SANGSTAT MEDICAL CORP
Form 10-K
April 01, 2002

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2001

OR

o **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: 0-22890

SANGSTAT MEDICAL CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-3076-069**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification Number)

6300 Dumbarton Circle
Fremont, California 94555

(Address of principal executive offices, including zip code)

510-789-4300 (Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock ($.001 par value)
Preferred Share Purchase Rights
(Title of Class)

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

Indicate by a 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. o

The aggregate market value of voting stock held by non-affiliates of the Registrant, as of March 18, 2002 was approximately $540,560,000 (based on the closing price for shares of the Registrant s Common Stock as reported by the Nasdaq National Market of $24.98 on that date). Shares of Common Stock held by each officer, director, and holder of 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 18, 2002 approximately 26,348,115 shares of the Registrant s Common Stock, $.001 par value, were outstanding.

Parts of the definitive Proxy Statement for the Registrant s 2002 Annual Meeting of Stockholders to be filed with the Securities Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference into Part III of this Form 10- K.

SANGSTAT MEDICAL CORPORATION

FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001

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SIGNATURES

PART I

ITEM 1. BUSINESS

The following discussion and analysis should be read in conjunction with Selected Consolidated Financial Data and our Consolidated Financial Statements and Notes thereto included elsewhere in this Annual Report on Form 10-K. Except for the historical information contained herein, the discussion contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, intentions and future results. The cautionary statements made in this Annual Report on Form 10-K should be read as being applicable to all related forward-looking statements wherever they appear. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those discussed in Risk Factors, as well as those discussed elsewhere herein. In particular, we have included forward-looking statements regarding the following: (i) our anticipated financial results for 2002; (ii) the timeline and potential results of preclinical development and clinical trials; (iii) potential outcomes of our and Abbott s litigation with Novartis; (iv) our plans for marketing a cyclosporine capsule in Europe; (v) anticipated expenditures and timing relating to FDA and foreign approval of our products and facilities; and (vi) anticipated potential strategic collaborations with others. These forward-looking statements are based on our current expectations, and we disclaim any obligation to update these forward-looking statements for subsequent events or to explain why actual results differ.

Overview

SangStat is a global biotechnology company expanding on its transplantation foundation to discover, develop and market high value therapeutic products in immunology, hematology/oncology and auto-immune disease. Since our incorporation in 1988, we have been dedicated to improving the outcome of organ and bone marrow transplantation through the development and marketing of products to address all phases of transplantation in the worldwide market. We are headquartered in Fremont, California. We maintain a strong European and U.S. presence, including direct sales and marketing forces in all major European markets and the U.S. and distributors throughout the rest of the world.

Historically, our business was comprised of two segments: pharmaceutical products and transplantation services. In October 2000, we implemented a new strategy focused on growing a core business in high value therapeutics that builds on our expertise in transplantation but extends into new therapeutic areas. As a result of this new strategy, we decided to dedicate significant resources to our pharmaceutical products segment, which consists of four marketed products and three principal product candidates. Consequently, on April 20, 2001, we sold our transplantation services segment, The Transplant Pharmacy, to Chronimed.

Our primary marketed product, Thymoglobulin, a treatment for acute rejection of a kidney transplant, was launched in February 1999. Thymoglobulin achieved worldwide sales of $30.6 million in 1999, $37.9 million in 2000 and $51.4 million in 2001. The success of Thymoglobulin and its potential in areas beyond solid organ transplantation has provided us with the ability to examine and develop new therapeutic opportunities outside of transplantation.

We are now focusing on a variety of therapeutic products and product candidates to address the pre-transplant, acute care and chronic phases of transplantation as well as product candidates in immunology, hematology/oncology and auto-immune disease.

We currently sell the following products:

Thymoglobulin® (sold under the name Thymoglobuline® outside the U.S.);

Gengraf® cyclosporine capsule (co-promoted with Abbott Laboratories in the U.S.);

Lymphoglobuline® (outside the U.S.); and

Celsior®.

Our principal products under development include:

A smaller-size cyclosporine capsule;

ABX-CBL (anti-CD147 antibody in co-development with Abgenix, Inc.); and

RDP58.

Background

Organ Transplantation

Organ transplantation can save or improve the lives of patients with organ failures. Transplantation involves surgically replacing the diseased or failed organ of a transplant recipient with a healthy organ from a donor. Industry sources report that each year approximately 20,000 patients in the U.S. receive donated organs, and we estimate that there are approximately twice that number of patients worldwide. While the size of the transplant population is difficult to ascertain at any given time, industry participants believe the population of organ transplant survivors to be more than 200,000 worldwide. Currently, there are approximately 260 transplant centers in the U.S.

In order to prevent rejection of implanted organs, most recipients must begin a life-long regimen of immunosuppressive therapy immediately upon receiving a donated organ. This immunosuppressive regimen usually requires daily therapy in order to prevent organ rejection and graft loss. Products that supplement immunosuppression can reduce the frequency and severity of rejection and infection episodes. These products can

potentially enhance patient outcomes, while providing potential cost savings in the treatment of transplantation and its associated side effects. Our product Gengraf, an immunosuppressant, is approved in the U.S. for the prevention of kidney, liver and heart rejection.

The Transplant Immune Response

The function of the immune system is to protect the body from damage caused by invading microorganisms or other foreign matter. Differences between a donor s and a recipient s antigens can lead to the recognition of the donor s organ as foreign matter by the recipient s immune system. Specifically, the donor organ antigens are recognized by the immune system of the graft recipient as being non-self, triggering the immune system to attack and invade the graft. When the recipient s immune system attacks and invades the donated graft, rejection and loss of the graft often occur. Thymoglobulin is approved for acute kidney graft rejection in the U.S., and Thymoglobulin and Lymphoglobuline are approved for both prevention and treatment of acute graft rejection in various countries outside the U.S.

The Transplant Process

A typical transplant patient progresses through three phases:

The Pre-Transplant Phase

A transplant candidate is registered on a national computerized waiting list. A candidate usually waits months or even years for a compatible organ. Organs harvested from donors are stored in a preservation solution such as Celsior to prevent deterioration. Each organ is cross-matched with potential recipients. The organ is then shipped in

the same organ preservation solution to the recipient s transplant center.

The Acute Phase (Surgery and First Year Post-Transplant)

After transplantation, the physician must prevent graft rejection for the transplant to be a success. Consequently, the success of the transplant is highly dependent on the immunosuppressive regimen that is initiated at the time of transplantation and continued daily for the rest of the patient s life. Organ recipients must be regularly monitored to measure the body s immune response and blood drug levels and to help identify acute rejection episodes. Many patients undergo one or more rejection episodes in the first year after transplant and require additional immunosuppressants.

The Chronic Phase (Lifetime Post-Transplant)

The use of immunosuppressants such as cyclosporine, initiated during the acute phase, is continued daily throughout the patient s lifetime to minimize or prevent the loss of the organ by rejection. These drugs impair the recipient s immune system in order to reduce the immune response against the graft. Even with the use of immunosuppressants, industry sources report that patients have an approximate 20% to 50% risk of losing a donated organ during the first three years following transplantation, and approximately 20% to 65% after five years. These percentages differ depending on the type of transplant. Chronic use of immunosuppressants can also lead to serious side effects, including life-threatening infections, kidney or liver toxicity and cancer.

Aplastic Anemia

Aplastic anemia, which primarily affects young people, is a disease in which the stem cells disappear from the bone marrow. Aplastic anemia has a high mortality rate and, even with treatment, quality of life is poor. A lack of stem cells in the bone marrow inhibits the production of blood cells. As a result, patients with this disease are dependent on weekly blood transfusions that require frequent visits to the physician s offices. Both Thymoglobulin and Lymphoglobuline are approved in certain countries outside of the U.S. for treatment of aplastic anemia, and we believe that the majority of sales of Lymphoglobuline in Japan are for the treatment of aplastic anemia. Current treatments for severe aplastic anemia include immunosuppressants and, if necessary, bone marrow transplantation.

Myelodysplastic Syndrome (MDS)

Myelodysplastic Syndrome, or MDS, also referred to as pre-leukemia, is a rare disease in which the bone marrow functions abnormally and does not produce enough normal blood cells. The incidence of MDS is not known, but it is believed that there are approximately 10,000 to 20,000 new cases in the U.S. each year with the number increasing. Approximately 30% of patients with MDS may have their disease progress to develop into acute leukemia, a form of cancer where the patient has too many white blood cells. Weekly blood transfusions remains the principal therapy for less advanced types of MDS. Current treatments for the advanced types of the disease include chemotherapy and/or bone marrow transplantation. However, these therapies are ineffective or not available in the majority of cases.

We have orphan drug status for Thymoglobulin for the treatment of MDS and have a Phase IIb clinical study ongoing.

Bone Marrow or Stem Cell Transplantation

Bone marrow or stem cell transplantation is a standard therapy for many disease states, primarily cancer or pre-cancerous diseases. Stem cells, found in the peripheral blood or in the bone marrow, are given by an intravenous infusion to re-establish marrow function in a patient after ablation of the patient s bone marrow.

Immunosuppressive therapy, primarily anti-thymocyte globulin, or ATG, such as Lymphoglobuline and Thymoglobulin, chemotherapeutic agents and/or irradiation are given as part of a conditioning regimen. The goal of this regimen is threefold: to limit the patient s ability to mount an immune response to the new bone marrow or stem cells, to provide space for the new cells, and to destroy any residual cancer if the patient is being treated for a malignancy.

Some of these patients experience graft versus host disease, or GVHD. This is a condition in which the graft (i.e. the new immune system) begins to reject the host (i.e. the body). GVHD is a life-threatening complication that frequently occurs following an allogeneic bone marrow transplant. An allogeneic bone marrow transplant procedure involves transferring donor hemopoetic stem cells, the graft, from a healthy person into an immunosuppressed patient, the host. The transplant is intended to restore normal circulating blood and immune cells to a patient whose own hemopoetic and immune system has been ablated by the treatment of an underlying disease such as cancer and the conditioning regimen. Often a portion of the donor graft recognizes the host s own cells as foreign, becomes activated and attacks them, resulting in GVHD. GVHD typically involves damage to multiple organ systems, including the skin, liver and intestines. ABX-CBL is initially being developed to treat steroid-resistant GVHD.

Crohn s Disease and Ulcerative Colitis

Crohn s disease and ulcerative colitis are similar diseases that are often grouped together as inflammatory bowel disease. Industry sources estimate that there may be up to 1,000,000 Americans who suffer from inflammatory bowel disease. Crohn s disease is a chronic inflammatory disease of the gastrointestinal tract that usually causes diarrhea, abdominal pain, fever and rectal bleeding. Ulcerative colitis is a similar disease to Crohn s disease, but only infects the large intestine and is characterized by inflammation and ulceration of the innermost lining of the colon. Symptoms include diarrhea and sometimes abdominal pain. We are developing RDP58 for the treatment of both diseases.

Products and Product Candidates

The following table summarizes our principal products and product candidates.

Marketed Product	Indications/Potential Clinical Use	Status	Marketing Rights
Thymoglobulin/ Thymoglobuline	Prevention and treatment of acute graft rejection, severe aplastic anemia and steroid resistant GVHD	U.S.: Approved for treatment of acute kidney rejection episodes EU: Approved for prophylaxis and rejection in kidney, pancreas, and liver transplants; treatment of rejection crisis and acute GVHD in allogeneic bone marrow transplantation; and aplastic anemia	SangStat
Gengraf	Chronic immuosuppression (prevents organ rejection)	U.S.: Approved	SangStat and Abbott Laboratories jointly (U.S.)
Lymphoglobuline	Prevention and treatment of acute graft rejection, severe aplastic anemia and steroid resistant GVHD	Over 45 countries other than the U.S.: Approved	SangStat
Celsior			SangStat

Preservation of organs prior to transplantation	U.S.: Approved only for cardiac transplantation

Product Candidate	Indications/Potential Clinical Use	Status	Commercialization Rights
Smaller-Size Cyclosporine Capsule	Chronic immunosuppression (prevents organ rejection)	Bioequivalence study ongoing	SangStat
ABX-CBL	Treatment of steroid resistant GVHD	Phase II/III	SangStat and Abgenix
RDP58	Ulcerative colitis, Crohn s disease	Phase IIb	SangStat

Marketed Products

Thymoglobulin

Thymoglobulin is a pasteurized anti-thymocyte rabbit immunoglobulin that induces immunosuppression as a result of T-cell depletion and immune modulation. Thymoglobulin is made up of a variety of antibodies that recognize key receptors on T-cells, the cells of a transplant recipient s immune system that recognize and ultimately reject foreign objects such as transplanted organs. While the exact mechanism is unknown, researchers believe Thymoglobulin antibodies may inactivate and kill these T-cells, thus neutralizing the rejection process and allowing the transplanted organ to recover. Thymoglobulin is also used to treat aplastic anemia and steroid resistant GVHD. Thymoglobulin is approved in the U.S. only for treatment of kidney transplant acute rejection episodes.

Market

We (or our distributors) market Thymoglobulin in 56 countries, with a majority of our revenues coming from Europe and the U.S. We launched Thymoglobulin in the U.S. in February 1999. In the U.S., Thymoglobulin is currently approved for treatment of acute rejection in kidney transplant recipients. In other countries where Thymoglobulin is marketed, it generally has the following indications:

- prophylaxis and rejection in kidney, pancreas, and liver transplants;
- treatment of rejection crisis and acute GVHD in allogeneic bone marrow transplantation; and
- aplastic anemia.

We market and sell Thymoglobulin outside Europe and North America through distributors. We have a distribution agreement with Aventis for most countries outside of Europe and North America where Thymoglobulin is marketed. We have also entered into distribution agreements with distributors in certain Asian countries and are currently re-negotiating our distribution agreement with Aventis to obtain the right to distribute directly in certain territories.

Additional Clinical Studies

Induction/Prevention

We have initiated a comparative induction study of Thymoglobulin versus Simulect, a monoclonal antibody marketed by Novartis Pharmaceuticals Inc. (Novartis) in high-risk renal transplant recipients. Our intent in this study is to generate data comparing the clinical effects of Thymoglobulin with Simulect. It is not our intent to use this trial, and the FDA has indicated that this trial will not be sufficient, to support label indication changes or expansion. This prospective, randomized, open-label study is being conducted in over 20 transplant centers in the U.S. and Europe. Primary endpoints at 6 months will be graft survival, patient survival and incidence of acute rejection. We will also capture other important clinical data such as infections and incidence of delayed graft

function. The study was closed early in March 2002, with a total enrollment of 279 participants out of a planned 340, after an interim analysis revealed significantly fewer acute rejections of implanted kidneys in patients treated with Thymoglobulin versus Simulect. In the interim analysis, the incidence of acute kidney rejection was 2.5 times greater among patients treated with Simulect compared to patients who received Thymoglobulin and this was statistically significant. Further, there was no statistically significant difference in the rate of severe adverse events in either arm of the study. These interim results are preliminary and subject to change upon finalization of the study results.

Hematological Disorders and Malignancies

We have also initiated an open-label prospective, randomized, multi-center Phase IIb trial with Thymoglobulin in MDS. SangStat received orphan drug designation for Thymoglobulin for treatment of MDS in September 2000. Orphan drug designation is granted to applicants when the prevalence of the disease for which approval is sought occurs in less than 200,000 patients in the U.S. The advantages of this designation include a waiver of the user fee, possible marketing exclusivity and tax credits for development costs. These advantages are intended to encourage sponsors to develop drugs for patients with rare diseases.

The standard of care for low-risk MDS patients is weekly blood transfusions. The primary endpoint in this trial is transfusion independence at six months post therapy. This is an open-label randomized trial comparing observation (the control arm) to treatment with Thymoglobulin (3.25mg/kg for four days). Patient enrollment began in October 2000. In part because this is a rare disease, as evidenced by its orphan drug status, patient enrollment to date has been relatively slow. There are currently 26 patients enrolled in the study. We continue to expand the number of centers participating in the study with the aim of completing enrollment of 72 patients into the study by the end of 2002.

Gengraf® Cyclosporine Capsules

Cyclosporine, first approved in the U.S. in 1983, is a potent immunosuppressive agent. Cyclosporine inhibits the synthesis and release of the cytokine interleukin-2, which is essential to the body s immune response to transplanted organs. Gengraf cyclosporine capsule, a product of Abbott Laboratories, Inc., is a generic version of Neoral® capsules, which is marketed by Novartis. SangStat and Abbott co-promote and distribute Gengraf in the U.S. Gengraf is normally taken daily over the lifetime of the organ recipient to prevent organ rejection.

Cyclosporine Market

Cyclosporine is the leading immunosuppressive drug used to prevent organ and graft rejection in transplantation. Industry sources report that each year approximately 20,000 patients in the U.S. receive donated organs, and we estimate that there are approximately twice that number of patients receiving donated organs worldwide. While the size of the transplant population is difficult to ascertain at any given time, industry participants believe the population of organ transplant survivors to be more than 200,000 patients worldwide. The majority of these patients are prescribed daily doses of cyclosporine for the rest of their lives. Cyclosporine is also indicated for the treatment of rheumatoid arthritis and adult non-immunocompromised psoriasis patients. Worldwide sales of cyclosporine are greater than $1 billion per year. The U.S. market is approximately $500 million.

We entered into an agreement with Abbott in May 1999 for the co-promotion, distribution and research in the U.S. of Gengraf and SangCya Oral Solution. SangCya Oral Solution, which is a generic version of Neoral oral solution, was withdrawn from the U.S. market in July 2000 and is currently being sold on a limited basis only in the United Kingdom.

We launched Gengraf cyclosporine capsules in May 2000 in the U.S. through our combined SangStat/Abbott sales force. Gengraf s indications are identical to Neoral s indications and include (i) the prophylaxis of organ rejection in kidney, liver and heart allogeneic transplants; (ii) the treatment of patients with severe, active rheumatoid arthritis where the disease has not adequately responded to methotrexate; and (iii) the treatment of adult, non-immunocompromised patients with severe (i.e. extensive and/or disabling), recalcitrant, plaque psoriasis who have failed to respond to at least one systemic therapy (e.g. PUVA, retinoids or methotrexate), or in patients for whom either systemic therapies are contraindicated or cannot be tolerated.

Lymphoglobuline®

Lymphoglobuline is an anti-thymocyte equine immunoglobulin that induces immunosuppression as a result of T-cell depletion and immune modulation. In certain countries outside the U.S., it is approved for the prevention and treatment of rejection episodes in kidney, heart, pancreas, or liver transplantation. In hematology, Lymphoglobuline is approved in certain countries outside the U.S. for treatment of aplastic anemia and in the treatment of steroid resistant GVHD.

Market

We (or our distributors) market Lymphoglobuline in over 45 countries outside the U.S. Our sales force markets this product in Europe and Canada. Outside these countries, we sell Lymphoglobuline through our distribution agreement with Aventis or through other distributors. Aventis markets this product in Japan, where we believe a high percentage of sales occur for treatment of aplastic anemia. We hope to address U.S. market opportunities for Lymphoglobuline with the sale of Thymoglobulin. Therefore, we have no plans to seek approval for Lymphoglobuline in the U.S.

Celsior®

Celsior is a storage solution for organs after removal from the donor and before transplantation into the recipient. It is a sterile, nonpyrogenic, extracellular solution for hypothermic flushing and storage of hearts. Early graft loss remains a significant problem associated with cardiac transplantation and damage to the heart tissue can occur due to inadequate preservation. Effective organ preservation includes initial flushing of the heart tissue during the recovery process and cold storage while the donor heart is transported to the recipient. Celsior is the first and only flush and cold storage solution approved by the FDA for cardiac transplantation. It was designed specifically for cardiac transplantation to minimize myocardial edema, oxygen free radical-induced reperfusion injury, and diastolic stiffness.

Market

We sell Celsior throughout Europe, and we commenced marketing the product in the U.S. in September 1999. Celsior is approved for marketing in the U.S. only in connection with cardiac transplantation. Outside of Europe and North America, we sell Celsior through our distribution agreement with Aventis or through other distributors. In 1999, industry sources report that there were approximately 4,000 cardiac and lung transplants worldwide.

Principal Products In Development

Consistent with our strategic changes in October of 2000, we leveraged our success with Thymoglobulin to expand our research and development initiatives to include areas outside of transplantation, including immunology, hematology/oncology and auto-immune disease. Our

research and development expenses were $14.5 million in 1999, $20.8 million in 2000, and $17.9 million in 2001. These expenses primarily relate to additional indications for marketed products and new products in development.

We currently have three principal products in development:

Cyclosporine Capsules

We have an exclusive license to a pending patent application on a novel smaller-size cyclosporine capsule formulation from Tris Pharma, a small U.S. research and development company. We expect that the capsule will be smaller than currently marketed cyclosporine capsules. We are conducting a bioequivalence trial in healthy volunteers to demonstrate the new capsule s bioequivalence to Neoral cyclosporine capsules in water. If the results of the bioequivalence trial and stability testing are positive, we presently expect to file for marketing approval in a European country in late 2002. We have withdrawn our Marketing Authorization Application in the U.K. for our cyclosporine capsule product known as Sang-2000 in favor of this newer formulation. We intend to follow the European Community Mutual Recognition Procedure for obtaining regulatory approval in multiple Member States.

ABX-CBL

In August 2000, we entered into a global co-development, supply and license agreement for ABX-CBL with Abgenix under which we obtained an exclusive worldwide license for the marketing and sale of ABX-CBL. ABX-CBL is an anti-CD147 monoclonal antibody for the treatment of steroid resistant GVHD. The CD147 antigen is selectively expressed on activated immune cells including T cells, B cells and natural killer cells. In allogeneic blood and marrow transplantation (BMT), these activated immune cells attack a host s own cells as foreign, resulting in GVHD, where the transplanted cells are attempting to reject the recipient. GVHD often leads to damage to multiple organ systems, including the skin, liver and intestines. First line therapy is high dose corticosteroids, which have a success rate of approximately 50%. Steroid resistant GVHD has a high mortality rate. We believe ABX-CBL has the ability to destroy activated immune cells without affecting the rest of the immune system.

ABX-CBL is currently in a multi-center, randomized, and controlled Phase II/III study. The study is designed to demonstrate statistically significant efficacy of a single dose level of ABX-CBL in comparison to a control group of patients. Many patients that undergo an allogeneic bone marrow transplant develop steroid resistant GVHD for which there is currently no standard approved therapy available. However, many physicians prescribe a treatment regimen using the polyclonal equine antibody, ATGAM. In this study, patients are randomized to receive ATGAM (30 mg/kg QOD for 6 doses) in the control group versus patients who received ABX-CBL (0.1 mg/kg/d for 14 days followed by 12 infusions over the next 6 weeks) in the treatment arm. Our primary endpoint of this study is patient survival at 180 days. As of March 1, 2002, we have enrolled 82 out of 92 patients planned for this study and presently expect to complete the study by the end of 2002.

We received orphan drug designation for ABX-CBL for the treatment of steroid resistant GVHD in November 2000.

RDP58

RDP58 is a novel inhibitor of TNF-alpha synthesis currently in Phase II clinical trials in the U.K. This is our first product candidate from our own research and development efforts to enter such a clinical trial. RDP58 was designed using our drug design approach, in collaboration with Synt:em, that integrates advanced biology, biophysics, chemistry and information technology in a coordinated effort to design and develop potential therapeutic products. We are investigating the use of RDP58 for treatment of various auto-immune disorders. Ulcerative colitis and Crohn s disease are the two auto-immune disorders being examined in the current Phase II study.

Overview

Cytokines are protein messengers that coordinate the functions of immune cells and certain other cells and tissues. TNF-alpha is a cytokine that, when released in excess, can trigger activation of immune responses and inflammation. Continuous excessive TNF-alpha release can cascade into a variety of auto-immune diseases including inflammatory bowel disease, rheumatoid arthritis and psoriasis. There are currently a number of therapeutic products that target inhibition of TNF-alpha release. TNF inhibitors, including Remicade and Enbrel, have been approved for treatment since 1998 and 1999, respectively. They are considered the standard of care in the treatment of a variety of auto-immune diseases including Crohn s disease and rheumatoid arthritis. These therapeutic agents are being examined as a treatment for a number of other auto-immune diseases, including psoriasis, psoriatic arthritis and ankylosing spondylitis.

Animal models, including studies in primates, suggest that RDP58 could decrease levels of TNF-alpha, reduce inflammation, and improve clinical outcomes. Currently marketed TNF-alpha inhibitors work by binding to TNF-alpha after synthesis and excretion by the cell, thus neutralizing TNF-alpha in the blood before it can participate in the inflammatory response. In contrast, we believe RDP58 prevents the translation of TNF-alpha RNA, thereby preventing the synthesis of TNF-alpha protein within the cell. We believe that RDP58 could be a more efficient inhibitor of TNF-alpha as it prevents the synthesis of the protein as opposed to current therapy which attempts to inhibit the effects of its expression post-synthesis.

RDP58 is currently being tested in an oral formulation consisting of D-isomer amino acids. This peptide is resistant to enzymatic break-down during the digestive process, which is important for any oral therapeutic agent. Current TNF-alpha inhibitors are only available in non-oral form, either through a subcutaneous injection or through

intravenous administration.

Clinical Studies

We filed for Clinical Trial Exemption (CTX) with the U.K. Medicines Control Agency (the U.K. equivalent to the U.S. FDA) for RDP58 in September 2001 after successful completion of a Phase I normal volunteer dose escalation safety study. In the Phase I study, three groups of nine healthy volunteers participated in a dose escalation study using 3 doses for a total of 28 days. Oral RDP58 was found to be safe and well tolerated. The CTX allowed us to initiate Phase II proof-of-principle clinical trials in the fourth quarter of 2001. The Phase II trials are prospective, randomized, blinded trials in patients with mild-to-moderate ulcerative colitis or Crohn s disease. We expect to complete patient enrollment and announce the results of these studies in the second half of 2002. Pending the results of these studies, a clinical development and regulatory pathway will be defined and implemented.

Other Preclinical Developments

RDP58 is the subject of four additional development programs: neurology, non-IBD gastro-intestinal disorders, dermatology and pulmonary.

Neurology. RDP58 has been studied in the experimental auto-immune encephalomyelitis model of multiple sclerosis in rodents. The model is the standard of preclinical investigation for new therapeutic agents in the treatment of multiple sclerosis. The model requires animals to be injected with myelin basic protein on day 0, thus developing a predictable paralysis of the tail and hind limbs that begins on day 10 (after injection), peaks on day 12-13 and is completely resolved by day 18-20. The paralysis is used to simulate the mechanism of action found in multiple sclerosis. RDP58, when given as a single dose via intra-thecal injection, diminishes the paralysis in a dose dependent manner in this acute model (using doses of 15ug, 45ug and 150ug). At the highest dose, the paralysis appears to be completely eliminated. The timing of the treatment also has an impact on the disease progression. RDP58 can be given as a single dose on day 4, day 7 or day 10 after inoculation with myelin basic protein.

The currently approved standard of care for the treatment of multiple sclerosis is beta-interferon. Beta-interferon as a treatment regimen is most efficacious when commenced at the earliest point in the disease s progression, usually immediately after diagnosis and before any symptoms of the disease present themselves. Furthermore, beta interferon has been shown to be increasingly ineffective as the disease progresses and has shown little efficacy in minimizing or halting symptoms, such as paralysis after they present themselves in a patient. We believe that RDP58 presents a unique opportunity in multiple sclerosis as our preclinical models demonstrate that disease progression may be halted after the presentation of symptoms.

Non-IBD Gastro-intestinal disorders. Chemotherapy-induced diarrhea and diarrhea related to HIV are two significant gastro-intestinal disorders that affect thousands of people each year. CPT-11 is the most active drug against colon adenaocarcinoma, a form of colon cancer. Diarrhea is the most common side effect that limits the amount of CPT-11 that patients can tolerate. Prevention of diarrhea will allow increases in the dosage of CPT-11, potentially increasing

their response to this treatment. RDP58 has been shown to significantly decrease the incidence of diarrhea and mortality in a murine model of CPT-11 toxicity. In this model, 93% of mice given 200mg/kg of CPT-11 developed diarrhea and had a 63% mortality rate. In the study, of the mice that were given RDP58 in their drinking water starting three days before treatment with CPT-11, only 33% developed diarrhea and 93% of the animals survived. These preliminary experiments are being followed by studies to prove that RDP58 does not increase the rate of tumor growth and that RDP58 allows an increase in the maximally tolerated dose of CPT-11.

HIV-related diarrhea is a malabsorption syndrome that results in nutrient loss and poor drug absorption. This translates into increased weight loss and viral tiers in patients who suffer from HIV-related colitis. Researchers at the University of California at Davis, with the support of scientists at SangStat, were awarded a National Institute of Health grant to study the impact of RDP58 on the gastro-intestinal complications of HIV in the HIV primate model. In this study, RDP58 was found to increase the CD4+ lymphocyte population of the gastrointestinal mucosa. We expect to explore this finding in a pilot clinical trial.

Dermatology. TNF-alpha appears to play an important role in psoriasis and possibly in atopic dermatitis. RDP58 has been fashioned into a topical gel that will be used to determine efficacy in these two dermatologic diseases.

Animal toxicology studies are underway. We expect to begin patient studies after completion of the toxicology studies.

Pulmonary. RDP58 is a powder formulation that may be used as an aerosol to provide inhalation therapy for asthma, chronic obstructive pulmonary disease, sarcoidosis and other pulmonary diseases. Preliminary animal experiments have been performed to demonstrate the feasibility of this approach. We are pursuing partners to continue development in this therapeutic arena.

Sales and Marketing

In the U.S., we market products through our direct sales force. As of December 31, 2001, we had 21 account managers, supervised by three regional sales directors, who call on or sell primarily to the approximately 260 transplant centers in the U.S. A number of the account managers have backgrounds in transplantation, either from selling other transplant products or with clinical backgrounds as nurses or as transplant coordinators in transplant centers. We also have two national account directors who call on group purchasing organizations and managed care groups.

Sales to Cardinal Health Inc., McKesson Corporation, AmeriSource and Bergen Brunswig Drug Company accounted for 26%, 18%, 12% and 11%, respectively, of total revenues in 2001. Sales to Cardinal Health Inc. and McKesson Corporation accounted for 13% and 15%, respectively, of total revenues in 2000. Sales to McKesson Corporation accounted for approximately 11% of our total revenues in 1999.

We have approximately 32 sales and marketing people throughout the major European markets.

Strategic Relationships

We evaluate on an ongoing basis potential collaborative relationships with corporate and other partners where such relationships may complement and expand SangStat s research, development, sales and marketing capabilities.

Abbott Laboratories

In May 1999, we signed a multi-year co-promotion, distribution and research agreement with Abbott for SangCya Oral Solution (which was withdrawn from the U.S. market in July 2000) and Gengraf in the U.S. We are the exclusive distributor for Gengraf and share marketing, promotional and development expenses as well as the profits from the co-promotion of the product with Abbott. The agreement ends December 31, 2004 unless both companies agree to extend it. Pursuant to this agreement, Abbott made an equity investment of $14 million during 1999 in exchange for approximately 894,000 shares of common stock, representing a premium to fair market value at that time aggregating to $1.3 million. In addition, Abbott made a series of up-front and milestone payments totaling $20.8 million, including $6.9 million received in 2000, and a long-term loan of $16 million to us received during 1999. In January 2000, we made a milestone payment of $4.0 million to Abbott under

the terms of the agreement. No further milestone payments are required from either company. All up-front and milestone payments received, net of milestone payments made, and the premium received on the sale of common stock to Abbott are recorded as deferred revenue and recognized ratably over the term of the agreement as revenue from collaborative agreements. In May 2000, Abbott and we launched Gengraf, the cyclosporine capsule developed by Abbott. In connection with the equity investment, Abbott and we entered into a Right of First Refusal Agreement and a Registration Rights Agreement, and amended and restated our existing Supply Agreement.

Abgenix

In August 2000, we entered into a global co-development, supply and license agreement with Abgenix, Inc., for ABX-CBL, an antibody developed by Abgenix. Under the agreement, we have an exclusive worldwide license for the marketing and sale of ABX-CBL. ABX-CBL is an anti-CD147 monoclonal antibody for the treatment of steroid resistant GVHD and is currently in a multicenter, randomized, and controlled Phase II/III study. Development costs will be shared equally, as would any potential profits from the sales of collaboration products. We share responsibility for product development with Abgenix, including the ongoing Phase II/III clinical trial. We will market any potential products and Abgenix will be responsible for manufacturing ABX-CBL. We also have the right, subject to the terms and conditions of the agreement, to commercialize other anti-CD147 antibodies developed

by Abgenix.

Under the terms of the agreement, we made an initial license fee payment of $1 million to Abgenix. Two additional milestone payments of $1 million are due to Abgenix under the terms of the agreement contingent on achievement of certain milestones. The license fee payment and the milestone payments, if any are paid to Abgenix, will be non-refundable and non-creditable against any future obligations under this agreement.

If ABX-CBL receives regulatory approval and is launched, we will be required to pay Abgenix for our share of development expenses incurred prior to January 1, 2000. The amount has not been determined, but the agreement limits our obligation to $6,100,000. We do not have any obligation to reimburse Abgenix until the first anniversary of the launch of ABX-CBL and the timing of reimbursement varies depending on ABX-CBL s sales. We also must reimburse Abgenix for one-half of the development costs incurred for ABX-CBL from January 1, 2000 to August 8, 2000, with our share being approximately $1.9 million. We have paid Abgenix $1.4 million as of December 31, 2001 and the remaining $0.5 million is payable by the end of June 2002. The license fee and the initial reimbursement of development expenses are recorded as research and development expenses.

Aventis

We entered into a Distribution Agreement with Aventis in May 1999 with an initial expiration date of March 31, 2002. The agreement automatically extends for additional one year periods unless either party gives notice of termination. The current expiration date is March 31, 2003. Aventis is our exclusive distributor for Thymoglobulin and Lymphoglobuline for most countries outside of North America, Europe and Japan (where Thymoglobuline and Lymphoglobuline are distributed by Aventis). Aventis sells these products either through its local subsidiary or through a distributor that often distributes other Aventis products. We renegotiated this agreement in 2001 and have contracted directly with distributors in Asia where Aventis has no direct presence (e.g. Israel and certain Asian countries). We are also in negotiations to extend the current contract directly with Aventis subsidiaries in the countries where Aventis does have a direct presence and with current Aventis distributors in certain other countries (e.g. Middle East and Africa).

Aventis also performs certain steps in the manufacturing process of Thymoglobulin and Lymphoglobuline. In addition, pursuant to the purchase of IMTIX on September 30, 1998, we pay Aventis royalties on Thymoglobulin and Lymphoglobuline contingent upon the sales of these products. In 1999 and 2000, royalty payments on Lymphoglobuline to Aventis totaled approximately $646,000 and $622,000 respectively. For the year ended December 31, 2001, royalty payments on Lymphoglobuline and Thymoglobulin totaled approximately $2,155,000. We expect these royalty payments to increase in future years since we began paying royalties on Thymoglobulin during the third quarter of 2001. The royalty payments on Thymoglobulin increased on the third anniversary of the purchase of IMTIX (October 1, 2001) and will decrease again three years thereafter.

Synt:em

In July 2001, we entered into a three year research collaboration agreement for the discovery of next generation RDP58 molecules with Synt:em, a French biopharmaceutical company. The aim of this collaboration is to design novel RDP58-like compounds for the inhibition of inflammation in new in vivo applications using Synt:em s proprietary rational design technology, Acti:map. The agreement builds on earlier development efforts between SangStat and Synt:em with Allotrap peptides which led to the original discovery of RDP58. Under the terms of the collaboration SangStat performs in vitro and in vivo testing of peptides and novel rationally designed peptides while Synt:em uses its Acti:map technology to

perform the rational design work.

Competition

The drug industry is very competitive. The drugs we market compete with existing and new drugs being created by pharmaceutical, biopharmaceutical, and biotechnology companies and universities. Many of these entities have significantly greater research and development capabilities, as well as substantial marketing, manufacturing, financial and managerial resources and represent significant competition for us. Many of the competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing the desired

therapeutic effect than products we are developing or marketing and may be more effective and less costly. In addition, many of our competitors have significantly greater experience than we do in conducting clinical trials of pharmaceutical products and obtaining regulatory approvals of such products. This could cause our competitors to succeed in commercializing products more rapidly than we can. The principal factors upon which our products compete are:

- product utility,
- therapeutic benefits,
- ease of use,
- pricing, and
- effective marketing

We believe we compete favorably with respect to all of these factors.

Competitive products with respect to our material products include the following:

Our Products	Competitive Products	Competitor
Thymoglobulin/ Lymphoglobuline.....	Orthoclone OKT®3	Ortho Biotech
	ATGAM®	Pharmacia
	Simulect®	Novartis AG
	Zenapax®	Roche
Gengraf & cyclosporine capsules.....	Neoral	Novartis AG
	Sandimmune	Novartis AG

	Prograf®	Fujisawa Pharmaceutical Co. Ltd.
	Rapamune	Wyeth
	Generic cyclosporine capsule	Eon Labs
	Generic cyclosporine capsule	Sidmak

Competitive products with respect to our product candidates include the following:

Our Product Candidates	Competitive Products	Competitor
ABX-CBL.....	MEDI-507	Medimmune/BioTransplant
	Nuvion (HuM291)	Protein Design Labs
RDP58.....	Enbrel®	Immunex-AHP
	Remicade®	Johnson & Johnson

Gengraf and our cyclosporine capsule in development are generic and compete against the branded cyclosporine products as well as other generic cyclosporine products that have been or may be approved. These products also compete against Prograf, marketed by Fujisawa Pharmaceutical Co. Ltd, which was approved by the FDA to be taken instead of cyclosporine. Roche s Cellcept® is indicated as a conjunctive therapy, to be taken with cyclosporine

rather than instead of cyclosporine. As noted above, Thymoglobulin competes with OKT3, ATGAM, Simulect, and Zenapax. In the U.S., Thymoglobulin has been successful in establishing a market share against these products, which were all previously on the market. In Europe, Novartis and Roche have just started selling Simulect and Zenapax, respectively, and we believe that the launch of these two products may impact sales of Thymoglobulin and Lymphoglobuline in Europe.

ABX-CBL is expected to compete against two products that are also in clinical trials for the treatment of GVHD: Medimmune/BioTransplant s MEDI-507 and Protein Design Labs Nuvion. In addition, other products are used for the prevention of GVHD and would therefore eliminate the need to use ABX-CBL for treatment.

RDP58 is an inhibitor of TNF-alpha synthesis. TNF-alpha is a cytokine released in excess in various autoimmune disorders. For that reason, many companies are pursuing development of a TNF-alpha inhibitor and we believe there could be substantial competition in this area. In addition, Immunex/AHP s Enbrel and Johnson & Johnson s Remicade are both TNF-alpha inhibitors that are currently approved for rheumatoid arthritis and Crohn s disease, respectively.

Patents and Proprietary Technology

We have twenty-seven issued patents and nine pending patent applications in the U.S. and are pursuing corresponding patent applications in other countries with respect to the products we are selling, the products we have in development and our research areas. We aggressively seek patent protection on our inventions and our policy is to enforce our intellectual property rights. We have no issued patents covering Thymoglobulin and Lymphoglobuline, and rely on our manufacturing know-how to protect these products. We have issued patents covering Celsior. With respect to our cyclosporine capsules, we have in-licensed a pending formulation patent application. The cyclosporine compound is no longer patent-protected and there are several generics on the market in the U.S. We are pursuing patent protection for RDP58 and we believe that an issued patent may give us a competitive advantage.

Our patents expire on various dates beginning in the year 2008 and ending in the year 2017.

In addition, as discussed above, we have also licensed certain patents and patent technology from others. We have an exclusive, worldwide license from Stanford University for certain issued patents and pending patent applications in the HLA and peptide area. We have licensed from Abgenix certain patents and patent applications that relate to ABX-CBL. We have licensed additional patents relating to cyclosporine from the University of North Carolina and a pending application from Tris Pharma. The licensor for each of these licenses is primarily responsible for prosecution of these patents and patent applications.

Patent applications in the U.S. are maintained in secrecy until patents are issued. Since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we were the first to discover compositions covered by our pending patent applications or the first to file patent applications on such compositions. Our pending patent applications may not result in issued patents, our issued patents may not afford protection against a competitor and our products may infringe on other patents.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements with our employees and consultants.

We have registered or applied for registration of the names of all of our marketed products and plan to register the names of our products under development once a name has been selected for the product candidate.

Manufacturing

Manufacturing pharmaceutical products is a highly regulated process. The FDA and other regulatory agencies require that manufacturing be done in accordance with current Good Manufacturing Practices, or GMP. Additionally, products can only be manufactured in facilities approved by the applicable regulatory authorities.

When we acquired IMTIX in 1998, we also acquired the manufacturing unit in Lyon, France that manufactured Thymoglobulin and Lymphoglobuline. Currently Aventis also performs certain steps in the manufacturing process

of Thymoglobulin and Lymphoglobuline under contract to us. We perform the remaining manufacturing steps ourselves in manufacturing facilities that we lease from Aventis. These agreements with Aventis expire on dates ranging from 2008 to 2013. We believe that our facility currently complies with GMP. However, we likely would be unable to quickly and efficiently replace our manufacturing capacity if we were unable to manufacture Thymoglobulin or Lymphoglobuline as a result of subsequent FDA or other regulatory inspections or otherwise, or if one of our manufacturers were unable to manufacture one of our other products for us.

We have no other manufacturing facility and the Lyon facility could not be used for products other than biologics. Therefore, we rely on third parties to manufacture our other products, both those that we sell and those in development. We depend on such third parties to perform their obligations in compliance with all regulatory requirements and on a timely basis. If any of our contract manufacturers fail to perform, such failure may delay our clinical development or submission of products for regulatory approval or result in product shortages with respect to our marketed products.

Abgenix is responsible for the manufacturing of ABX-CBL. If the supplier they have chosen is unwilling or unable to perform, it may delay our clinical development or submission of products for regulatory approval, or result in product shortages with respect to our marketed products.

With respect to raw materials, we have agreements for commercial scale production of cyclosporine bulk material with Gensia Sicor and Abbott. Our Gensia Sicor agreement runs until December 31, 2005 and has an automatic one-year term renewal unless one party gives notice. Our Abbott agreement terminates December 31, 2004 and is automatically renewed until one party gives notice. Bulk cyclosporine is difficult to manufacture since it must be extracted from whole cells and carefully purified. At December 31, 2001 there were no commitments to purchase any bulk cyclosporine. We believe we have sufficient quantities of bulk cyclosporine to meet our current needs. We believe we also have sufficient quantities of raw materials for our other products and product candidates.

Warehousing and Distribution

We use a logistics provider to store and distribute our products from one central warehousing location in Memphis, Tennessee. When our logistics provider receives a purchase order through electronic data input, phone, mail or facsimile, it sends the order to the warehouse for shipment, usually within 24 hours, to the customer placing the order. The logistics provider is also responsible for invoicing and collections.

Government Regulation

Our research and development activities, preclinical studies and clinical trials, and ultimately the manufacturing, marketing and labeling of our products, are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries (Regulatory Agencies). The U.S. Federal Food, Drug, and Cosmetic Act (the Act) and the regulations promulgated thereunder and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising, promotion, import and export of our products and product candidates. Preclinical study and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would harm our ability to commercialize any product candidates we develop and our ability to receive product revenues. If regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed.

Our products in clinical trials during 2002 may include Thymoglobulin for expanded labeling, ABX-CBL, RDP58, and bioequivalence studies for our cyclosporine capsule product.

Our clinical trials may not be completed successfully or within any specified time period. Either the FDA or we may suspend clinical trials at any time, if either of us concludes that clinical subjects are being exposed to an unacceptable health risk, or for other reasons. The conduct of clinical trials is complex and difficult, especially in Phase III. The design or the performance of the Phase III clinical trial protocols may not be successful.

The results of preclinical studies and clinical trials, if successful, are submitted in an application to seek FDA

approval to market the drug or biological product for a specified use. The testing and approval process requires substantial time and effort, and there can be no assurance that any approval will be granted for any product or that approval will be granted according to any schedule. The FDA may refuse to approve an application if it believes that applicable regulatory criteria are not satisfied. The FDA may also require additional testing for safety and efficacy of the drug. Moreover, if regulatory approval of a drug product is granted, the approval will be limited to specific indications. Our product candidates may not receive regulatory approvals for marketing, or if approved, that approval may not be for the indications that we requested.

Other Regulatory Agencies follow similar procedures to those required by the FDA and require that the safety and efficacy of our pharmaceutical product candidates be supported through adequate and well-controlled clinical trials. If the results of our pivotal clinical trials submitted in application for approval do not establish the safety and efficacy of our product candidate to the satisfaction of any Regulatory Agency, we will not receive the approvals necessary to market our product candidate in that country.

In the European Union, or EU, the registration process for products can be done through a decentralized procedure. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more Member States, certify that the dossier is identical to that on which the first approval was based or explain any differences and certify that identical dossiers are being submitted to all Member States from which recognition is sought. Within 90 days of receiving the application and assessment report, each Member State must decide whether to recognize the approval. The procedure encourages Member States to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. If such disputes cannot be resolved within the 90-day period provided for review, the application will be subject to a binding arbitration procedure.

Following approval, Regulatory Agencies continue to regulate our approved and marketed products. We must report adverse drug events associated with our products to Regulatory Agencies. In addition, Regulatory Agencies also inspect on a regular basis the equipment and facilities used to manufacture our products. A Regulatory Agency may suspend the manufacturing facilities (and order a recall of our products manufactured in that facility) if the Regulatory Agency believes that the product has not been manufactured in compliance with regulations.

Employees

As of December 31, 2001, we employed 263 people worldwide, of which 101 are in the U.S. and Canada and 162 are in Europe, which includes approximately 65 employees in our manufacturing facility in Lyon, France. Most of our employees in the Lyon, France, facility are represented by labor unions. We believe that we maintain good relations with our employees.

Management

Our executive officers and directors and their ages at December 31, 2001 are as follows:

Name	Age	Position
Jean-Jacques Bienaimé.....	48	Chairman of the Board, Chief Executive Officer and President
Steve Aselage.....	50	Senior Vice President, North American Sales and Marketing
Roland Buelow, Ph.D.....	43	Senior Vice President, Discovery Research
Stephen G. Dance.....	50	Senior Vice President, Finance
Ralph E. Levy.....	53	Senior Vice President, Operations
Raymond J. Tesi, M.D.....	46	Senior Vice President, Clinical Development and Medical Affairs
Robert C. Floc h, Ph.D.....	53	General Manager of IMTIX-SangStat

Fredric J. Feldman, Ph.D.....	62	Director
Richard D. Murdock.....	55	Director
Andrew J. Perlman, M.D., Ph.D.....	54	Director
Nicholas J. Simon III.....	47	Director
Vincent R. Worms.....	49	Director

Jean-Jacques Bienaimé has been our President since June 1998 and became Chief Executive Officer in February 1999. He also served as our Chief Operating Officer from June 1998 to February 1999. He was elected to the Board of Directors in March 1999. Mr. Bienaimé became Chairman of the Board of Directors in October 2000. From September 1992 to May 1998 Mr. Bienaimé was with Rhone Poulenc Rorer, Inc., a pharmaceutical company, rising to the position of Senior Vice President, Corporate Marketing and Business Development. He is currently a member of the board of Fox Chase Cancer Center and AeroGen Inc., a public drug delivery company. Mr. Bienaimé received his degree in economics from Ecole Superieure de Commerce de Paris in France and an M.B.A. from the Wharton School, University of Pennsylvania.

Steve Aselage joined us in February 1999 and currently is our Senior Vice President, North American Sales and Marketing. From 1995 to January 1999, Mr. Aselage was the Director of Sales and Marketing at Advanced Tissue Sciences, a tissue engineering company. Mr. Aselage received a B.S. in biology from the University of Notre Dame.

Roland Buelow, Ph.D. joined us in 1993 and currently is our Senior Vice President of Discovery Research. Dr. Buelow received a Ph.D. in Biology from the Max-Planck Institute for Biology in Tuebingen, Germany. Dr. Buelow visited the University of Texas as a Fulbright scholar and spent two years at Stanford Medical School.

Stephen G. Dance has been our Senior Vice President, Finance since April 1999. From July 1998 to April 1999, Mr. Dance was Director of Financial Accounting, Planning and Reporting at Plantronics, Inc., a telecommunications company. From 1983 to July 1998, Mr. Dance held various positions with Syntex Corporation, a pharmaceutical company, which was acquired by Roche Holding Ltd., also a pharmaceutical company, in 1994, serving most recently as Controller, Syntex Laboratories, Inc. Mr. Dance holds a B.A. in French from Leeds University in England, is a Certified Public Accountant in the State of California and a fellow of the Institute of Chartered Accountants in England and Wales.

Ralph E. Levy joined us in 1990 and currently is our Senior Vice President, Operations. Mr. Levy received a B.S. in chemistry from the City College of New York and an M.S. in chemistry from Seton Hall University.

Raymond J. Tesi, M.D. joined us in May 1997 and currently is our Senior Vice President, Clinical Development and Medical Affairs. From 1994 until 1997, Dr. Tesi was an associate professor of surgery and director of the extra-renal transplantation program at Tulane Medical School in New Orleans, Louisiana. He was a transplantation surgical fellow at the Ohio State University Hospital. Dr. Tesi received an M.D. from the Washington University School of Medicine in St. Louis, Missouri.

Robert C. Floc h, Ph.D. has been the General Manager of our IMTIX-SangStat subsidiary since we acquired IMTIX in September 1998. In addition, Dr. Floc h has been General Manager at SangStat Atlantique, our previous operating subsidiary in France, since 1992. Dr. Floc h received a doctor of pharmacy degree and a Ph.D. in medical chemistry from the University of Nantes.

Fredric J. Feldman, Ph.D. has been a director since March 1992. He has been the President of FJF Associates, a consultant to health care venture capital and emerging companies, since February 1992. From September 1995 to June 1996 he was the Chief Executive Officer of Biex, Inc. a women s healthcare company. Dr. Feldman returned to his position as Chief Executive Officer of Biex from 1999 to 2000. He is a director of OrthoLogic Corporation and Ostex International, Inc., both public medical device companies. Dr. Feldman received his Ph.D. in Analytical Chemistry from the University of Maryland and his B.S. in Chemistry from Brooklyn College of City University of New York.

Richard D. Murdock has been a director since October 1993. Since October 2001, Mr. Murdock has been the President, Chief Executive Officer and Director of InPro Biotechnology, a biotechnology company involved in the diagnosis and treatment of neurodegenerative diseases. From December 1998 until March 2001, Mr. Murdock was the President and Chief Executive Officer and a director of Kyphon, Inc., an orthopedic medical device company. From September 1991 to October 1998, Mr. Murdock served as the Chief Executive Officer and a director of CellPro, Incorporated, a public biotechnology company. Mr. Murdock received his B.S. in Zoology from the University of California at Berkeley.

Andrew J. Perlman, M.D., Ph.D. has been a director since December 1992. In February 2002, he became Chief Executive Officer and a director of Affymax, Inc., a privately held biopharmaceutical company. Prior to that, Dr. Perlman had been Executive Vice President at Tularik, Inc., a public biotechnology company, since September 1999. From November 1997 to September 1999, Dr. Perlman served as Tularik s Vice President, Medical Research and Corporate Development. From January 1993 to November 1997, Dr. Perlman served as Tularik s Vice President of Medical Research. Dr. Perlman received his M.D. and his Ph.D. in Physiology from New York University.

Nicholas J. Simon III has been a director since July 2001. Mr. Simon is a General Partner at MPM Capital, a leading life sciences venture capital firm. Prior to joining MPM Capital, Mr. Simon was CEO of Collabra Pharma, Inc., a pharmaceuticals development company, from March 2000 until joining MPM Capital in October 2001. Mr. Simon joined Genentech, Inc. in December 1989 and from 1994 to April 2000 served as Vice President of Business and Corporate Development. Mr. Simon is also Chairman of the Board of Deltagen, Inc., and a director of InterMune, Inc. both public biotechnology companies. In addition, he serves on the board of directors of several private companies. Mr. Simon holds an M.B.A. from Loyola College.

Vincent R. Worms has been a director since October 1991. Mr. Worms has been a General Partner of Partech International, a venture capital management fund, since 1982. Mr. Worms is presently a director of Informatica, a public software company. He received his engineering degree from Ecole Polytechnique in Paris, and his M.S. degree from the Massachusetts Institute of Technology.

Risk Factors

We have a history of operating losses and our future profitability is uncertain.

We were incorporated in 1988 and have experienced significant operating losses since that date. As of December 31, 2001, our accumulated deficit was $187.0 million. While the quarter ended December 31, 2001 was our first profitable quarter, we may recognize losses in subsequent quarters for a variety of reasons. If we are unable to maintain or increase sales of our existing products, particularly Thymoglobulin, and develop and subsequently market our products in development, our business and operating results will be adversely affected.

To date, our product revenues have been primarily derived from sales of Thymoglobulin, Lymphoglobuline, and Gengraf. Revenues from Thymoglobulin were 69%, 60% and 54% of total revenues in 1999, 2000 and 2001, respectively. Revenues from Lymphoglobuline were 19%, 12% and 8% of total revenues in 1999, 2000 and 2001, respectively. In addition, revenues from Gengraf were 18% and 31% of total revenues in 2000 and 2001, respectively. Revenues from SangCya Oral Solution were immaterial in 1999, 2000 and 2001.

Our expectations with respect to achieving positive cash flow and financial reporting profitability are subject to risk and uncertainty. While we recently had our first profitable quarter, we may not be able to establish positive cash flow or to maintain or increase our financial reporting profitability on a quarterly or annual basis. Our ability to achieve positive cash flow and financial reporting profitability will be significantly dependent upon our success in, among other things:

maintaining and increasing revenues from Thymoglobulin, Lymphoglobuline and Gengraf, particularly Thymoglobulin;

successfully commercializing our product candidates, especially ABX-CBL and RDP58;

limiting our manufacturing and selling, general and administrative expenses; and

controlling research and development expenses.

Our operating results may also be affected by the licensing of complementary products or the acquisition of strategic companies we may effect in the future. Any such acquisition or licensing could have the immediate effect of causing an operating loss in future periods.

Fluctuations in quarterly and annual operating results may decrease our stock price.

Our quarterly and annual operating results may fluctuate due to a variety of factors, and these fluctuations may not match the expectations of investors and any securities analysts. This could cause the trading price of our common stock to decline. We therefore believe that quarter-to-quarter comparisons of our operating results may not be a good indication of our future performance, and you should not rely on them to predict our future performance or the future performance of our stock. Our operating losses have been substantial each year since inception. We also expect our operating results to fluctuate significantly as a result of a number of factors, including:

- the uncertainty in the timing and the amount of revenue we earn upon product sales;
- our achievement of research and development milestones;
- expenses we incur for product development, clinical trials and marketing and sales activities;
- the licensing of new products or the acquisition of other companies;
- the introduction of new products by our competition;
- regulatory actions;
- market acceptance of our products;
- manufacturing capabilities;
- cost of litigation; and
- third-party reimbursement policies.

Fluctuations in our operating results have affected our stock price in the past and are likely to continue to do so in the future.

Our future growth depends on sales of key products.

We expect to derive most of our future revenues from sales of Thymoglobulin, Lymphoglobuline, and Gengraf. We have limited experience selling our products in the U.S. Our sales of Thymoglobulin began in the U.S. in February 1999. We began distributing Gengraf in May 2000. We are marketing Gengraf in the U.S. under a co-promotion agreement with Abbott Laboratories. Abbott may not effectively market Gengraf, and its failure to do so may adversely impact sales of these products.

Because we expect Thymoglobulin, Lymphoglobuline and Gengraf to be key revenue-generating products, any factor decreasing sales of these products, particularly Thymoglobulin, would harm our financial results. In addition, a delay in regulatory approval of our cyclosporine capsule product would harm our future financial results. The following factors could harm the sale or approval of these products:

- the timing of regulatory approval and market entry relative to competitive products;
- the availability of alternative therapies;
- perceived clinical benefits and risks;
- competitive changes;

regulatory issues;

ease of use;

changes in the prescribing practices of physicians;

the availability of third-party reimbursement; or

product liability claims.

In particular, with respect to Thymoglobulin, the following factors may decrease sales:

the price of our products relative to alternative therapies;

manufacturing or supply interruptions; or

competitive pressures from Novartis, Pharmacia and Roche.

With respect to Gengraf and our proposed smaller-size cyclosporine capsule, the following factors may, in particular, decrease revenue:

perceptions of both patients and physicians regarding use of a generic version of a critical, life-saving therapeutic;

perception of bioequivalence;

number of contracts with managed care providers and group purchasing organizations;

pricing pressure from other generic competitors;

intense competitive pressure from Novartis; and

Novartis s litigation with the Food and Drug Administration, the Medicines Control Agency in the U.K. and Abbott.

From time to time, we have experienced seasonality in our product sales, which in the past has resulted in weakness in our first quarter results. We may experience similar seasonality in this or other quarters in the future.

Four wholesalers account for a high percentage of our revenues, and the failure to maintain or expand these relationships could harm our business.

A substantial portion of demand for our products is from customers such as hospitals and pharmacies who purchase our products from wholesalers, including Cardinal Health Inc. and McKesson Corporation. Approximately 13% and 15%, respectively, of total revenues in 2000 were derived from sales to customers who place orders through these two wholesalers, and in 2001, sales to Cardinal Health Inc., McKesson Corporation, AmeriSource and Bergen Brunswig Drug Company accounted for approximately 26%, 18%, 12% and 11%, respectively, of total revenues. We expect that we will continue to derive a substantial portion of our revenue from Cardinal Health Inc. and McKesson Corporation. The loss of either of these wholesalers could harm our business and operating results.

We may not be able to manufacture or obtain sufficient quantities of our products, which could lead to product shortages and harm our business.

Our manufacturing facility in Lyon, France, must meet FDA standards of Good Manufacturing Practices and other regulatory guidelines. The FDA and other regulatory authorities inspect our manufacturing facility to ensure that it meets regulatory standards. The FDA, as well as the Canadian and French health authorities, inspected our Lyon facility in February and March 2002. If the FDA or Canadian authority believes that we are not complying with its guidelines, it can issue a warning letter or prevent the import of Thymoglobulin into the U.S. or Canada, which would cause an immediate and significant adverse effect on our business and operating results. In addition,

Thymoglobulin and Lymphoglobuline are biological products, which are more difficult to manufacture than chemical compounds. We rely on Aventis for certain important manufacturing services, including quality assurance, quality control, and lyophilization, a step in the manufacturing process which involves removing the water from the product, similar to freeze-drying. Aventis may not continue to effectively and continuously provide us these critical manufacturing services. In addition, we may have difficulties manufacturing Thymoglobulin or Lymphoglobuline in the future that may impair our ability to deliver products to our customers, which could reduce our revenues.

Although we primarily use our own facilities to manufacture Thymoglobulin and Lymphoglobuline, we rely on third parties to supply us with raw materials. These third parties may stop supplying us with the materials we need at any time, and we may have to find new suppliers. We have six suppliers of rabbit serum used for the manufacturing of Thymoglobulin. We recently had a dispute with two former suppliers of rabbit serum. IFFA CREDO and Elevage Scientifique des Dombes, two affiliated suppliers, sued our French subsidiary for breach of contract after we reduced our orders of rabbit serum from them. As a result of a court ruling against us in this lawsuit, we recorded a charge of $3,250,000 to other expense net for the year ended December 31, 2001, which, combined with reserves recorded in fiscal 2000, fully provided for the court award of $3,600,000. On March 22, 2002, the appeals court upheld the lower court decision and assessed interest against us of approximately $204,000 which has been recorded as a charge to other expense net for the year ended December 31, 2001.

Our reliance on third parties for manufacturing may delay product approval or, once approved, result in a product shortage, which would reduce our revenues.

Except for Thymoglobulin and Lymphoglobuline, third parties manufacture all of our products and product candidates. We rely on Abbott Laboratories and Gensia Sicor for the manufacture of bulk cyclosporine. Abbott Laboratories manufactures Gengraf, and Federa (Fresenius Kabi France) manufactures Celsior for us. Some of the risks associated with using third parties for manufacturing are as follows:

the manufacturer may not pass a pre-approval inspection or, once approved, may not continue to manufacture to the FDA s and other regulatory authorities standards;

the manufacturer may not timely deliver adequate supplies of a sufficiently high quality product in the timeline necessary to meet product demand; and

we may not be able to obtain commercial quantities of a product at an economically viable price.

In addition, we may not be able to enter into commercial scale manufacturing contracts on a timely or commercially reasonable basis, or at all, for our product candidates. Abgenix, from whom we have licensed ABX-CBL, is responsible for maintaining the manufacturing agreement for ABX-CBL with Lonza Biologics PLC, the third party manufacturer of this product candidate. Similarly, we rely on Accucaps Industries Limited to supply us with cyclosporine capsules and UCB S.A. to supply us with bulk RDP58 for research and clinical purposes. For some of our potential products, we will need to develop our production technologies further for use on a larger scale to conduct human clinical trials and produce such products for sale at an acceptable cost.

If our manufacturers fail to perform their obligations effectively and on a timely basis, these failures may delay clinical development or submission of products for regulatory approval or, once a product is approved, result in product shortages, which could harm our business and operating results. Additionally, because our manufacturers can only manufacture our products in facilities approved by the applicable regulatory authorities, we may not be able to replace our manufacturing capacity quickly or efficiently in the event that our manufacturers are unable to manufacture our products.

Government regulation imposes significant costs and restrictions on the development and commercialization of our products, and we may not obtain regulatory approvals for our products.

Our research, preclinical development, clinical trials, manufacturing, marketing and distribution of our products in the U.S. and other countries are subject to extensive regulation by numerous governmental authorities including, but not limited to, the FDA. In order to obtain regulatory approval of a drug product, we must demonstrate to regulatory agencies, among other things, that the product is safe and effective for its intended uses and that the manufacturing

facilities are in compliance with Good Manufacturing Practices requirements. The process of obtaining FDA and other required regulatory approvals is lengthy and will require the expenditure of substantial resources, and we do not know if we will obtain the necessary approvals for our product candidates. Further, for our approved products, the marketing, distribution and manufacture of our products remains subject to extensive ongoing regulatory requirements administered by the FDA and other regulatory bodies. Failure to comply with applicable regulatory requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval, withdrawal of approvals and criminal prosecution of SangStat and our employees.

We may not achieve the anticipated benefits from the acquisition or licensing of other products or companies, and any such transaction could harm our business and operating results.

We may use a portion of our funds for the licensing of new products or the acquisition of other companies. We expect that the licensing or acquisition of products or companies in an early stage of development would require substantial additional investment prior to yielding anticipated returns. Moreover, we may fail to ultimately realize any anticipated benefits for a variety of reasons including risks inherent to the research and development of early-stage products, competition, and integration risks related to new products, technology and human resources. Moreover, integration of new products or companies may strain our existing financial and managerial controls, reporting systems and procedures. This may result in the diversion of management and financial resources from our core business objectives and needs. Because we only recently expect to realize quarterly profitability, we would expect that any such acquisition or licensing could have the immediate effect of causing an operating loss in future periods. Furthermore, the licensing or acquisition of new products or companies for cash could limit our financial resources, and the issuance of our stock in such a transaction could result in substantial dilution to existing stockholders.

Significant movements in foreign currency exchange rates may harm our financial results.

Many of our foreign sales are invoiced in local currencies, creating receivables denominated in currencies other than the U.S. dollar, primarily in the Euro and the Japanese yen but also in the U.K. pound. The risk due to foreign currency fluctuations associated with these receivables is partially reduced by local payables denominated in the same currencies, and presently we do not consider it necessary to hedge these exposures. We may revise our hedging policy from time to time as our foreign operations change.

A change in marketing strategy and a delay in product approval have created excess perishable inventories that may result in significant reductions in our future gross margins.

We have significant amounts of bulk cyclosporine active ingredient inventory that we are not using to manufacture finished product in the amount anticipated. This inventory was originally purchased for use in cyclosporine finished products to be sold in the U.S. and Europe. However, since we are now distributing Gengraf in the U.S. and we have withdrawn SangCya Oral Solution from the U.S. market, we are dependent on the European market to use this inventory. We recalled SangCya Oral Solution from the U.S. in July 2000 in response to a study in healthy volunteers that identified that SangCya is not bioequivalent to Neoral oral solution when mixed with apple juice as recommended in its labeling. We are no longer marketing this product. In addition, since our CycloTech product is only intended for use with the SangCya Oral Solution, we have discontinued the distribution of CycloTech. Although we plan to obtain marketing approval for a cyclosporine capsule product in Europe, the inherent uncertainty of the approval process makes it very difficult to forecast a launch date for this product. We currently expect to file for marketing approval of a cyclosporine capsule product in a European country by the end of 2002. If the approval and product launch are delayed, we may not be able to convert all the inventory into finished product and sell it before its expiration date. As a result, we could write off portions of our bulk active ingredient in the future, which could significantly reduce the gross margin reported for that future period.

If we do not develop and market new products, our business will be harmed.

To maintain profitable operations, we must successfully develop, obtain regulatory approval for, manufacture, introduce and market new products and product candidates. We may not be able to successfully do this. Our product candidates will require extensive development and testing, as well as regulatory approval before marketing to the

public. Our cyclosporine capsule product candidate in Europe has been delayed and we do not anticipate filing for approval of a cyclosporine capsule product in Europe until late 2002. In addition, cost overruns and product approval delays could occur due to the following:

unanticipated regulatory delays or demands;

unexpected adverse side effects; or

insufficient therapeutic efficacy.

These events would prevent or substantially slow down the development effort and ultimately would harm our business. Furthermore, there can be no assurance that our product candidates under development will be safe, effective or capable of being manufactured in commercial quantities at an economical cost, or that our products will not infringe the proprietary rights of others or will be accepted in the marketplace.

If our preclinical and clinical testing of potential products is unsuccessful, our business will be harmed.

Before obtaining regulatory approval for the sale of any of our product candidates, we must subject these product candidates to extensive preclinical and clinical testing to establish their safety and efficacy. If these tests are unsuccessful, we will be unable to commercialize these products. Interim results of trials do not necessarily predict final results, and acceptable results in early trials may not be repeated in later trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, we have delayed our expected filing for our cyclosporine capsule by approximately six months due to unanticipated results on an initial clinical trial for that product, and we could experience further delays in the future for this and other products. Moreover, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be repeated or a program to be terminated. We typically rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to perform data collection and analysis and, as a result, we may face additional delaying factors outside our control. The rate of completion of clinical trials depends, in part, on the enrollment of patients, which in turn depends on many factors such as the size of the patient population, the proximity of target patients to clinical sites, the eligibility criteria for the trial, the trial design, perceived risks and benefits, availability of the study drug and the existence of competitive experimental or approved therapies. Any delay in planned patient enrollment in our current or future clinical trials may result in increased costs, trial delays or both. Our product development costs will increase if we have delays in testing or approval or if we need to perform more or larger clinical trials than planned. If the delays are significant, our financial results and the commercial prospects for our products will be harmed.

Our business exposes us to the risk of product liability claims for which we may not be adequately insured.

We face an inherent business risk of exposure to product liability claims in the event that the use of our products is alleged to have resulted in adverse effects. Such risk exists even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise received regulatory approval for commercial sale. We could be subject to significant product liability claims. We currently have product liability insurance in the amount of $25 million per claim and $25 million in the aggregate on a claims-made basis, which may not be adequate to cover

potential liability exposures. In addition, adequate insurance coverage may not be available in the future on commercially reasonable terms, if at all. The loss of insurance coverage or the assertion of a product liability claim or claims could harm our operating results.

We may be unable to attract or retain key personnel.

Our ability to develop our business depends in part upon our attracting and retaining qualified management and scientific personnel. As the number of qualified personnel is limited, competition for such personnel is intense. We may not be able to continue to attract or retain such people on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and nonprofit research institutions. The loss of our key personnel or the failure to recruit additional key personnel could significantly impede attainment of our objectives and harm our financial condition and operating results.

Our litigation with Novartis may be resolved adversely and could consume our time and resources.

We are involved in litigation with Novartis in the U.S., Italy and the U.K., which could potentially harm sales of Gengraf in the U.S. (due to the U.S. regulatory litigation which would impact the labeling for all generic cyclosporine products), and SangCya Oral Solution and our cyclosporine capsule product candidates in Europe. The course of litigation is inherently uncertain, and we may not achieve a favorable outcome. The litigation, whether or not resolved favorably to us, is likely to be expensive, lengthy and time consuming, and divert management s attention.

Novartis s patent lawsuit against Abbott with respect to Gengraf may be resolved adversely.

Novartis sued Abbott in August 2000 claiming that Gengraf infringes certain Novartis patents. The trial is scheduled for July 23, 2002. Novartis s complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the U.S. The course of litigation is inherently uncertain: Novartis may choose to name us in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to our interests. If Novartis names us in this suit, we may incur expenses before reimbursement, if any, by Abbott, who is obligated under our agreement to indemnify us against such suits but their indemnity may not cover lost sales, if any. Should Novartis succeed in obtaining a preliminary or permanent injunction, this injunction may temporarily or permanently remove Gengraf from the market. If Abbott or we were forced to remove Gengraf from the market before our co-promotion agreement with Abbott expires on December 31, 2004, our revenues would decrease materially.

Failure to protect our intellectual property will harm our competitive position.

Our success depends in part on our ability to obtain and enforce patent protection for our products and to preserve our trade secrets. We hold patents and pending patent applications in the U.S. and abroad. Some of our patents involve specific claims and thus do not provide broad coverage. Our patent applications or any claims of these patent applications may not be allowed, valid or enforceable. These patents or claims of these patents may not provide us with competitive advantages for our products. Our competitors may successfully challenge or circumvent our issued patents and any patents issued under our pending patent applications. Further, although we received orphan drug designation for Thymoglobulin for treatment of Myelodysplastic Syndrome, also known as pre-leukemia, we do not have patents on Thymoglobulin or Lymphoglobuline. Therefore, we are primarily dependent upon our trade secrets for these products. We have not conducted extensive patent and prior art searches with respect to our product candidates and technologies, and we do not know if third-party patents or patent applications exist or have been filed in the U.S., Europe or other countries. This would have an adverse effect on our ability to market our products. We do not know if claims in our patent applications would be allowed, be valid or enforceable, or that any of our products would not infringe on others patents or proprietary rights in the U.S. or abroad. We also have patent licenses from third parties whose patents and patent applications are subject to the same risks as ours.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements with our employees and consultants. Our employees and/or consultants, however, may breach these agreements. We may not have adequate remedies for any such breach. In addition, our trade secrets may be independently developed or misappropriated by competitors, which could harm our business and operating results.

We have registered or applied for trademark registration of the names of all of our marketed products and plan to register the names of our products under development once we select a name for the product candidate. We have registered or applied for trademark registration of the names of most of our products under development or commercialized for research and development use. However, we may fail to obtain these trademark registrations or our competitors may challenge them.

We face substantial competition.

Each of the drugs we develop competes with existing and new drugs being created by pharmaceutical, biopharmaceutical, biotechnology companies and universities. Many of these entities have significantly greater research and development capabilities, as well as substantial marketing, manufacturing, financial and managerial resources and represent significant competition. The principal factors upon which our products compete are product utility, therapeutic benefits, ease of use, effectiveness, marketing, distribution and price. With respect to our

products, we are competing against large companies that have significantly greater financial resources and established marketing and distribution channels for competing products. A list of our key products and product candidates, identifying principal competitive products as well as the relevant competitors, is included in the Business section of this Annual Report on Form 10-K under Competition.

The drug industry is intensely price competitive, and we expect we will face this and other forms of competition. Developments by others may render our products or technologies obsolete or noncompetitive, and we may not be able to keep pace with technological developments. Many of our competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for products that compete with our own. Some of these products may have an entirely different approach or means of accomplishing the desired therapeutic effect than our products and may be more effective, more convenient or less costly. In addition, many of these competitors have significantly greater experience than we do in undertaking preclinical testing and human clinical trials of pharmaceutical products, obtaining regulatory approval of such products and manufacturing them. Accordingly, our competitors may succeed in commercializing products more rapidly than we can.

Other treatments for problems associated with transplantation that our products seek to address are currently available and under development. To the extent these products address the problems associated with the diseases on which we have focused, they may represent significant competition.

We depend on collaborative relationships and any failure by our strategic partners to perform may harm our competitive position.

We have several strategic relationships for the development and distribution of our products. In particular, we have entered into a multi-year co-promotion, distribution and research agreement for Gengraf in the U.S. with Abbott. We are dependent upon Abbott for certain regulatory, manufacturing, marketing, and sales activities under the agreement and for defending the Novartis patent lawsuit. Abbott may not perform satisfactorily and any such failure may impair our ability to deliver products on a timely basis, or otherwise impair our competitive position, which would harm our business. We have also entered into a Co-Development, Supply and License Agreement with Abgenix, Inc. with respect to the development, marketing and sale of ABX-CBL. We are dependent upon Abgenix for certain development and manufacturing activities under the agreement. Abgenix may not perform satisfactorily and any such failure may delay regulatory approval, product launch, impair our ability to deliver products on a timely basis, or otherwise impair our competitive position, which would harm our business. We may enter into additional collaborative relationships with corporate and other partners to develop and commercialize certain of our potential products. We may not be able to negotiate acceptable collaborative arrangements in the future, or such collaborations may not be available to us on acceptable terms or, if established, be scientifically or commercially successful.

Our stock price has historically been volatile, and you could lose some or all of your investment.

The market prices for securities of pharmaceutical and biotechnology companies, including ours, are highly volatile. For example, during 2001, the price of our common stock ranged from $7.50 to $24.87 per share. The stock market has from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. The market price for our common stock may fluctuate as a result of factors such as:

- announcements of new therapeutic products by us or our competitors;
- announcements regarding collaborative agreements;

governmental regulations;

our clinical trial results or clinical trial results from our competitors;

fluctuations in our revenues or profitability;

the licensing or acquisition of new products or other companies;

developments in patent or other proprietary rights;

public concern as to the safety of drugs developed by us or others;

comments made by securities analysts; and

general market conditions.

Adverse economic conditions could affect our customers.

A recession or other downturn in the U.S. or other regional economy could adversely affect our customers, including wholesalers, which could reduce our sales or make it more difficult to collect payments from them on a timely basis. Terrorist attacks in New York, Washington, D.C. and Pennsylvania in September of 2001 disrupted commerce throughout the U.S. and Europe. The continued threat of terrorism within the U.S. and Europe and any ongoing military action and heightened security measures in response to this threat may cause significant disruption to commerce throughout the world. To the extent that this disruption results in delays or cancellations of orders, a general decrease in spending on pharmaceutical products or our inability to effectively market and ship our products, our business and operating results could be harmed. In particular, our Thymoglobulin and Lymphoglobuline products are perishable and require express shipping, which may be curtailed or delayed because of security restrictions and border inspections. We are unable to predict whether the threat of terrorism or the responses thereto will result in any long-term commercial disruptions or if such activities or responses will have a long-term adverse effect on our business or operating results.

The uncertainty of pharmaceutical pricing and reimbursement may decrease the commercial potential of our products.

Our ability to successfully commercialize our products may depend in part on the extent to which adequate reimbursement for the cost of such products and related treatment will be available from third-party payers, such as government health administration authorities, private health coverage insurers and other organizations. Third-party payers increasingly are challenging or seeking to negotiate the pricing of medical services and products. In some cases, third-party payers will pay or reimburse a user or supplier of a prescription drug product only a portion of the purchase price of the product. In the case of our prescription products, payment or reimbursement by third-party payers of only a portion of the cost of such products could make such products less attractive, from a cost perspective, to users, suppliers and prescribing physicians. Reimbursement, if available, may not be adequate. If government entities or other third-party payers for our products do not provide adequate reimbursement levels, our results of operations would be harmed. The pricing, availability of distribution channels and reimbursement status of newly approved healthcare products is highly uncertain.

Healthcare providers may purchase Thymoglobulin, and other products, for off-label use (that is, a use not specifically approved by the FDA or similar authority for other countries). Actions by the FDA or other authority to prevent off-label use or a decision by third-party payers not to pay for off-label use would adversely affect sales. As a result, adequate third-party coverage may not be available for us to maintain price levels sufficient for realization of an appropriate return on our investment in product development. In certain foreign markets, pricing or profitability of healthcare products is subject to government control. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. In addition, we believe that an increasing emphasis on managed care in the U.S. has increased, and will continue to increase, the pressure on pharmaceutical pricing. While we cannot predict the adoption of any such legislative or regulatory proposals or the effect such proposals or managed care efforts may have on our business, the announcement of such proposals or efforts could harm our ability to raise capital, and the adoption of such proposals or efforts could harm our operating results. Further, to the extent that such proposals or efforts harm other pharmaceutical companies that are our prospective corporate partners, this may reduce our ability to establish corporate collaborations. We do not know whether consumers, third-party payers and others will consider our

products and product candidates, if approved, cost effective or that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive basis.

Our use of hazardous materials could result in unexpected costs or liabilities.

In connection with our manufacturing, research and development activities and operations, we are subject to foreign, federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. As a result, we may incur significant costs to comply with environmental and health and safety regulations. Our manufacturing, research and development involves the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and infectious biological specimens. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by foreign, state and federal regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our ability to pay.

Anti-takeover provisions could limit our share price and delay or deter a change in management.

Certain provisions of our Certificate of Incorporation and Bylaws contain provisions that could significantly impede the ability of the holders of our common stock to change management or delay or make it more difficult or even prevent a third party from acquiring us without the approval of our incumbent Board of Directors. These provisions could limit or adversely affect the price that investors might be willing to pay in the future for shares of our common stock. These provisions, among other things:

limit the right of stockholders to call special meetings of stockholders;

limit the right of stockholders to present proposals, nominate directors for election or otherwise raise matters at annual meetings of stockholders without giving advance notice;

eliminate the ability of stockholders to take action by written consent;

prohibit cumulative voting in any election of directors, which may make it more difficult for a third party to gain control of our Board of Directors; and

authorize our Board of Directors to issue up to five million shares of preferred stock in one or more series and to determine the price, rights, preferences, privileges, and restrictions of those shares without any further vote or action on the part of stockholders.

In addition, we have adopted a stockholder rights plan. Under this plan we may issue a dividend to stockholders who hold rights to acquire our shares or, under certain circumstances, the shares of an acquiring corporation, at less than half their fair market value. The plan could have the effect of delaying, deferring or preventing a change in control or management. The rights plan, if triggered, could cause substantial dilution to a person or group that attempts to acquire us on terms not approved by the Board of Directors.

Further, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which will prohibit us from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, even if such combination is favored by a majority of stockholders, unless the business combination is approved in a prescribed manner. The application of Section 203 also could have the effect of delaying or preventing a change of control or management.

ITEM 2. PROPERTIES

Our global headquarters are located in Fremont, California. Floor space in Fremont is approximately 44,000 square feet, including offices, laboratory space, storage area and specialized areas for some pilot production and preclinical testing. The lease for the Fremont building space will expire in 2005 and may be renewed for subsequent years.

Our European headquarters are located in Lyon, France. We lease approximately 38,300 square feet from Aventis in Marcy L Etoile (just outside of Lyon), France for administration and manufacturing. The leases for non-manufacturing operations expire at various dates up to 2006 and may be renewed for subsequent years. The manufacturing lease expires in 2013 but may be terminated at our option upon giving one year s notice. In addition,

we lease 12,400 square feet in Lyon, France for sales, marketing, finance, clinical, and administration, and lease administrative offices in various other countries.

We believe that our current facilities are suitable and adequate to meet our needs for the foreseeable future and anticipate that we will be able to expand our facilities to nearby locations as the need develops.

ITEM 3. LEGAL PROCEEDINGS

Novartis Patent Litigation With Respect to Gengraf

Novartis sued Abbott claiming that Gengraf® infringes its patents. Novartis s complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the U.S., but to date Novartis has not moved for a preliminary injunction. The trial is scheduled for July 23, 2002. Abbott informed us that it does not believe it infringes the Novartis patents. We have not been named a defendant in this lawsuit, and we have only limited access to information about it. Under our agreement with Abbott, Abbott is obligated to indemnify us against such suits, but their indemnity may not cover lost sales, if any. The course of litigation is inherently uncertain, however. Novartis may choose to name us in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to our interests. Should we be named in this suit, we may incur expenses prior to reimbursement (if any) by Abbott pursuant to its indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, Gengraf may be temporarily or permanently removed from the market, or we and Abbott may be required to negotiate a license on unfavorable terms.

Novartis Regulatory Litigation

U.S. Regulatory Litigation. Novartis U.S. sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia (case number 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis initially asked the Court to (i) allow Novartis to keep its microemulsion labeling; (ii) declare microemulsion to be a separate dosage form; and (iii) rescind the AB rating that was given to SangCya Oral Solution. We intervened in this lawsuit. The Court granted our motion to dismiss the counts that relate specifically to the approval of SangCya Oral Solution, but Novartis may appeal this decision. We remain a party in the case. Novartis has filed motions related to the remaining issues in the case, and the Court has not yet ruled on Novartis s motions. Because we permanently withdrew SangCya Oral Solution from the U.S. market in July 2000, we do not believe that this lawsuit will have any material impact on SangCya revenues but if the court declares microemulsion to be a separate dosage form, this ruling would require rescission of the AB rating for Gengraf, which would have a material impact on Gengraf revenues.

U.K. Regulatory Litigation SangCya Oral Solution. On October 18, 1999, Novartis U.K. was granted leave to seek judicial review of the decision by the Medicines Control Agency, or MCA, to approve SangCya Oral Solution (Case No. HC-1969/99). On March 30, 2000, the High Court in London dismissed Novartis s application for judicial review and ruled that the MCA acted properly in granting the SangCya Oral Solution marketing authorization. Novartis appealed the High Court s decision, and the hearing was held before the Court of Appeal on November 13 and 14, 2000. The Court of Appeal has stayed ruling on this matter pending the answer of certain questions of law to be submitted to the European Court of Justice, or ECJ. No date has been set for the ECJ hearing, but it is likely to be scheduled sometime in early 2002, with a ruling approximately six months thereafter. Following the ECJ ruling, the parties would go back to the Court of Appeal, which will then apply the ECJ ruling on the law to the facts of this case.

U.K. Regulatory Litigation Cyclosporine Capsules. In November 1999, Novartis filed a request with the High Court in London for judicial review of the refusal by MCA to state that it would not reference Neoral data in approving any generic copies of Novartis s cyclosporine capsule. An agreement was reached between the parties in which Novartis agreed to stay the judicial review until the earlier of (i) the decision on the judicial review of SangCya Oral Solution or (ii) MCA s approval of SangStat s marketing authorization for its cyclosporine capsule product; in return, we agreed that we would not launch or commence mutual recognition procedures in relation to the cyclosporine capsule marketing authorization (including a request to MCA to prepare an assessment report) for a

period of 28 days commencing on the day on which we notify Novartis s solicitors of capsule approval. The parties have agreed to continue the stay until the appeal of the High Court decision with respect to the judicial review of SangCya Oral Solution. The stay of this application for judicial review will remain in place pending the ECJ ruling on the questions of law and resulting Court of Appeal judgment.

Novartis has also indicated that it will seek an injunction to prevent our cyclosporine capsule from being sold in the United Kingdom until final resolution of the judicial review relating to our cyclosporine oral solution. Because the High Court ruled in favor of the MCA with respect to the SangCya Oral Solution marketing authorization and the Court of Appeal has referred questions of law to the ECJ, we believe that it is unlikely that a court would grant Novartis a preliminary injunction with respect to our cyclosporine capsule marketing authorization. If the Court of Appeals reverses the High Court s ruling following the ECJ s decisions on questions of law, either the MCA could still approve our cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve our cyclosporine capsule marketing authorization until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004).

Italian Regulatory/Trade Secret Litigation. On May 5, 2000, Novartis Farma S.p.A. (Novartis Italy) served IMTIX-SangStat S.r.l., an Italian SangStat subsidiary, and IMTIX-SangStat Ltd. with a summons to the Milan Tribunal. Novartis Italy alleges that by requesting mutual recognition from the Italian Health Authorities of the SangCya Oral Solution dossier approved by the MCA, we implicitly requested that the Italian Health Authorities review the Neoral dossier. Novartis alleges that this request is an act of unfair competition in that (i) the Neoral data has ten year exclusivity and (ii) the data is secret and by requesting mutual recognition, we are responsible for the Health Authorities act of unfair competition following use of the Neoral dossier in reviewing the SangCya Oral Solution dossier. While the summons acknowledges that the U.K. High Court did not invalidate the SangCya Oral Solution marketing authorization, it does not acknowledge that the High Court ruled that the MCA could review the Neoral data. To the best of our knowledge, Novartis Italy has not filed suit against the Italian Health Authorities. The initial appearance of the parties before the Milan Tribunal was scheduled for January 2001. We filed our response to the complaint at that time, and the hearing has been postponed until June 2002.

We do not yet have marketing approval for SangCya Oral Solution in Italy. Novartis Italy is seeking damages and an injunction to prevent the sale by SangStat of SangCya Oral Solution, or any other product for which we may obtain approval based upon a reference to the Neoral dossier, which we believe is intended to block our cyclosporine capsule from sale in Italy. We believe that resolution of this matter will depend on the resolution of the U.K. regulatory litigation, since the MCA s actions are the basis for the Italian lawsuit.

Summary

Although we are optimistic that these disputes will ultimately be resolved in our favor, the course of litigation is inherently uncertain. With respect to Novartis s lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, our revenues would be reduced. With respect to the European regulatory and trade secret lawsuits, Novartis s requested relief, if granted, could have a negative economic impact on us depending on how the MCA would proceed with our Marketing Authorization Application (MAA) for our capsule product. The MCA could approve our MAA for cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve our MAA for our cyclosporine capsule until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004). If we cannot obtain approval of our cyclosporine capsule in Europe until 2004, this could have an adverse impact on our future revenues and results of operations. With respect to the FDA lawsuit, Novartis s requested relief would mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would harm revenues. The litigation, if not resolved favorably to us, could have a material adverse effect on our business, financial condition, cash flows and operating results.

IFFA CREDO and Elevage Scientifique des Dombes Breach of Contract Suit

In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes, sued our French subsidiary, IMTIX-SangStat SAS, for breach of contract. On May 2, 2001 we were notified that the Commercial Court of Lyon ruled against IMTIX-SangStat in the breach of contract suit and the court awarded the suppliers 26.5

million French Francs (approximately $3.6 million) for lost profits and reimbursement of capital expenditures. IMTIX-SangStat recorded a charge of $3,250,000 to other expense net for the year ended December 31, 2001, which, combined with reserves recorded in fiscal 2000, fully provided for the court award of $3,600,000. On March 22, 2002, the appeals court upheld the lower court decision and assessed interest against us of approximately $204,000 which has been recorded as a charge to other expense net for the year ended December 31, 2001.

Our rabbit serum requirements are currently being met by our other suppliers.

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

None

PART II

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

Since 1993, our common stock has traded on the Nasdaq National Market. We currently trade under the symbol SANG. The following table sets forth the high and low reported sale prices for our common stock for the periods indicated as reported on the Nasdaq National Market.

	High	Low
Fiscal year ended December 31, 2001		
First Quarter	$ 13.188	$ 7.500
Second Quarter	17.000	8.875
Third Quarter	19.060	12.350
Fourth Quarter	24.870	15.880
Fiscal year ended December 31, 2000		
First Quarter	$ 48.000	$ 25.875
Second Quarter	33.813	21.813
Third Quarter	29.875	12.813
Fourth Quarter	14.500	6.500

On March 18, 2002, the last reported sale price of our common stock on the Nasdaq National Market was $24.98 per share. As of March 18, 2002, we had approximately 80 stockholders of record.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We do not intend to declare or pay any cash dividends on our common stock in the foreseeable future. We plan to retain any earnings for use in the operation of our business and to fund future growth.

SALE OF UNREGISTERED SECURITIES

Since January 1, 2000 until December 31, 2001, we sold unregistered securities in reliance on the exemption from registration found in Regulation D and/or Section 4(2) of the Securities Act of 1933, as amended. The recipient of securities in each transaction was an accredited investor that represented its intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to share certificates and other instruments issued in such transactions.

1. In February 2000, BioPharma Equities Holding NV purchased 451,128 shares of our common stock for approximately $15 million.

2. In December 2000 and January 2001, Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, SDS Merchant Fund, LP and S.A.C. Capital Associates, LLC purchased 1,315,800 shares of our common stock for approximately $12.5 million.

3. In June 2001, S.A.C. Capital Associates, LLC, Royal Bank of Canada, Narragansett I. LP, Narragansett Offshore, Ltd., and Société Générale purchased 1,363,635 shares of our common stock for approximately $15 million.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated financial data set forth below with respect to our statements of operations for each of the three years in the period ended December 31, 2001, and with respect to the balance sheets as of December 31, 2001 and 2000, are derived from our Consolidated Financial Statements, which are included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 1998 and 1997 and the balance sheet data as of December 31, 1999, 1998 and 1997, are derived from audited consolidated financial statements not included herein. The data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our Consolidated Financial Statements and the Notes thereto included elsewhere in this Annual Report on Form 10-K. The table below has been restated to account for The Transplant Pharmacy as a discontinued operation. See Note 16 of the Notes to Consolidated Financial Statements.

	Year Ended December 31,				
	2001	2000 (2)	1999	1998	1997
	(in thousands, except per share data)				
Consolidated Statements of Operations Data					
Revenues:					
Net product sales	$ 91,302	$ 60,447	$ 42,243	$ 10,202	$ 2,456
Revenue from collaborative agreements	3,207	2,698	2,060	1,092	750
Total revenues	94,509	63,145	44,303	11,294	3,206
Costs and operating expenses:					
Cost of product sales	42,816	39,246	18,989	5,110	2,646
Research and development	17,863	20,788	14,470	17,688	16,210
Selling, general and administrative	33,782	41,766	39,170	23,707	9,442
Acquired in-process research and development				3,218	
Amortization of intangible assets	1,922	1,392	1,398	351	
Total costs and operating expenses	96,383	103,192	74,027	50,074	28,298
Loss from operations of continuing operations	(1,874)	(40,047)	(29,724)	(38,780)	(25,092)
Other income (expense) - net	(6,368)	(1,602)	(913)	3,053	5,506
Loss from continuing operations before income taxes	(8,242)	(41,649)	(30,637)	(35,727)	(19,586)
Income tax benefit (provision)	7	(368)	(345)	(257)	
Net loss from continuing operations	(8,235)	(42,017)	(30,982)	(35,984)	(19,586)
Net loss from operations of discontinued operation	(763)	(2,342)	(2,025)	(2,480)	(1,394)
Net loss from disposal of discontinued operation	(381)				
Net loss	$ (9,379)	$ (44,359)	$ (33,007)	$ (38,464)	$ (20,980)
Net loss per share - basic and diluted (1)					
Continuing operations	$ (0.40)	$ (2.35)	$ (1.83)	$ (2.24)	$ (1.27)
Discontinued operation	(0.06)	(0.13)	(0.12)	(0.15)	(0.09)
	$ (0.46)	$ (2.48)	$ (1.95)	$ (2.39)	$ (1.36)
Shares used in per share computations (1)	20,216	17,910	16,888	16,080	15,376

	December 31,				
	2001	2000	1999	1998	1997
	(in thousands)				
Consolidated Balance Sheet Data:					
	$ 32,822	$ 20,607	$ 26,519	$ 29,660	$ 92,036

Cash, cash equivalents and short-term investments					
Working capital	33,266	39,774	63,991	46,828	93,812
Total assets	114,559	114,316	117,297	107,327	104,354
Long-term obligations, excluding current portion	30,539	35,214	40,192	16,402	1,557
Deferred revenue	6,317	9,475	9,304		
Accumulated deficit	(187,015)	(177,636)	(133,277)	(100,270)	(61,806)
Total stockholders equity	32,359	21,924	41,009	59,587	97,470

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(1) For a description of the computation of net loss per common share see Note 1 of Notes to Consolidated Financial Statements.

(2) Includes product recall charges of $872,000, $11,774,000, $50,000 and $379,000 for net product sales returns, cost of product sales, research and development expenses and selling, general and administrative expenses respectively.

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

The following discussion and analysis should be read in conjunction with Selected Consolidated Financial Data and our Consolidated Financial Statements and Notes thereto included elsewhere in this Annual Report on Form 10-K. Except for the historical information contained herein, the discussion contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations ,intentions and future results. The cautionary statements made in this Annual Report on Form 10-K should be read as being applicable t

all related forward-looking statements wherever they appear. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those discussed in Risk Factors, as well as those discussed elsewhere herein. In particular, we have included forward-looking statements regarding the following: (i) our anticipated financial results for 2002; (ii) the timeline and potential results of preclinical development and clinical trials; (iii) potential outcomes of our and Abbott s litigation with Novartis; (iv) our plans for marketing a cyclosporine capsule in Europe; (v) anticipated expenditures and timing relating to FDA and foreign approval of our products and facilities; and (vi) anticipated potential strategic collaborations with others. These forward-looking statements are based on our current expectations, and we disclaim any obligation to update these forward-looking statements for subsequent events or to explain why actual results differ.

SangStat is a global biotechnology company expanding on its transplantation foundation to discover, develop and market high value therapeutic products in immunology, hematology/oncology and auto-immune disease. Since 1988, we have been dedicated to improving the outcome of organ and bone marrow transplantation through the development and marketing of products to address all phases of transplantation in the worldwide market. We are headquartered in Fremont, California. We maintain a strong European and U.S.presence, including direct sales and marketing forces in all major European markets and the U.S. and distributors throughout the rest of the world.

Historically, our business was comprised of two segments: pharmaceutical products and transplantation services. In October 2000, we implemented a new strategy focused on growing a core business in high value therapeutics that builds on our expertise in transplantation but extends into new therapeutic areas. As a result of this new strategy, we decided to dedicate significant resources to our pharmaceutical products segment, which consists of four marketed products and three principal product candidates. On April 20, 2001, we sold our transplantation services segment, The Transplant Pharmacy, to Chronimed, for cash proceeds of $1.8 million. Consequently, the historical consolidated statements of operations and cash flows have been restated for all periods presented to account for the transplantation services segment business as a discontinued operation. Unless otherwise indicated, the following discussion relates to our continuing operations and excludes our discontinued operation.

In February 2002, we completed a public offering of 5,175,000 shares of our common stock for consideration net of underwriting discounts of $84,145,500. We anticipate that the net proceeds from this offering will be used for repayment of existing indebtedness to Abbott Laboratories and general corporate purposes, including in-licensing and partnering opportunities.

Critical Accounting Policies

We have identified the policies below as critical to our business operations and the understanding of our results of operations.

Revenue Recognition

Revenue from product sales, net of estimated sales allowances and rebates, is recognized upon receipt by the customer, when a purchase order has been received, the sales price is fixed or determinable and collection of the resulting receivable is reasonably assured. We record estimated reductions to revenue for customer programs, including contract pricing agreements, promotions, other volume based incentives and estimated future returns, in the same period as the related revenues are recorded. The estimates for returns are adjusted periodically based upon historical rates of return, and other related factors. The estimates and reserves for rebates and price protection are based on historical rates. In addition, our revenue recognition policy determines the timing of certain expenses, such as commissions and royalties that are recorded in the same period as

the related revenue. While we believe we can make reliable estimates for these revenue adjustments, it is possible that actual amounts realized could vary from our estimates and that the amounts of such changes could affect our operating results.

Revenue from collaborative agreements is recognized in accordance with the related contract terms. Upfront or milestone payments received under such agreements are generally recognized as revenues ratably over the life of the agreement where significant obligations for future services or the Company s participation exist or as milestones are met and no significant obligation for future services exists.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market. We classify inventory not expected to be utilized within the next twelve months as long term assets. We evaluate our inventory levels based on our estimates of marketing approval and forecasts of future sales, among other things. If these estimates or forecasts change at some time in the future we may be required to record additional charges for the write-down of excess or obsolete inventories. At December 31, 2001 we classified approximately $15 million of bulk cyclosporine raw materials inventory, net of reserves, as other long term assets.

Foreign currency gains and losses

Many of our foreign sales are invoiced in local currencies, creating receivables denominated in currencies other than the U.S. dollar, primarily in the Euro and the Japanese yen but also in the U.K. pound. The risk due to foreign currency fluctuations associated with these receivables is partially reduced by local payables denominated in the same currencies, and presently we do not consider it necessary to hedge these exposures. However, we may revise our hedging policy from time to time as our foreign operations change. Gains and losses resulting from foreign currency transactions are included on other income (expense) net in our statement of operations and were not significant for any period presented.

Income taxes

SangStat has operations in several countries other than the United States, including France where we manufacture Thymoglobulin. This product is then sold to other SangStat entities in other countries, including the United States. We believe that we record these sales at an appropriate transfer price; however it is possible that the tax authorities could challenge these transfer prices and assess additional taxes on prior period transactions. Any such assessment could require us to record an additional tax provision in our statement of operations.

We have substantial deferred tax assets that relate to prior period losses, primarily in the United States. We evaluate these deferred tax assets in each tax jurisdiction by estimating the likelihood of the Company generating future profits to realize these assets. In most cases, we have assumed that we will not be able to generate sufficient future taxable income to realize these assets and have created valuation reserves to reduce the net asset values to zero. If these estimates and assumptions change in the future, we may be required to record additional valuation allowances against the net deferred tax assets resulting in additional income tax expense in our consolidated statement of operations. Conversely, we may be able to reverse the valuation allowances in future periods should the Company generate taxable income. At December 31, 2001, we had approximately $75 million of valuation allowances related to our net deferred tax assets.

Results of Operations

Revenues. Total revenues for the year ended December 31, 2001 were $94,509,000, an increase of $31,364,000 or 50% over total revenues of $63,145,000 for the year ended December 31, 2000. The increase was due primarily to increased sales of Gengraf and Thymoglobulin in the US, which accounted for $18,167,000 and $13,551,000 of the

increase, respectively. This increase was partially offset by lower sales of other products. It should be noted that net product sales in fiscal 2001 included a full year of sales of Gengraf, which was launched in the US in May 2000, compared with only eight months of sales in fiscal 2000.

On June 29, 2000 we, in discussions with the FDA that began on June 24, 2000, concluded that a recall of SangCya Oral Solution from the US market would be required. Following further discussions with the FDA as to the type of recall and mechanism for conducting it, we announced this decision on July 10, 2000. As a result, net sales for the year ended December 31, 2000 were reduced by $872,000 for returns of SangCya Oral Solution from customers following the product recall.

Total revenues for the year ended December 31, 2000 were $63,145,000, an increase of $18,842,000 or 43% over total revenues of $44,303,000 for the year ended December 31, 1999. The increase was due primarily to sales of Gengraf, which was launched in the US in May 2000, and increased sales of Thymoglobulin in the US, which accounted for $11,423,000 and $10,563,000 of the increase, respectively. This increase was partially offset by lower sales outside the US. In particular, sales in Europe for the year ended December 31, 2000 were adversely affected

by weakening currencies. Had average exchange rates remained the same as in fiscal 1999, total revenues in fiscal 2000 would have been higher by approximately $3,100,000.

Included in total revenues was revenue from collaborative agreements of $3,207,000 in 2001, an increase of $509,000 or 19% over revenue from collaborative agreements of $2,698,000 in 2000. Revenue from such agreements in fiscal 2000 represented an increase of $638,000 or 31% over revenue of $2,060,000 for the year ended December 31, 1999. In 2001, 2000 and 1999, we recognized revenue of $3,157,000, $2,698,000 and $1,510,000 from milestone payments from Abbott Laboratories under the co-promotion agreement for cyclosporine. The unamortized portion of these milestone payments is shown as deferred revenue on our consolidated balance sheet and will be recognized as revenue on a straight-line basis over the remaining term of the co-promotion agreement. We also recognized revenue from milestone payments of $550,000 in 1999 from Amgen under the collaborative distribution agreement for our cyclosporine products in certain territories outside the US.

Cost of sales. Cost of sales were $42,816,000 for the year ended December 31, 2001, an increase of $3,570,000 or 9% over cost of sales of $39,246,000 for the year ended December 31, 2000. The increase in cost of sales for the year ended December 31, 2001 was due to the overall increase in sales and the higher cost of Gengraf compared to our other products.

Cost of sales of $39,246,000 for the year ended December 31, 2000 represented an increase of $20,257,000 or 107% over cost of sales of $18,989,000 for the year ended December 31, 1999. The increase for the year ended December 31, 2000 was primarily due to the establishment of inventory reserves resulting from the US recall of SangCya Oral Solution. These product recall charges, which totaled $11,774,000, included a 100 percent reserve for all SangCya Oral Solution and CycloTech finished goods and components, as well as a partial reserve against our bulk cyclosporine inventories that we do not expect to use prior to lot expiration. The remainder of the increase in cost of sales for the year ended December 31, 2000 was due to the overall increase in sales and the higher cost of Gengraf compared to our other products.

Research and development. Research and development expenses were $17,863,000 for the year ended December 31, 2001, a decrease of $2,925,000 or 14% over research and development expenses of $20,788,000 for the year ended December 31, 2000. The decrease in spending on research and development mainly relates to payments to Abgenix for a license fee payment and SangStat s negotiated share of prior development costs incurred by Abgenix for ABX-CBL totaling $2,900,000 which did not recur in 2001, and a decrease in spending on SangCya Oral Solution and related products. This decrease in spending was partially offset by an increase in spending on RDP58 and the ongoing development of ABX-CBL for the year ended December 31, 2001.

Research and development expenses of $20,788,000 for the year ended December 31, 2000 represented an increase of $6,318,000 or 44% over research and development expenses of $14,470,000 for the year ended December 31, 1999. The increase in spending on research and development for the year ended December 31, 2000 mainly relates to charges for a license fee and reimbursement of development costs for ABX-CBL totaling $3,400,000, clinical trials to pursue label expansion of Thymoglobulin and continued pre-clinical work on RDP58. The expenses for the year ended December 31, 2000 also included $50,000 to cover the cost of terminating SangCya Oral Solution clinical trials following the previously discussed product recall.

While we allocate scientists and track resources when required pursuant to the terms of a partnering or similar arrangement, members of our research team typically work on a number of products concurrently, and our equipment and intellectual property resources often are deployed

over a range of products with a view to maximizing the benefit of our investment. Accordingly, the Company has not and does not intend to separately track the costs for each of its research projects so as to enable accurate disclosure of the actual costs incurred to date on a product by product basis. For the year ended December 31, 2001, however, we estimate that the majority of our research and development expense was associated with our three leading product candidates, RDP58, ABX-CBL and cyclosporine capsules. The balance of our expense was associated primarily with ongoing development of our marketed products, primarily clinical trials for Thymoglobulin, and early-stage product candidates.

We have completed Phase I clinical trials for RDP58 and subsequently started a Phase IIa trial in October 2001. We currently expect to announce results of this trial in the second half of 2002. We are also conducting a Phase II / III study for ABX-CBL, which we expect to complete by the end of 2002. We are conducting bioequivalence and

stability studies for a cyclosporine capsule. If the results from these studies are favorable, we expect to file for marketing approval for this product in a major European country, which we currently estimate will occur in late 2002. We also have under way two clinical trials involving Thymoglobulin. One trial compares Thymoglobulin with Simulect. The study was closed early in March 2002, with a total enrollment of 279 participants out of a planned 340, after an interim analysis revealed significantly fewer acute rejections of implanted kidneys in patients treated with Thymoglobulin versus Simulect. The second trial investigates the use of Thymoglobulin in myelodysplastic syndrome; we aim to complete enrollment of patients into this study by the end of 2002. The primary end-point is 180 days after enrollment. Of course our timeline is an estimate that is subject to change from time to time. Due to the inherent risks and uncertainties associated with the development of our proposed drugs, we are unable to further specify with meaningful certainty the estimated completion date or estimated cost of completion of our proposed products, or whether any of our products will eventually be successfully developed. For a discussion of the risks and uncertainties surrounding the development and cost of these products and effectively precluding such disclosure, see Risk Factors - If we do not develop and market new products, our business will be harmed.

Selling, general and administrative. Selling, general and administrative expenses for the year ended December 31, 2001 were $33,782,000, a decrease of $7,984,000 or 19% over selling, general and administrative expenses of $41,766,000 for the year ended December 31, 2000. The decrease in expenses for the year ended December 31, 2001 reflects the results of SangStat s cost control efforts through the continuation of its cost-containment program, including a reduction in launch and marketing expenses for Gengraf, a reduction in SangStat s share of Phase IV Gengraf study expenses, and a reduction in legal expenses associated with the Novartis lawsuits.

Selling, general and administrative expenses for the year ended December 31, 2000 were $41,766,000, an increase of $2,596,000 or 7% over selling, general and administrative expenses of $39,170,000 for the year ended December 31, 1999. The increase was due primarily to expenses of $2,758,000 associated with the launch of Gengraf. Expenses for the year ended December 31, 2000 also included $379,000 to cover the cost of managing the product recall of SangCya Oral Solution and terminating ongoing marketing programs. These increases in expenses were partially offset by an overall reduction in spending resulting from the cost containment measures announced in October 2000.

Amortization of intangible assets. Amortization expense for the IMTIX acquisition-related intangible assets was $1,922,000, $1,392,000 and $1,398,000 for the years ended December 31, 2001, 2000 and 1999, respectively. Amortization expense in 2001 includes the write-off of $482,000 representing the net book value of the intangible asset related to distribution rights for Multitest and Celiptium, two minor products formerly sold in Europe. Sales of these two products were discontinued in the fourth quarter of 2001.

Interest income. Interest income for the year ended December 31, 2001 was $1,203,000 compared to $2,016,000 for the year ended December 31, 2000, and $1,865,000 for the year ended December 31, 1999. For both fiscal 2001 and 2000, the change in interest income versus the prior year primarily reflected the change in the average cash balances available for investment.

Interest expense. Interest expense for the year ended December 31, 2001 was $4,830,000 compared to $4,368,000 for the year ended December 31, 2000 and $3,034,000 for the year ended December 31, 1999. The increase in interest expense in fiscal 2001 over 2000 reflected the effects of the FINOVA loan termination agreement. We recorded a full year of interest expense in fiscal 2000 on the notes payable to Aventis, Abbott Laboratories and the convertible note and eight months expense on the FINOVA note payable compared to twelve months for Aventis, six months for

Abbott and ten months for the convertible debt in fiscal 1999.

Other income (expense) - net. Other income (expense) - net for the year ended December 31, 2001 was an expense of $2,741,000 compared to income of $750,000 and $256,000, respectively, for the years ended December 31, 2000 and 1999. The increase in other expense in fiscal 2001 was due primarily to the expenses of $3,454,000 related to a breach of contract suit in Europe including $204,000 in interest and other charges that was assessed by the Appeals Court in Lyon, France on March 22, 2002, partially offset by an $856,000 reimbursement claim we received from a supplier. In fiscal 2000 and 1999, income was provided primarily by gains on the sale of equity securities of $437,000 and $223,000, respectively.

Income taxes. For the years ended December 31, 2001, 2000 and 1999, we recorded a tax benefit of $7,000 and a provision of $368,000 and $345,000 respectively, for European income taxes based upon the financial results of our European affiliates.

Net loss from continuing operations. Net loss from continuing operations for the year ended December 31, 2001 was $8,235,000, a decrease of $33,782,000 or 80% compared to the net loss of $42,017,000 for the year ended December 31, 2000. The decrease in net loss for the year ended December 31, 2001 was primarily due to higher product sales and lower selling, general and administration and research and development expenses, partially offset by higher cost of sales and manufacturing expenses, resulting primarily from the higher product sales. In addition, the fiscal year ended December 31, 2000 included product recall returns and charges totaling $13,075,000 that did not recur in 2001. Net loss from continuing operations for the year ended December 31, 2000 was $42,017,000, an increase of $11,035,000 or 36% compared to the net loss of $30,982,000 for the year ended December 31, 1999. The increase in net loss for fiscal 2000 was due primarily to the product recall returns and charges totaling $13,075,000 and increases in research and development and selling, general and administrative expenses, partially offset by the increase in net sales net of related cost of sales.

Net loss from operations of discontinued operation. Net sales of transplantation services for the year ended December 31, 2001 were $5,233,000, a decrease of $12,269,000 or 70% from sales of $17,502,000 for the year ended December 31, 2000. The decrease in net sales reflects the sale of our transplantation services business, The Transplant Pharmacy, that closed on April 20, 2001. Net sales of transplantation services in fiscal 2000 represented an increase of $3,637,000 or 26% over sales of $13,865,000 for the year ended December 31, 1999. The increase in net sales in fiscal 2000 was due primarily to an increase in the number of patients serviced by The Transplant Pharmacy. Net sales for all periods consisted entirely of drug sales to transplant patients.

Net loss for transplantation services for the year ended December 31, 2001 was $763,000, compared to a net loss of $2,342,000 for the year ended December 30, 2000. The decrease in net loss reflects the sale of our transplantation services business, The Transplant Pharmacy, that closed on April 20, 2001. Net loss for transplantation services for the year ended December 31, 2000 was $2,342,000, an increase of $317,000 or 16% compared to the net loss of $2,025,000 for the year ended December 31, 1999. The increase in net loss for 2000 was due primarily to the increase in operating expenses, partially offset by an increase in sales of The Transplant Pharmacy.

Net loss from disposal of discontinued operation. Net loss on disposal of discontinued operation of $381,000 represents sale proceeds of $1,800,000 less estimated expenses of $2,181,000 incurred for the discontinued operation. These expenses primarily related to the costs associated with the closure of The Transplant Pharmacy operation including employee severance and the estimated future lease obligations for the facilities supporting The Transplant Pharmacy.

Liquidity and Capital Resources

From inception through December 31, 2001, we financed our operations substantially from proceeds of approximately $137,977,000 from public offerings of our Common Stock, $76,398,000 from private placements of equity securities and $25,550,000 from the convertible note and the note payable to Abbott Laboratories. As of December 31, 2001, we had cash, cash equivalents and short-term investments of $32,822,000 and total assets of $114,559,000.

During the year ended December 31, 2001, net cash provided by operating activities was approximately $4,407,000 as compared to net cash used in operating activities of $25,610,000 and $39,885,000 respectively for the years ended December 31, 2000 and 1999. The decrease in net cash used in operating activities in fiscal 2001 was due substantially to a significant reduction in net loss and a reduction in other current assets due to the reclassification of $5,000,000 to cash and cash equivalents. This cash had previously been treated as restricted since it served as collateral for the loan with FINOVA. However, the loan was repaid in June 2001 and therefore the cash is no longer restricted. Other factors contributing to the net cash provided by operating activities included an increase in accounts payable and accrued liabilities and a decrease in other receivables. Net cash used in operating activities in fiscal 2000 was substantially due to a reduction in net inventories and increases in accounts payable and accrued liabilities, partially offset by an increase in net loss. The reduction in inventories is primarily due to provisions of $11,774,000 relating to the SangCya Oral Solution product recall, which resulted in a corresponding increase in net loss for fiscal

2000. Net cash used in 2000 also included an increase in other current assets reflecting $5,000,000 cash used as collateral for the note payable to FINOVA. In fiscal year 1999, net cash used in operating activities was primarily due to the amount of net loss incurred, as well as an increase in inventories and a decrease in accounts payable over the prior year partially offset by deferred revenue of $13,730,000 representing milestone payments from Abbott Laboratories in connection with our co-promotion agreement with Abbott.

Net cash provided by investing activities totaled $5,438,000, $3,694,000 and $4,245,000 during the years ended December 31, 2001, 2000 and 1999 respectively. The amount for fiscal 2001 is primarily the result of a decrease in other assets, proceeds from the sale of The Transplant Pharmacy and maturities of short term investments, partially offset by purchases of property and equipment. In fiscal years 2000 and 1999, cash was provided by maturities of short-term investments, partially offset by purchases of property and equipment and purchases of short-term investments.

Net cash provided by financing activities totaled $7,699,000, $27,221,000, and $39,521,000 during the years ended December 31, 2001, 2000 and 1999 respectively. In fiscal year 2001, net cash was provided primarily by the sale of common stock, partially offset by repayments of notes and capital lease obligations. In both fiscal years 2000 and 1999, cash was provided by the issuance of notes payable and the sale of common stock which are described in more detail in the following paragraphs.

On April 21, 2000 we signed an agreement with FINOVA to provide a line of credit of up to $30 million (the Loan Agreement). At December 31, 2000 we had drawn down $5.0 million under the line of credit and had set aside a corresponding compensating balance, which was included in Other Current Assets on our consolidated balance sheet. Subsequently, we repaid the loan balance of $5,000,000 on June 29, 2001, and terminated the Loan Agreement. Since the loan has been repaid, the $5,000,000 compensating cash balance previously classified as other current assets has now been classified as cash in the accompanying consolidated balance sheet. In connection with this financing, we issued a warrant to purchase 50,000 shares of our common stock at an exercise price of $23.438. This warrant was valued using the Black-Scholes pricing model with the following weighted average assumptions: expected life, five years; stock volatility, 72%; risk free interest rate, 6.0%; and no dividend payments during the expected term. The calculated value of the warrant of $744,000 and the additional financing fees of $750,000 were reflected as additional interest expense over the life of the loan.

In August 2000, we entered into a global co-development, supply and license agreement with Abgenix, Inc. for ABX-CBL, an antibody developed by Abgenix. The agreement provides us with an exclusive worldwide license for the marketing and sale of ABX-CBL, an anti-CD147 monoclonal antibody for the treatment of steroid resistant graft versus host disease (GVHD). ABX-CBL is currently in a multicenter, randomized, and controlled Phase II/III study. We made an initial license fee payment of $1,000,000 and an additional payment to Abgenix of $1,000,000 as partial reimbursement of one-half of the development costs incurred by Abgenix between January 1, 2000 and August 8, 2000. The agreement requires us to pay a further $900,000 as reimbursement of these development costs in two equal installments at the end of June 2001 and 2002, the first of which has been paid. Development costs incurred after August 8, 2000 are being shared equally, as would any potential profits from future sales of collaboration products. We share responsibility for product development, including the ongoing clinical trial. Abgenix will be responsible for manufacturing ABX-CBL. We also have the right, subject to the terms and conditions of the agreement, to commercialize other anti-CD147 antibodies developed by Abgenix. If ABX-CBL receives regulatory approval and is launched, we will be required to pay Abgenix for our share of development expenses incurred prior to January 1, 2000. The amount has not been determined, but the agreement limits our obligation to $6,100,000. We do not have any obligation to reimburse Abgenix until the first anniversary of the launch of ABX-CBL and the timing of reimbursement varies depending on ABX-CBL s sales.

In March 1999, we issued a $10 million convertible note due March 30, 2004. This note bears interest at the rate of 6.5% through March 30, 2004 and thereafter at the rate of 8.5% on any overdue amount. The interest is payable semi-annually in September and March. The note, or any portion thereof, is convertible at the option of the holder at any time before March 30, 2004 into shares of our common stock at the rate of 50.0773 shares of common stock for each $1,000 of principal amount. We received net proceeds of $9,550,000.

In May 1999, we received a loan of $16 million from Abbott Laboratories. The loan bears interest at 8.75%, payable annually. The loan matures on December 31, 2004, and can be pre-paid without penalty at any time prior to

maturity. In February 2002, the Company repaid $8 million on the loan.

Notes payable include $8,273,000 and $13,293,000 at December 31, 2001 and 2000, respectively, representing the current accreted value of the non-interest bearing note issued in connection with the acquisition of IMTIX. The note was discounted at a rate of 9.25% and the remaining unpaid balance of $9 million at December 31, 2001 is payable as follows: $5 million in 2002, and $4 million in 2003.

In fiscal years 2001, 2000 and 1999 we purchased $1,146,000, $3,790,000 and $4,020,000, respectively, of new property and equipment. In fiscal year 2001 purchases consisted primarily of manufacturing and other equipment. In fiscal years 2000 and 1999 this purchasing consisted primarily of manufacturing equipment, leasehold improvements for our new corporate headquarters in Fremont, California and expenditures associated with the implementation of a global enterprise resource planning (ERP) system.

At December 31, 2001, we had federal, state and foreign net operating loss (NOL) carryforwards of approximately $139,653,000, $12,916,000 and $2,048,000, respectively, available to reduce future taxable income. Such carryforwards expire beginning in 2002 through 2021. In addition, we had available research and experimentation credit carryforwards of approximately $4,635,000 and $2,859,000 for federal and state tax purposes respectively. The federal tax credit carryforwards expire beginning in 2004 through 2013 and the state tax credit carryforwards have no expiration dates. Our ability to realize the benefits of the NOL and credit carryforwards is dependent upon the generation of sufficient taxable income in the respective taxing jurisdictions prior to their expiration. There can be no assurance that we will be able to generate sufficient taxable income to avail ourselves of such benefits. Furthermore, utilization of the net operating losses and credits may be subject to an annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

We believe we have sufficient funds to continue operations for at least the next twelve months. However, we may need to raise additional funds through additional financings, including private or public equity and/or debt offerings and collaborative research and development arrangements with corporate partners in order to pursue new business opportunities. Our future capital requirements will depend on many factors, including our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property, the status of competitive products, the maintenance of our manufacturing facility and the establishment of third-party manufacturing arrangements, the maintenance of sales and marketing capabilities, the establishment of collaborative relationships with other parties, and the costs of manufacturing scale-up and working capital requirements for inventory and financing of accounts receivable.

Euro-Currency

The Single European Currency (Euro) was introduced on January 1, 1999 with complete transition to this new currency required by January 2002. We have completed all necessary changes to our internal systems and have fully transitioned to the Euro. We expect that use of the Euro may affect our foreign exchange activities and may result in increased fluctuations in foreign currency results.

Recently Issued Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 133, *Accounting for Derivative Instruments and Hedging Activities.* This statement requires companies to record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting. We adopted SFAS No. 133, as amended, effective January 1, 2001. The adoption of this statement did not have a material effect on our financial position, operating results or cash flows, as we had no stand-alone or embedded derivatives at December 31, 2000 and had not historically entered into any derivative transactions to hedge currency or other exposures.

In September 2000, the FASB issued SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. SFAS No. 140 replaces SFAS No. 125, *Accounting for Transfers and Servicing*

of Financial Assets and Extinguishments of Liabilities. It revises the standards for accounting for securitizations and other transfers of financial assets and collateral and requires certain disclosures, but carries over most of SFAS No. 125 s provisions without reconsideration. We adopted the applicable disclosure requirements of SFAS No. 140 in our consolidated financial statements as of December 31, 2000 and adopted the remaining provision of SFAS No. 140 on April 1, 2001. We have concluded that the adoption of the remaining provisions of SFAS No. 140 after March 31, 2001 did not have a significant impact on our financial position or results of operations.

In June 2001, the FASB issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired outside of a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives not be amortized, but will rather be tested at least annually for impairment. We will adopt SFAS No. 142 for our fiscal year beginning January 1, 2002. We are in the process of evaluating existing goodwill and intangibles under the transitional impairment test in SFAS No. 142 and, accordingly, have not yet determined whether or not there will be an impairment loss. Any transitional impairment loss will be recognized as a change in accounting principle.

In July 2001, the FASB issued SFAS No. 143, *Accounting for Asset Retirement Obligations*. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development, and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The provisions of SFAS No. 143 will be effective for fiscal years beginning after June 15, 2002; however early application is permitted. We are currently in the process of evaluating the impact of this Statement on our financial condition and operating results.

In August 2001, the FASB issued SFAS No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*. SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, and addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This statement is effective for fiscal years beginning after December 15, 2001. We will adopt SFAS No. 144 on January 1, 2002. The adoption of this statement is not expected to have a significant impact on our financial position or results of operations.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates, equity security prices and foreign currency exchange rates.

Interest Rate Sensitivity. We maintain a short-term investment portfolio consisting mainly of government and corporate bonds purchased with an average maturity of less than one year. These available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. If market rates were to increase immediately and uniformly by 10% from levels at December 31, 2001, the fair value of the portfolio would decline by an immaterial amount, which is consistent with the estimated effects at December 31, 2000. We generally have the ability to hold fixed income investments until maturity and therefore do not expect operating results or cash flows to

be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

Substantially all of our long-term obligations bear interest at fixed rates which are not subject to future increases in interest rates. The fair value of these long-term obligations, including current portion, at December 31, 2001 was $36.7 million compared to book value of $35.8 million (see Note 9 to Consolidated Financial Statements). The corresponding fair value at December 31, 2000 was $45.2 million compared to book value of $47.5 million. We therefore do not expect operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates. If our notes payable and convertible debt were subject to rate fluctuation, a hypothetical interest rate increase of 1% would have added approximately $358,000 to our interest expense for 2001 and $475,000 for 2000.

	December 31, 2001				
	Expected Maturity Date				
	2002	2003	2004	Total	Fair Value
Liabilities					in thousands
Long-term Debt					
Fixed Rate denominated	$ 4,424	$ 4,220	$ 25,993	$ 34,637	$ 35,489
Average interest rate	7.3%	7.0%	6.6%	7.0%	
Variable Rate denominated	1,191			1,191	1,191
Average interest rate	4.4%			4.4%	
Total	$ 5,615	$ 4,220	$ 25,993	$ 35,828	$ 36,680

Equity Price Risk. Following the sale of our portfolio of corporate equity securities in December 1999 and January 2000 for a net gain of $660,000, we no longer hold any such securities.

Foreign Currency Risk. Many of our foreign sales are invoiced in local currencies, creating receivables denominated in currencies other than the U.S. dollar, primarily in the Euro and the Japanese yen. The risk due to foreign currency fluctuation associated with these receivables is partially reduced by local payables denominated in the same currencies, and presently we do not consider it necessary to hedge these exposures. We intend to re-assess our hedging policy from time to time as our foreign operations change. A 10% movement in the currency exchange rate would not have a material impact on our financial position or our results of operations.

All of the potential changes noted above are based on sensitivity analyses performed on our financial positions at December 31, 2001 and 2000. Actual results may differ materially.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Reference is made to item 14(a)(1) of this Annual Report on Form 10- K.

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

None.

PART III

The information required by Items 10 through 13 of Part III is incorporated by reference from the registrant s Proxy Statement, under the captio*ns Election of Directors - Nominees, Security Ownership of Certain Beneficial Owners and Management, Executive Compensation, Compensation Committee Interlocks and Insider Participation,* and *Certain Transactions* , which Proxy Statement will be mailed to stockholders in connection with the registrant s annual meeting of stockholders which is expected to be held in May 2002. Information on the Executive Officers is contained in Item 1 under the heading, *Management.*

PART IV

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

(a) The following documents are filed as a part of this Annual Report on Form 10-K:

1. Financial Statements.

Independent Auditors Report

Consolidated Balance Sheets December 31, 2001 and 2000

Consolidated Statements of Operations for the years ended December 31, 2001, 2000 and 1999

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2001, 2000 and 1999

Consolidated Statements of Stockholders Equity for the years ended December 31, 2001, 2000 and 1999

Consolidated Statements of Cash Flows for the years ended December 31, 2001, 2000 and 1999

Notes to Consolidated Financial Statements for the years ended December 31, 2001, 2000 and 1999

2. Financial Statement Schedule.

Schedule II Valuation and Qualifying Accounts

All other schedules are omitted because they are not required, are not applicable or the information is included in the consolidated financial statements and notes thereto.

3. Exhibits. Reference is made to Item 14(c) of this Annual Report on Form 10-K.

(b) Reports on Form 8-K.

On October 9, 2001, we filed a report on Form 8-K, reporting under Item 5 that the Board of Directors of the Company had approved the First Amendment to Rights Agreement, dated as of October 8, 2001, by and among the Company, Fleet National Bank (f/k/a The First National Bank of Boston) and EquiServe Trust Company, N.A. (the Amendment). The Amendment was adopted to appoint EquiServe Trust Company, N.A. as successor rights agent to the Rights Agreement, dated as of August 14, 1995, between the Company and The First National Bank of Boston as Rights Agent, and to conform the Rights Agreement to current Delaware law regarding the use of continuing director provisions.

On October 22, 2001, we filed a report on Form 8-K, reporting under Item 5 that Carole L. Nuechterlein, Senior Vice President, General Counsel and Secretary of the Company, had resigned and that Adrian Arima, Vice President and Associate General Counsel of the Company, would assume responsibility for the Company s legal affairs.

(c) Exhibits.

Exhibits	Description of Exhibit
2.1	Agreement and Plan of Merger, dated as of July 24, 1995, between SangStat Delaware, Inc. and SangStat Medical Corporation, a California corporation, as filed with the Delaware Secretary of State on August 11, 1995 (filed as Exhibit 2.1 to the Registrant s Registration Statement on Form 8-B, filed on December 4, 1995, and incorporated herein by reference).
2.2	Master Agreement between SangStat Medical Corporation and Pasteur Merieux Serums & Vaccins, S.A., dated June 10, 1998, including Exhibit 8 thereto (filed as Exhibit 2.1 to the Registrant s Current Report on Form 8-K, filed on October 15, 1998 and as amended on December 14, 1998, and incorporated herein by reference).
3.1	Certificate of Incorporation of SangStat Delaware, Inc. (filed as Exhibit 3.1 to the Registrant s Registration Statement on Form 8-B, filed on December 4, 1995, and incorporated herein by reference).
3.2	Certificate of Amendment of the Certification of Incorporation, filed with the Delaware Secretary of State on July 24, 2000 (filed as Exhibit 3.6 to the Registrant s Current Report on Form 8-K, filed on August 30, 2000, and incorporated herein by reference).
3.3	Certificate of Designation for the Series A Junior Participating Preferred Stock, filed with the Delaware Secretary of State on August 16, 1995 (filed as Exhibit 3.4 to the Registrant s Current Report on Form 8-K, filed on September 1, 1995, and incorporated herein by reference).
3.4	Second Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 30, 2000, filed on May 15, 2000, and incorporated herein by reference).
4.1	Specimen Common Stock Certificate of Registrant (filed as Exhibit 4.5 to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.1*	1993 Stock Option/Stock Issuance Plan (filed as Exhibit 10.7 to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.2	Form of Indemnification Agreement between the Registrant and its directors, officers and certain other employees (filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2001, filed on November 14, 2001, and incorporated herein by reference).
10.3**	License Agreement, dated November 15, 1993, between the Registrant and the Board of Trustees of Leland Stanford Junior University (filed as Exhibit 10.19 to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.4	Rights Agreement, dated as of August 14, 1995, between the Registrant and First National Bank of Boston (filed as Exhibit 2 to the Registrant s Registration Statement on Form 8-A, filed on August 25, 1995, and incorporated herein by reference).

Exhibits	Description of Exhibit
10.5	First Amendment to Rights Agreement, dated as of October 8, 2001, among the Registrant, Fleet National Bank (f/k/a The First National Bank of Boston) and EquiServe Trust Company, N.A. (filed as Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed on October 9, 2001, and incorporated herein by reference).
10.6	Real Property Sub-Lease, dated March 8, 1999, between the Registrant and Kelley-Clarke, Inc. to the Real Property lease, dated September 1, 1988, between Kelly-Clarke Inc. and Kaiser Development Company, as amended on February 26, 1990, May 1, 1990, May 5, 1990, and April 19, 1995 (filed as Exhibit 10.26 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1998, filed on March 31, 1999, and incorporated herein by reference).
10.7**	Co-Promotion Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.28 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000, filed on March 30, 2001, and incorporated herein by reference).
10.8	Right of First Refusal Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.28 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed on August 16, 1999, and incorporated herein by reference).
10.9	Registration Rights Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.29 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed on August 16, 1999, and incorporated herein by reference).
10.10	Convertible Promissory Note, dated March 1999, for $10,000,000 with Warburg Dillon Read LLC (filed as Exhibit 10.32 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1999, filed on April 14, 2000, and incorporated herein by reference).
10.11**	Co-Development, Supply and License Agreement, dated as of August 8, 2000, between the Registrant and Abgenix, Inc. (filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000, and incorporated herein by reference).
10.12	Securities Purchase Agreement, dated December 29, 2000, between the Registrant and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, and SDS Capital Partners, LLC (filed as Exhibit 10.35 to the Registrant s Current Report on Form 8-K, filed on January 8, 2001, and incorporated herein by reference).
10.13	Registration Rights Agreement, dated December 29, 2000, between the Registrant and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, and SDS Capital Partners, LLC (filed as Exhibit 10.36 to the Registrant s Current Report on Form 8-K, filed on January 8, 2001, and incorporated herein by reference).
10.14	Securities Purchase Agreement, dated as of June 20, 2001, between the Company and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, S.A.C. Capital Associates, LLC, and Société Générale (filed as Exhibit 10.39 to the Registrant s Current Report on Form 8-K, filed on June 21, 2001, and incorporated herein by reference).

Exhibits	Description of Exhibit
10.15	Registration Rights Agreement, dated as of June 20, 2001, between the Company and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, S.A.C. Capital Associates, LLC, and Société Générale (filed as Exhibit 10.40 to the Registrant s Current Report on Form 8-K, filed on June 21, 2001, and incorporated herein by reference).
10.16	Registration Rights Agreement, dated March 19, 1999, by and between Registrant and Warburg Dillon Read LLC (filed as Exhibit 4.4 to the Registrant s Registration Statement on Form S-3, file no. 333-46578, and incorporated herein by reference).
21.1	Subsidiaries of Registrant.
23.1	Independent Auditors Consent.
24.1	Power of Attorney (reference is made to the signature page hereof).

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* Management contract or compensatory plan or arrangement.

**Confidential treatment has been granted for the deleted portions of this document. The non-public information has been filed separately with the SEC.

INDEPENDENT AUDITORS REPORT

To the Board of Directors and Stockholders
of SangStat Medical Corporation:

We have audited the accompanying consolidated balance sheets of SangStat Medical Corporation and subsidiaries (collectively, the Company) as of December 31, 2001 and 2000, and the related consolidated statements of operations, comprehensive loss, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2001. Our audits also included the consolidated financial statement schedule listed in Item 14(a)2. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such consolidated financial statement schedule referenced above, when considered in relation to the basic consolidated financial statements as a whole, presents fairly, in all material respects, the information set forth therein.

DELOITTE & TOUCHE LLP

San Jose, California
January 21, 2002 (March 27, 2002 as to Note 5, the second paragraph of Note 10, the ninth paragraph of Note 19 and Note 20)

SANGSTAT MEDICAL CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

ASSETS

	December 31, 2001	2000
CURRENT ASSETS:		
Cash and cash equivalents	$ 32,822	$ 19,046
Short-term investments		1,561
Accounts receivable (net of allowance for doubtful accounts of $4,072 in 2001 and $3,128 in 2000)	19,872	17,569
Other receivables	480	2,333
Inventories	22,942	40,056
Prepaid expenses and other current assets	2,494	6,912
Total current assets	78,610	87,477
PROPERTY AND EQUIPMENT net	5,469	6,539
INTANGIBLE ASSETS (net of accumulated amortization of $4,324 in 2001 and $3,141 in 2000)	9,220	11,142
OTHER ASSETS	21,260	9,158
TOTAL	$ 114,559	$ 114,316

LIABILITIES AND STOCKHOLDERS EQUITY

CURRENT LIABILITIES:		
Accounts payable	$ 22,019	$ 17,553
Accrued liabilities	14,375	13,938
Capital lease obligations current portion	177	257
Deferred revenue current portion	3,158	3,158
Notes payable current portion	5,615	12,797
Total current liabilities	45,344	47,703
CAPITAL LEASE OBLIGATIONS	326	535
DEFERRED REVENUE	6,317	9,475
NOTES PAYABLE	30,213	34,679
COMMITMENTS AND CONTINGENCIES (Notes 10, 11 and 19)		
STOCKHOLDERS EQUITY:		
Preferred stock, $.001 par value 5,000 shares authorized; none outstanding		
	222,521	201,766

Common stock. $.001 par value, 35,000 shares authorized; outstanding: 2001, 20,961 shares; 2000, 18,942 shares				
Accumulated deficit		(187,015)		(177,636)
Accumulated other comprehensive loss		(3,147)		(2,206)
Total stockholders equity		32,359		21,924
TOTAL	$	114,559	$	114,316

See notes to consolidated financial statements.

SANGSTAT MEDICAL CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2001	**2000**	**1999**
REVENUES:			
Net product sales	$ 91,302	$ 61,319	$ 42,243
Product recall returns		(872)	
Revenue from collaborative agreements (Note 10)	3,207	2,698	2,060
Total revenues	94,509	63,145	44,303
COSTS AND OPERATING EXPENSES:			
Cost of sales:			
Cost of product sales	42,816	27,472	18,989
Product recall charges		11,774	
Research and development (incl. product recall expenses of $50 for the year ended December 31, 2000)	17,863	20,788	14,470
Selling, general and administrative (incl. product recall expenses of $379 for the year ended December 31, 2000)	33,782	41,766	39,170
Amortization of intangible assets	1,922	1,392	1,398
Total costs and operating expenses	96,383	103,192	74,027
Loss from operations of continuing operations	(1,874)	(40,047)	(29,724)
OTHER INCOME (EXPENSE), NET:			
Interest income	1,203	2,016	1,865
Interest expense	(4,830)	(4,368)	(3,034)
Other income (expense), net	(2,741)	750	256
Other income (expense), net	(6,368)	(1,602)	(913)
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	(8,242)	(41,649)	(30,637)
INCOME TAX BENEFIT (PROVISION)	7	(368)	(345)
NET LOSS FROM CONTINUING OPERATIONS	(8,235)	(42,017)	(30,982)
NET LOSS FROM OPERATIONS OF DISCONTINUED OPERATION	(763)	(2,342)	(2,025)
NET LOSS FROM DISPOSAL OF DISCONTINUED OPERATION	(381)		
NET LOSS	$ (9,379)	$ (44,359)	$ (33,007)

NET LOSS PER SHARE-Basic and diluted (Note 1)			
Continuing operations	$ (0.40)	$ (2.35)	$ (1.83)
Discontinued operation	(0.06)	(0.13)	(0.12)
	$ (0.46)	$ (2.48)	$ (1.95)
WEIGHTED AVERAGE COMMON SHARES	20,216	17,910	16,888

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	Year Ended December 31,		
	2001	**2000**	**1999**
Net loss	$ (9,379)	$ (44,359)	$ (33,007)
Reversal of unrealized gain on marketable securities sold during the period	(6)	(644)	
Unrealized gains on marketable securities classified as available for sale in the current period		40	1078
Foreign currency translation adjustments	(935)	(898)	(1,388)
Total comprehensive loss	$ (10,320)	$ (45,861)	$ (33,317)

See notes to consolidated financial statements.

SANGSTAT MEDICAL CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
(in thousands, except share data)

	Common stock		Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Deficit	Loss	Total
Balances, January 1, 1999	16,214,851	$ 160,251	$ (100,270)	$ (394)	$ 59,587
Issuance of common stock	893,996	12,661			12,661
Exercise of stock options	244,927	1,859			1,859
Issuance of stock for services		160			160
Stock option compensation expense		59			59
Foreign currency translation adjustment				(1,388)	(1,388)
Unrealized gain on investments				1,078	1,078
Net loss			(33,007)		(33,007)
Balances, December 31, 1999	17,353,774	174,990	(133,277)	(704)	41,009
Issuance of common stock	1,345,928	23,401			23,401
Exercise of stock options	242,644	2,631			2,631
Warrant issued in connection with financing		744			744
Foreign currency translation adjustment				(898)	(898)
Reversal of unrealized gain on marketable securities sold during the period, net				(604)	(604)
Net loss			(44,359)		(44,359)
Balances, December 31, 2000	18,942,346	201,766	(177,636)	(2,206)	21,924
Issuance of common stock	1,784,635	18,774			18,774
Exercise of stock options	233,693	1,931			1,931
Stock option compensation expense		50			50
Foreign currency translation adjustment				(935)	(935)
Reversal of unrealized gain on marketable securities sold during the period, net				(6)	(6)
Net loss			(9,379)		(9,379)
Balances, December 31, 2001	20,960,674	$ 222,521	$ (187,015)	$ (3,147)	$ 32,359

See notes to consolidated financial statements.

SANGSTAT MEDICAL CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2001	**2000**	**1999**
OPERATING ACTIVITIES:			
Net loss from continuing operations	$ (8,235)	$ (42,017)	$ (30,982)
Adjustments to reconcile net loss from continuing operations to net cash provided by (used in) continuing operating activities:			
Depreciation and amortization	3,777	3,780	2,921
Non-cash interest expense	1,069	1,365	1,476
Loss on disposal of property and equipment	249	836	167
Stock compensation expense	50		219
Deferred income taxes	84	130	88
Changes in assets and liabilities:			
Accounts receivable	(2,303)	(4,787)	(1,819)
Other receivables	1,853	573	(465)
Inventories	1,784	6,214	(12,895)
Prepaid expenses and other current assets	4,418	(4,606)	(579)
Accounts payable	4,466	5,702	(13,973)
Accrued liabilities	353	8,297	2,227
Deferred revenue	(3,158)	(1,097)	13,730
Net cash provided by (used in) continuing operating activities	4,407	(25,610)	(39,885)
Net cash used in discontinued operation	(2,944)	(2,223)	(1,917)
INVESTING ACTIVITIES:			
Purchases of property and equipment	(1,146)	(3,790)	(4,020)
Maturities of short-term investments	1,556	7,492	8,517
Purchase of short-term investments			(3,721)
Proceeds from the sale of discontinued operation	1,800		
Other assets	3,228	(8)	3,469
Net cash provided by investing activities	5,438	3,694	4,245
FINANCING ACTIVITIES:			
Sale of common stock	20,705	26,032	14,520
Notes payable borrowings	465	6,574	28,513
Notes payable repayments	(13,182)	(4,834)	(3,079)
Repayment of capital lease obligations	(289)	(551)	(433)
Net cash provided by financing activities	7,699	27,221	39,521
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(824)	(898)	(1,388)

NET INCREASE IN CASH AND EQUIVALENTS	13,776	2,184	576
CASH AND EQUIVALENTS, Beginning of year	19,046	16,862	16,286
CASH AND EQUIVALENTS, End of year	$ 32,822	$ 19,046	$ 16,862
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid during the period for interest	$ 4,260	$ 1,158	$ 1,401
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Warrants issued in connection with financing	$	$ 744	$
Property acquired under capital leases	$	$ 518	$ 493
Unrealized gain (loss) on investments	$ (5)	$ 604	$ 1,078

See notes to consolidated financial statements.

SANGSTAT MEDICAL CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2001, 2000 and 1999

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Organization- SangStat Medical Corporation and subsidiaries (the Company) is a global biotechnology company building on its foundation in transplantation to discover, develop and market high value therapeutic products in the transplantation, immunology and hematology/oncology areas.

Principles of Consolidation- The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany accounts and transactions are eliminated.

Revenue Recognition- Revenue from product sales, net of estimated sales allowances and rebates, is recognized upon receipt by the customer, when a purchase order has been received, the sales price is fixed or determinable and collection of the resulting receivable is reasonably assured. Revenue from collaborative agreements is recognized in accordance with the related contract terms. Up-front or milestone payments received under such agreements are generally recognized as revenues ratably over the life of the agreement where significant obligations for future services or Company participation exist or as milestones are met and no significant obligation for future services exists.

Research and Development- Research and development costs are expensed as incurred and include expenses associated with new product research, clinical trials of existing technologies, regulatory affairs activities associated with product candidates and costs incurred under our co-development agreements.

Advertising Expenses- Advertising costs, which also include promotional expenses, are expensed as incurred. Advertising expenses for the years ended December 31, 2001, 2000 and 1999 were approximately $2.4 million, $4.5 million and $3.2 million, respectively.

Cash and Cash Equivalents- The Company considers all highly liquid debt instruments with a remaining maturity date of three months or less when purchased to be cash equivalents.

Short-Term Investments- The Company has classified all of its investments as available-for-sale securities. While the Company s practice is to hold debt securities to maturity, the Company has classified all debt securities as available-for-sale securities, as the sale of such securities may be required prior to maturity to implement management strategies. The carrying value of all securities is adjusted to fair market value, with unrealized gains and losses, net of deferred taxes, being excluded from earnings and reported as a separate component of stockholders equity and included in accumulated other comprehensive loss. Cost is based on the specific identification method for purposes of computing realized gains or losses.

Inventories- Inventories are stated at the lower of cost (first-in, first-out) or market. The Company classifies inventory not expected to be utilized within the next twelve months as Other Assets (See Notes 3 and 6).

Property and Equipment- Property and equipment are stated at cost. Depreciation is calculated using the straight-line method over estimated useful lives of three to ten years. Leasehold improvements and assets under capital leases are amortized over the shorter of their lease term or estimated useful life.

Valuation of Long-lived Assets- The carrying value of the Company s long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that an asset may not be recoverable. The Company looks to current and future undiscounted cash flows, excluding financing costs, as primary indicators of recoverability. If an impairment is determined to exist, any related impairment loss is calculated based on fair value.

Foreign Currency Translation- Operations for the majority of the Company s foreign subsidiaries are measured using local currency as the functional currency. Assets and liabilities of such subsidiaries are translated into US dollars at the exchange rates in effect as of the balance sheet dates, and results of operations for each subsidiary are translated using average rates in effect for the periods presented. Gains or losses resulting from foreign currency

translation are included as a component of accumulated other comprehensive loss.

The Company s subsidiary SangStat Atlantique uses the US dollar as its functional currency. Foreign currency denominated assets and liabilities are translated at the year-end exchange rates except for inventories, prepaid expenses, and property and equipment, which are translated at historical exchange rates. Gains or losses resulting from foreign currency translation and other foreign currency transaction gains and losses are included in other income (expense) - net in the consolidated statements of operations and were not significant for any period presented.

Stock-Based Compensation- The Company accounts for stock-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board (APB) No. 25, *Accounting for Stock Issued to Employees* (APB 25) *and* the Financial Accounting Standards Board (FASB) Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*. The Company accounts for stock based awards to non-employees in accordance with Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation.*

Net Loss Per Share- Basic EPS excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted into common stock. Common share equivalents including stock options and convertible notes payable, aggregating 337,875 shares, 1,215,203 shares and 1,011,247 shares for the years ended December 31, 2001, 2000 and 1999 , respectively, have been excluded from diluted EPS, as their effect would be antidilutive.

The following is a reconciliation of the numerators and denominators of the basic and diluted net loss per share computations:

	Year Ended December 31,		
	2001	**2000**	**1999**
Net loss (numerator)			
Continuing operations	$ 8,235	$ 42,017	$ 30,982
Discontinued operation	1,144	2,342	2,025
	$ 9,379	$ 44,359	$ 33,007
Shares (denominator)			
Weighted average common shares outstanding	20,216	17,910	16,888
Net loss per share - basic and diluted			
Continuing operations	$ 0.40	$ 2.35	$ 1.83
Discontinued operation	0.06	0.13	0.12
	$ 0.46	$ 2.48	$ 1.95

Certain Significant Risks and Uncertainties- The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The Company sells its products primarily to organizations in the healthcare industry in the US, Canada and Europe, and does not require its customers to provide collateral or other security to support accounts receivable. The Company maintains allowances for estimated bad debt losses.

The Company participates in the dynamic biopharmaceutical industry. The Company believes that changes in any of the following areas could have a negative impact on the Company in terms of its future financial position and results of operations: ability to obtain additional financing; successful product development; manufacturing and marketing capabilities; ability to negotiate acceptable collaborative relationships; obtaining necessary FDA and foreign regulatory approvals; ability to attract and retain key personnel; litigation and other claims against the Company,

including, but not limited to, patent claims; increased competition; uncertainty regarding health care reimbursement and reform; and potential exposure for product liability and hazardous materials.

Accumulated Other Comprehensive Loss- The following are the components of accumulated other comprehensive loss (in thousands):

	December 31,		
	2001	**2000**	**1999**
Unrealized gain on investments	$	$ 6	$ 609
Foreign currency translation adjustments	(3,147)	(2,212)	(1,313)
Total	$ (3,147)	$ (2,206)	$ (704)

Recently Issued Accounting Pronouncements- In June 1998, the FASB issued SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. This Statement requires companies to record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting. The Company adopted SFAS No. 133, as amended, effective January 1, 2001. The adoption of this Statement did not have a material effect on the Company s financial position, results of operations or cash flows, as the Company had no stand-alone or embedded derivatives at December 31, 2000 and had not historically entered into any derivative transactions to hedge currency or other exposures.

In September 2000, the FASB issued SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. SFAS No. 140 replaces SFAS No. 125, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. It revises the standards for accounting for securitizations and other transfers of financial assets and collateral and requires certain disclosures, but carries over most of SFAS No. 125 s provisions without reconsideration. The Company adopted the applicable disclosure requirements of SFAS No. 140 in its consolidated financial statements as of December 31, 2000 and adopted the remaining provision of SFAS No. 140 on April 1, 2001. The Company has concluded that the adoption of the remaining provisions of SFAS No. 140 after March 31, 2001 did not have a significant impact on the Company s financial position or results of operations.

In June 2001, the FASB issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangible Assets.* SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired outside of a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives not be amortized, but will rather be tested at least annually for impairment. The Company will adopt SFAS No. 142 for its fiscal year beginning January 1, 2002. The Company is in the process of evaluating existing goodwill and intangibles under the transitional impairment test in SFAS No. 142 and, accordingly, has not yet determined whether or not there will be an impairment loss. Any transitional impairment loss will be recognized as a change in accounting principle.

In July 2001, the Financial Accounting Standards Board issued SFAS No.143, *Accounting for Asset Retirement Obligations*. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development, and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The provisions of SFAS No. 143 will be effective for fiscal years beginning after June 15, 2002; however early application is permitted. The Company is currently in the process of evaluating the impact of this Statement on its financial condition and results of operations.

In August 2001, the FASB issued SFAS No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*.

SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, and addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This Statement is effective for fiscal years beginning after December 15, 2001. The Company will adopt SFAS No. 144 on January 1, 2002. Adoption of this Statement is not expected to have a significant impact on the Company s financial position or results of operations.

2. INVESTMENTS

At December 31, 2001 there were no available-for-sale securities. At December 31, 2000 the available-for-sale securities consist of the following (in thousands):

	December 31, 2000			
	Amortized Cost	**Unrealized Gain on Investments**	**Unrealized Loss on Investments**	**Estimated Fair Value**
Corporate bonds	$ 1,415	$ 6	$	$ 1,421
1 year CD	140			140
Total	$ 1,555	$ 6	$	$ 1,561

3. INVENTORIES

Inventories consist of (in thousands):

	December 31,	
	2001	**2000**
Raw materials	$ 2,976	$ 18,860
Work in process	13,868	14,107
Finished goods	6,098	7,089
Total	$ 22,942	$ 40,056

In addition to these inventories, the Company has classified approximately $15 million of raw materials inventory as other assets in the accompanying consolidated balance sheet at December 31, 2001, as it is not expected that any significant portion of the inventory will be utilized in operations during the next twelve months.

4. PROPERTY AND EQUIPMENT

Property and equipment consist of (in thousands):

	December 31,	
	2001	2000
Machinery and equipment	$ 8,176	$ 8,072
Capitalized software	3,135	3,011
Furniture and fixtures	401	392
Projects in process	249	107
Leasehold improvements	1,464	1,440
Total	13,425	13,022
Accumulated depreciation and amortization	(7,956)	(6,483)
Property and equipment - net	$ 5,469	$ 6,539

Included in machinery and equipment at December 31, 2001 and 2000 are assets leased under capital leases of $2,236,000 and $2,287,000 (net of accumulated amortization of $1,784,000 and $1,584,000), respectively. Depreciation and amortization expense of property and equipment totaled $1,774,000, $2,507,000 and $1,412,000

for the years ended December 31, 2001, 2000 and 1999, respectively.

5. INTANGIBLE ASSETS

Intangible assets consist of (in thousands):

	December 31,	
	2001	**2000**
Developed technology	$ 7,613	$ 7,613
Avoided royalties	2,514	2,514
Assembled workforce	1,653	1,653
Distribution rights		739
Trademarks	762	762
Customer list	1,002	1,002
	13,544	14,283
Accumulated amortization	(4,324)	(3,141)
Intangible assets - net	$ 9,220	$ 11,142

Intangible assets are stated at cost. Amortization is calculated using the straight-line method over the estimated useful lives ranging from five to fourteen years. Amortization expense totaled $1,922,000, $1,392,000 and $1,398,000 for the years ended December 31, 2001, 2000 and 1999, respectively. Amortization expense in 2001 includes the write-off of $482,000 representing the net book value of the intangible asset related to distribution rights for Multitest and Celiptium, two minor products formerly sold in Europe. Sales of these two products were discontinued in the fourth quarter of 2001. Intangible assets resulted from the acquisition of IMTIX in 1998.

6. OTHER ASSETS

Other assets consist of (in thousands):

	December 31,	
	2001	**2000**
Inventory-raw materials (Note 3)	$ 15,263	$
Advance - Gensia Sicor	1,000	1,000
Deferred income tax benefits		303
Restricted cash	4,000	6,000
Finova warrant and closing costs (Note 8)		1,284
Other assets	997	571
Total	$ 21,260	$ 9,158

7. ACCRUED LIABILITIES

Accrued liabilities consist of (in thousands):

	December 31,	
	2001	2000
Salaries & related benefits	$ 4,483	$ 3,689
Interest payable	186	1,894
Research and development expenses (Note 10)	1,550	2,420
Marketing and development expenses (Note 10)	2,047	2,436
Other accrued liabilities	6,109	3,499
Total	$ 14,375	$ 13,938

8. NOTES PAYABLE

Notes payable consist of (in thousands):

	December 31,	
	2001	2000
Note payable to Aventis	$ 9,000	$ 15,000
Discount on note payable to Aventis	(727)	(1,707)
Convertible note	9,779	9,691
Note payable to Abbott Laboratories	16,000	16,000
Note payable to FINOVA		5,000
Other debt	1,776	3,492
Total	35,828	47,476
Less current portion	(5,615)	(12,797)
Long-term	$ 30,213	$ 34,679

In connection with the acquisition of IMTIX from Aventis in September 1998, the Company issued a $21 million non-interest bearing note payable over five years with remaining payments due as follows: $5 million in 2002 and $4 million in 2003. The note payable was discounted at a rate of 9.25%, which the Company believes was consistent with its normal borrowing rate. The resulting discount of approximately $4.8 million is being accreted as an addition to interest expense over the term of the note. During the years ended December 31, 2001, 2000 and 1999, $980,000, $1,282,000 and $1,418,000, respectively, of amortization was recognized. The Company had approximately $4.0 million and $6.0 million of restricted cash at December 31, 2001 and 2000, respectively, that serves as a collateral for a standby letter of credit in favor of Aventis.

In March 1999, the Company issued a $10 million convertible note due March 30, 2004. This note bears interest at the rate of 6.5% through March 30, 2004 and thereafter at the rate of 8.5% on any overdue amount. The interest is payable semi-annually in September and March. The note, or any portion thereof, is convertible at the option of the holder at any time before March 30, 2004 into shares of common stock of the Company at the rate of 50.0773 shares of common stock for each $1,000 principal amount. The net proceeds received by the Company were $9,550,000. The note is being accreted to its face amount over the five year term. As of December 31, 2001 there has been no conversion into common stock.

In May 1999, the Company received a loan of $16 million from Abbott Laboratories. The loan bears interest at 8.75%, payable annually, and is secured by a security interest in the US marketing rights for SangCya Oral Solution. The loan matures on December 31, 2004, and can be pre-paid by the Company without penalty at any time prior to maturity.

On April 21, 2000 the Company signed an agreement with FINOVA to provide a line of credit of up to $30 million (the Loan Agreement). The Loan Agreement had an initial three year term. The line of credit consisted of two elements: a $15 million line of credit bearing interest at the prime rate (9.0% at December 31, 2000) and secured by

a matching compensating cash balance, and a $15 million line of credit bearing interest at the prime rate plus 1.5% and based on eligible domestic accounts receivable and inventory, as defined in the Loan Agreement. Under the terms of the Loan Agreement, the Company was required to maintain a loan balance of at least $5 million. As collateral for the line of credit, the Company granted FINOVA a first priority security interest in certain of its tangible and intangible assets and pledged the stock of its two French subsidiaries, IMTIX-SangStat SAS and SangStat Atlantique SA. In addition, the Company was required to meet certain financial covenants. At December 31, 2000, the Company had drawn down $5.0 million under the line of credit and had set aside a corresponding compensating balance, which is included in Other Current Assets on the consolidated balance sheet. As of December 31, 2000, the Company was in default of the Tangible Net Worth covenant under the Loan Agreement as a result of the reserve the Company took against inventory due to the SangCya Oral Solution recall. The Loan Agreement did not provide for a cure period for such a default. The parties entered into an Amendment dated May 11, 2001, which provided that the Loan Agreement would terminate as of December 31, 2001, the portion of the line of credit collateralized by accounts receivable and inventory would be eliminated, and FINOVA would waive the existing default and all early termination penalties with respect to the Loan Agreement. Subsequently, the Company repaid the loan balance of $5,000,000 on June 29, 2001, thereby terminating the Loan Agreement. Since the loan has been repaid, the $5,000,000 compensating cash balance previously classified as other current assets has now been classified as cash in the accompanying consolidated balance sheet. In connection with this financing, the Company issued a warrant to purchase 50,000 shares of the Company s common stock at an exercise price of $23.438. This warrant was valued using the Black-Scholes pricing model with the following weighted average assumptions: expected life, five years; stock volatility, 72%; risk free interest rate, 6.0%; and no dividend payments during the expected term. The calculated value of the warrant of $744,000 and the additional financing fees of $750,000 have been amortized as additional interest expense $1,327,000 in 2001 and $167,000 in 2000.

Other debt at December 31, 2001 consisted primarily of borrowings by IMTIX against four revolving lines of credit from French banks. These lines of credit, which are renegotiable annually, bear interest at variable rates based on Eonia (Euro Over Night Index Average, 3.38% at December 31, 2001) plus 0.75% to 1.1%, and are secured by accounts receivable from unaffiliated customers. At December 31, 2001, accounts receivable subject to such security totaled approximately $3,103,000. At December 31, 2001, approximately $1.4 million remained available for borrowing under these credit lines. Interest rates on other debt at December 31, 2001 range between 3.55% and 8.25%.

As of December 31, 2001, future principal payments of notes payable (net of discounts) are as follows (in thousands):

Years Ending December 31,		
2002	$	5,615
2003		4,220
2004		25,993
Total	$	35,828

9. FINANCIAL INSTRUMENTS

The following methods and assumptions were used to estimate the fair value of each class of financial instruments for which it is practicable to estimate fair value.

Short-term investments and corporate equity securities are recorded at fair value based on quoted market prices (see Note 2).

The fair value of the convertible note is based on market quotations, the major element of which is a comparison of the fixed conversion price and the closing price of the Company s common stock at December 31, 2001 and 2000. The fair value of the notes payable to Aventis and Abbott Laboratories is based on the present value of future cash flows discounted at an interest rate of 10.0% at December 31, 2001 and 2000, respectively. These estimates are approximate since no liquid market exists for these notes. The fair value of the Company s other debt is based on

carrying value as those obligations have short-term variable interest rates.

The estimated fair values of the Company s debt, including current portion, are as follows (in thousands):

	December 31, 2001		December 31, 2000	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Note payable to Aventis	$ 8,273	$ 7,851	$ 13,293	$ 12,592
Note payable to Abbott Laboratories	16,000	15,503	16,000	15,366
Note payable to Finova			5,000	5,000
Convertible debt	9,779	11,550	9,691	8,796
Other debt	1,776	1,776	3,492	3,492
Total	$ 35,828	$ 36,680	$ 47,476	$ 45,246

10. COLLABORATIVE AGREEMENTS

In May 1999, the Company and Abbott Laboratories (Abbott) signed a multi-year co-promotion, distribution and research agreement for SangCya Oral Solution and cyclosporine capsules (the products) in the US. The Company is the exclusive distributor for the products and shares marketing, promotional and development expenses as well as the profits from the co-promotion of the products with Abbott. The agreement ends December 31, 2004 unless both parties agree to extend it. Pursuant to this agreement, Abbott made an equity investment of $14 million during 1999 in exchange for approximately 894,000 shares of common stock, representing a premium to fair market value at that time aggregating to $1.3 million. In addition, Abbott made a series of up-front and milestone payments totaling $20.8 million through May 2000, and a long-term loan of $16 million (see Note 8) to the Company. In January 2000, the Company made a milestone payment to Abbott of $4 million under the terms of the agreement. No further milestone payments are required from either party. All up-front and milestone payments received, net of milestone payments made, and the premium received on the sale of the common stock to Abbott are recorded as deferred revenue and are being recognized ratably over the term of the agreement. For the years ended December 31, 2001, 2000 and 1999, the Company amortized $3.2 million, $2.7 million and $1.5 million, respectively, to revenue. In May 2000, the Company and Abbott launched the cyclosporine capsule developed by Abbott under the brand name Gengraf®. In connection with the equity investment, Abbott and the Company entered into a Right of First Refusal Agreement and a Registration Rights Agreement, and amended and restated their existing Supply Agreement.

As part of the agreement with Abbott, the Company agreed to fund part of a phase IV clinical trial for Gengraf during 2000 and 2001 up to a maximum of $2,475,000. In February 2002, the Company received notification from Abbott that the Company s share of these costs incurred was approximately $449,000 less than originally estimated.

In August 2000, the Company entered into a global co-development, supply and license agreement with Abgenix, Inc. for ABX-CBL, an antibody developed by Abgenix. The agreement provides the Company with an exclusive worldwide license for the marketing and sale of ABX-CBL, an anti-CD147 monoclonal antibody for the treatment of steroid resistant graft versus host disease (GVHD). ABX-CBL is currently in a multicenter, randomized, and controlled Phase II/III study. Under the terms of the agreement, the Company made an initial license fee payment of $1,000,000 and an additional payment to Abgenix of $1,000,000 as partial reimbursement of one-half of the development costs incurred by Abgenix between January 1, 2000 and August 8, 2000. The agreement requires the Company to pay a further $900,000 as reimbursement of these development costs in two equal installments at the end of June 2001 and 2002, the first of which installments has been paid. Development costs incurred after August 8, 2000 are being shared equally, as would any potential profits from future sales of collaboration products. The Company and Abgenix share responsibility for product development, including the ongoing clinical trial. Abgenix will be

responsible for manufacturing ABX-CBL. The Company also has the right, subject to the terms and conditions of the agreement, to commercialize other anti-CD147 antibodies developed by Abgenix. If ABX-CBL receives regulatory approval and is launched, the Company will be required to pay Abgenix for one-half of the of development expenses incurred prior to January 1, 2000. The amount has not been determined, but the agreement limits the Company obligation to $6,100,000. The Company shall have no obligation to reimburse Abgenix until the first anniversary of the launch of ABX-CBL and the timing of reimbursement varies depending on ABX-CBL s sales. For the years ended December 31, 2001 and 2000, the Company paid approximately $2,800,000 and $1,500,000 as its share of the development costs incurred after August 8, 2000.

The Company entered into a Distribution Agreement with Aventis in May 1999 with an initial expiration date of March 31, 2002. The agreement automatically extends for additional one year periods unless either party gives notice of termination. The current expiration date is March 31, 2003. Aventis is the Company s exclusive distributor for Thymoglobulin and Lymphoglobuline for most countries outside of North America and Europe. Aventis sells these products either through its local subsidiary or through a distributor that often distributes other Aventis products. The company renegotiated this agreement in 2001 and has contracted directly with distributors in Asia where Aventis has no direct presence (e.g. Israel and certain Asian countries). The Company is also in negotiations to extend the current contract directly with Aventis subsidiaries in the countries where Aventis does have a direct presence and with current Aventis distributors in certain other countries (e.g. Middle East and Africa).

Aventis also performs certain steps in the manufacturing process of Thymoglobulin and Lymphoglobuline. Pursuant to the purchase of IMTIX on September 30, 1998, the Company pays Aventis royalties on Thymoglobulin and Lymphoglobuline contingent upon the sales of these products. In the years ended December 31, 2001, 2000 and 1999, royalty payments on Lymphoglobuline to Aventis totaled approximately $616,000, $622,000 and $646,000, respectively. The Company began paying royalties on sales of Thymoglobulin commencing on the third anniversary of the purchase of IMTIX (October 1, 2001). For the year ended December 31, 2001 the royalty payments on Thymoglobulin to Aventis totaled approximately $1,539,000.

In December 1997, the Company signed an agreement with Amgen Inc. (Amgen) for the exclusive registration, marketing and distribution of its cyclosporine products in selected territories in the Asia/Pacific Rim region. The licensing agreement included an initial $750,000 payment to the Company, which was received in 1997, and other milestone and reimbursement payments based on key regulatory submissions and approvals. Payments and reimbursements under the agreement of $550,000 received in the year ended December 31, 1999 are included in revenue from collaborative agreements in the Consolidated Statements of Operations. Amgen terminated the agreement effective August 15, 2001.

11. LEASING ARRANGEMENTS

The Company leases administrative facilities under operating leases and machinery and equipment under capital leases expiring through 2013. The Company also leases manufacturing facilities from Aventis in Lyon, France under a lease that expires in 2013. This lease may be terminated at the Company s option with one year s notice. As of December 31, 2001, future minimum annual payments under capital and operating leases are as follows (in thousands):

Years Ending December 31,	Capital Leases	Operating Leases
2002	$ 205	$ 1,482
2003	170	1,455
2004	167	1,367
2005		971
2006		603
Thereafter		3,898
Total minimum lease payments	542	$ 9,776
Less amounts representing interest	(39)	
Present value of minimum lease payments	503	
Less current portion	(177)	
Capital lease obligations	$ 326	

Rent expense for the years ended December 31, 2001, 2000 and 1999 was $1,642,000, $1,493,000 and $1,047,000, respectively.

12. STOCKHOLDERS EQUITY

Issuance of Common Stock On January 5, 2001, the Company completed a private placement of approximately 1.3 million shares of common stock for aggregate proceeds of approximately $12.5 million with a group of institutional investors. Shares were purchased at a discount to the closing market price on the date the agreements were signed. The transaction occurred in two tranches, of approximately $8.5 million (894,800 shares) and $4.0 million (421,000 shares) respectively, the first of which closed December 29, 2000, the second of which closed January 5, 2001. The Company did not pay any investment banking fees and did not issue any warrants with respect to this placement.

In June 2001, the Company sold 1,363,635 shares of common stock to the same group of investors for net proceeds of approximately $15 million.

Stockholder Rights Plan The Company has a stockholder rights plan to protect stockholders rights in the event of a proposed takeover of the Company. Under the plan a preferred share purchase right (Right) is attached to each share of common stock. The Rights are exercisable only if a person or group acquires 15% or more of the Company s common stock or announces a tender offer, the consummation of which would result in ownership by a person or group of 15% or more of the Company s common stock. Each Right will entitle stockholders to buy one one-hundredth of a share of a new series of junior participating preferred stock at an exercise price of $45 upon certain events. If, after the Rights become exercisable, the Company is acquired in a merger or other business combination transaction, or sells 50% or more of its assets or earnings power, each Right will entitle its holder to purchase, at the Right s then-current price, a number of the acquiring company s common shares having a market value at the time of twice the Right s exercise price. If a person or group acquires 15% or more of the Company s outstanding common stock, each Right will entitle its holder (other than such person or members of such group) to purchase, at the Right s then-current exercise price, a number of the Company s common shares (or cash, other securities or property) having a market value twice the Right s exercise price. At any time within ten days after a person or group has acquired beneficial ownership of 15% or more of the Company s common stock, the Rights are redeemable for $.01 per Right at the option of the Board of Directors. The Rights expire on August 25, 2005, unless earlier redeemed or exchanged. On October 8, 2001, the plan was amended to appoint EquiServe Trust Company, N.A., as successor rights agent to the plan and to conform the plan to current Delaware law regarding the use of continuing director provisions.

Stock Option Plans The Company has two stock option plans: the 1993 Stock Option Plan (the 1993 Plan) and the 1996 Non-Employee Directors Stock Option Plan (the Directors Plan). Under the Company s stock option plans, incentive or non-statutory stock options to purchase up to 5,192,200 shares of common stock may be granted to employees, directors, and consultants. Incentive and non-statutory options must be granted at not less than fair market value at the date of grant.

A summary of stock option activity is as follows:

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	Number of Shares	Weighted Average Exercise Price
Balances, January 1, 1999.....	2,555,643	$ 19.32
Options granted (weighted average fair value of $19.16).	913,394	18.11
Options exercised.....	(244,927)	7.59
Options canceled.....	(413,151)	25.19
Balances, December 31, 1999 (1,258,563 vested at a weighted average exercise price of $19.62).....	2,810,959	19.43
Options granted (weighted average fair value of $18.11).	1,331,725	21.19
Options exercised.....	(242,644)	10.84
Options canceled.....	(702,266)	23.15
Balances, December 31, 2000 (1,305,037 vested at a weighted average exercise price of $19.77).....	3,197,774	19.97
Options granted (weighted average fair value of $12.07).	1,320,544	12.36
Options exercised.....	(233,693)	8.26
Options canceled.....	(849,048)	19.13
Balances, December 31, 2001.....	3,435,577	$ 18.05

Under the 1993 Plan, options to purchase common stock generally vest over a period of four years, are exercisable upon vesting and expire ten years from the date of grant. As of December 31, 2001, 277,390 shares were available under the 1993 Plan for future grants. During 1999, the Company recorded a charge of $160,000 related to certain fully vested non-employee options.

Under the Directors Plan, up to a total 500,000 options to purchase shares of the Company s common stock may be issued. Also in accordance with the Directors Plan, during 2001, 2000 and 1999, each of the non-employee Directors was granted options to purchase 8,000, 4,000 and 4,000 shares of the Company s common stock, respectively. All options granted under the Directors Plan are immediately exercisable, but the Company may repurchase at the exercise price any unvested shares held by a non-employee Board member when his or her service terminates. The first 25% of the shares acquired under the Directors Plan vest when the non-employee director completes the first 12 months of service after the date of grant, and the balance vests in equal monthly installments as the non-employee director completes each of the next 36 months of service. The shares vest in full if the non-employee Board member s service terminates due to death or permanent disability or if the Company is subject to a change in control or a party to a merger or certain other transactions. In addition, the Directors Plan permits non-employee directors to receive all or part of his or her basic retainer payments from the Company in the form of non statutory stock options. If a Board member makes an election to receive options in lieu of cash retainer, then options will automatically be granted to him or her under the Directors Plan. As of December 31, 2001, there were no outstanding shares subject to repurchase rights and 204,514 shares were available under the Directors Plan for future grants. Options granted under the Directors Plan are also included in the above table.

Additional information regarding options outstanding as of December 31, 2001 is as follows:

	Options Outstanding			Vested Options		
Range of Exercise Prices	Number Outstanding	Weighted Avg. Remaining Contractual Life (yrs)	Weighted Avg. Exercise Price	Number vested	Weighted Avg. Exercise Price
$ 0.00 - 5.00	45,700	2.0	$ 2.75	45,700	$ 2.75
5.01 - 10.00	106,656	6.7	7.40	51,246	6.58
10.01 - 15.00	1,208,990	8.6	11.47	293,735	12.17
15.01 - 20.00	887,346	5.7	18.64	479,384	19.54
20.01 - 25.00	613,221	6.7	22.49	279,666	22.64
25.01 - 30.00	344,226	6.6	26.81	219,891	26.67
30.01 - 35.00	207,772	3.3	32.54	195,968	32.59
35.01 - 45.00	21,666	7.9	42.81	9,954	42.84
	3,435,577	6.8	18.05	1,575,544	20.57

Additional Stock Plan Information SFAS No. 123 requires the disclosure of pro forma net income (loss) and earnings (loss) per share as though the Company had adopted the fair value method. Under SFAS No. 123, the fair value of stock-based awards to employees is calculated through the use of option pricing models, even though such models were developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differ from the Company s stock option awards. These models also require subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. The Company s calculations were made using the Black-Scholes option pricing model with the following weighted average assumptions: expected life, five and a half years; stock volatility, 64% in 2001, 108% in 2000 and 72% in 1999; risk free interest rate, approximately 5.0% in 2001, 5.50% in 2000 and 1999; and no dividend payments during the expected term. The Company s calculations are based on a single option valuation approach and forfeitures are recognized as they occur. If the computed fair values of the plan awards had been amortized to expense over the vesting period of the awards, pro forma net loss would have been approximately as follows:

	Year Ended December 31,		
	2001	2000	1999
Net loss (numerator)			
Continuing operations	$ 10,159	$ 44,418	$ 36,148
Discontinued operation	1,144	2,704	2,158
	$ 11,303	$ 47,122	$ 38,306
Shares (denominator)			
Weighted average common shares outstanding	20,216	17,910	16,888
Net loss per share basic and diluted			
Continuing operations	$ 0.50	$ 2.48	$ 2.14
Discontinued operation	0.06	0.15	0.13
	$ 0.56	$ 2.63	$ 2.27

13. INCOME TAXES

Loss before income taxes and the provision for income taxes consists of the following (in thousands):

	December 31,		
	2001	**2000**	**1999**
Income (loss) from continuing operations before income taxes			
Domestic	$ 957	$ (38,448)	$ (28,023)
Foreign	(9,199)	(3,201)	(2,614)
Net loss from discontinued operation			
Domestic	(1,144)	(2,342)	(2,025)
Income tax benefit (provision)			
Domestic			
Foreign	7	(368)	(345)
Net Loss	$ (9,379)	$ (44,359)	$ (33,007)

No domestic income tax provision (benefit) has been provided due to the Company s continuing losses. The difference between the Company s effective tax rate and the Federal statutory rate of 35% is attributable primarily to the recording of valuation allowances on net deferred tax assets during the respective periods.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, as well as operating loss and tax credit carryforwards. Significant components of the Company s deferred income tax assets are as follows (in thousands):

	December 31,	
	2001	**2000**
Deferred tax assets:		
Net operating loss carryforwards	$ 48,987	$ 47,999
General business credits	7,536	5,604
Deferred revenue	3,774	5,032
Capitalized research and development	4,576	3,299
Accruals and reserves deductible in different periods	8,607	8,524
Depreciation	2,244	2,584
	75,724	73,042
Valuation allowance	(75,331)	(72,739)
Total	$ 393	$ 303

Based on its history of US operating losses, the Company has placed a valuation allowance of $75,331,000 and $72,739,000 against its otherwise recognizable domestic net deferred tax assets at December 31, 2001 and 2000, respectively, due to the uncertainty surrounding the realizability of these benefits.

At December 31, 2001, the Company had federal, California and foreign net operating loss carryforwards of approximately $139,653,000, $12,916,000 and $2,048,000 respectively, available to reduce future taxable income. Such carryforwards expire beginning in 2002 through 2021.

Also at December 31, 2001, the Company had research and experimentation credit carryforwards available of approximately $4,635,000 and $2,859,000 for federal and state tax purposes, respectively. The federal tax credit carryforwards expire beginning in 2004 through 2013 and the state tax credit carryforwards have no expiration date.

Included in the deferred tax assets at December 31, 2001 is approximately $5,109,000 of cumulative tax benefit related to equity transactions which will be credited to stockholders equity, if and when realized after the other tax deductions in the carryforwards have been realized.

Utilization of the above net operating loss and credit carryforwards may be subject to an annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The

annual limitation may result in the expiration of net operating loss and credit carryforwards before utilization.

14. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) tax-deferred savings plan, whereby eligible employees may contribute a portion of their eligible compensation. Company contributions are discretionary. Through December 31, 2001 the Company had not made any contributions.

15. MAJOR CUSTOMERS

For the year ended December 31, 2001, the Company had four customers that accounted for approximately 26%, 18%, 12% and 11%, respectively, of total revenues. For the year ended December 31, 2000, the Company had two customers that accounted for approximately 15% and 13%, respectively, of total revenues. For the year ended December 31, 1999, the Company had one customer that accounted for approximately 11% of total revenues.

16. DISCONTINUED OPERATION

On March 13, 2001, the Company committed to a formal plan to sell its division known as The Transplant Pharmacy (TTP). On April 20, 2001, the Company closed the sale of TTP to Chronimed for $1.8 million in cash. The Company retained the inventory and accounts receivable related to the business and has converted these assets into cash. The disposition of TTP has been accounted for as a discontinued operation in accordance with Accounting Principles Board (APB) Opinion No. 30. Accordingly, prior period consolidated statements of operations and cash flows have been restated to account for TTP as a discontinued operation. During the year ended December 31, 2001 the Company recorded a loss on disposal of $381,000 for the discontinued operation, primarily related to estimated future lease obligations for facilities that supported TTP.

The consolidated balance sheets at December 31, 2001 and 2000, include the remaining assets and liabilities of TTP as follows (in thousands):

	December 31,	
	2001	**2000**
Accounts receivable - net	$	$ 3,986
Inventories	8	1,137
Other Assets		96
Accounts payable & accrued expenses	(296)	(601)
Net assets (liabilities) of discontinued operation	$ (288)	$ 4,618

The historical consolidated statements of operations and cash flows have been restated for all periods presented to account for TTP as a discontinued operation. The financial data of TTP reflects the historical sales and expenses of the transplantation services segment. Discontinued operations include TTP net sales which totaled $5,233,000, $17,502,000 and $13,865,000 for the years ended December 31, 2001, 2000 and 1999, respectively. Net loss from the operations of TTP was $763,000, $2,342,000 and $2,025,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

17. BUSINESS SEGMENT DATA

As stated in Note 16, the Company has presented the results of TTP, which represents its previously reported transplantation services segment, as a discontinued operation. As a result, the Company s continuing operations are organized and operate in one business segment: pharmaceutical products. Pharmaceutical products consist primarily of therapeutic products for preventing and treating organ rejection. The Company s segment information has been restated to reflect the results of such decision.

The Company is engaged in the business of developing and marketing products in the areas of immunology, hematology/oncology and auto-immune disease. The Company s operations in Europe primarily relate to the manufacture, marketing and selling, research and development and clinical study of therapeutic products for transplantation. The Company s operations in the rest of the world are principally sales and marketing related.

Summarized data for the Company s domestic and foreign revenues and long-lived assets are as follows (in thousands):

	United States	Europe	Canada	Rest of the World	Consolidated
Year ended December 31, 2001:					
Sales to unaffiliated customers	$ 70,388	$ 15,820	$ 1,372	$ 6,929	$ 94,509
Long-lived assets	$ 3,776	$ 10,910	$ 3	$	$ 14,689
Year ended December 31, 2000:					
Sales to unaffiliated customers	$ 41,272	$ 14,667	$ 1,289	$ 5,917	$ 63,145
Long-lived assets	$ 5,003	$ 12,669	$ 9	$	$ 17,681
Year ended December 31, 1999:					
Sales to unaffiliated customers	$ 18,094	$ 22,428	$ 1,401	$ 2,380	$ 44,303
Long-lived assets	$ 4,909	$ 13,184	$ 15	$	$ 18,108

18. RECALL OF SANGCYA ORAL SOLUTION

On June 29, 2000, the Company in discussions with the FDA, which began on June 24, 2000, concluded that a recall of SangCya Oral Solution from the US market would be required. Following further discussions with the FDA as to the type of recall and mechanism for conducting it, this decision was announced on July 10, 2000. The recall was a Class II recall and was limited to the wholesale level and not extended to the pharmacy or the patient. A study in healthy volunteers had found that, when SangCya Oral Solution is mixed with apple juice as recommended in its labeling, it is not bioequivalent to Neoral® oral solution. The Company also announced at the same time its decision to voluntarily withdraw SangCya Oral Solution from the US market.

In the UK, the Company is selling SangCya Oral Solution on a named patient only basis subject to an amendment to the labeling. The Company is working with the Medicines Control Agency (MCA) to complete a labeling change.

The Company included in its financial results for the year ended December 31, 2000, charges to cover the losses resulting from the recall. These charges, which are reported in the consolidated statements of operations under revenues, cost of sales, research and development expenses and selling, general and administrative expenses, include $872,000 for sales returns, $11,774,000 for the write-off of all SangCya Oral Solution and CycloTech finished goods and components and a partial write-down of bulk cyclosporine inventories, and $429,000 for costs to terminate

ongoing marketing and clinical programs, and to administer the recall. The inventory reserves are non-cash in nature since the inventories in question have already been paid for.

19. LITIGATION

Novartis Patent Litigation With Respect to Gengraf

Novartis sued Abbott claiming that Gengraf® infringes its patents. Novartis s complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the U.S., but to date Novartis has not moved for a preliminary injunction. The trial is scheduled for July 23, 2002. Abbott has informed the Company that it does not believe it infringes the Novartis patents. The Company has not been named a defendant in this lawsuit, and the Company has only limited access to information about it. Under the Company s agreement with Abbott, Abbott is obligated to indemnify the Company against such suits, but their indemnity may not cover lost sales, if any. The course of litigation is inherently uncertain, however. Novartis may choose to name the Company in this suit. Abbott may not

prevail, or Abbott may choose to settle on terms adverse to the Company s interests. Should the Company be named in this suit, the Company may incur expenses prior to reimbursement (if any) by Abbott pursuant to its indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, Gengraf may be temporarily or permanently removed from the market, or the Company and Abbott may be required to negotiate a license on unfavorable terms.

Novartis Regulatory Litigation

U.S. Regulatory Litigation. Novartis U.S. sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia (case number 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis initially asked the Court to (i) allow Novartis to keep its microemulsion labeling; (ii) declare microemulsion to be a separate dosage form; and (iii) rescind the AB rating that was given to SangCya Oral Solution. The Company intervened in this lawsuit. The Court granted the Company s motion to dismiss the counts that relate specifically to the approval of SangCya Oral Solution, but Novartis may appeal this decision. The Company may remain a party in the case. Novartis has filed motions related to the remaining issues in the case, and the Court has not yet ruled on Novartis s motions. Because the Company permanently withdrew SangCya Oral Solution from the U.S. market in July 2000, the Company does not believe that this lawsuit will have any material impact on SangCya revenues but if the court declares microemulsion to be a separate dosage form, this ruling would require rescission of the AB rating for Gengraf, which would have a material impact on Gengraf revenues.

U.K. Regulatory Litigation SangCya Oral Solution. On October 18, 1999, Novartis U.K. was granted leave to seek judicial review of the decision by the Medicines Control Agency, or MCA, to approve SangCya Oral Solution (Case No. HC-1969/99). On March 30, 2000, the High Court in London dismissed Novartis s application for judicial review and ruled that the MCA acted properly in granting the SangCya Oral Solution marketing authorization. Novartis appealed the High Court s decision, and the hearing was held before the Court of Appeal on November 13 and 14, 2000. The Court of Appeal has stayed ruling on this matter pending the answer of certain questions of law to be submitted to the European Court of Justice, or ECJ. No date has been set for the ECJ hearing, but it is likely to be scheduled sometime in early 2002, with a ruling approximately six months thereafter. Following the ECJ ruling, the parties would go back to the Court of Appeal, which will then apply the ECJ ruling on the law to the facts of this case.

U.K. Regulatory Litigation Cyclosporine Capsules. In November 1999, Novartis filed a request with the High Court in London for judicial review of the refusal by MCA to state that it would not reference Neoral data in approving any generic copies of Novartis s cyclosporine capsule. An agreement was reached between the parties in which Novartis agreed to stay the judicial review until the earlier of (i) the decision on the judicial review of SangCya Oral Solution or (ii) MCA s approval of SangStat s marketing authorization for its cyclosporine capsule product; in return, the Company agreed that it would not launch or commence mutual recognition procedures in relation to the cyclosporine capsule marketing authorization (including a request to MCA to prepare an assessment report) for a period of 28 days commencing on the day on which the Company notifies Novartis s solicitors of capsule approval. The parties have agreed to continue the stay until the appeal of the High Court decision with respect to the judicial review of SangCya Oral Solution. The stay of this application for judicial review will remain in place pending the ECJ ruling on the

questions of law and resulting Court of Appeal judgment.

Novartis has also indicated that it will seek an injunction to prevent the Company s cyclosporine capsule from being sold in the United Kingdom until final resolution of the judicial review relating to the Company s cyclosporine capsule. Because the High Court ruled in favor of the MCA with respect to the SangCya Oral Solution marketing authorization and the Court of Appeal has referred questions of law to the ECJ, the Company believes that it is unlikely that a court would grant Novartis a preliminary injunction with respect to its cyclosporine capsule marketing authorization. If the Court of Appeals reverses the High Court s ruling following the ECJ s decisions on questions of law, either the MCA could still approve the Company s cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve the Company s cyclosporine capsule marketing authorization until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004).

Italian Regulatory/Trade Secret Litigation. On May 5, 2000, Novartis Farma S.p.A. (Novartis Italy) served IMTIX-SangStat S.r.l., an Italian SangStat subsidiary, and IMTIX-SangStat Ltd. with a summons to the Milan Tribunal. Novartis Italy alleges that by requesting mutual recognition from the Italian Health Authorities of the SangCya Oral Solution dossier approved by the MCA, the Company implicitly requested that the Italian Health Authorities review the Neoral dossier. Novartis alleges that this request is an act of unfair competition in that (i) the Neoral data has ten year exclusivity and (ii) the data is secret and by requesting mutual recognition, the Company is responsible for the Health Authorities act of unfair competition following use of the Neoral dossier in reviewing the SangCya Oral Solution dossier. While the summons acknowledges that the U.K. High Court did not invalidate the SangCya Oral Solution marketing authorization, it does not acknowledge that the High Court ruled that the MCA could review the Neoral data. To the best of the Company s knowledge, Novartis Italy has not filed suit against the Italian Health Authorities. The initial appearance of the parties before the Milan Tribunal was scheduled for January 2001. The Company filed its response to the complaint at that time, and the hearing has been postponed until June 2002.

The Company does not yet have marketing approval for SangCya Oral Solution in Italy. Novartis Italy is seeking damages and an injunction to prevent the sale by SangStat of SangCya Oral Solution, or any other product for which the Company may obtain approval based upon a reference to the Neoral dossier, which the Company believes is intended to block its cyclosporine capsule from sale in Italy. The Company believes that resolution of this matter will depend on the resolution of the U.K. regulatory litigation, since the MCA s actions are the basis for the Italian lawsuit.

Summary

Although the Company is optimistic that these disputes will ultimately be resolved in its favor, the course of litigation is inherently uncertain. With respect to Novartis s lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, the Company s revenues would be reduced. With respect to the European regulatory and trade secret lawsuits, Novartis s requested relief, if granted, could have a negative economic impact on the Company depending on how the MCA would proceed with the Company s Marketing Authorization Application (MAA) for its capsule product. The MCA could approve the Company s MAA for cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve the Company s MAA for its cyclosporine capsule until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004). If the Company cannot obtain approval of its cyclosporine capsule in Europe until 2004, this could have an adverse impact on the Company s future revenues and results of operations. With respect to the FDA lawsuit, Novartis s requested relief would mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would harm revenues. The litigation, if not resolved favorably to the Company, could have a material adverse effect on the Company s business, financial condition, cash flows and operating results.

IFFA CREDO and Elevage Scientifique des Dombes Breach of Contract Suit

In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes, sued the Company s French subsidiary, IMTIX-SangStat SAS, for breach of contract. On May 2, 2001 the Company was notified that the Commercial Court of Lyon ruled against IMTIX-SangStat in the breach of contract suit and the court awarded the suppliers 26.5 million French Francs (approximately $3.6 million) for lost profits and reimbursement of capital expenditures. IMTIX-SangStat recorded a charge of $3,250,000 to other expense net for the year ended December 31, 2001, which, combined with reserves recorded in fiscal 2000, fully provided for the court award. On March 22, 2002, the appeals court upheld the lower court decision and assessed interest against the Company of approximately $204,000

which has been recorded as a charge to other expense net for the year ended December 31, 2001. The Company also recorded a deferred tax benefit related to such charge of $70,000 (see Note 13).

The Company s rabbit serum requirements are currently being met by its other suppliers.

20. SUBSEQUENT EVENTS

On February 20, 2002, the Company completed the issuance of 5,175,000 shares of common stock in a public

offering for proceeds net of underwriting discounts of approximately $84.1 million. The Company intends to use the proceeds for repayment of existing debt and general corporate purposes, including in-licensing and partnering opportunities. In addition, the Company may use a portion of the net proceeds to acquire complementary products, product candidates or businesses. On February 11, 2002 the Company repaid $8 million of the Abbott Laboratories loan (see note 8).

21. UNAUDITED QUARTERLY FINANCIAL INFORMATION

Selected Quarterly Consolidated Financial Data:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year ended December 31, 2001:				
Total revenues	$ 20,325	$ 21,784	$ 25,100	$ 27,300
Gross profit	11,704	12,462	13,459	14,068
Net income (loss):				
Continuing operations	(5,709)	(2,622)	(329)	425
Discontinued operation	(763)		(381)	
	$ (6,472)	$ (2,622)	$ (710)	$ 425
Net income (loss) per share - basic and diluted				
Continuing operations	$ (0.29)	$ (0.13)	$ (0.01)	$ 0.02
Discontinued operation	(0.04)		(0.02)	
	$ (0.33)	$ (0.13)	$ (0.03)	$ 0.02
Year ended December 31, 2000:				
Total revenues	$ 11,798	$ 15,991	$ 16,894	$ 18,462
Gross profit	7,509	(3,519)	10,578	9,331
Net (loss):				
Continuing operations	(7,094)	(19,836)	(10,366)	(4,721)
Discontinued operation	(695)	(382)	(512)	(753)
	$ (7,789)	$ (20,218)	$ (10,878)	$ (5,474)
Net (loss) per share - basic and diluted				
Continuing operations	$ (0.40)	$ (1.11)	$ (0.57)	$ (0.26)
Discontinued operation	(0.04)	(0.02)	(0.03)	(0.04)
	$ (0.44)	$ (1.13)	$ (0.60)	$ (0.30)

Schedule II

SANGSTAT MEDICAL CORPORATION
Valuation and Qualifying Accounts

(In thousands)

	Balance at begininng of period	Additions charged to costs and expenses	Deductions	Other	Balance at end of period
1999					
Allowance for doubtful accounts	$ 929	$ 1,125	$ 585(1)	$	$ 1,469
2000					
Allowance for doubtful accounts	$ 1,469	$ 3,789	$ 2,130(1)	$	$ 3,128
2001					
Allowance for doubtful accounts	$ 3,128	$ 6,611	$ 5,667(1)	$	$ 4,072

(1) Accounts written off, net of recoveries

SANGSTAT MEDICAL CORPORATION

SIGNATURES

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

Date: March 31 , 2002 SANGSTAT MEDICAL CORPORATION

By: /s/ Jean-Jacques Bienaimé
Jean-Jacques Bienaimé
Chairman, President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jean-Jacques Bienaimé and Stephen G. Dance, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Jean-Jacques Bienaimé Jean-Jacques Bienaimé	Chairman of the Board of Directors, President & Chief Executive Officer (Principal Executive Officer)	March 31 , 2002
/s/ Stephen G. Dance Stephen G. Dance, CPA, FCA.	Senior Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	March 31 , 2002

/s/ Fredric J. Feldman Fredric J. Feldman, Ph.D.	Director	March 31, 2002
/s/ Richard D. Murdock Richard D. Murdock	Director	March 31, 2002
/s/ Andrew Perlman Andrew Perlman, M.D., Ph.D.	Director	March 31, 2002
/s/ Nicholas J. Simon Nicholas J. Simon III	Director	March 31, 2002
/s/ Vincent Worms Vincent Worms	Director	March 31, 2002

EXHIBIT INDEX

Exhibits	Description of Exhibit
2.1	Agreement and Plan of Merger, dated as of July 24, 1995, between SangStat Delaware, Inc. and SangStat Medical Corporation, a California corporation, as filed with the Delaware Secretary of State on August 11, 1995 (filed as Exhibit 2.1 to the Registrant s Registration Statement on Form 8-B, filed on December 4, 1995, and incorporated herein by reference).
2.2	Master Agreement between SangStat Medical Corporation and Pasteur Merieux Serums & Vaccins, S.A., dated June 10, 1998, including Exhibit 8 thereto (filed as Exhibit 2.1 to the Registrant s Current Report on Form 8-K, filed on October 15, 1998 and as amended on December 14, 1998, and incorporated herein by reference).
3.1	Certificate of Incorporation of SangStat Delaware, Inc. (filed as Exhibit 3.1 to the Registrant s Registration Statement on Form 8-B, filed on December 4, 1995, and incorporated herein by reference).
3.2	Certificate of Amendment of the Certification of Incorporation, filed with the Delaware Secretary of State on July 24, 2000 (filed as Exhibit 3.6 to the Registrant s Current Report on Form 8-K, filed on August 30, 2000, and incorporated herein by reference).
3.3	Certificate of Designation for the Series A Junior Participating Preferred Stock, filed with the Delaware Secretary of State on August 16, 1995 (filed as Exhibit 3.4 to the Registrant s Current Report on Form 8-K, filed on September 1, 1995, and incorporated herein by reference).
3.4	Second Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 30, 2000, filed on May 15, 2000, and incorporated herein by reference).
4.1	Specimen Common Stock Certificate of Registrant (filed as Exhibit 4.5 to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.1*	1993 Stock Option/Stock Issuance Plan (filed as Exhibit 10.7 to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.2	Form of Indemnification Agreement between the Registrant and its directors, officers and certain other employees (filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2001, filed on November 14, 2001, and incorporated herein by reference).
10.3**	License Agreement, dated November 15, 1993, between the Registrant and the Board of Trustees of Leland Stanford Junior University (filed as Exhibit 10.19 to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.4	Rights Agreement, dated as of August 14, 1995, between the Registrant and First National Bank of Boston (filed as Exhibit 2 to the Registrant s Registration Statement on Form 8-A, filed on August 25, 1995, and incorporated herein by reference).

Exhibits	Description of Exhibit
10.5	First Amendment to Rights Agreement, dated as of October 8, 2001, among the Registrant, Fleet National Bank (f/k/a The First National Bank of Boston) and EquiServe Trust Company, N.A. (filed as Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed on October 9, 2001, and incorporated herein by reference).
10.6	Real Property Sub-Lease, dated March 8, 1999, between the Registrant and Kelley-Clarke, Inc. to the Real Property lease, dated September 1, 1988, between Kelly-Clarke Inc. and Kaiser Development Company, as amended on February 26, 1990, May 1, 1990, May 5, 1990, and April 19, 1995 (filed as Exhibit 10.26 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1998, filed on March 31, 1999, and incorporated herein by reference).
10.7**	Co-Promotion Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.28 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000, filed on March 30, 2001, and incorporated herein by reference).
10.8	Right of First Refusal Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.28 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed on August 16, 1999, and incorporated herein by reference).
10.9	Registration Rights Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.29 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed on August 16, 1999, and incorporated herein by reference).
10.10	Convertible Promissory Note, dated March 1999, for $10,000,000 with Warburg Dillon Read LLC (filed as Exhibit 10.32 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1999, filed on April 14, 2000, and incorporated herein by reference).
10.11**	Co-Development, Supply and License Agreement, dated as of August 8, 2000, between the Registrant and Abgenix, Inc. (filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000, and incorporated herein by reference).
10.12	Securities Purchase Agreement, dated December 29, 2000, between the Registrant and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, and SDS Capital Partners, LLC (filed as Exhibit 10.35 to the Registrant s Current Report on Form 8-K, filed on January 8, 2001, and incorporated herein by reference).
10.13	Registration Rights Agreement, dated December 29, 2000, between the Registrant and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, and SDS Capital Partners, LLC (filed as Exhibit 10.36 to the Registrant s Current Report on Form 8-K, filed on January 8, 2001, and incorporated herein by reference).
10.14	Securities Purchase Agreement, dated as of June 20, 2001, between the Company and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, S.A.C. Capital Associates, LLC, and Société Générale (filed as Exhibit 10.39 to the Registrant s Current Report on Form 8-K, filed on June 21, 2001, and incorporated herein by reference).

Exhibits	Description of Exhibit
10.15	Registration Rights Agreement, dated as of June 20, 2001, between the Company and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, S.A.C. Capital Associates, LLC, and Société Générale (filed as Exhibit 10.40 to the Registrant s Current Report on Form 8-K, filed on June 21, 2001, and incorporated herein by reference).
10.16	Registration Rights Agreement, dated March 19, 1999, by and between Registrant and Warburg Dillon Read LLC (filed as Exhibit 4.4 to the Registrant s Registration Statement on Form S-3, file no. 333-46578, and incorporated herein by reference).
21.1	Subsidiaries of Registrant.
23.1	Independent Auditors Consent.
24.1	Power of Attorney (reference is made to the signature page hereof).

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* Management contract or compensatory plan or arrangement.

**Confidential treatment has been granted for the deleted portions of this document. The non-public information has been filed separately with the SEC.

Exhibit 21.1

Subsidiaries of Registrant

SangStat Atlantique S.A.S.

IMTIX-SangStat S.A.S.

SangStat Luxembourg S.à.r.l.

IMTIX-SangStat B.V.

IMTIX-SangStat GmbH

IMTIX-SangStat (Switzerland) GmbH

SangStat Spain S.L.

IMTIX-SangStat Austria GmbH

IMTIX-SangStat S.r.l.

SangStat Canada, Ltd.

SangStat U.K., Ltd

SangStat Medical International Cayman

SangStat Netherlands B.V.

Chronimmune Pharmaceuticals, Inc.

Human Organ Science Inc.

XenoStat, Inc.

IMTIX-SangStat, S.L.

IMTIX-SangStat (UK) Limited

Exhibit 23.1

INDEPENDENT AUDITORS CONSENT

We consent to the incorporation by reference in Registration Statement Nos. 33-77300, 33-80155, 333-53181, 333-63345, and 333-94555 on Form S-8, and Nos. 33-96766, 333-46574, 333-46578, 333-53720 and 333-76028 on Form S-3 of SangStat Medical Corporation of our report dated January 21, 2002 (March 27, 2002 as to Note 5, the second paragraph of Note 10, the ninth paragraph of Note 19 and Note 20), appearing in this Annual Report on Form 10-K of SangStat Medical Corporation for the year ended December 31, 2001.

DELOITTE & TOUCHE LLP

San Jose, California

March 27, 2002