary know-how and continuing technological innovations to develop and maintain its

competitive position. In this regard, the Company seeks restrictions in its agreements with third parties, including research institutions, with respect to the use and disclosure of the Company's proprietary technology. The Company also has confidentiality agreements with its employees, consultants and scientific advisors.

The Company currently controls 23 U.S. patents and 92 foreign patents. In addition, the Company currently has pending 26 applications for U.S. patents, 7 of which have been allowed, and 30 applications for foreign patents, 3 of which have been allowed. In addition, other institutions have granted exclusive rights under their United States and foreign patents and patent applications to the Company.

In September 1997, the Company was issued U.S. Patent No. 5,665,543, which claims a method of identifying compounds that specifically modulate expression of target genes using cells engineered to include reporter genes. In July 1998, the Company was issued U.S. Patent 5,776,502, which claims a method of specifically modulating gene transcription in a multicellular organism using a low molecular weight compound. The Company has additional patent applications pending, some of which have been allowed, which should enhance the Company's patent position in the area of gene transcription.

There can be no assurance that patents will issue based upon the Company's pending patent applications or any applications which it may file in the future, that any patent issued will adequately protect a commercially marketable product or process or that any patent issued will not be circumvented or infringed by others or declared invalid or unenforceable. Moreover, there can be no assurance that others may not independently develop the same or similar technology or obtain access to the Company's proprietary technology. The Company is aware of patents issued to other entities with respect to technology potentially useful to the Company and, in some cases, related to products and processes being used or developed by the Company. The Company currently cannot assess the effect, if any, that these patents may have on its operations in the future. The extent to which efforts by other researchers resulted or will result in patents and the extent to which the issuance of patents to other entities would have a material adverse effect on the Company or would force the Company to seek licenses from such other entities currently is unknown as is the availability to the Company of licenses from such other entities, and whether, if available, such licenses can be obtained on terms acceptable to the Company.

In the cancer diagnostic area the Company has an issued U.S. patent and a granted European patent relating to an assay the Company, in collaboration with Bayer, is seeking to develop for the detection of a protein encoded by the neu oncogene ("neu") in serum. The U.S. Patent Office has declared an interference between the Company's issued U.S. Patent and a pending patent application owned by Chiron Diagnostics Inc. ("Chiron"). In addition, Chiron has filed an opposition against the corresponding granted European patent. These legal proceedings, if not settled, could result in substantial legal expenses being incurred by the Company. Also, the Company cannot predict whether it would prevail in these proceedings. If the Company does not prevail, it may not be able to commercialize its assay for neu in serum without a license from Chiron, which may not be available on acceptable terms or at all.

The Company is aware of several U.S. and foreign patents owned by others who may allege infringement by products, including TGF-Beta 3, which is the subject of the Company's collaboration with Novartis. Genentech, Inc. ("Genentech") has U.S. patents relating to certain recombinant materials and procedures for producing members of the TGF-Beta family, including TGF-Beta 3. In addition, the Company believes that Genentech has license rights under a U.S. Government patent relating to work done at the National Institute of Health of the U.S. Department of Health and Human Services involving the identification

and isolation of TGF-Beta 1. Furthermore, Celtrix Pharmaceuticals, Inc. ("Celtrix") had been granted a European patent relating to TGF-Beta 2. This patent was recently revoked in opposition proceedings, but could be reinstated on appeal. The Company and Novartis have taken and continue to take such actions, including the pursuit of opposition proceedings against foreign patents, as they deem prudent to minimize the possibility of any charge of patent infringement being validly raised against Novartis or the Company based on such patents.

The Company has received communications from Sibia Neuroscience, Inc. ("Sibia") in which Sibia has stated the Company's live-cell assay technology may infringe a patent issued to Sibia covering cell-based





assays. The Company does not believe that it is infringing any valid claim of Sibia's patent or of any patents owned by any other third parties. However, there can be no assurance that a contrary position will not be asserted, or that, if asserted, such a position would not prevail. If a patent infringement lawsuit were brought against the Company or its licensees, the Company could incur substantial costs in defense of such a suit, which could have a material adverse effect on the Company's business, financial condition and results of operation, regardless of whether the Company were successful in the defense. Furthermore, if Sibia (or any other third party) were to establish that the Company's assays infringe Sibia's patent (or any patent of any other third party), then the Company would be required to design non-infringing assays or take a license under Sibia's patent. There can be no assurance the Company would successfully design such assays or that such a license would be available on acceptable terms or at all. Moreover, the Company's royalties may be reduced by up to 50% if its licensees or collaborative partners are required to obtain licenses from third parties whose patent rights are infringed by the Company's products, technology or operations.

COMPETITION

The pharmaceutical, biotechnology and diagnostic industries are intensely competitive. The Company faces, and will continue to face, intense competition from organizations such as large pharmaceutical companies, biotechnology companies, diagnostic companies, academic and research institutions and government agencies. The Company is subject to significant competition from industry participants who are pursuing the same or similar technologies as those which constitute the Company's technology platform and from organizations that are pursuing pharmaceutical products or therapies or diagnostic products that are competitive with the Company's potential products. Most of the organizations competing with the Company have greater capital resources, greater research and development staffs and facilities, and greater experience in drug discovery and development, obtaining regulatory approval and pharmaceutical product manufacturing and marketing. The Company's major competitors include fully integrated pharmaceutical companies, such as Merck & Co., Inc., Glaxo Wellcome Inc. and SmithKline Beecham plc, that conduct extensive drug discovery efforts and are developing novel small molecule pharmaceuticals, as well as numerous smaller companies.

The Company's technology platform consists principally of utilizing genetically engineered live-cells, gene transcription technologies, high throughput drug screening, and medicinal, combinatorial and natural product chemistry. Pharmaceutical and biotechnology companies and others are active in all of these areas. Ligand Pharmaceuticals Inc. and Aurora, publicly owned companies, employ live-cell assays, gene transcription, and high throughput robotics in their drug discovery operations. Numerous other companies use one or more of these technologies. Several private companies, including Tularik Inc.,

Signal Pharmaceuticals Inc. and Scriptgen Pharmaceuticals, Inc., pursue drug discovery using gene transcription methods. Other organizations may acquire or develop technology superior to that of the Company.

Companies pursuing different but related fields also present significant competition for the Company. For example, research efforts with respect to gene sequencing and mapping are identifying new and possibly superior target genes. In addition, alternative drug discovery strategies, such as rational drug design, may prove more effective than those pursued by the Company. Furthermore, competing entities may have access to more diverse compounds for testing by virtue of larger compound libraries or through combinatorial chemistry skills or other means. These include Pharmacopeia, Inc., CombiChem, Inc., ArQule, Inc. and AxyS Pharmaceuticals, Inc., all of which have major collaborations with leading pharmaceutical companies. There can be no assurance that the Company's competitors will not succeed in developing technologies or products that are more effective than those of the Company or that would render the Company's products or technologies obsolete or noncompetitive.

With respect to the Company's small molecule drug discovery programs, other companies have potential drugs in clinical trials to treat disease areas for which the Company is seeking to discover and develop drug candidates. These competing drug candidates may be further advanced in clinical development than are any of the Company's potential products in its small molecule programs and may result in effective, commercially successful products. Even if the Company and its collaborative partners are successful in developing effective drugs, there can be no assurance that the Company's products will compete effectively with such products. No assurance can be given that the Company's competitors will not succeed in developing and marketing products





that either are more effective than those that may be developed by the Company and its collaborative partners or are marketed prior to any products developed by the Company or its collaborative partners.

The Company believes that its ability to compete successfully will be based on, among other things, its ability to create and maintain scientifically advanced technology, attract and retain scientific personnel with a broad range of expertise, obtain patent protection or otherwise develop proprietary products or processes, enter into collaborative arrangements, and, independently or with its collaborative partners, conduct clinical trials, obtain required government approvals on a timely basis, and commercialize its products.

MANUFACTURING

OSDI has developed a GMP capability for the production of immunoassay kits and monoclonal antibodies at its Cambridge, Massachusetts facility. GMP is essential for conducting clinical trials for tumor markers like HER-2/neu and for sale of FDA approved products to the diagnostic market. The Company plans to expand OSDI's manufacturing capacity by automating several of the current manufacturing processes. OSDI currently manufactures an FDA approved product known as Transprobe(R). Transprobe(R) is a nucleic acid based probe that aids in the diagnosis of chronic myelogenous leukemia by identifying the bcr-abl translocation.

The Company is, and will remain, dependent on its collaborative partners and third parties for the manufacture of all products. There can be no assurance that the Company will be able to manufacture products that will meet the Company's demands for quality, quantity, cost and timeliness or otherwise contract for manufacturing capabilities on acceptable terms. The failure of the Company to successfully contract for the manufacture of products that satisfy

its requirements for quality, quantity, cost and timeliness would prevent the Company from conducting pre-clinical testing and clinical trials and commercializing its products.

Novartis has the exclusive right to, and the Company will rely on Novartis for, the manufacture of TGF-Beta 3 for all of the Company's requirements for clinical trials and commercial purposes. The Company believes that, if Novartis should fail to meet its requirements, there are other companies that could manufacture and supply TGF-Beta 3, although there can be no assurance that this could be accomplished on a timely basis, or at all.

MARKETING AND SALES

The Company does not expect to develop significant marketing and sales capabilities. Potential therapeutic products subject to the Company's collaborative agreements with Pfizer, HMRI, Sankyo, and Novartis, and potential diagnostic products under the Company's collaboration with Bayer and Fujirebio, will be marketed by those companies worldwide. The Company will receive royalties of up to 8% on net sales of products, depending upon the nature of the product and the ownership of the underlying technology. The Company expects that products resulting from future collaborations in drug discovery and development and diagnostic product development will be marketed under arrangements which are similar to these agreements, although any collaborations established for products resulting from proprietary programs may vary significantly.

GOVERNMENT REGULATION

The Company and its collaborative partners are, and any potential products discovered and developed thereto, will be subject to 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 process required by the FDA before pharmaceutical products may be approved for marketing in the United States generally involves: (i) pre-clinical laboratory and animal tests, (ii) submission to FDA of an investigational new drug application ("IND"), which must become effective before clinical trials may begin,





(iii) adequate and well controlled human clinical trials to establish the safety and efficacy of the drug for its intended indication, (iv) submission to the FDA of a new drug application ("NDA") or, in the case of biological products, such as TGF-Beta 3, a product license application ("PLA"), and (v) FDA review of the NDA or PLA in order to determine, among other things, whether the drug is safe and effective for its intended uses. There is no assurance that FDA review process will result in product approval on a timely basis, if at all.

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 are subject to FDA regulations regarding current Good Laboratory Practices. The results of the pre-clinical tests are submitted to the FDA as part of an IND and are reviewed by the FDA prior to the commencement of clinical trials.

Clinical trials are conducted under protocols that detail such matters as

the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

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, metabolism, distribution and excretion. Phase II involves studies in a limited patient population to: (i) evaluate preliminarily the efficacy of the product for specific, targeted indications, (ii) determine dosage tolerance and optimal dosage, and (iii) identify possible adverse effects and safety risks. Pivotal or Phase III trials are undertaken in order to further evaluate clinical efficacy and to further test for safety within an expanded patient population. The FDA may suspend or terminate clinical trials at any point in this process if it concludes that clinical subjects are being exposed to an unacceptable health risk.

FDA approval of the Company's and its collaborators' products, including a review of the manufacturing processes and facilities used to produce such products, will be required before such products may be marketed in the United States. The process of obtaining approvals from the FDA can be costly, time consuming and subject to unanticipated delays. There can be no assurance that approvals of the Company's proposed products, processes or facilities will be granted on a timely basis, if at all. Any failure to obtain or delay in obtaining such approvals would have a material adverse effect on the Company's business, financial condition and results of operations. Moreover, even if regulatory approval is granted, such approval may include significant limitations on indicated uses for which a product could be marketed.

Among the conditions for NDA approval is the requirement that the prospective manufacturer's manufacturing procedures conform to GMP requirements, which must be followed at all times. In complying with those requirements, manufacturers (including a drug sponsor's third-party contract manufacturers) must continue to expend time, money and effort in the area of production and quality control to ensure compliance. Domestic manufacturing establishments are subject to periodic inspections by the FDA in order to assess, among other things, GMP compliance. To supply products for use in the United States, foreign manufacturing establishments must comply with GMP 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 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 the pre-clinical and clinical testing process, the approval process, or thereafter (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 such 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 the Company's products under development.

For marketing outside the United States, the Company and its collaborators and the drugs developed thereby, if any, will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for drugs and diagnostic products. The requirements governing the conduct of clinical

trials, product licensing, pricing and reimbursement vary widely from country to country. In addition, before a new drug may be exported from the United States, it must be the subject of an approved NDA or comply with FDA regulations pertaining to INDs.

In addition to regulations enforced by the FDA, the Company also is subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and future federal, state or local regulations. The Company's R&D activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although the Company believes that its safety procedures for handling and disposing of such 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. In the event of such an accident, the Company could be held liable for any damages that result and any such liability could exceed the resources of the Company.

Diagnostic tests undergo different FDA review processes depending upon whether they are classified as "biologicals" or "medical devices." For medical devices, a 510(k) application (for a product substantially equivalent to a product already on the market) or a premarket approval application (generally, a new product or method that is not substantially equivalent to an existing product) must be filed with, and approved by, the FDA prior to commercialization. Obtaining premarket approval is a costly and time-consuming process, comparable to that for new drugs. There can be no assurance that the Company's cancer diagnostic product candidates will be submitted for regulatory approval, or if submitted, that the Company would not be required to seek premarket approval as opposed to filing a 510(k) application.

EMPLOYEES

The Company believes that its success is largely dependent upon its ability to attract and retain qualified personnel in scientific and technical fields. As of December 1, 1998, the Company employed 164 persons worldwide (126 in the United States), of whom 134 were primarily involved in research and development activities, with the remainder engaged in executive and administrative capacities. Although the Company believes that it has been successful to date in attracting skilled and experienced scientific personnel, competition for such personnel is intense and there can be no assurance that the Company will continue to be able to attract and retain personnel of high scientific caliber. The Company considers its employee relations to be good.

CAUTIONARY FACTORS FOR CONSIDERATION IN CONNECTION WITH FORWARD LOOKING STATEMENTS

This report contains forward-looking statements that do not convey historical information, but relate to predicted or potential future events, such as statements of the Company's plans, strategies and intentions, or its future performance or goals for the Company's product development programs. Such statements can often be identified by the use of forward-looking terminology such as "believes," "expects," "intends," "may," "will," "should" or "anticipates" or similar terminology. These statements involve risks and uncertainties and are based on various assumptions, and investors and prospective investors are cautioned that such statements are only projections. The following risks and uncertainties, among others, could cause the Company's 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:

Uncertainties Related to Clinical Trials

The Company has limited experience in conducting clinical trials and has relied primarily on the pharmaceutical companies with which it collaborates, including Pfizer, HMRI, Sankyo and Novartis for clinical development and regulatory approval of its product candidates. Before obtaining regulatory approvals for the commercial sale of its products, the Company or its collaborative partners will be required to demonstrate through pre-clinical studies and clinical trials that the proposed products are safe and effective for use in each target indication. The results from pre-clinical studies and early clinical trials may not be predictive of results that will be obtained in large-scale testing, and there can be no assurance that the clinical





trials conducted by the Company or its partners will demonstrate sufficient safety and efficacy to obtain the required regulatory approvals or will result in marketable products. In addition, clinical trials are often conducted with patients having the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested, but which can nevertheless affect clinical trial results. Various companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. In addition, clinical trials for the product candidates being developed by the Company and its collaborators may be delayed by many factors. Any delays in, or termination of, the clinical trials of any of the Company's product candidates would have a material adverse effect on the Company's business, financial condition and results of operations.

To date, in the Company's small molecule drug discovery operations, only one product candidate has entered clinical trials. Furthermore, thus far only one of the compounds discovered using the Company's small molecule discovery technology has been proven safe in humans and none have yet demonstrated efficacy. Moreover, the Company's drug discovery assays are focused on various genes and other targets, the functions of many of which have not yet been fully elucidated. As such, the safety and efficacy of drugs that affect these targets has not yet been established. No assurance can be given that any lead small molecule compounds or diagnostic product candidates emerging from the Company's discovery and development operations will successfully complete clinical trials or receive marketing approval from FDA or any foreign regulatory authorities on a timely basis or at all.

Dependence on Collaborative Relationships

The Company does not intend to conduct late-stage clinical trials or manufacturing or marketing activities with respect to any of its product candidates in the foreseeable future. The Company has collaborations with Pfizer, HMRI, Sankyo and Novartis for the development of potential drug candidates, and currently its most advanced program is in an oncogene inhibitor with Pfizer for the treatment of certain cancers. The Company is largely dependent on the pharmaceutical companies with which it collaborates for the pre-clinical testing, clinical development, regulatory approval, manufacturing and marketing of its products. The Company's collaborative agreements allow its collaborative partners significant discretion in electing to pursue or not to pursue any of these activities. The Company cannot control the amount and timing of resources its collaborative partners devote to the Company's programs or potential products. If any of the Company's collaborative partners were to breach or terminate its agreements with the Company or otherwise fail to conduct its collaborative activities successfully in a timely manner, the pre-clinical

or clinical development or commercialization of product candidates or research programs would be delayed or terminated. Any such delay or termination could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company relies on its collaborative partners to provide funding in support of its research operations. As of September 30, 1998, the Company had received or accrued an aggregate of $97.4 million in research funding and milestone payments from its collaborative partners. The Company would be required to devote additional internal resources to product development, or scale back or terminate certain development programs or seek alternative collaborative partners, if funding from one or more of its collaborative programs were reduced or terminated.

Although the Company has worked to expand its proprietary compound libraries (through acquisition of the fungal collection of MYCOsearch and the licensing of Dow's library of approximately 140,000 small molecule compounds), the Company still owns or controls the rights to only a relatively small number of the compounds that it tests in its drug discovery operations. The Company is dependent on access to the compound libraries of its collaborative partners and others in order to enhance the value of its drug discovery platforms. Failure by the Company to gain access to the compound libraries of its collaborative partners for its collaborative programs and others would restrict its ability to exploit fully its high throughput screening capabilities and would have a material adverse effect on its business, financial condition and results of operations.





Disputes may arise in the future with respect to the ownership of rights to any technology developed with third parties. These and other possible disagreements between collaborators and the Company could lead to delays in the collaborative research, development or commercialization of certain product candidates, or could require or result in litigation or arbitration, which would be time-consuming and expensive, and would have a material adverse effect on the Company's business, financial condition and results of operations.

Generally, in its collaborative research agreements, the Company agrees not to conduct independently, or with any third party, any research that is competitive with the research conducted under its collaborative programs. The Company's collaborative relationships may have the effect of limiting the areas of research the Company may pursue. For example, under its collaborative research agreements with some of its partners, the Company is prohibited during the term of the agreements from pursuing or sponsoring research aimed at the discovery of drugs which are the subject of the collaborations. However, the Company's collaborative partners may develop, either alone or with others, products that are similar to or competitive with the products or potential products that are the subject of the Company's collaborations with such partners. Competing products, either developed by the collaborative partners or to which the collaborative partners have rights, may result in their withdrawal of support for the Company's product candidates, which would have a material adverse effect on the Company's business, financial condition and results of operations.

All of the Company's collaborative programs with pharmaceutical companies have terms of six or fewer years, which is generally less than the period required for the discovery, clinical development and commercialization of most drugs. The continuation of any of the Company's drug discovery and development programs is dependent on the periodic renewal of the relevant collaborative partnership. Furthermore, all of the Company's collaborative research agreements

are subject to termination under various circumstances. Certain of the Company's collaborative research agreements provide that, upon expiration of a specified period after commencement of the agreement, its collaborative partners have the right to terminate the agreement on short notice without cause. The termination or nonrenewal of any collaborative relationship could have a material adverse effect on the Company's business, financial condition and results of operations.

There have been a significant number of consolidations among large pharmaceutical and diagnostic companies. Such consolidations among these companies with which the Company is engaged in collaborative research can result in the diminution or termination of, or delays in, one or more of the Company's collaborative programs. For example, in 1995, the pharmaceutical operations of three companies with which the Company had collaborative research agreements, Hoechst AG, Hoechst Roussel Pharmaceuticals, Inc. and Marion Merrell Dow Inc. were combined in one entity, HMRI. This combination resulted in delays in the Company's collaborative programs with each of the constituent companies and a reduction in the aggregate funding received by the Company.

The Company's strategy for the discovery, development, clinical testing, manufacturing and marketing of certain of its potential products includes establishing additional collaborations. There can be no assurance that the Company will be able to negotiate such collaborative arrangements on acceptable terms, if at all, or that such collaborations will be successful.

Uncertainties Related to the Early Stage of Development; Technological Uncertainties

To date, the Company has generated no revenue from the sale of pharmaceutical products. Except for CP-358,774, with respect to which Pfizer has completed Phase I safety and toxicity studies and has initiated Phase II clinical trials, all of the lead compounds in the Company's small molecule drug discovery programs are in either a discovery or pre-clinical evaluation phase. The Company has commercialized one diagnostic product, which to date has not generated significant sales and is not expected to generate significant sales in the future. Any products resulting from the Company's development programs are not expected to be commercially available for several years, if at all.

All of the Company's potential products will require significant research and development and are subject to significant risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. Potential products may be found ineffective or cause harmful side effects during pre-clinical testing or clinical trials, fail to receive necessary regulatory approvals, be difficult to





manufacture on a large scale, be uneconomical to produce, fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties. There can be no assurance that the Company's or its collaborative partners' product development efforts will be successfully completed, that required regulatory approvals will be obtained or that any products, if introduced, will be successfully marketed or achieve customer acceptance.

The Company's live-cell assays are novel as a drug discovery method and have not yet been shown to be successful in the development of any commercialized drug. Furthermore, the Company's drug discovery assays are focused on several target genes and other molecular targets, the functions of many of which have not yet been fully elucidated. There can be no assurance that the Company's live-cell assay technology will result in lead compounds that will be safe and efficacious. Development of new pharmaceutical products is highly uncertain, and no assurance can be given that the Company's drug discovery

technology will result in any commercially successful products.

Uncertainty of Future Profitability

OSI has had net operating losses since its inception in 1983. At September 30, 1998, the Company's accumulated deficit was approximately $55.8 million. The Company's losses have resulted principally from costs incurred in research and development, and from general and administrative costs associated with the Company's operations. These costs have exceeded the Company's revenues, which to date have been generated principally from collaborative research agreements. OSI expects to incur substantial additional operating expenses over the next several years as a result of increases in its expenses for research and development, including enhancements in its drug discovery technologies and with respect to its internal proprietary projects. If the Company does not obtain additional third party funding for such expenses, the Company expects that such expenses will result in increased losses from operations. OSI does not expect to generate revenues from the sale of its small molecule products for several years. The Company currently has limited sales of only one diagnostic product. The Company's future profitability depends, in part, on its collaborative partners obtaining regulatory approval for products derived from its collaborative research efforts, the Company's collaborative partners successfully producing and marketing products derived from technology or rights licensed from the Company, and the Company's entering into agreements for the development, commercialization, manufacture and marketing of any products derived from the Company's internal proprietary programs. There can be no assurance that the Company or its collaborative partners will obtain required regulatory approvals, or successfully develop, commercialize, manufacture and market product candidates or that the Company will ever achieve product revenues or profitability.

Need for Additional Funding; Uncertainty of Access to Capital

The Company will require substantial funding in order to continue its research, product development, pre-clinical testing and clinical trials of its product candidates. The Company's internal proprietary programs and operations will require a significant amount of funding that will not be provided by the Company's existing collaborative partners. The Company's strategy includes, in addition to its funded collaborations, developing product candidates in its internal proprietary programs through early stage clinical development, before forming collaborations for the further development of such product candidates. These activities will require investment of significant funds by the Company. No assurance can be given that the Company will have adequate resources to support such existing and future activities or that the Company will be able to enter into collaborative arrangements on acceptable terms, if at all.

The Company's future capital requirements will depend on many factors, including continued scientific progress in its research and development programs, the size and complexity of these programs, progress with pre-clinical testing and early stage clinical trials, the time and costs involved in obtaining regulatory approvals for its product candidates, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the establishment of additional collaborative arrangements, the cost of manufacturing arrangements, commercialization activities, and the cost of product in-licensing and strategic acquisitions, if any. The Company evaluates on an ongoing basis potential collaborative arrangements with third parties and acquisitions of companies or technologies that may complement its business.



The Company intends to seek additional funding through arrangements with

corporate collaborators and may seek additional funding through public or private sales of the Company's securities, including equity securities. There can be no assurance, however, that additional funding will be available on reasonable or acceptable terms, if at all. Any additional equity financings would be dilutive to the Company's stockholders. If adequate funds are not available, the Company may be required to curtail significantly one or more of its research and development programs or obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies or product candidates, which could have a material adverse effect on the Company's business, financial condition and results of operations.

Generally, the Company's funding pursuant to any particular collaborative research agreement is subject to reduction or termination under various circumstances. There can be no assurance that scheduled payments will be made by third parties, that current agreements will not be cancelled, that government research grants will continue to be received at current levels or that unanticipated events requiring the expenditure of funds will not occur. There can be no assurance that the Company's cash reserves and other liquid assets will be adequate to satisfy its capital and operating requirements for the foreseeable future.

No Assurance of Protection of Patents and Proprietary Technology

The Company's success will depend in part on its ability or the ability of its collaborative partners to obtain patent protection for product candidates, to maintain trade secret protection and to operate without infringing on the proprietary rights of third parties.

The patent positions of pharmaceutical, biopharmaceutical and biotechnology companies, including OSI, are generally uncertain and involve complex legal and factual questions. There can be no assurance that any of the Company's pending patent applications will be approved, that the Company will develop additional proprietary technologies that are patentable, that any patents issued to the Company or its licensors will provide a basis for commercially viable products or will provide the Company with any competitive advantages or will not be challenged by third parties, or that the patents of others will not have an adverse effect on the ability of the Company to do business. In addition, patent law relating to the scope of claims in the technology fields in which the Company operates is still evolving. The degree of future protection for the Company's proprietary rights, therefore, is uncertain. Furthermore, there can be no assurance that others will not independently develop similar or alternative technologies, duplicate any of the Company's technologies, or, if patents are issued to the Company, design around the patented technologies developed by the Company. In addition, the Company could incur substantial costs in litigation if it is required to defend itself in patent suits brought by third parties or if it initiates such suits.

In the cancer diagnostics area, the Company has an issued U.S. patent and a granted European patent relating to an assay which the Company, in collaboration with Bayer, is seeking to develop for the detection of a protein encoded by neu in serum. The U.S. Patent Office has declared an interference between the Company's issued U.S. Patent and a pending patent application owned by Chiron. In addition, Chiron has filed an opposition against the corresponding granted European patent. These legal proceedings, if not settled, could result in substantial legal expenses being incurred by the Company. Also, the Company cannot predict whether it would prevail in these proceedings. If the Company does not prevail, it may not be able to commercialize its assay for neu in serum without a license from Chiron, which may not be available on acceptable terms or at all.

The Company is aware of several U.S. and foreign patents owned by others who may allege infringement by TGF-Beta 3, which the Company is seeking to develop in collaboration within Novartis for bone repair. Genentech, Inc. has U.S. patents relating to certain recombinant materials and procedures for producing members of the TGF-Beta family, including TGF-Beta 3. In addition, the Company believes that Genentech, Inc. has license rights under a U.S. Government patent relating to work done at the National Institute of Health of the U.S. Department of Health and Human Services involving the identification and isolation of TGF-Beta 1. Furthermore, Celtrix has been granted a European patent relating to TGF-Beta 2. There can be no assurance that the activities or products of the Company or its collaborative partners do not or will not





infringe the claims of these or other issued patents held by third parties or any other patent issued in the future. Furthermore, there can be no assurance that any license required under any such patents would be made available or, if available, would be available on acceptable terms. Failure to obtain patent protection or a required license could prevent the Company and Novartis from commercializing TGF-Beta 3 products. The inability of the Company and Novartis to commercialize TGF-Beta 3 products could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company is seeking to license to other companies rights to practice under the Company's gene transcription patent estate. Technology and practices covered by these patents are in widespread use in the pharmaceutical and biotechnology industries. To date, the Company has entered into only one agreement (with Aurora) to license out this technology. If other pharmaceutical and biotechnology firms using the Company's patented technology are not willing to negotiate license arrangements with the Company on reasonable terms, the Company may have to choose between (i) abandoning its licensing strategy and (ii) initiating legal proceedings against those firms. Such legal action, including patent infringement litigation, would be extremely costly. There can be no assurance that the Company's strategy to commercialize its gene transcription patent estate through licensing will be successful.

The extent to which efforts by other researchers have resulted or will result in patents and the extent to which the issuance of patents to others would have a material adverse effect on the Company or would force the Company or its collaborative partners or other licensees to obtain licenses from others, if available, is currently unknown. Generally, the Company's royalties on any commercialized products could be reduced by up to 50% if its licensees or collaborative partners are required to obtain such licenses. There can be no assurance that the Company's products, operations or technology will not infringe upon the rights of any third party.

The Company relies on trade secrets to protect technology where patent protection is not believed to be appropriate or obtainable. The Company has entered, and will continue to enter, into confidentiality agreements with its employees, consultants, licensors and collaborative partners. There can be no assurance, however, that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to the Company's trade secrets, that such obligations of confidentiality will be honored or that the Company will be able to effectively protect its rights to proprietary information.

Competition and Risk of Technological Obsolescence

The pharmaceutical, biotechnology and diagnostics industries are intensely competitive, and the Company faces, and will continue to face, intense

competition from organizations such as large pharmaceutical companies, diagnostic companies, biotechnology companies, academic and research institutions and government agencies. The Company is subject to significant competition from industry participants who are pursuing the same or similar technologies as those which constitute the Company's technology platform and from organizations that are pursuing pharmaceutical products or therapies or diagnostic products that are competitive with the Company's potential products. Most of the organizations competing with the Company have greater capital resources, greater research and development staffs and facilities, and greater experience in drug discovery and development, obtaining regulatory approval and pharmaceutical product manufacturing and marketing. The Company's major competitors include fully integrated pharmaceutical companies, such as Merck & Co., Inc., Glaxo Wellcome Inc. and Smith Kline Beecham, that have extensive drug discovery efforts and are developing novel small molecule pharmaceuticals, as well as numerous smaller companies.

The Company's technology platform consists principally of a variety of lead seeking assay methodologies, transcription technologies, chemical libraries, medical and combinational chemistry and pharmaceutical development technologies. Pharmaceutical and biotechnology companies and others are active in all of these areas, and there can be no assurance that other organizations will not acquire or develop technology superior to that of the Company. Ligand Pharmaceuticals Inc. and Aurora, publicly owned companies, employ live-cell assays, gene transcription, and high throughput robotics in its drug discovery operations. Numerous other companies use one or more of these technologies. Several private companies, including Tularik Inc., Signal Pharmaceuticals Inc. and Scriptgen Pharmaceuticals, Inc., pursue drug discovery using gene transcription methods.





Companies pursuing different but related fields also present significant competition for the Company. For example, research efforts with respect to gene sequencing and mapping are identifying new and potentially superior target genes. In addition, alternative drug discovery strategies, such as rational drug design, may prove more effective than those pursued by the Company. Furthermore, competing entities may have access to more diverse compounds for testing by virtue of larger compound libraries or through combinatorial chemistry skills or other means. These include Pharmacopeia, Inc., CombiChem, Inc., ArQule, Inc. and AxyS Pharmaceuticals, Inc., all of which have major collaborations with leading pharmaceutical companies. There can be no assurance that the Company's competitors will not succeed in developing technologies or products that are more effective than those of the Company or that would render the Company's products or technologies obsolete or noncompetitive.

With respect to the Company's small molecule drug discovery programs, other companies have potential drugs in clinical trials to treat all the disease areas for which the Company is seeking to discover and develop drug candidates. These competing drug candidates are further advanced in clinical development than are any of the Company's potential products in its small molecule programs and may result in effective, commercially successful products. Even if the Company and its collaborative partners are successful in developing effective drugs, there can be no assurance that the Company's products will compete effectively with such products. No assurance can be given that the Company's competitors will not succeed in developing and marketing products either that are more effective than those that may be developed by the Company and its collaborators or that are marketed prior to any products developed by the Company or its collaborators.

The Company will, for the foreseeable future, rely on its collaborative partners for some pre-clinical evaluation and clinical development of its potential products and manufacturing and marketing of any products. In addition,

the Company relies on its collaborative partners for support in its drug discovery operations. It is likely that all of the pharmaceutical companies with which the Company has collaborations are conducting multiple product development efforts within each disease area. Generally, the Company's collaborative research agreements do not restrict a party from pursuing competing internal development efforts based on reasonable commercial judgment and other factors. Any product candidate of the Company, therefore, may be subject to competition with a potential product under development by the pharmaceutical company with which the Company is collaborating in connection with such product candidate.

Biotechnology and related pharmaceutical technology have undergone rapid and significant change. The Company expects the technology associated with the Company's research and development will continue to develop rapidly, and the Company's future success will depend in large part on its ability to maintain a competitive position with respect to this technology. Rapid technological development by the Company or others may result in compounds, products or processes becoming obsolete before the Company recovers any expenses it incurs in connection with developing such products.

Government Regulation; No Assurance of Regulatory Approval

Prior to marketing by a collaborative partner, any new drug discovered by the Company 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, and may include post-marketing surveillance, of each compound to establish its safety and efficacy, can take many years and require the expenditure of substantial resources. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in FDA policies for drug approval during the period of product development and FDA regulatory review of each submitted an NDA in the case of new pharmaceutical agents, or PLA in the case of a biologic, such as the Company's TGF-Beta 3 product candidate. Similar delays may also be encountered in the regulatory approval of any diagnostic product. Such delays may also be encountered in obtaining regulatory approval in foreign countries. There can be no assurance that regulatory approval will be obtained for any drugs discovered, or diagnostic products developed, by the Company. Furthermore, regulatory approval may entail limitations on the indicated use of the drug.



Even if regulatory approval is obtained, a marketed product and its manufacturer are subject to continuing review. Discovery of previously unknown problems with a product of the Company or its manufacturer may have adverse effects on the Company's business, financial condition and results of operations, including withdrawal of the product from the market. Violations of regulatory requirements at any stage, including pre-clinical testing and clinical trials, the approval process or post-approval, may result in various adverse consequences to the Company, including the FDA's delay in approving or its 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. Although Pfizer submitted an IND to the FDA with respect to the epidermal growth factor receptor inhibitor CP-358,774, the Company has not submitted an IND for any product candidate, and no product candidate has been approved for commercialization in the United States or elsewhere. The Company intends to file INDs for product candidates in its internal proprietary programs, but to rely on its partners to file INDs in its collaborative programs. No assurance can be given that the Company or any of its collaborative partners will be able to conduct clinical testing or obtain the necessary

approvals from the FDA or other regulatory authorities for any products. Failure to obtain required governmental approvals will delay or preclude the Company's partners from marketing drugs discovered, or diagnostic products developed, by the Company or limit the commercial use of such products and will have a material adverse effect on the Company's business, financial condition and results of operations.

No Manufacturing Capacity; Reliance on Third-Party Manufacturing

The Company does not intend to develop or acquire facilities for the manufacture of drug candidates or diagnostic products for clinical trials or commercial purposes, and has been, and will remain, dependent on its collaborative partners or third parties for the manufacture of product candidates for pre-clinical, clinical and commercialization purposes.

The manufacture of the Company's candidate products for clinical trials and the manufacture of resulting products for commercialization purposes is subject to current GMP regulations promulgated by the FDA. The Company will rely on collaborative partners or outside contractors to manufacture its products in their FDA approved manufacturing facilities. The Company's products may be in competition with other products for priority of access to these facilities. Consequently, the Company's products may be subject to delays in manufacture if collaborative partners or outside contractors give other products greater priority than the Company's products. For this and other reasons, there can be no assurance that the Company's collaborative partners will manufacture such products in an effective or timely manner. If not performed in a timely manner, the clinical trial development of the Company's product candidates or their submission for regulatory approval could be delayed, and the Company's ability to deliver products on a timely basis could be impaired or precluded. There can be no assurance that the Company will be able to enter into any necessary third party manufacturing arrangements on acceptable terms if at all. The Company's current dependence upon others for the manufacture of its products may adversely affect its future profit margin, if any, and its ability to commercialize products on a timely and competitive basis.

Uncertainties Related to Pharmaceutical Pricing and Reimbursement

The Company's business, financial condition and results of operations may be materially adversely affected by the continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, the Company expects that there will continue to be a number of federal and state proposals to implement similar government control. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products and diagnostic tests. Cost control initiatives could decrease the price that the Company or any of its collaborative partners or other licensees receives for any drugs it may discover or develop or diagnostic products it may develop in the future and have a material adverse effect on the Company's business, financial condition and results of operations. Further, to the extent that cost control



initiatives have a material adverse effect on the Company's collaborative partners, the Company's ability to commercialize its products and to realize royalties may be adversely affected.

The Company's or any collaborative partner's or licensee's ability to commercialize pharmaceutical or diagnostic products may depend in part on the

extent to which reimbursement for the products will be available from government and health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors, including Medicare, are increasingly challenging the prices charged for medical products and services. There can be no assurance that any third-party insurance coverage will be available to patients for any products discovered and developed by the Company and its collaborative partners. Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing in some cases to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. If adequate coverage and reimbursement levels are not provided by government and other third-party payors for the Company's products, the market acceptance of these products would be adversely affected, which would have a material adverse effect on the Company's business, financial condition and results of operations.

Potential Product Liability

The use of any of the Company's potential products in clinical trials and the sale of any approved products may expose the Company to liability claims resulting from the use of products or product candidates. These claims might be made directly by consumers, pharmaceutical companies, including the Company's collaborative partners, or others. The Company is currently an additional named insured under a clinical trials liability insurance policy carried by Novartis with respect to its TGF-Beta 3 clinical trials in the amount of $3 million. The Company does not independently maintain product liability insurance coverage for claims arising from the use of its products in clinical trials. Insurance coverage is becoming increasingly expensive, and no assurance can be given that the Company will continue to be a named insured with respect to trials underway or obtain insurance in the future at a reasonable cost or in sufficient amounts to protect the Company. The Company's inability to obtain adequate liability insurance could have a material adverse effect on the Company's business, financial condition and results of operations. There can be no assurance that the Company will be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future or that insurance coverage and the resources of the Company would be sufficient to satisfy any liability resulting from product liability claims. A successful product liability claim or series of claims brought against the Company could have a material adverse effect on its business, financial condition and results of operations.

Year 2000

The Company is currently working to resolve the potential impact of the Year 2000 problem on the processing of date-sensitive information by the Company's computerized information system. The Company is currently not in a position to estimate the likelihood of disruption caused by Year 2000 problems experienced by it or the Company's suppliers, vendors or collaborators. The Company may be faced with unforeseen difficulties in implementing future Year 2000 compliance plans or contingency plans. Such difficulties and failure of suppliers, vendors or collaborators to be Year 2000 compliant could result in risks and uncertainties that may have a material adverse effect on the Company's business, financial condition and results of operation.

ITEM 2. PROPERTIES

The Company leases two facilities, one located at 106 Charles Lindbergh Boulevard, Uniondale, New York consisting of 30,000 square feet and the other located at 50 Charles Lindbergh Boulevard, Uniondale, New York consisting of 4,500 square feet. The larger facility houses the Company's principal executive

offices and drug discovery laboratory. The smaller facility houses the Company's Finance and Administrative offices. The Company also leases an 11,000 square foot facility located at 80 Rogers Street/129 Binney Street, Cambridge, Massachusetts. This facility contains the offices and laboratories of the Company's diagnostic





product operations. The Company also has two wholly-owned subsidiaries, Aston and MYCOsearch, each of which lease facilities which house their offices and drug discovery laboratories. Aston leases a 9,689 square foot facility located at 10 Holt Court South, Aston Science Park, Birmingham, England. MYCOsearch leases two facilities, one located at Five Oaks Office Park, 4905 Pine Cone Drive, Durham, North Carolina consisting of 4,280 square feet and the other located at 4727 University Drive, Durham, North Carolina consisting of 8,000 square feet. The Company expects a modest expansion of space of its Aston facility in the United Kingdom. Otherwise, the Company believes that its facilities will be adequate to meet current requirements. If any of the Company's collaborative programs is expanded, the Company may need to acquire additional space, which the Company believes it would be able to secure on reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

There are no material legal proceedings pending against the Company.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of security holders during the fourth quarter of fiscal 1998.

PART II

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

The Company's 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 the Company's Common Stock from the first quarter of fiscal 1997 through September 30, 1998 as reported on the NASDAQ National Market:

<TABLE>
<CAPTION>

| 1998 FISCAL YEAR | HIGH | LOW |
|---|---|---|
| <S> | <C> | <C> |
| First Quarter | $11 1/2 | $5 7/8 |
| Second Quarter | 8 | 5 7/8 |
| Third Quarter | 7 7/8 | 5 1/8 |
| Fourth Quarter | 6 3/4 | 2 29/32 |

</TABLE>

<TABLE>
<CAPTION>

| 1997 FISCAL YEAR | HIGH | LOW |
|---|---|---|
| <S> | <C> | <C> |
| First Quarter | $ 9 | $6 1/4 |
| Second Quarter | 7 7/8 | 5 5/8 |
| Third Quarter | 6 15/16 | 4 3/4 |
| Fourth Quarter | 11 3/4 | 5 5/8 |

</TABLE>

As of November 30, 1998, there were approximately 617 holders of record of the Company's Common Stock. The Company has not paid any dividends since its inception and does not intend to pay any dividends in the foreseeable future. Declaration of dividends will depend, among other things, upon future earnings, the operating and financial condition of the Company, its capital requirements and general business conditions.





ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth selected consolidated financial data with respect to the Company for each of the years in the five-year period ended September 30, 1998. The information set forth below should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this report.

<TABLE>
<CAPTION>

| | YEARS ENDED SEPTEMBER 30, | | | | |
|---|---|---|---|---|---|
| | 1998(a) | 1997(b) | 1996(c) | 1995(d) | 1994(e) |
| <S> | <C> | <C> | <C> | <C> | <C> |
| Statement of Operations Data: | | | | | |
| Revenues | $ 19,468,337 | $ 14,777,323 | $ 9,718,437 | $15,864,999 | $16,299,489 |
| Expenses: | | | | | |
| Research and development | 20,350,063 | 16,896,617 | 13,918,968 | 13,523,043 | 12,125,210 |
| Production and service costs | 955,464 | 635,768 | 134,529 | 1,252,990 | 1,427,981 |
| Selling, general and administrative | 8,076,662 | 7,424,265 | 6,314,697 | 7,140,208 | 7,487,090 |
| Amortization of intangibles | 1,460,740 | 1,460,748 | 1,452,755 | 1,696,561 | 1,745,163 |
| Loss from operations | (11,374,592) | (11,640,075) | (12,102,512) | (7,747,803) | (6,485,955) |
| Other income, net | 1,190,124 | 2,053,838 | 2,160,377 | 768,744 | 762,031 |
| Gain on sale of Research Products Business | -- | -- | -- | 2,720,389 | -- |
| Net loss | (10,184,468) | (9,586,237) | (9,942,135) | (4,258,670) | (5,723,924) |
| Basic loss per share | (0.48) | (0.44) | (0.50) | (0.25) | (0.35) |
| Weighted average number of shares of common stock outstanding | 21,372,655 | 21,604,344 | 19,712,274 | 16,757,370 | |

16,335,000

| | SEPTEMBER 30, | | | | |
|---|---|---|---|---|---|
| | 1998 | 1997 | 1996 | 1995 | 1994 |
| Balance Sheet Data: | | | | | |
| Cash and short-term investments..... | $ 24,418,281 | $ 31,834,669 | $ 47,542,745 | $26,786,566 | $18,157,891 |
| Accounts receivable..... | 1,720,737 | 1,215,672 | 2,031,950 | 1,320,015 | 3,032,839 |
| Working capital..... | 22,268,346 | 29,612,616 | 47,181,407 | 26,127,781 | 21,208,145 |
| Total assets..... | 50,417,980 | 59,585,565 | 73,537,054 | 44,057,421 | 42,040,900 |
| Stockholders' equity..... | 43,059,246 | 52,944,868 | 68,286,959 | 40,549,636 | 38,656,314 |

</TABLE>

- ---

(a) During fiscal 1998, the Company entered into collaborative agreements with Fujirebio and Vanderbilt, expanded its co-venture agreement with Anaderm, and entered into a license agreement with Aurora (See Notes 2, 5(b), 5(c), and 5(n) to the Consolidated Financial Statements).

(b) During fiscal 1997, the Company entered into collaborative agreements with Sankyo and Bayer, expanded its collaboration with HMRI, entered into co-venture agreements with Sepracor and Helicon, entered into a license agreement with Dow, and repurchased its Common Stock held by Becton, Dickinson and Company (See Notes 3(d), 5 and 9(a) to the Consolidated Financial Statements).

(c) During fiscal 1996, the Company acquired MYCOsearch and Aston and completed an offering of its Common Stock (See Notes 3 and 9(b) to the Consolidated Financial Statements).

(d) During fiscal 1995, the Company sold its Research Products Business and also sold shares of its Common Stock to Novartis.

(e) During fiscal 1994, the Company changed its method of accounting for marketable securities to adopt the provisions of the Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities."





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

REVENUES

Total revenues of $19.5 million in fiscal 1998 increased approximately $4.7 million or 32% compared to fiscal 1997 and total revenues of $14.8 million in fiscal 1997 increased approximately $5.1 million or 52% compared to fiscal 1996. Collaborative program revenues increased approximately $4.0 million or 32%, in fiscal year 1998 due to the commencement on October 1, 1997 of the funded phase of the collaborative research and license agreement among the Company, Anaderm and Pfizer as well as an increased level of research in the collaborative

program with Sankyo to discover and develop novel pharmaceutical products to treat influenza. This increase in revenues was partially offset by a decrease in revenues related to the Company's collaborative program with HMRI to discover and develop small molecules that induce gene expression of the protein erythropoietin. This decrease in revenues attributable to the Company's receipt of a $1 million initiation fee from HMRI for the erythopoletin program in the second quarter of fiscal 1997 reduced funding in connection with the extension of the first phase of this program in April 1998. This program did not achieve sufficient positive data to warrant further development. Consequently, in October 1998, this program was terminated. The increase in revenue was also offset by the completion in fiscal 1997 of the funded discovery phase of the Company's collaborative program with Wyeth-Ayerst Laboratories ("Wyeth") relating to the discovery and development of drugs for the treatment of diabetes and osteoporosis.

Sales revenue, representing primarily service revenue from the pharmaceutical division of the Company's Aston subsidiary, which the Company acquired in September 1996, decreased approximately $46,000 or 4% compared to the prior year. The decrease was primarily due to the Company's decision to devote certain of Aston's resources to internal programs as opposed to sales outside the Company. Other research revenues, representing primarily government grants and other research grants, increased approximately $20,000 or 1% compared to the prior fiscal year. The Company recognized license revenue of approximately $752,000 for the year ended September 30, 1998. This revenue is primarily related to the signing of a license agreement in May 1998 with Aurora covering the Company's gene transcription patent estate. Under the terms of the agreement, the Company received 75,000 shares of Aurora common stock with a fair market value of approximately $400,000 and $300,000 in cash for Aurora's non-exclusive license and certain sub-licensing rights to the Company's reporter gene patent, and options to the Company's Methods of Modulation patent. The Company may enter into additional licensing agreements for these patents in the future.

The increase in total revenues of approximately $5.1 million in fiscal 1997 compared to fiscal 1996 was attributable to the new collaborative research and license agreements with each of: (1) HMRI, to develop drugs for the treatment of chronic anemia; (2) Sankyo to discover and develop novel pharmaceutical products to treat influenza; and (3) Bayer for the continuing development of serum-based cancer diagnostics. Also contributing to the increase in total revenues is the sales revenues related to the inclusion of the Company's Aston subsidiary. The increase in revenues was partially offset by a decrease in revenues related to the completion on December 31, 1996 of the funded discovery phase of the Company's collaborative program with Wyeth relating to the discovery and development of drugs for the treatment of diabetes and osteoporosis and the completion on September 30, 1996 of the funded collaboration with Becton, Dickinson and Company ("Becton") relating to the development of serum-based cancer diagnostics.

EXPENSES

Research and development expenses increased by approximately $3.5 million or 20% in fiscal 1998 compared to fiscal 1997 and increased by approximately $3.0 million or 21% in fiscal 1997 compared to fiscal 1996. The increase in fiscal 1998 was due to the expansion of the Company's joint venture with Anaderm for the discovery and development of novel compounds to treat pigmentation disorders, wrinkles and baldness and the collaborative agreement with Sankyo for the discovery and development of novel pharmaceutical products

to treat influenza, which commenced in February 1997. In addition, research and development expenses include the amortization of the Company's compound library assets which increased by approximately $70,000 to $1.8 million in fiscal 1998 reflecting a full year of amortization of the Dow Compound Library License acquired in March 1997.

The increase in fiscal 1997 was due to the expansion of the Company's joint ventures with Anaderm and BioChem Pharma, and the new collaborative agreements with Sankyo and HMRI. Although the Company incurred expense in connection with its serum-based cancer diagnostic collaboration with Bayer, these expenses generally were offset by the elimination of expenditures with respect to (i) the Company's former tissue-based cancer diagnostics collaboration with Becton, which expired on September 30, 1996 and (ii) the discovery and development of drugs for the treatment of diabetes and osteoporosis by Wyeth which was competed December 31, 1996. Also contributing to the increase in expenses were costs associated with the expansion of the Company's natural products discovery and medicinal chemistry operations at its MYCOsearch acquired in April 1996 and Aston subsidiaries. In addition, research and development expenses included the amortization of the Company's compound library assets which increased by approximately $600,000 in fiscal 1997 reflecting a full year of amortization of the fungi cultures acquired upon the acquisition of MYCOsearch.

Production and service costs increased approximately $320,000 and $501,000 in fiscal 1998 and 1997, respectively. The increase in fiscal 1998 is primarily related to increases in diagnostic costs in preparation for launching the Company's new serum based cancer diagnostic products. The OSDI division (a wholly-owned subsidiary of the Company), through a partnership with Bayer, expects to seek FDA approval for its Her-2/neu serum kits during fiscal 1999. In addition, other new assays are also being developed that the Company believes will provide oncologists with essential information necessary to determine which patients will respond best to the newly developed therapies directed at oncogenes and tumor suppressor genes. The increase in fiscal 1997 was due to the acquisition of Aston's pharmaceutical development business.

Selling, general and administrative expenses increased approximately $652,000 or 9% in fiscal 1998 compared to fiscal 1997. Selling, general and administrative expenses increased approximately $1.1 million or 18% in fiscal 1997 compared to fiscal 1996. The increase between fiscal 1998 compared to fiscal 1997 were primarily related to the expenses associated with the expansion of the Company's Aston and OSDI subsidiaries. The Aston facility has expertise in pharmacokinetics and pharmaceutical chemistry and the management and generation of GMP accredited data as generally required for regulatory submissions to agencies such as the FDA. The Company has invested significant resources in expanding the drug development capabilities of this division. In addition, the Company invested in the sales and marketing resources of its OSDI (Diagnostics division) in preparation for launching its new serum based cancer diagnostic products. The increases between fiscal 1997 compared to fiscal 1996 were primarily related to the expenses associated with the Company's general and administrative costs associated with the expansion of the Company's recently acquired subsidiaries.

Amortization of intangibles in fiscal 1998, 1997, and 1996 represents amortization of patents and goodwill that resulted from the acquisition of the cancer diagnostic business of Applied bioTechnology, Inc. in fiscal 1991 and Aston in fiscal 1996. The goodwill related to Applied bioTechnology, Inc. approximated $686,000 per annum and was fully amortized as of September 1996. Amortization expense in fiscal 1997 includes the first year of amortization of the goodwill from the acquisition of Aston totaling $694,000.

OTHER INCOME AND EXPENSE

Net investment income decreased approximately $625,000 or 30% in fiscal 1998 compared to fiscal 1997 and $70,000 or 3% in fiscal 1997 compared to fiscal 1996. This decrease was a result of the decline in principal balance invested.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 1998, working capital (representing primarily cash, cash equivalents and short-term investments) aggregated approximately $21.9 million. The Company is dependent upon collaborative research





revenues, government research grants, interest income and cash balances, and will remain so until products developed from its technology are successfully commercialized.

The Company believes that with the funding from its collaborative research programs, government research grants, interest income, and cash balances, its financial resources are adequate for its operations for approximately the next four years based on its current business plan even if no milestone payments or royalties are received during this period. However, the Company's capital requirements may vary as a result of a number of factors, including, but not limited to, competitive and technological developments, funds required for further expansion or enhancement of the Company's technology platform, (including possible additional joint ventures, collaborations and acquisitions), potential milestone payments, and the time and expense required to obtain governmental approval of products, some of which factors are beyond the Company's control.

One of the Company's strategic objectives is to manage its financial resources and the growth of its drug discovery and development programs so as to balance its proprietary efforts and funded collaborations. In pursuing this objective, the Company in fiscal 1998 has expanded the scope of its discovery and development activities without significantly increasing its rate of cash consumption. The Company expects to continue its current level of expenditures and capital investment over the next several years to enhance its drug discovery technologies and pursue internal proprietary drug discovery programs.

There can be no assurance that scheduled payments will be made by third parties, that current agreements will not be canceled, that government research grants will continue to be received at current levels, that milestone payments will be made, or that unanticipated events requiring the expenditure of funds will not occur. Further, there can be no assurance that the Company will be able to obtain any additional required funds on acceptable terms, if at all. Failure to obtain additional funds when required would have a material adverse effect on the Company's business, financial condition and results of operations.

YEAR 2000

The Company is aware of the challenges associated with the inability of certain systems to properly format information after December 31, 1999. The Company is currently working to resolve the potential impact of the Year 2000 problem on the processing of date-sensitive information by the Company's computerized information systems. The Year 2000 problem is the result of computer programs being written using two digits (rather than four) to define an applicable year. Substantially all of the Company's biology and chemistry databases are stored on Oracle tables and ISIS chemical structure databases, which are Year 2000 compliant, as are its Novell network servers. The Company is currently converting its financial records to an Oracle based system and is in the process of implementing a new planning and budgeting package, both of which are Year 2000 compliant. The Company expects these systems to be operational by

December 31, 1999. The Company believes it will fully remediate any of its Year 2000 programs in advance of the Year 2000 and does not anticipate any material disruption in its operations as the result of any failure by the Company to fully remediate such programs. Based on current information, the cost of addressing remaining potential Year 2000 problems associated with the Company's internal systems and operations are not expected to have a material adverse impact to the Company's financial position, results of operations, or cash flows in future periods.

The Company has not conducted an evaluation of the extent to which the operations of the material third parties with whom it regularly deals may be disrupted by any Year 2000 non-compliance of any of their systems. These third parties include the Company's collaborative partners and its suppliers and vendors. Disruption of the operations of any of its partners could delay or halt important research and development programs, cause the loss of data or have other unforeseen consequences. The Company is currently planning to contact all significant collaborators, suppliers, vendors and financial institutions in order to identify potential areas of concern. It is anticipated that this inquiry will be completed during the second quarter of fiscal 1999. Year 2000 problems experienced by the Company's suppliers and vendors could cause a disruption of the Company's operations. The Company currently is unable to estimate the likelihood of any of these risks being realized, or if realized, the impact they may have on the Company. Any such occurrence could have a material adverse effect on the Company's business, financial condition and results of operations.





If necessary, the Company intends to create a contingency plan to identify and document potential business disruptions and continuity planning procedures. The focus of this activity would be on potential failures of external systems required to carry out normal business operations including services provided by the public infrastructure such as, but not limited to, power, electric, transportation and telecommunications. The Company expects this activity to be on an on-going process throughout fiscal 1999.

NEW ACCOUNTING PRONOUNCEMENT

In February 1998, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 132 "Employers' Disclosures about Pensions and Other Postretirement Benefits", which revises current disclosures about pension and other postretirement benefit plans. It does not change the measurement or recognition of those plans. SFAS No. 132: (1) standardizes the disclosure requirements for pension and other postretirement benefits to the extent practicable; (2) requires additional information on changes in the benefit obligations and fair values of plan assets that will facilitate financial analysis; (3) eliminates certain disclosures that are no longer useful; (4) suggests combined formats for presentation of pension and other postretirement benefits; and (5) permits reduced disclosures for nonpublic entities. SFAS No. 132 is effective for fiscal years beginning after December 15, 1997. These standards expand or modify current disclosures and, accordingly, will have no impact on the Company's reported financial position, results of operations and cash flows.

In June 1998, the FASB issued SFAS No. 133, "Accounting for Derivative and Hedging Activities." SFAS No. 133 establishes a comprehensive standard on accounting for derivatives and hedging activities and is effective for periods beginning after June 15, 1999. Management does not believe that the future adoption of SFAS No. 133 will have a material effect on the Company's financial position and results of operations.

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 such matters and subject areas is qualified by the inherent risks and uncertainties surrounding future expectations generally, and such discussion may materially differ from the Company's actual future experience involving any one or more of such 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 for Consideration in Connection with Forward Looking Statements."

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

The Company's cash flow and earnings are subject to fluctuations due to changes in interest rates in its investment portfolio of debt securities, to the fair value of equity instruments held, and, to an immaterial extent, to foreign currency exchange rates. The Company maintains 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 separate component of stockholders' equity. The Company's investments in certain biotechnology companies are carried on either the equity method of accounting or at cost for equity securities that do not have readily determinable fair values. Other-than-temporary losses are recorded against earnings in the same period the loss was deemed to have occurred. The Company does not currently hedge this exposure and there can be no assurance that other-than-temporary losses will not have a material adverse impact on the Company's results of operations in the future.





ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

<TABLE>
<CAPTION>



</TABLE>





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, 1998 and 1997, 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, 1998. 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 generally accepted auditing standards. 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 at September 30, 1998 and 1997, and the results of their operations and their cash flows for each of the years in the three-year period ended September 30, 1998 in conformity with generally accepted accounting principles.

KPMG PEAT MARWICK LLP

Melville, New York
December 4, 1998





OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 1998 AND 1997

<TABLE>
<CAPTION>

| | 1998 | 1997 |
|---|---|---|
| <S> | <C> | <C> |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $11,315,166 | $ 8,636,634 |
| Short-term investments | 13,103,115 | 23,198,035 |
| Receivables, including trade receivables of $258,905 and $350,100 at September 30, 1998 and 1997, respectively | 1,720,737 | 1,215,672 |
| Interest receivable | 283,908 | 475,800 |
| Grants receivable | 406,149 | 179,740 |
| Prepaid expenses and other | 788,496 | 820,151 |
| Total current assets | 27,617,571 | 34,526,032 |
| Property, equipment and leasehold improvements -- net | 7,996,555 | 7,752,286 |
| Compound library assets -- net | 5,515,517 | 6,800,406 |
| Loans to officers and employees | 6,433 | 34,317 |
| Other assets | 1,557,903 | 1,287,782 |

| | | |
|---|---|---|
| Intangible assets -- net | 7,724,001 | 9,184,742 |
| | $50,417,980 | $59,585,565 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 4,232,540 | $ 4,180,039 |
| Current portion of unearned revenue | 1,116,685 | 733,377 |
| Total current liabilities | 5,349,225 | 4,913,416 |
| Other liabilities: | | |
| Loan payable | 49,326 | 151,985 |
| Deferred acquisition costs | 670,916 | 630,796 |
| Accrued postretirement benefit cost | 1,289,267 | 944,500 |
| Total liabilities | 7,358,734 | 6,640,697 |
| Stockholders' equity: | | |
| Common stock, $.01 par value; 50,000,000 shares authorized, 22,288,583 shares issued at September 30, 1998 and 22,262,220 shares issued at September 30, 1997 | 222,886 | 222,622 |
| Additional paid-in capital | 104,963,082 | 104,864,056 |
| Accumulated deficit | (55,842,181) | (45,657,713) |
| Cumulative translation adjustments | (18,755) | (101,531) |
| Unrealized holding gain (loss) on short-term investments | 19,080 | (97,700) |
| | 49,344,112 | 59,229,734 |
| Less: treasury stock, at cost; 897,838 shares at September 30, 1998 and 1997 | (6,284,866) | (6,284,866) |
| Total stockholders' equity | 43,059,246 | 52,944,868 |
| Commitments and contingencies | $50,417,980 | $59,585,565 |

</TABLE>

See accompanying notes to consolidated financial statements.





OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

<TABLE>
<CAPTION>

| | YEARS ENDED SEPTEMBER 30, | | |
|---|---|---|---|
| | 1998 | 1997 | 1996 |
| <S> | <C> | <C> | <C> |
| Revenues: | | | |
| Collaborative program revenues, principally from related parties | $ 16,165,613 | $12,200,801 | $ 8,347,560 |
| Sales | 1,121,449 | 1,167,604 | 105,356 |
| Other research revenue | 1,428,853 | 1,408,918 | |

| | | | |
|---|---|---|---|
| 1,265,521 | | | |
| Patent license fees | 752,422 | -- | - |
| - | | | |
| | 19,468,337 | 14,777,323 | |
| 9,718,437 | | | |
| - | | | |
| Expenses: | | | |
| Research and development | 20,350,063 | 16,896,617 | |
| 13,918,968 | | | |
| Production and service costs | 955,464 | 635,768 | |
| 134,529 | | | |
| Selling, general and administrative | 8,076,662 | 7,424,265 | |
| 6,314,697 | | | |
| Amortization of intangibles | 1,460,740 | 1,460,748 | |
| 1,452,755 | | | |
| - | | | |
| | 30,842,929 | 26,417,398 | |
| 21,820,949 | | | |
| - | | | |
| Loss from operations | (11,374,592) | (11,640,075) | |
| (12,102,512) | | | |
| - | | | |
| Other income (expense): | | | |
| Net investment income | 1,467,412 | 2,092,331 | |
| 2,162,294 | | | |
| Other expense -- net | (277,288) | (38,493) | |
| (1,917) | | | |
| - | | | |
| Net loss | $(10,184,468) | $(9,586,237) | $ |
| (9,942,135) | | | |
| ============ | | | |
| Weighted average number of shares of common stock outstanding | 21,372,655 | 21,604,344 | |
| 19,712,274 | | | |
| ============ | | | |
| Basic loss per weighted average share of common stock outstanding | $ (.48) | $ (.44) | $ |
| (.50) | | | |
| ============ | | | |

</TABLE>

See accompanying notes to consolidated financial statements.





OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

<TABLE>
<CAPTION>

| | COMMON STOCK | | ADDITIONAL | | UNREALIZED HOLDING GAIN (LOSS) | | |
|---|---|---|---|---|---|---|---|
| | SHARES | AMOUNT | PAID-IN CAPITAL | ACCUMULATED DEFICIT | CUMULATIVE TRANSLATION ADJUSTMENT | ON SHORT-TERM INVESTMENTS | TREASURY STOCK |
| <S> | <C> | <C> | <C> | <C> | <C> | <C> | |
| BALANCE AT SEPTEMBER 30, 1995.... | 17,683,047 | $176,830 | $ 66,735,375 | $(26,129,341) | $(55,669) | $ (35,000) | $ (142,559) |
| Options exercised..... | 491,544 | 4,915 | 1,640,653 | -- | -- | -- | -- |
| Issuance of common stock for employee purchase plan..... | 3,860 | 39 | 10,214 | -- | -- | -- | -- |
| Unrealized holding loss on short-term investments..... | -- | -- | -- | -- | -- | (170,193) | -- |
| Sale of common stock..... | 3,618,750 | 36,188 | 30,293,757 | -- | -- | -- | -- |
| Issuance of common stock and treasury stock for acquisitions..... | 378,013 | 3,780 | 5,667,232 | -- | -- | -- | 142,559 |
| Translation adjustment..... | -- | -- | -- | -- | 50,314 | -- | -- |
| Net loss..... | -- | -- | -- | (9,942,135) | -- | -- | -- |
| BALANCE AT SEPTEMBER 30, 1996.... | 22,175,214 | 221,752 | 104,347,231 | (36,071,476) | (5,355) | (205,193) | -- |
| Options exercised..... | 74,618 | 746 | 407,503 | -- | -- | -- | -- |
| Issuance of common stock for employee purchase plan..... | 12,388 | 124 | 74,456 | -- | -- | -- | -- |
| Unrealized holding gain on short-term investments..... | -- | -- | -- | -- | -- | 107,493 | -- |
| Purchase of treasury stock..... | -- | -- | -- | -- | -- | -- | (8,750,000) |
| Issuance of treasury stock for Dow Compound Library License... | -- | -- | 34,866 | -- | -- | -- | 2,465,134 |
| Translation adjustment..... | -- | -- | -- | -- | (96,176) | -- | -- |
| Net loss..... | -- | -- | -- | (9,586,237) | -- | -- | -- |
| BALANCE AT SEPTEMBER 30, 1997.... | 22,262,220 | 222,622 | 104,864,056 | (45,657,713) | (101,531) | (97,700) | (6,284,866) |
| Options exercised..... | 5,699 | 57 | 24,007 | -- | -- | -- | -- |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Issuance of common stock for employee purchase plan..... | 20,664 | 207 | 75,019 | -- | -- | -- | | |
| Unrealized holding gain on short-term investments..... | -- | -- | -- | -- | 116,780 | -- | | |
| Translation adjustment..... | -- | -- | -- | -- | 82,776 | -- | | |
| Net loss..... | -- | -- | -- | (10,184,468) | -- | -- | | |
| BALANCE AT SEPTEMBER 30, 1998.... | 22,288,583 | $222,886 | $104,963,082 | $(55,842,181) | $(18,755) | $ 19,080 | $(6,284,866) | |

<CAPTION>

| | TOTAL STOCKHOLDERS' EQUITY |
|---|---|
| <S> | <C> |
| BALANCE AT SEPTEMBER 30, 1995.... | $ 40,549,636 |
| Options exercised..... | 1,645,568 |
| Issuance of common stock for employee purchase plan..... | 10,253 |
| Unrealized holding loss on short-term investments..... | (170,193) |
| Sale of common stock..... | 30,329,945 |
| Issuance of common stock and treasury stock for acquisitions..... | 5,813,571 |
| Translation adjustment..... | 50,314 |
| Net loss..... | (9,942,135) |
| BALANCE AT SEPTEMBER 30, 1996.... | 68,286,959 |
| Options exercised..... | 408,249 |
| Issuance of common stock for employee purchase plan..... | 74,580 |
| Unrealized holding gain on short-term investments..... | 107,493 |
| Purchase of treasury stock..... | (8,750,000) |
| Issuance of treasury stock for Dow Compound Library License... | 2,500,000 |
| Translation adjustment..... | (96,176) |
| Net loss..... | (9,586,237) |
| BALANCE AT SEPTEMBER 30, 1997.... | 52,944,868 |
| Options exercised..... | 24,064 |
| Issuance of common stock for employee purchase plan..... | 75,226 |
| Unrealized holding gain on short-term investments..... | 116,780 |
| Translation adjustment..... | 82,776 |
| Net loss..... | (10,184,468) |
| BALANCE AT SEPTEMBER 30, 1998.... | $ 43,059,246 |

</TABLE>

See accompanying notes to consolidated financial statements.





OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

<TABLE>
<CAPTION>

| | YEARS ENDED SEPTEMBER 30, | | |
|---|---|---|---|
| | 1998 | 1997 | 1996 |
| <S> | <C> | <C> | <C> |
| Cash flow from operating activities: | | | |
| Net loss | $(10,184,468) | $(9,586,237) | $ (9,942,135) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| (Gain) loss on sale of investments | 45,847 | 36,523 | (33,305) |
| Depreciation and amortization | 1,944,344 | 1,518,751 | 1,837,873 |
| Amortization of library assets | 1,811,583 | 1,101,509 | 458,962 |
| Amortization of intangibles | 1,460,740 | 1,460,739 | 1,452,755 |
| Amortization of deferred acquisition costs | 40,120 | 40,121 | -- |
| Cashless exercise of stock options | -- | 126,600 | -- |
| Common stock received for patent license fee | (402,422) | -- | -- |
| Foreign exchange (gain) loss | 82,776 | (96,176) | 50,314 |
| Changes in assets and liabilities, net of the effects of acquisitions of MYCOsearch and Aston Molecules: | | | |
| Receivables | (505,065) | 816,278 | (412,935) |
| Interest receivable | 191,892 | 4,250 | (434,787) |
| Grants receivable | (226,409) | 151,274 | 102,516 |
| Prepaid expenses and other | 31,655 | (196,324) | (105,677) |
| Other receivable | -- | -- | 262,703 |
| Other assets | 6,079 | (72,514) | (108,949) |
| Accounts payable and accrued expenses | 52,501 | 493,401 | 391,857 |
| Unearned revenue | 383,308 | 487,339 | (69,842) |
| Accrued postretirement benefit cost | 344,767 | 301,000 | 277,297 |

| | | | |
|---|---|---|---|
| Net cash used by operating activities | (4,922,752) | (3,413,466) | (6,273,353) |
| Cash flows from investing activities: | | | |
| Additions to short-term investments | (4,004,770) | (4,019,935) | (37,216,936) |
| Maturities and sales of short-term investments | 14,573,046 | 15,025,749 | 11,814,126 |
| Change in other assets | (276,200) | (914,319) | 150,000 |
| Additions to property, equipment and leasehold improvements | (2,188,613) | (2,775,925) | (2,421,040) |
| Additions to compound library assets | (526,694) | (353,332) | -- |
| Payments for acquisition of MYCOsearch | -- | -- | (1,889,960) |
| Payments for acquisition of Aston Molecules | -- | -- | (635,441) |
| Net change in loans to officers and employees | 27,884 | 3,025 | (11,826) |
| Net cash provided by (used in) investing activities | 7,604,653 | 6,965,263 | (30,211,077) |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of common stock, net | -- | -- | 30,329,945 |
| Purchase of treasury stock | -- | (8,750,000) | -- |
| Proceeds from exercise of stock options and employee stock purchase plan | 99,290 | 356,230 | 1,655,821 |
| Net change in loan payable | (102,659) | 68,741 | (11,079) |
| Net cash provided by (used in) financing activities | (3,369) | (8,325,029) | 31,974,687 |
| Net increase (decrease) in cash and cash equivalents | 2,678,532 | (4,773,232) | (4,509,743) |
| Cash and cash equivalents at beginning of year | 8,636,634 | 13,409,866 | 17,919,609 |
| Cash and cash equivalents at end of year | $ 11,315,166 | $ 8,636,634 | $ 13,409,866 |
| Non-cash activities: | | | |
| Issuance of common stock, treasury stock and warrants for acquisition of MYCOsearch and Aston Molecules | -- | -- | $ 5,816,736 |

| | | | |
|---|---|---|---|
| Liabilities assumed from acquisition of MYCOsearch and Aston Molecules | -- | -- | $ 563,402 |
| Deferred purchase obligation incurred for acquisition of Aston Molecules | -- | -- | $ 590,675 |
| Issuance of treasury stock for acquisition of Dow Compound Library License | -- | $ 2,500,000 | -- |

</TABLE>

See accompanying notes to consolidated financial statements.





OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Principles of Consolidation

The consolidated financial statements of the Company include the accounts of OSI Pharmaceuticals, Inc., known as Oncogene Science, Inc. prior to October 1, 1997, and its wholly-owned subsidiaries Applied bioTechnology, Inc. ("Applied bioTechnology"), MYCOsearch, Inc. ("MYCOsearch"), Oncogene Science Diagnostics, Inc. and Aston Molecules Ltd. ("Aston"). All intercompany balances and transactions have been eliminated. The Company utilizes a platform of proprietary technologies in order to discover and develop novel, small molecule compounds for the treatment of major human diseases. It conducts the full range of drug discovery activities, from target identification to drug candidate.

(b) Revenue Recognition

Collaborative research revenues represent funding arrangements for the conduct of research and development ("R&D") in the field of biotechnology and are recognized when earned in accordance with the terms of the contracts and the related development activities undertaken. Other research revenues are recognized pursuant to the terms of grants which provide reimbursement of certain expenses related to the Company's other R&D activities. Collaborative and other research revenues are accrued for expenses incurred in advance of the reimbursement and deferred for cash payments received in advance of expenditures. Such deferred revenues are recorded as revenue when earned (See Note 5). Patent license fee revenues are recognized pursuant to the terms of the license agreement.

Revenue from the sale of diagnostic and research reagent products is recognized at time of shipment. Revenues from the performance of chemistry services provided by Aston are recognized when performed.

(c) Patents and Goodwill

As a result of the Company's research and development programs, including programs funded pursuant to the research and development funding agreements (See Note 5), the Company has applied for a number of patents in the United States and abroad. Such patent rights are of significant importance to the Company to protect products and processes developed. Costs incurred in connection with patent applications for the Company's research and development programs have been expensed as incurred.

Patents and goodwill acquired in connection with the acquisition of Applied bioTechnology's cancer business in October 1991 have been capitalized and are being amortized on a straight-line basis over the remaining lives of the respective patents, and over five years for goodwill. The goodwill acquired in connection with the acquisition of Aston in September 1996 is being amortized on a straight-line basis over five years (See Note 3). The Company continually evaluates the recoverability of its intangible assets by assessing whether the unamortized value can be recovered through expected future results.

(d) Research and Development Costs

Research and development costs are charged to operations as incurred and include direct costs of research scientists and equipment and an allocation of laboratory facility and central service. In fiscal years 1998, 1997, and 1996, R&D activities include approximately $5,772,000, $5,052,000 and $6,365,000 of independent R&D, respectively. Independent R&D represents those research and development activities, including research and development activities funded by government research grants, substantially all the rights to which the Company will retain. The balance of research and development represents expenses under the collaborative agreements and co-ventures with Pfizer Inc. ("Pfizer"), The Bayer Corporation ("Bayer"), Fujirebio, Inc. ("Fujirebio"), Anaderm Research Corp. ("Anaderm"), Sankyo Company, Ltd. ("Sankyo"), Hoechst Marion Roussel, Inc. ("HMRI"), Helicon Therapeutics, Inc. ("Helicon"), Novartis Pharma AG





("Novartis"), Becton, Dickinson and Company ("Becton"), Wyeth-Ayerst, a division of American Home Products ("Wyeth"), BioChem Pharma (International) Inc. ("BioChem Pharma"), and Sepracor, Inc, ("Sepracor"). HMRI was formed on July 18, 1995 pursuant to the merger of Marion Merrell Dow Inc. ("Marion"), Hoechst AG, and Hoechst-Roussel Pharmaceuticals, Inc. ("Hoechst Roussel").

(e) Depreciation and Amortization

Depreciation of equipment is provided 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 remaining term of their lease.

Amortization of the fungal cultures acquired in connection with the acquisition of MYCOsearch (See Note 3(a)), and amortization of the Dow Compound Library License (See Note 3(d)) are on a straight-line basis over five years, which represents the estimated period over which the fungal cultures and compounds will be used in the Company's R&D efforts.

(f) 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.

(g) Investments

Investment securities at September 30, 1998 and 1997 consist of U.S. Treasury obligations and corporate debt and equity securities. The Company classifies its investments as available-for-sale. These securities are recorded at their fair value. Unrealized holding gains and losses, net of the related tax effect, on available-for-sale securities are excluded from earnings and are reported as a separate component of stockholders' equity until realized. Realized gains and losses from the sale of available-for-sale securities are determined on a specific identification basis.

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. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. Dividend and interest income are recognized when earned.

(h) Net Loss Per Share

Effective October 1, 1997, the Company adopted the provisions of Statement of Financial Accounting Standards ("SFAS") No. 128 "Earnings Per Share," which replaced the calculation of primary and fully diluted earnings per share with basic and diluted earnings per share. Basic loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted loss per share is not presented because the inclusion of common share equivalents (stock options and warrants) in the computation would be anti-dilutive.





(i) Cash and Cash Equivalents

The Company includes as cash equivalents reverse repurchase agreements, treasury bills, and other time deposits with original maturities of three months or less.

(j) Use of Estimates

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

(2) LICENSE AGREEMENT

Pursuant to a License Agreement effective May 26, 1998, the Company granted to Aurora Biosciences Corporation ("Aurora") a non-exclusive worldwide license to practice the technology under the Company's patent for live-cell gene transcription assays utilizing a reporter gene. The Company also granted Aurora an option to obtain a non-exclusive license to practice the technology under the Company's patent concerning Methods of Modulation. The duration of each license is to be coextensive with the life of the last to expire of the underlying patents. Under the License Agreement, Aurora has the right to grant sublicenses. The Company received 75,000 shares of Aurora's common stock with an estimated discounted fair market value of $400,000 and a license fee of $300,000 upon execution of the agreement. In addition, Aurora will pay the Company an annual fee of $50,000, milestone payments and royalties on sales of products derived from the licensed patents, if any. The Company has exclusive control over prosecution, maintenance and enforcement of the patents subject to the agreement.

(3) ACQUISITIONS AND COMPOUND LIBRARY LICENSE

(a) MYCOsearch, Inc.

On April 11, 1996, the Company acquired all the outstanding shares of MYCOsearch, a privately owned company, that specializes in the collection of fungal cultures and the development of extracts derived therefrom. On the date of the acquisition, MYCOsearch became a wholly-owned subsidiary of the Company. Prior to the acquisition, the Company had purchased extracts and certain services from MYCOsearch. Such expenses totaled $301,000, in fiscal 1996 (through April 11, 1996) which are included in research and development expenses in the accompanying consolidated statements of operations.

The purchase price paid by the Company to the shareholders of MYCOsearch consisted of $1.75 million in cash, $2.95 million in common stock of the Company (316,553 shares at $9.319 per share, of which 222,521 shares represented the reissuance of shares held in treasury), and warrants to purchase 100,000 shares of the Company's stock at $9.319 per share, valued at $483,000. The warrants are exercisable for a three-year period starting on April 11, 1998. The Company also incurred other direct costs totaling approximately $137,000 in connection with the acquisition resulting in a total purchase price of $5.3 million.







The acquisition has been accounted for using the purchase method of accounting, and, accordingly, the purchase price has been allocated to the assets purchased and the liabilities assumed based on the fair values at the date of acquisition. The purchase price was allocated as follows (in thousands):

<TABLE>

| <S> | <C> |
|---|---|
| Fungi cultures | $5,508 |
| Fixed assets | 21 |
| Other assets | 16 |
| Other liabilities | (225) |
| Purchase price | $5,320 |

</TABLE>

The fungal cultures contain natural chemical structures that will be tested against target proteins using the Company's drug screens. The Company is amortizing the fungal cultures on a straight-line basis over a five-year period and will continually evaluate the recoverability of this asset based on the results of its testing. Amortization of the fungal cultures totaling $1,102,000, 1,102,000 and $459,000 for the fiscal years ended September 30, 1998, 1997 and 1996, respectively, is reflected as research and development expense in the accompanying consolidated statement of operations.

(b) Aston Molecules Ltd.

On September 19, 1996, the Company completed the acquisition of all the outstanding capital stock of Aston, a privately held United Kingdom company. On the date of the acquisition, Aston became a wholly-owned subsidiary of the Company. Its operations and personnel will be maintained at its present site in Birmingham, UK.

The consideration paid for Aston included 283,981 shares of the Company's common stock having a fair market value of approximately $2.4 million. In addition, the Company also issued rights exercisable at the end of three and five years following the closing date (for an aggregate exercise price of $7,500) to obtain a number of shares of the Company's common stock having an aggregate value of $750,000 (based on the then current market value). The present value of this additional consideration of $670,916 and $630,796 is reflected as deferred acquisition costs in the accompanying consolidated balance sheet as of September 30, 1998 and 1997, respectively. Other direct costs of the acquisition approximated $635,000 resulting in a total acquisition cost of $3.6 million.

The acquisition has been accounted for using the purchase method of accounting, and, accordingly, the purchase price has been allocated to the assets purchased and the liabilities assumed based on the fair values at the date of acquisition. The purchase price was allocated as follows (in thousands):

<TABLE>

| <S> | <C> |
|---|---|
| Goodwill | $3,468 |
| Fixed assets | 181 |
| Other assets | 299 |
| Other liabilities | (338) |
| Purchase price | $3,610 |

</TABLE>

The goodwill resulting from the acquisition is being amortized on a straight-line basis over a five year period. Prior to the acquisition, the Company purchased certain chemistry services from Aston. Such expenses totaled $879,000, in fiscal 1996 (through September 19, 1996) which are included in research and development expenses in the accompanying consolidated statements of operations.

Concurrent with the acquisition, the Company entered into employment agreements with certain of Aston's executives and scientific personnel and granted stock options covering an aggregate of 125,000 shares

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)
YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

of its common stock to such persons. The exercise price of $8.51 per share was based on the fair market value of the Company's stock on the date of the grant.

(c) Pro Forma Information (Unaudited)

The operating results of MYCOsearch and Aston have been included in the consolidated statements of operations from the respective dates of the acquisitions. The following unaudited pro forma information presents a summary of consolidated results of operations for the year ended September 30, 1996 assuming the acquisitions had taken place as of October 1, 1995.

<TABLE>
<CAPTION>

| | 1996 |
|---|---|
| <S> | <C> |
| Revenues | $ 10,566,000 |
| Net loss | (12,108,000) |
| Net loss per share | (.61) |

</TABLE>

The pro forma results give effect to the amortization of the fungi cultures and goodwill, elimination of intercompany sales, reduction of investment income, and an increase in the number of common shares outstanding. The pro forma financial information is not necessarily indicative of the results of operations as they would have been had the acquisitions been affected on the assumed dates.

(d) Compound Library License

On March 18, 1997, the Company entered into a license agreement with The Dow Chemical Company ("Dow") giving the Company exclusive worldwide rights to use more than 140,000 compounds for screening and potential development of small molecule drugs and cosmeceuticals. The initial payment for the license was 352,162 shares of the Company's common stock with a fair market value of approximately $2,500,000. Dow is also entitled, in certain instances where pre-existing Dow patents are in effect, to royalty payments from any new drug products that may result from the screening of the subset of the compound library covered by such patents. The common stock issued to Dow was from the shares held in treasury. The Company will amortize the license agreement cost on a straight-line basis over a five-year period, which represents the estimated period over which the compounds will be used in the Company's research and development efforts. Since the Company did not conduct significant research utilizing these compounds during fiscal 1997, the Company began amortizing the license agreement cost in October 1997 and recorded $505,446 of amortization expense in fiscal 1998.

(4) INVESTMENTS

The Company invests its excess cash in U.S. Government securities and debt instruments of financial institutions and corporations with strong credit ratings. The Company has established guidelines relative to diversification of its investments and their maturities that should maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. The Company uses the specific identification method to determine the cost of securities sold.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)
YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

The following is a summary of available-for-sale securities as of September 30, 1998 and 1997:

<TABLE>
<CAPTION>

| 1998 | COST | GROSS UNREALIZED (LOSSES) GAINS | FAIR VALUE |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| US Treasury Securities and obligations of US Government agencies | $ 9,201,681 | $(17,154) | $ 9,184,527 |
| Corporate debt securities | 3,479,932 | 36,234 | 3,516,166 |
| Corporate equity securities | 402,422 | -- | 402,422 |
| Total | $13,084,035 | $ 19,080 | $13,103,115 |

</TABLE>

<TABLE>
<CAPTION>

| 1997 | COST | GROSS UNREALIZED (LOSSES) GAINS | FAIR VALUE |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| US Treasury Securities and obligations of US Government agencies | $14,869,695 | $(126,253) | $14,743,442 |
| Corporate debt securities | 8,426,040 | 28,553 | 8,454,593 |
| Total | $23,295,735 | $ (97,700) | $23,198,035 |

</TABLE>

Net realized losses on sales of investments during fiscal 1998 and 1997 were approximately $46,000 and $37,000 respectively.

The Company also has investments in certain biotechnology companies which are included in other noncurrent assets in the accompanying balance sheets. The net investments are summarized as follows:

<TABLE>
<CAPTION>

| | SEPTEMBER 30, | |
|---|---|---|
| | 1998 | 1997 |
| <S> | <C> | <C> |
| Anaderm Research Corp. | $ 977,471 | $ 677,471 |
| Helicon Therapeutics, Inc. | 200,000 | 123,800 |
| Tularik Inc. in 1998; Amplicon Corp. in 1997 | 250,000 | 250,000 |
| NuGene Technologies, Inc. | -- | 100,000 |
| | $1,427,471 | $1,151,271 |

</TABLE>

As further discussed in Note 5, the Company has collaborative research agreements with Anaderm and Helicon and the investments are carried based on the equity method of accounting. The investments in Tularik Inc. ("Tularik"), Amplicon Corp. ("Amplicon"), and NuGene Technologies, Inc. ("NuGene") are carried at cost and approximate fair market value. In November 1997, Amplicon was acquired by Tularik. The Company's Amplicon securities were exchanged for common shares of Tularik. During fiscal 1998, based on the recurring operating losses of NuGene, the Company decided to fully reserve its investment in NuGene in the amount of $125,000.

(5) PRODUCT DEVELOPMENT CONTRACTS

(a) Pfizer

Effective April 1, 1996, the Company and Pfizer renewed their ten-year-old collaboration for a new five-year term by entering into new Collaborative Research and License Agreements. Under these agreements, all patent rights and patentable inventions derived from the research under this collaboration are owned jointly by the Company and Pfizer. Under the collaborative research agreement, Pfizer has committed to provide research funding to the Company in an aggregate amount of approximately $18.8 million. Pursuant to a schedule set forth in the collaborative research agreement, Pfizer will make maximum annual research





funding payments to the Company, which will gradually increase from approximately $3.5 million in the first year of the five-year term to approximately $4 million in the fifth year. The collaborative research agreement will expire on April 1, 2001. However, it may be terminated earlier by either party upon the occurrence of certain defaults by the other party. Any termination of the collaboration resulting from a Pfizer default will cause a termination of Pfizer's license rights. Pfizer will retain its license rights if it terminates the agreement in response to a default by the Company. Furthermore, between July 1 and September 30, 1999, Pfizer may terminate the collaborative research agreement, with or without cause, effective March 31, 2000. Upon such early termination by Pfizer, Pfizer will retain its license rights. The Company also granted Pfizer an exclusive, worldwide license to make, use, and sell the therapeutic products resulting from this collaboration in exchange for royalty payments. This license terminates on the date of the last to expire of the Company's relevant patent rights.

(b) Bayer

Effective January 1, 1997, the Company and Bayer entered into an agreement to develop serum-based cancer diagnostic products. Under the agreement, the Company granted to Bayer licenses to manufacture, use and sell clinical diagnostic products based on the Company's cancer diagnostic technology in exchange for royalties on net sales. Bayer will own all technology, and has the exclusive right to commercialize automated clinical diagnostic products derived from the collaboration. OSI has retained rights and is actively selling non-automated, or manual, versions of these tests to the clinical research market and has retained the right to commercialize automated the manual versions in the clinical diagnostic market. Bayer's license is perpetual with respect to non-patented technology and will terminate with respect to patented technology

upon the expiration of the last to expire of the Company's patents. Bayer will provide funding for the Company's research under the collaboration in the amount of $1.5 million for each of the first two contract years, and $1 million for each subsequent year. After the first two contract years, the Company will be required to provide up to $500,000 in annual funding for the collaboration to the extent the Company derives net revenues from out-licensing any cancer diagnostics technology or the sale of any clinical diagnostic or clinical research products. The agreement will terminate on December 31, 2002. Bayer has the right to terminate the agreement at any time after December 31, 1997 upon 12 months notice. During fiscal 1998 and 1997, the Company recorded revenue of approximately $1.5 million and $1.1 million, respectively, from Bayer pursuant to this agreement.

(c) Fujirebio, Inc.

The Company, through its wholly-owned subsidiary, Oncogene Science Diagnostics, Inc., entered into a Research Collaboration and License Agreement with Fujirebio effective April 1, 1998, creating a collaborative program focused on discovering and developing certain proprietary cancer assays and commercializing cancer products. Under the agreement, Fujirebio is to fund the Company's research and development of cancer assays over a four-year term. The Company is to provide Fujirebio with antibodies, antigens and other substances necessary to manufacture the diagnostic products derived from the collaboration. Further, the Company has granted to Fujirebio a non-exclusive license to, among other things, develop, manufacture and sell the products developed pursuant to the collaboration in exchange for license fees and royalties on product sales. The duration of the license is to be coextensive with the lives of the patents related to the licensed products. Each of the parties has rights and obligations to prosecute and maintain patent rights related to specified areas of the research under the agreement. The agreement is subject to early termination by either party in the event of certain defaults. During fiscal 1998, the Company recorded $100,000 of revenue under this agreement.





(d) Anaderm

In April 1996, in connection with the formation of Anaderm, the Company entered into a Stockholders' Agreement ("Stockholders' Agreement") among the Company, Pfizer, Anaderm, New York University ("NYU") and certain NYU faculty members ("Faculty Members"), and a Collaborative Research Agreement ("Research Agreement") among the Company, Pfizer and Anaderm. Anaderm issued common stock to Pfizer and the Company and options to purchase common stock to NYU and the Faculty Members. NYU and the Faculty Members have exercised their options fully, and Pfizer holds 82%, the Company holds 14%, and NYU and the Faculty Members collectively hold 4% of Anaderm's common stock. In exchange for its 14% of the outstanding shares of Anaderm common stock, the Company will provide formatting for high throughput screens and will conduct compound screening for 18 months at its own expense under the Research Agreement. The term of the Research Agreement is three years. During the initial phase of the agreement (the first 18 months), the Company was required to provide at its own cost formatting for high throughput screens and perform screening of its own compounds and those compounds provided by Pfizer. Upon the termination of the initial phase, the Board of Directors of Anaderm made a determination that the initial phase was successfully completed. With Pfizer's approval, the funded phase commenced on October 1, 1997 and will continue for the term of the Research Agreement. During

this phase, Anaderm will make payments to the Company equal to its research costs, including overhead, plus 10%. Anaderm or Pfizer will pay royalties to the Company on the sales of products resulting from this collaboration. In December 1997, the Company and Pfizer entered into an agreement for a second round of equity financing for Anaderm. The agreement called for an equity contribution of $14 million, of which the Company will contribute $2 million in drug discovery resources, including assay biology, high throughout screening, lead optimization and chemistry, through 1999. Pfizer will contribute $12 million, approximately $7 million of which will be used to support the Company in its ongoing drug discovery activities. Through September 1998, the Company had contributed $770,000 of its $2 million contribution in resources.

As of September 30, 1998, the Company has expended approximately $6.2 million, of which, $2.4 million has been capitalized as the cost of the Company's 14% interest in Anaderm. This capitalized cost has been offset by approximately $1.4 million which includes the Company's estimated interest in the loss of Anaderm as of September 30, 1998 of $1.0 million and an additional reserve of $400,000. The Company's net investment in Anaderm at September 30, 1998 of $977,000 is included in other assets in the accompanying consolidated balance sheet. During fiscal 1998 and 1997, the Company recorded revenue of approximately $3.5 million and $388,000, respectively, from Anaderm for contracted research activities.

(e) Sankyo

Effective as of February 12, 1997, the Company entered into a Collaborative Research and License Agreement with Sankyo to be conducted in partnership with MRC Collaborative Center ("MRC CC"), London, U.K. The collaboration is focused on discovering and developing novel pharmaceutical products to treat influenza. The Company is responsible for conducting research as directed by a research committee, including, without limitation, compound screening in exchange for research funding from Sankyo. Sankyo has the responsibility and the exclusive right to conduct pre-clinical and clinical development of all candidate compounds in exchange for milestone payments to the Company. During 1997, the Company received and recorded $267,000 for a non-refundable technology disclosure fee upon signing the agreement. During fiscal 1998 and 1997, the Company recorded revenue of approximately $2.6 million and $1.0 million, respectively, from Sankyo pursuant to this agreement.

The Company and MRC CC have granted to Sankyo exclusive, worldwide licenses to, among other things, use, manufacture and sell all products resulting from the collaboration. In exchange for these licenses, Sankyo will pay to the Company and MRC CC license fees and royalties on product sales. The duration of the





licenses is coextensive with the lives of the patents related to the licensed compound. If Sankyo discontinues development of all candidate compounds, the Company will have the sole and exclusive right to develop, use, manufacture and sell all products resulting from the collaboration, and it will pay royalties to Sankyo.

(f) Hoechst Marion Roussel

Effective as of April 1, 1997, the Company and HMRI entered into an Amended

Collaborative Research and License Agreement that consolidated and extended formerly separate collaborative programs between the Company and each of Marion, Hoechst Roussel and Hoechst AG. This resulted from the corporate reorganization of HMRI in July 1995 in which the pharmaceutical operations Marion, Hoechst Roussel and Hoechst AG were combined into HMRI. This Amended Collaborative Research and License Agreement provides for HMRI and the Company to collaborate in the discovery and development of drugs for the treatment of various diseases.

Under this collaboration, a research committee, with equal representation from the Company and HMRI, meets at least three times a year to evaluate the progress of the research program, make priority and program decisions, and prepare research plans identifying the drug targets to be pursued. New targets are added to the program on an ongoing basis by mutual agreement. The Company is responsible for achieving objectives outlined in the annual research plans. HMRI is responsible for assisting the Company in the pursuit of such objectives and for the clinical development and commercialization of drugs resulting from the program. HMRI is responsible for funding the costs of the Company's discovery efforts, and as of September 30, 1998, the Company had received or accrued an aggregate of $20.4 million in research funding from HMRI and its predecessors.

The Company has granted to HMRI an exclusive, worldwide license (and rights to acquire additional licenses) with respect to, among other things, the use, manufacture and sale of products resulting from OSI's lead seeking efforts against individual drug targets. In exchange for these licenses, HMRI will pay royalties to the Company on sales of such products. The Company and HMRI have mutually exclusive rights and obligations to prosecute and maintain certain patent rights related to various specified areas of the research.

Effective as of January 1, 1997, the Company entered into a Collaborative Research and License Agreement with HMRI to develop orally active, small molecule inducers of erythropoietin gene expression for the treatment of anemia due to chronic renal failure and anemia associated with chemotherapy for AIDS and cancer. This collaboration identified active lead compounds that were advanced to a pre-clinical development stage. During fiscal 1997, the Company received and recorded as income a $1.0 million initiation fee from HMRI in connection with this collaboration. This research effort, however, did not achieve sufficient data to warrant further development. Consequently, in October 1998, this program was terminated.

(g) Helicon

In July 1997, the Company, Cold Spring Harbor Laboratory and Hoffman-La Roche Inc. ("Roche") formed Helicon Therapeutics, Inc., a new Delaware corporation. In exchange for approximately 30% of Helicon's outstanding capital stock, the Company contributed to Helicon molecular screening services and a nonexclusive license with respect to certain screening technology. Such services were completed in fiscal 1998. Cold Spring Harbor Laboratory contributed a royalty-free license to commercialize certain technology relating to genes associated with long-term memory in exchange for a portion of Helicon's outstanding capital stock. Roche contributed cash for a portion of Helicon's outstanding capital stock. Certain individuals associated with Cold Spring Harbor Laboratory hold the remaining outstanding capital stock of Helicon.

The parties have entered into various collaborative research and license agreements pursuant to which they will jointly pursue the discovery, development and commercialization of novel drugs for the treatment of

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)
YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

long-term memory disorders and other central nervous system dysfunctions. The Company and Cold Spring Harbor Laboratory are to conduct research under the program, which is being funded by Helicon (except for the molecular screening services that the Company is contributing to Helicon). Helicon is to receive this funding from Roche for the first two years of the program. Roche, however, will have the right to terminate the program at the end of the second year, or otherwise if certain milestones identified by the research committee are not achieved. If the program is not previously terminated, Roche is to continue to provide funding for the third year of the program, with the actual amount to be determined by a research committee established to oversee the collaborative program. Helicon has granted to Roche a worldwide license to commercialize pharmaceutical products resulting from the collaborative program in exchange for certain milestone payments and royalties on Roche's sales of such products.

As of September 30, 1998, the Company has expended approximately $1.2 million of which $1.0 million has been capitalized as the cost of the Company's 30% interest in Helicon. This capitalized cost has been offset by approximately $800,000 which represents the Company's estimated interest in the loss of Helicon as of September 30, 1998 of $370,000 and an additional reserve of $430,000. The Company's net investment in Helicon at September 30, 1998 of $200,000 is included in other assets in the accompanying consolidated balance sheet. The Company recorded revenue of $203,000 from Helicon in fiscal 1998.

(h) Novartis

The Company entered into an agreement with Novartis Pharma AG ("Novartis") in April 1995 for the development of TGF-Beta 3 for various indications. TGF-Beta 3 is a naturally occurring human growth factor, first isolated by the Company, that exerts either stimulatory or inhibitory effects depending upon the particular cell type to which it is applied. This agreement granted to Novartis an exclusive, worldwide license to use and sell TGF-Beta 3 products for wound healing and oral mucositis, as well as certain other indications, in exchange for royalty payments to the Company on the sale of TGF-Beta 3 products.

During 1998, Phase II clinical trials being conducted by Novartis for both wound healing and oral mucositis failed to achieve their primary clinical end points. Consequently, no further clinical development of TGF-Beta 3 by Novartis for either wound healing or oral mucositis is anticipated. Novartis has an option through April 1999 (which it has not yet exercised) to obtain exclusive rights to all other indications for TGF-Beta 3 by making a $10 million payment in exchange for the Company's Common Stock at the higher of $5.50 per share or the then current market price. Novartis is currently conducting pre-clinical evaluation of TGF-Beta 3 for bone repair. Novartis and the Company are currently renegotiating this agreement to allow for the continued development of TGF-Beta 3 for this and other indications. The Company's agreement with Novartis ends upon the expiration of the last of the Company's patents relating to TGF-Beta 3.

(i) Becton Dickinson

On October 4, 1991, the Company and Becton established a collaborative research program to develop cancer diagnostic products. The Company and Becton shared equally the cost of discovery phase and pre-clinical research and development. This collaborative research program expired on September 30, 1996 and was not renewed. To the extent Becton commercializes any products derived from this program, it will pay certain royalties to the Company on sales of such products, if any.

(j) Wyeth-Ayerst

Effective December 31, 1991, the Company entered into a collaborative research agreement with Wyeth. This agreement was extended and expanded in January 1994 for an additional three years through December 31, 1996 to provide for additional funding of approximately $4.3 million. The Company had received approximately $1.6 million annually in research and development funding from Wyeth pursuant to





OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)
YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

this collaborative agreement. The funded portions of the research collaboration expired on December 31, 1996. To the extent Wyeth commercializes any products derived from this collaboration, it will pay certain royalties to the Company on sales of such products, if any.

(k) BioChem Pharma

fff Effective May 1, 1996, the Company entered into a Collaborative Research, Development and Commercialization Agreement with BioChem Pharma. Under this agreement, the parties were seeking to discover and develop anti-viral drugs for the treatment of Hepatitis B virus, Hepatitis C virus and HIV. This agreement provided that the Company and BioChem Pharma would jointly commit resources to the collaborative program. During fiscal 1998 and 1997, the Company has recognized $100,000 and $518,000 in revenue, respectively, which represents (i) a $100,000 annual technology fee for the right to receive all available upgrades and annual improvements to the equipment, software and license technology and (ii) reimbursement for all out-of-pocket costs to build, deliver and install robotic equipment at a BioChem Pharma location. The Company expects this agreement to be terminated in the near future.

(l) Sepracor

Pursuant to an Amendatory and Collaborative Agreement dated March 31, 1998, the Company and Sepracor amended their Collaborative Research Development and Commercialization Agreement dated March 7, 1997, terminating certain provisions contained therein, including, without limitation, provisions establishing the research program. Each party will be free to independently pursue the discovery of new compounds in the anti-infective area without incurring any responsibility to the other party. To the extent Sepracor commercializes certain compounds arising out of the joint venture, however, it will pay royalties to the Company. The Company provided discovery biology and certain other services to Sepracor until September 1, 1998, in exchange for fees. In fiscal 1998, the Company had received approximately $197,000 in research and development funding from Sepracor pursuant to this amended agreement.

(m) Xenometrix

On June 27, 1997, the Company and Xenometrix, Inc. ("Xenometrix") entered into an agreement pursuant to which they will jointly seek a corporate partner to fund a technology collaboration for the development of automated systems to generate and analyze certain data relating to toxicological, metabolic and undesirable systemic effects of drug candidates. The parties have cross-licensed certain of their respective assay technologies on a worldwide, royalty-free nonexclusive basis. The agreement is for a period of nine months, with automatic successive three-month renewal periods.

(n) Vanderbilt

Effective as of April 28, 1998, the Company 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. The collaborative research is funded by the Company in exchange for which the Company has the option to negotiate a commercially reasonable, worldwide, exclusive license from Vanderbilt to develop, make, use, and sell, products derived from the research program. The Company and Vanderbilt will commit equal resources to the program, including, among other things, access to all their respective laboratory facilities and dedicated teams of research scientists. The Company has certain rights and obligations to prosecute and maintain patent rights related to specified areas of the research under the agreement. The agreement is for a term of one year, but shall be automatically extended upon the execution of a third-party research





collaboration agreement for the term of such collaboration. Each party is prohibited from entering, on its own without the other party, into a funded collaboration agreement with a third-party for drug discovery in the area of diabetes using certain targets which are the subject of the collaboration.

(o) Other

Under the terms of aforementioned collaborative research agreements, the collaborative partners will pay the Company royalties ranging from 2% to 8% of net sales of products resulting from these research programs. To date, the Company has not received any royalties pursuant to these agreements. The Company or its collaborative partners may terminate each of the collaborative research programs upon the occurrence of certain events.

The Company does not intend to conduct late-stage clinical trials, manufacturing or marketing activities with respect to any of its product candidates in the foreseeable future. The Company is dependent on the companies with which it collaborates for the pre-clinical testing, clinical development, regulatory approval, manufacturing and marketing of potential products developed under its collaborative research programs. The Company's collaborative agreements allow its collaborative partners significant discretion in electing to pursue or not to pursue any of these activities. The Company cannot control the amount and timing of resources its collaborative partners devote to the Company's programs or potential products. If any of the Company's collaborative partners were to breach or terminate its agreements with the Company or otherwise fail to conduct its collaborative activities successfully in a timely manner, the pre-clinical or clinical development or commercialization of product candidates or research programs could be delayed or terminated. Any such delay or termination could have a material adverse effect on the Company's business, financial condition and results of operations.

Total program research revenues under the aforementioned agreements are as follows:

<TABLE>
<CAPTION>

YEARS ENDED SEPTEMBER 30,

| | 1998 | 1997 | 1996 |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| Related Parties: | | | |
| Pfizer | $ 3,682,056 | $ 3,622,363 | $3,208,077 |
| HMRI | 4,301,263 | 5,136,257 | 2,439,358 |
| BioChem Pharma | 100,000 | 517,888 | -- |
| Becton | -- | -- | 1,150,125 |
| Anaderm | 3,467,203 | 388,254 | -- |
| Helicon | 203,437 | -- | -- |
| Total Related Parties | 11,753,959 | 9,664,762 | 6,797,560 |
| Bayer | 1,500,000 | 1,125,000 | -- |
| Sankyo | 2,614,297 | 1,011,039 | -- |
| Sepracor | 197,357 | -- | -- |
| Fujirebio | 100,000 | -- | -- |
| Wyeth | -- | 400,000 | 1,550,000 |
| Total | $16,165,613 | $12,200,801 | $8,347,560 |

</TABLE>





OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)
YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

Included in receivables are the following amounts due from related parties:

<TABLE>
<CAPTION>

| | SEPTEMBER 30, | |
|---|---|---|
| | 1998 | 1997 |
| <S> | <C> | <C> |
| Pfizer | $ 125,975 | $ 5,020 |
| HMRI | 74,623 | 178,310 |
| Anaderm | 803,240 | -- |
| Helicon | 173,137 | -- |
| Total | $1,176,975 | $183,330 |

</TABLE>

(6) PROPERTY, EQUIPMENT AND LEASEHOLD IMPROVEMENTS

Property, equipment and leasehold improvements are recorded at cost and consist of the following:

<TABLE>
<CAPTION>

| | ESTIMATED LIFE (YEARS) | SEPTEMBER 30, 1998 | SEPTEMBER 30, 1997 |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| Laboratory equipment | 5-15 | $10,728,319 | $9,073,179 |
| Office furniture and equipment | 5-10 | 3,945,292 | 3,587,698 |

| | | | |
|---|---|---|---|
| Automobile equipment..... | 3 | 122,775 | 152,474 |
| Leasehold improvements..... | Life of lease | 5,520,703 | 5,315,125 |
| | | 20,317,089 | 18,128,476 |
| Less: accumulated depreciation and amortization..... | | 12,320,534 | 10,376,190 |
| Net property, equipment and leasehold improvements..... | | $ 7,996,555 | $7,752,286 |

</TABLE>

(7) INTANGIBLE ASSETS

The components of intangible assets are as follows:

<TABLE>
<CAPTION>

| | SEPTEMBER 30, | |
|---|---|---|
| | 1998 | 1997 |
| <S> | <C> | <C> |
| Patents..... | $5,643,401 | $6,410,614 |
| Goodwill..... | 2,080,600 | 2,774,128 |
| | $7,724,001 | $9,184,742 |

</TABLE>

The above amounts reflect accumulated amortization of $6,757,655 and $8,721,613 at September 30, 1998 and 1997, respectively. During fiscal 1996, goodwill increased $3,467,656 in connection with the acquisition of Aston (See Note 3(b)).





(8) ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses at September 30, 1998 and 1997 are comprised of:

<TABLE>
<CAPTION>

| | SEPTEMBER 30, | |
|---|---|---|
| | 1998 | 1997 |
| <S> | <C> | <C> |
| Accounts payable..... | $2,393,274 | $2,411,133 |
| Accrued future lease escalations..... | 446,137 | 448,137 |
| Accrued payroll and employee benefits..... | 350,831 | 367,242 |
| Accrued incentive compensation..... | 625,000 | 615,000 |
| Accrued expenses..... | 417,298 | 338,527 |
| | $4,232,540 | $4,180,039 |

</TABLE>

(9) STOCKHOLDERS' EQUITY

(a) Stock Redemption

On February 18, 1997, the Company repurchased all 1.25 million shares of the Company's common stock held by Becton for an aggregate price of $8.75 million. The Company's collaborative research agreement with Becton had ended on its scheduled expiration date of September 30, 1996. See Note 5(i).

(b) Stock Offering

In April 1996, the Company completed a public offering for 3,118,750 shares of common stock. The sale price was $9.125 per share. Concurrent with the public offering, the Company sold 500,000 shares at $9.125 per share directly to BioChem Pharma. The proceeds to the Company from these sales, net of underwriting commissions and other costs, were approximately $30.3 million. The net proceeds were added to the Company's general funds and are to be used for research and development expenses, including funds for enhancing the Company's drug discovery technologies and for general corporate purposes.

(c) Stock Option Plans

The Company has established four stock option plans for its employees, officers, directors and consultants. 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 may expire no later than 10 years from date of grant. The total authorized shares under these plans is 5,400,000.





The following table summarizes changes in the number of common shares subject to options in the stock option plans:

<TABLE>
<CAPTION>

| | | EXERCISE PRICE | | |
|---|---|---|---|---|
| WEIGHTED | SHARES | LOW | HIGH | AVERAGE |
| <S> | <C> | <C> | <C> | <C> |
| Balance at September 30, 1995 | | | | |
| Unexercised | 2,021,279 | $1.75 | $5.63 | $3.75 |
| Granted | 776,000 | 7.88 | 9.32 | 8.98 |
| Exercised | (491,544) | 1.75 | 4.88 | 3.35 |
| Forfeited | (87,678) | 3.50 | 5.63 | 3.98 |
| Balance at September 30, 1996 | | | | |

| | | | | |
|---|---|---|---|---|
| Unexercised | 2,218,057 | $1.75 | $9.32 | $5.67 |
| Granted | 907,500 | 6.50 | 7.09 | 6.82 |
| Exercised | (84,618) | 2.50 | 9.25 | 4.32 |
| Forfeited | (55,887) | 3.50 | 9.00 | 5.19 |
| Balance at September 30, 1997 | | | | |
| Unexercised | 2,985,052 | $1.75 | $9.32 | $6.07 |
| Granted | 840,250 | 3.25 | 6.75 | 5.26 |
| Exercised | (5,699) | 3.50 | 9.25 | 4.22 |
| Forfeited | (37,872) | 3.75 | 9.00 | 6.66 |
| Balance at September 30, 1998 | | | | |
| Unexercised | 3,781,731 | $1.75 | $9.32 | $5.89 |

</TABLE>

At September 30, 1998, the Company has reserved 4,335,593 shares of its authorized common stock for all shares issuable under options. At September 30, 1998, 1997, and 1996 options exercisable were 2,454,082, 1,290,829, and 872,513, respectively.

On March 22, 1995, the Company granted the right to current option holders to surrender their current options in exchange for replacement options on the basis of three replacement options for four options surrendered. The exercise price of the replacement options was $3.50 per share, which was greater than the market price on the date of exchange. The replacement options vested 25% upon grant with the remaining 75% vesting pro rata on a monthly basis over the following three years. Option holders surrendered 606,000 options in exchange for 454,500 replacement options.

Stock option grants are set at the closing price of the Company's common stock on the date of grant and the related number of shares granted are fixed at that point in time. Therefore under the principles of APB Opinion No. 25, the Company does not recognize compensation expense associated with the grant of stock options. SFAS No. 123, "Accounting for Stock-Based Compensation," requires the use of option valuation models to provide supplemental information regarding options granted after 1995. Pro forma information regarding net income and earnings per share shown below was determined as if the Company had accounted for its employee stock options and shares sold under its stock purchase plan under the fair value method of that statement.

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 1998, 1997 and 1996 respectively: risk-free interest rates of 4.38%, 5.84% and 6.26%; dividend yields of 0%; volatility factors of the expected market price of the Company's common stock of 64.9%, 65.8% and 64.8% and expected life of the options of 3.7 years for all





three years. These assumptions resulted in weighted-average fair values of $2.87, $3.61 and $4.75 per share for stock options granted in 1998, 1997 and 1996, respectively.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized over the options' vesting periods. The pro forma effect on

net income for 1998 and 1997 is not representative of the pro forma effect on net income in future years because it does not take into consideration pro forma compensation expense related to grants made prior to 1996. Pro forma information in future years will reflect the amortization of a larger number of stock options granted in several succeeding years. The Company's pro forma information is as follows (in thousands, except per share information):

<TABLE>
<CAPTION>

| | SEPTEMBER 30, | | |
|---|---|---|---|
| | 1998 | 1997 | 1996 |
| <S> | <C> | <C> | <C> |
| Pro forma net loss..... | $(12,802) | $(11,205) | $(10,327) |
| Pro forma net loss per share: | | | |
| Basic..... | $ (0.57) | $ (0.51) | $ (0.52) |

</TABLE>

Information regarding stock options outstanding as of September 30, 1998, is as follows (options in thousands):

<TABLE>
<CAPTION>

| | OPTIONS OUTSTANDING | | | OPTIONS EXERCISABLE | |
|---|---|---|---|---|---|
| PRICE RANGE | SHARES (IN THOUS) | WEIGHTED AVERAGE EXERCISE PRICE | WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE | SHARES (IN THOUS) | WEIGHTED AVERAGE EXERCISE PRICE |
| <S> | <C> | <C> | <C> | <C> | <C> |
| Under $4.50..... | 1,424 | $3.78 | 5.44 | 1,239 | $3.87 |
| $4.50 - $7.00..... | 1,558 | 6.26 | 8.72 | 589 | 6.56 |
| Over $7.00..... | 800 | 8.89 | 6.43 | 626 | 8.93 |

</TABLE>

(d) Sale of Common Stock and Warrant to Marion Merrell Dow

In December 1992, the Company entered into the common stock purchase and common stock warrant purchase agreements with Marion. The Company issued 1,090,909 shares of common stock at $5.50 per share and a warrant to purchase up to 500,000 additional shares at $5.50 per share which is exercisable during the period December 1994 to December 1999. The proceeds to the Company were $6 million.

(e) Employee Stock Purchase Plan

On May 1, 1993, the Company adopted an Employee Stock Purchase Plan under which eligible employees may contribute up to 10% of their base earnings toward the quarterly purchase of the Company's common stock. The employees 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 1998, 1997 and 1996, 20,664, 12,388, and 3,860 shares were issued with 52, 48 and 34 employees participating in the plan, respectively.

(10) INCOME TAXES

There is no provision (benefit) for federal or state income taxes, since the Company has incurred operating losses since inception and has established a valuation allowance equal to the total deferred tax asset.





OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)
YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

The tax effect of temporary differences, net operating loss carry forwards and research and development tax credit carry forwards as of September 30, 1998 and 1997 are as follows:

<TABLE>
<CAPTION>

| | SEPTEMBER 30, | |
|---|---|---|
| | 1998 | 1997 |
| <S> | <C> | <C> |
| Deferred tax assets: | | |
| Net operating loss carry forwards | $ 16,942,035 | $ 14,170,792 |
| Research and development credits | 874,246 | 824,246 |
| Intangible assets | 797,137 | 946,094 |
| Other | 2,041,480 | 1,750,156 |
| | 20,654,898 | 17,691,288 |
| Valuation allowance | (20,654,898) | (17,691,288) |
| | $ -- | $ -- |

</TABLE>

As of September 30, 1998, the Company has available federal net operating loss carry forwards of approximately $50 million which will expire in various years from 1999 to 2013, and may be subject to certain annual limitations. The Company's research and development tax credit carry forwards noted above expire through the year 2013.

(11) COMMITMENTS AND CONTINGENCIES

(a) Lease Commitments

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

Rent expense was approximately $1,090,000, $1,081,000 and $727,000 for the fiscal years ended September 30, 1998, 1997, and 1996, respectively.

The following is a schedule by fiscal years of future minimum rental payments required as of September 30, 1998, assuming expiration of the leases for the two Uniondale facilities on July 31, 2003 and June 30, 2006, respectively, the Cambridge facility on December 31, 2003, the Durham facility on October 31, 2004, and the Birmingham facility on May 31, 2002.

<TABLE>

| <S> | <C> |
|---|---|
| 1999 | $1,094,978 |
| 2000 | 1,172,662 |
| 2001 | 1,184,129 |
| 2002 | 1,122,652 |
| 2003 | 960,993 |
| 2004 and thereafter | 1,567,866 |
| | $7,103,280 |

</TABLE>

(b) Contingencies

The Company has received several letters from other companies and universities advising the Company that various products being marketed and research being conducted by the Company may be infringing on existing patents of such entities. These matters are presently under review by management and outside counsel for the Company. Where valid patents of other parties are found by the Company to be in place, management will consider entering into licensing arrangements with the universities and/or other companies or modify the conduct of its research. The Company's royalties may be reduced by up to 50% if its licensees or collaborative





partners are required to obtain licenses from third parties whose patent rights are infringed by the Company's products, technology or operations. In addition, should any infringement claims result in a patent infringement lawsuit, the Company could incur substantial costs in defense of such a suit, which could have a material adverse effect on the Company's business financial condition and results of operations, regardless of whether the Company were successful in the defense.

(c) Lines of Credit

As of September 30, 1998, the Company has a line of credit with a commercial bank in the amount of $10 million. This line expires annually on March 31st, and its current rate of interest is prime plus 3/4. The Company has had no borrowings under this line of credit.

(12) RELATED PARTY TRANSACTIONS

Effective January 1, 1993, the Company compensates its independent outside directors on a $1,000 retainer per month. This amount increased to $1,500 effective January 1, 1995. For the years ended September 30, 1998, 1997 and 1996, such fees amounted to $135,000, $126,000 and $108,000, respectively. The Company also has compensated directors for consulting services performed. For the years ended September 30, 1998, 1997 and 1996, consulting services in the amounts of $157,000, $144,000, and $100,000 respectively, were paid by the Company pursuant to these arrangements.

One director is a partner in a law firm which represents the Company on its patent and license matters. Fees paid to this firm for the years ended September 30, 1998, 1997 and 1996 were approximately $604,000 $404,000, and $413,000 respectively.

During fiscal 1997, the Board of Directors of the Company approved the cashless exercise of certain stock options held by a director. The Company recorded a charge of $126,750, which represents the fair market value of the common stock issued.

A board member is an officer of Cold Spring Harbor Laboratory which was a founder of Amplicon (which was recently acquired by Tularik) and Helicon. A board member is the chief executive officer and director of Helicon and member of the board of directors of Xenometrix. A board member is the chief executive officer of NuGene. The Company's chairman is a member of the boards of directors of NuGene, Anaderm and Helicon, and may become the chairman or co-chairman of Helicon and vice president of Anaderm. An executive officer of the Company is vice president of Helicon. The Company has investments in Tularik, Helicon, and NuGene and collaborative research agreements with Helicon and Xenometrix.

(13) EMPLOYEE SAVINGS AND INVESTMENT PLAN

The Company sponsors an Employee Savings and Investment Plan under Section 401(k) of the Internal Revenue Code. The plan allows employees to defer from 2% to 10% of their income on a pre-tax basis through contributions into designated investment funds. For each dollar the employee invests up to 6% of his or her earnings, the Company will contribute an additional 50 cents into the funds. For the years ended September 30, 1998, 1997, and 1996, the Company's expenses related to the plan were approximately $197,000, $233,000 and $164,000, respectively.

(14) EMPLOYEE RETIREMENT PLAN

On November 10, 1992, the Company adopted a plan which provides postretirement medical and life insurance benefits to eligible employees, board members and qualified dependents. Eligibility is determined





based on age and service requirements. These benefits are subject to deductibles, co-payment provisions and other limitations.

The Company utilizes 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 post retirement medical and life insurance benefits is accrued over the active service periods of employees to the date they attain full eligibility for such benefits. As permitted by SFAS No. 106, the Company elected to amortize over a 20 year period the accumulated postretirement benefit obligation related to prior service costs.

Net postretirement benefit cost for the years ended September 30, 1998, 1997 and 1996 includes the following components:

<TABLE>
<CAPTION>

| | 1998 | 1997 | 1996 |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| Service cost for benefits earned during the Period..... | $220,785 | $194,900 | $161,800 |

| | | | |
|---|---|---|---|
| Interest cost on accumulated postretirement benefit obligation | 104,831 | 99,600 | 89,300 |
| Amortization of unrecognized net loss | 3,327 | 9,600 | 18,700 |
| Amortization of initial benefits attributed to past service | 17,493 | 17,500 | 17,500 |
| Net postretirement benefit cost | $346,436 | $321,600 | $287,300 |

</TABLE>

The accrued postretirement benefit cost at September 30, 1998 and 1997 were as follows:

<TABLE>
<CAPTION>

| | 1998 | 1997 |
|---|---|---|
| <S> | <C> | <C> |
| Accumulated postretirement benefit obligation -- fully eligible active plan participants | $1,721,206 | $1,672,500 |
| Unrecognized cumulative net loss | (181,832) | (460,400) |
| Unrecognized transition obligation | (250,107) | (267,600) |
| Accrued postretirement benefit cost | $1,289,267 | $ 944,500 |

</TABLE>

The accumulated postretirement benefit obligation was determined using a discount rate of 7.5 percent in 1998 and in 1997 and a health care cost trend rate of approximately 7 percent in 1997, decreasing down to 5 percent in 1999 and thereafter. Increasing the assumed health care cost trend rates by one percentage point in each year and holding all other assumptions constant would increase the accumulated postretirement benefit obligation as of September 30, 1998 by approximately $226,000 and the net postretirement benefit cost by approximately $92,000.

(15) NEW ACCOUNTING PRONOUNCEMENTS

In June 1997, the Financial Accounting Standards Board issued SFAS Nos. 130 and 131, "Reporting Comprehensive Income" and "Disclosures about Segments of an Enterprise and Related Information," respectively (the "Statements"). The Statements are effective for fiscal years beginning after December 15, 1997. SFAS No. 130 establishes standards for reporting of comprehensive income and its components in annual financial statements. SFAS No. 131 establishes standards for reporting financial and descriptive information about an enterprise's operating segments in its annual financial statements and selected segment information in interim financial reports. Reclassification or restatement of comparative financial statements or financial information for earlier periods is required upon adoption of SFAS No. 130 and SFAS No. 131, respectively. Application of the Statements' disclosure requirements will have no impact on the Company's consolidated financial position, results of operations or earnings per share data as currently reported.

In February 1998, the Financial Accounting Standards Board issued SFAS No. 132, "Employers' Disclosures about Pensions and Other Postretirement Benefits" which revises current disclosures about pension and other postretirement benefit plans. It does not change the measurement or recognition of those plans. The Statement: (1) standardizes the disclosure requirements for pension and other postretirement benefits to the extent practicable; (2) requires additional information on changes in the benefit obligations and fair values of plan assets that will facilitate financial analysis; (3) eliminates certain disclosures that are no longer useful; (4) suggests combined formats for presentation of pension and other postretirement benefits; and (5) permits reduced disclosures for nonpublic entities. SFAS No. 132 is effective for fiscal years beginning after December 15, 1997. These standards expand or modify current disclosures and, accordingly, will have no impact on the Company's reported financial position, results of operations and cash flows.

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative and Hedging Activities." SFAS No. 133 establishes a comprehensive standard on accounting for derivatives and hedging activities and is effective for periods beginning after June 15, 1999. Management does not believe that the future adoption of SFAS No. 133 will have a material effect on the Company's financial position and results of operations.





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

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this item is incorporated by reference to the similarly named section of the Registrant's Proxy Statement for its 1999 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after September 30, 1998 (the "1999 Proxy").

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the similarly named section of the Registrant's 1999 Proxy.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is incorporated by reference to the similarly named section of the Registrant's 1999 Proxy.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference to the similarly named section of the Registrant's 1999 Proxy.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) (1) The following consolidated financial statements are included in Part II, Item 8 of this report:

Consolidated Balance Sheets
Consolidated Statements of Operations
Consolidated Statements of Stockholders' Equity
Consolidated Statements of Cash Flows
Notes to Consolidated Financial Statements

(2) All schedules are omitted as the required information is inapplicable or the information is presented in the financial statements or related notes.

(3) The exhibits listed in the Index to Exhibits are attached or incorporated herein by reference and filed as a part of this report.

(b) Reports on Form 8-K
None.





SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OSI PHARMACEUTICALS, INC.

By: /s/ COLIN GODDARD, PH.D.

---

Colin Goddard, Ph.D.
President and Chief Executive Officer

Date: December 22, 1998

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company and in the capacities and on the days indicated.

<TABLE>
<CAPTION>

| SIGNATURE | TITLE | DATE |
|---|---|---|
| --- | --- | --- |
| <S> | <C> | <C> |
| /s/ COLIN GODDARD, PH.D.<br>Colin Goddard, Ph.D. | President and Chief Executive Officer and Director | December 22, 1998 |
| /s/ ROBERT L. VAN NOSTRAND<br>Robert L. Van Nostrand | Vice President and Chief Financial Officer | December 22, 1998 |
| /s/ G. MORGAN BROWNE | Director | December 22, 1998 |

| | | |
|---|---|---|
| G. Morgan Browne | | |
| /s/ GARY E. FRASHIER<br>Gary E. Frashier | Chairman of the Board of Directors | December 22, 1998 |
| /s/ JOHN H. FRENCH, II<br>John H. French, II | Director | December 22, 1998 |
| /s/ EDWIN A. GEE, PH.D.<br>Edwin A. Gee, Ph.D. | Director | December 22, 1998 |
| /s/ DARYL K. GRANNER, M.D.<br>Daryl K. Granner, M.D. | Director | December 22, 1998 |
| /s/ WALTER M. LOVENBERG, PH.D.<br>Walter M. Lovenberg, Ph.D. | Director | December 22, 1998 |
| /s/ STEVEN M. PELTZMAN<br>Steven M. Peltzman | Director | December 22, 1998 |
| /s/ JOHN P. WHITE<br>John P. White, Esquire | Director | December 22, 1998 |





## INDEX TO EXHIBITS

| EXHIBITS | |
|---|---|
| 3.1 | Certificate of Incorporation, as amended(1) |
| 3.2 | By-Laws, as amended(2) |
| 10.1 | 1985 Stock Option Plan (filed as an exhibit to the Company's registration statement on Form S-1 (file no. 33-3148) and incorporated herein by reference) |
| 10.2 | 1989 Incentive and Non-Qualified Stock Option Plan (filed as an exhibit to the Company's registration statement on Form S-8 (file no. 33-38443) and incorporated herein by reference) |
| 10.3 | 1993 Incentive and Non-Qualified Stock Option Plan, as amended (filed as an exhibit to the Company's registration statement on Form S-8 (file no. 33-64713) and incorporated |

herein by reference)

| | |
|---|---|
| 10.4 | Stock Purchase Plan for Non-Employee Directors (filed as an exhibit to the Company's registration statement on Form S-8 (file no. 333-06861) and incorporated herein by reference) |
| 10.5 | 1995 Employee Stock Purchase Plan (filed as an exhibit to the Company's registration statement on Form S-8 (file no. 333-06861) and incorporated herein by reference) |
| 10.6 | 1997 Incentive and Non-Qualified Stock Option Plan (filed as an exhibit to the Company's registration statement on Form S-8 (file no. 333-39509) and incorporated herein by reference) |
| 10.7+ | Collaborative Research Agreement dated April 1, 1996 between the Company and Pfizer Inc.(3) |
| 10.8+ | License Agreement dated April 1, 1996 between the Company and Pfizer Inc.(3) |
| 10.9+ | Stockholders' Agreement dated April 23, 1996 among Anaderm Research Corp., the Company, Pfizer Inc., New York University and certain individuals(3) |
| 10.10+ | Collaborative Research Agreement dated April 23, 1996 amount the Company, Pfizer Inc. and Anaderm Research Corp.(3) |
| 10.11 | Form of Warrants issued by the Company to the former stockholders of MYCOsearch, Inc. and their designees covering an aggregate of 100,000 shares of common stock(3) |
| 10.12 | Employment Agreement dated April 11, 1996 between the Company and Dr. Barry Katz(3) |
| 10.13 | Common Stock Purchase Warrant granted to Marion Merrell Dow, Inc. dated December 11, 1992(4) |
| 10.14 | Collaborative Agreement dated as of April 19, 1995 between the Company and Novartis Pharma AG(5) |
| 10.15 | Letter Agreement dated as of April 19, 1995 between the Company and Novartis Pharma AG(5) |
| 10.16 | Registration Rights Agreement dated as of April 19, 1995 between the Company and Novartis Pharma AG(5) |
| 10.17+ | Agreement dated September 27, 1996 between the Company and Becton, Dickinson and Company(6) |
| 10.18+ | Collaborative Research and License Agreement dated as of January 1, 1997 between the Company and Bayer Corporation(7) |
| 10.19+ | Collaborative Research, Development and License Agreement dated as of February 12, 1997 by and among the Company, Sankyo Company, Ltd., and MRC Collaborative Center(8) |
| 10.20+ | License Agreement dated as of March 18, 1997 between the Company and The Dow Chemical Company(8) |
| 10.21 | Amended and Restated Collaborative Research and License Agreement effective as of April 1, 1997 by and among the Company, Hoechst Marion Roussel, Inc. and Hoechst Aktiengesellschaft(9) |
| 10.22+ | Stock Subscription Agreement dated as of July 17, 1997 by and between the Company and Helicon Therapeutics, Inc.(4) |

</TABLE>





<TABLE>
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EXHIBITS

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| 10.23+ | License and Services Agreement dated as of July 17, 1997 by and between the Company and Helicon Therapeutics, Inc.(4) |
| 10.24+ | Stockholders' Agreement dated as of July 17, 1997 by and |

| | |
|---|---|
| | among Helicon Therapeutics, Inc. and certain stockholders of Helicon Therapeutics, Inc.(4) |
| 10.25+ | Convertible Preferred Stock Purchase Agreement dated as of July 17, 1997 by and among Helicon Therapeutics, Inc., the Company, Hoffman-La Roche, Inc. and Cold Spring Harbor Laboratory.(4) |
| 10.26+ | Collaborative Research and License Agreement effective as of July 1, 1997 by and between Hoffman-La Roche, Inc. and Helicon Therapeutics, Inc.(4) |
| 10.27 | Employment Agreement, dated April 30, 1998, between the Company and Colin Goddard, Ph.D.(10) |
| 10.28+ | Amendatory and Collaborative Agreement, dated as of March 31, 1998, by and between the Company and Sepracor, Inc.(10) |
| 10.29+ | Research Collaboration and License Agreement, dated as of April 1, 1998, by and among the Company, Oncogene Science Diagnostics, Inc. and Fujirebio, Inc.(10) |
| 10.30+ | License Agreement, dated as of May 26, 1998, by and between the Company and Aurora Biosciences Corporation.(10) |
| 21* | Subsidiaries of the Company |
| 23* | Consent of KPMG Peat Marwick, LLP, independent public accountants |
| 27* | Financial Data Schedule |

</TABLE>

- ---

* Filed herewith.

\+ Portions of this exhibit have been redacted and are subject to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

(1) Filed as an exhibit to the Company's quarterly report filed on Form 10-Q for the quarter ended December 31, 1997, filed on February 27, 1998, and incorporated herein by reference.

(2) Filed as an exhibit to the Company's registration statement on Form S-3 (file no. 333-937) and incorporated herein by reference.

(3) Filed as an exhibit to the Company's quarterly report on Form 10-Q for the fiscal quarter ended March 31, 1996, as amended, and incorporated herein by reference.

(4) Filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended September 30, 1997, and incorporated herein by reference.

(5) Filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended September 30, 1995, as amended, and incorporated herein by reference.

(6) Filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended September 30, 1996 and incorporated herein by reference.

(7) Filed as an exhibit to the Company's quarterly report on Form 10-Q for the fiscal quarter ended December 31, 1996 and incorporated herein by reference.

(8) Filed as an exhibit to the Company's quarterly report on Form 10-Q for the fiscal quarter ended March 31, 1997 and incorporated herein by reference.

(9) Filed as an exhibit to the Company's quarterly report on Form 10-Q for the

fiscal quarter ended June 30, 1997 and incorporated herein by reference.

(10) Filed as an exhibit to the Company's quarterly report on Form 10-Q for the fiscal quarter ended June 30, 1998 and incorporated herein by reference.



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EXHIBIT 21

SUBSIDIARIES OF THE COMPANY

Aston Molecules, Inc., organized under the laws of the United Kingdom

MYCOsearch Inc., incorporated under the laws of the State of Delaware

Applied bioTechnology, Inc., incorporated under the laws of the State of Delaware

Oncogene Science Diagnostics, Inc., incorporated under the laws of the State of Delaware

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EXHIBIT 23

INDEPENDENT AUDITORS' CONSENT

The Board of Directors
OSI Pharmaceuticals, Inc.

We consent to incorporation by reference in the registration statements on Forms S-3 (No. 333-12593 and No. 333-2451) and on Forms S-8 (No. 333-06861, No. 33-64713, No. 33-60182, No. 33-38443, No. 33-8980 and No. 333-39509) of OSI Pharmaceuticals, Inc. of our report dated December 4, 1998, relating to the consolidated balance sheets of OSI Pharmaceuticals, Inc. and subsidiaries as of

September 30, 1998 and 1997, 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, 1998, which report appears in the September 30, 1998 annual report on Form 10-K of OSI Pharmaceuticals, Inc.

/s/ KPMG PEAT MARWICK LLP

Melville, New York
December 21, 1998

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