SANGSTAT MEDICAL CORP
Form 10-K
March 26, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2002

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	No
x	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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act)

Yes	No
x	o

The approximate aggregate market value of the Common Stock held by non-affiliates of the Registrant, based upon the last sale price of the Common Stock reported on the Nasdaq National Market on June 30, 2002, was $481,390,000. 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 14, 2003 approximately 26,443,805 shares of the Registrant s Common Stock, $.001 par value, were outstanding.

Certain parts of the Registrant s Proxy Statement relating to the Annual Meeting of Stockholders to be held on May 15, 2003 (the Proxy Statement) are incorporated by reference into Part III of this Annual Report on Form 10-K.

SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

This Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to the safe harbor created by those sections. The forward-looking statements are based on the Registrant s current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as may, will, should, could, predicts, potential, continue, expects, anticipates, future, inter estimates, and similar expressions. In particular, we have included forward-looking statements regarding the following: (i) our anticipated financial results for 2003; (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 made as of the date of this Report on Form 10-K. These forward-looking statements are based on current beliefs, expectations and assumptions and involve certain risks and uncertainties that could cause actual results, levels of activity, performance, achievements and events to differ materially from those implied by such forward-looking statements. The cautionary statements made in this 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. The Registrant disclaims any obligation to update these forward-looking statements.

SANGSTAT MEDICAL CORPORATION

FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2002

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PART I

TRADEMARKS

SangStat®, Thymoglobulin®, Thymoglobuline®, Lymphoglobuline® and Celsior® are registered trademarks of SangStat Medical Corporation or its subsidiaries and Gengraf™ is a trademark of Abbott Laboratories, Inc.

PART I

ITEM 1. BUSINESS

Overview

SangStat is a global biopharmaceutical company focused on immunology and working to discover, develop and market high-value therapeutic products in immunology, transplantation medicine, hematology/oncology and auto-immune disorders. 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 that address 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, the U.S. and Canada and distributors throughout the rest of the world.

Our primary marketed product, Thymoglobulin, a treatment for acute rejection of a kidney transplant, was launched in the U.S. in February 1999. Thymoglobulin achieved worldwide sales of $37.9 million in 2000, $51.4 million in 2001 and $69.5 million in 2002. The success of Thymoglobulin and its potential in areas beyond solid organ transplantation have 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® (also 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 in research and development include:

- A smaller-size cyclosporine capsule;
- RDP58; and
- Humanized polyclonal antibodies.

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.

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 our product Celsior to prevent organ 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 such as our Thymoglobulin product.

The Chronic Phase (Lifetime Post-Transplant)

The use of immunosuppressants such as cyclosporine (including the Gengraf cyclosporine capsules we distribute), 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, patients are always at risk of losing a transplanted organ through acute or chronic rejection.during the first three years following transplantation. 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.

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. Thymoglobulin and Lymphoglobuline are approved for the treatment of steroid resistant GVHD in various countries outside the U.S.

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. Weekly blood transfusions remain 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.

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 Crohn s disease and ulcerative colitis.

Chemotherapy-Induced Diarrhea

Chemotherapy-induced diarrhea is a significant gastro-intestinal complication from treatment of cancer with certain chemotherapeutic agents. 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 may increase patients tolerance of the dose of CPT-11, potentially increasing

their response to this treatment.

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 in solid organ transplantation, treatment of severe aplastic anemia and steroid resistant GVHD	U.S.: Approved for treatment of acute kidney rejection episodes EU: Approved for prophylaxis and treatment of rejection in kidney, heart, pancreas, and liver transplants; treatment of acute GVHD in allogeneic bone marrow transplantation; and treatment of 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 in solid organ transplantation, treatment of severe aplastic anemia and steroid resistant GVHD	Over 50 countries other than the U.S.: Approved	SangStat
Celsior	Preservation of organs prior to transplantation	U.S.: Approved for cardiac transplantation EU: Approved for cardiac and abdominal organ transplantation	SangStat

Product Candidate	Indications/Potential Clinical Use	Status	Commercialization Rights
Smaller-Size Cyclosporine Capsule	Chronic immunosuppression (prevents organ rejection)	Marketing authorization applied for in a European country	SangStat
RDP58	Ulcerative colitis, Crohn s disease	Phase IIa	SangStat
RDP58	Chemotherapy Induced Diarrhea	Phase Ib	SangStat

Future Technology	Indications/Potential Clinical Use	Status	Commercialization Rights
Humanized Polyclonal Antibodies	Hematological cancers; autoimmune disease	Research	SangStat and Therapeutic Human Polyclonals, Inc.

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 market Thymoglobulin in over 50 countries directly or through our distributor, with a majority of our revenues coming from Europe and the U.S. We launched Thymoglobulin in the U.S. in February 1999. Thymoglobulin is currently approved for treatment of acute rejection in kidney transplant recipients in the U.S. In other countries where Thymoglobulin is marketed, it generally has the following indications:

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

We market and sell Thymoglobulin in Western Europe and North America. Outside those territories, we market through Aventis or through other distributors.

Additional Clinical Studies

Induction/Prevention

We have completed a comparative induction study of Thymoglobulin versus Simulect, a monoclonal antibody marketed by Novartis Pharmaceuticals Inc. for certain high-risk renal transplants. Our intent in this study was to generate data comparing the clinical effects of Thymoglobulin with Simulect. It was 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 was conducted in over 20 transplant centers in the U.S. and Europe. Primary endpoints at 6 months were graft survival, patient survival and incidence of acute rejection. We also captured 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.

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. The 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 a chronic therapeutic normally taken daily over the lifetime of the organ recipient to prevent organ rejection.

Cyclosporine Market

Cyclosporine is a leading immunosuppressive drug used to prevent organ and graft rejection in transplantation. 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 approximately $1 billion per year.

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 not sold.

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. Our ability to continue marketing Gengraf may be limited as a result of a recent judgment that Gengraf infringed a Novartis patent.

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 50 countries outside the U.S. Our sales force markets this product in Western 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, as a medical device 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 market 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. We are selling Celsior in Europe also for abdominal organ (kidney, pancreas and liver) flushing and storage. Outside of Western Europe and North America, we sell Celsior through our distribution agreement with Aventis or through other distributors.

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 $20.8 million in 2000, $17.9 million in 2001 and $18.9 million in 2002. These expenses primarily relate to additional indications for marketed products and new products in development.

We currently have two 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 filed regulatory application for marketing approval in a European country in January 2003. We intend to follow the European Community Mutual Recognition Procedure for obtaining marketing authorization in multiple member states following initial approval.

RDP58

RDP58 is a novel inhibitor of several inflammatory cytokines, notablyTNF-alpha. Interleukin(IL) 2, IL12, and Interferon (IFN)-gamma are also inhibited. RDP58 is currently in Phase IIa clinical trials in Europe. 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. RDP58 inhibits production of other cytokines that contribute to the inflammatory process. In addition to TNF-alpha, we have determined that RDP58 inhibits IFN-gamma, IL12 and IL2. RDP58 decreases IFN-gamma production by regulating IFN-gamma gene expression. Studies are in progress to understand how IL2 and IL12 are inhibited.

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 breakdown 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

Inflammatory Bowel Disease. 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, dose-ranging 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 completed patient enrollment and expect to announce the results of these studies in the second quarter of 2003. As our lead and primary product in development, adverse or inconclusive results from this trial would have a significant and material adverse effect on our research and development program and our prospects.

Chemotherapy Induced Diarrhea. 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. Our preclinical studies show that when RDP58 is given concurrently, the maximum tolerated dose of CPT-11 is increased.

In addition, TNF-alpha, IFN-gamma, and IL12 production in the gut are at normal levels. When tested in an animal model of cancer, RDP58 allowed the CPT-11 dose to be doubled resulting in a greater than 80% reduction in tumor volume compared to about 40% reduction at the lower concentration. RDP58 by itself did not affect the rate of tumor growth.

We have filed an Investigative New Drug (IND) with U.S. FDA under which we have begun a U.S. Phase Ib safety study of RDP58 for chemotherapy induced diarrhea (CID). The purpose of the study is to investigate the safety of RDP58 in patients who are undergoing chemotherapy treatment. We have begun enrollment and expect to complete the study by the end of 2003 or early 2004.

Other Preclinical Developments

RDP58 is the subject of five additional development programs: interstitial cystitis, neurology, HIV, dermatology and pulmonary.

Interstitial Cystitis. Interstitial cystitis, or IC, is a chronic inflammation of the bladder resulting in frequent and urgent urination that is accompanied with lower abdominal or urethral pain. Recent epidemiological data suggest that there may be greater than 700,000 cases of IC in the US. Three general treatment approaches are: oral medication, intravesical therapy (bladder instillation) or surgery. Surgery is indicated for those patients that have failed the other two approaches, and multiple forms are used. The only FDA approved oral drug specifically for IC is pentosan polysulfate sodium, a derivative of heparin sulfate, which is presumed to treat the lining of the bladder to restore normal function. Other oral medications include analgesics (pain relievers), anti-depressants, antihistamines and muscle relaxants. The more common intravesical therapies consist primarily of intravesical (inserted by a catheter through the urethra) instillation of DMSO, heparin sulfate, Bacillus Calmette-Guerin, or a cocktail of drugs. According to the Interstitial Cystitis Association, at this time there is no cure for IC, nor is there an effective treatment which works for everyone. Preliminary studies in a mouse model of IC showed that RDP58 may have therapeutic activity in IC. Mouse bladders were inflamed by intravesical instillation of lipopolysaccharide (LPS), a potent inflammatory compound. Histological analysis (viewing tissues under a microscope) showed heavy infiltration of leukocytes (immune cells) and severe edema (swelling). Treatment with RDP58 after LPS instillation reduced these indicators of inflammation on average by 70%.

Neurology. RDP58 was studied in a standard experimental model simulating the symptoms of multiple sclerosis or MS, in rats. Animals were immunized with myelin basic protein to develop an autoimmune response resulting in paralysis of the tail and hind limbs. When RDP58 was given as a single dose via intra-cerebroventricular (in a cavity of the brain) injection, it dramatically diminished the onset of paralysis. In some animals, paralysis was completely prevented. The beneficial effects were best when RDP58 was given up to 10 days after inoculation with myelin basic protein when clinical symptoms were beginning to appear.

The currently approved standard of care for the treatment of MS 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.

HIV Gastro-intestinal disorders. Diarrhea related to HIV is a significant gastro-intestinal disorder affecting HIV-infected persons. HIV-related diarrhea is a malabsorption syndrome that results in nutrient loss and poor drug absorption. This translates into increased weight loss and viral titers 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, when given with anti-viral therapy, was found to enhance the rate of repopulation of the CD4+ and CD4+CD8+ lymphocyte populations in the gastrointestinal mucosa compared to animals receiving anti-viral therapy only.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. Preliminary results in a mouse model of skin inflammation showed that, RDP58, when applied to the affected skin, reduces TNF-alpha expression, edema (swelling), and inflammatory cell infiltration.

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 data in animal models of Pulmonary Fibrosis (PF) and Chronic Obstructive Pulmonary Disease (COPD) show that RDP58 significantly reduces TNF-alpha levels and inflammatory cell infiltration in the lungs. 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, 2002, we had 21 account managers, supervised by 3 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 28%, 19%, 14% and 15%, respectively, of total revenues in 2002, and 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.

As of December 31, 2002, we had approximately 39 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.

Therapeutic Human Polyclonals

In November 2002, we entered into a collaboration with Human Therapeutic Polyclonals, Inc. or THP for the development of humanized polyclonal therapeutic products to be generated by the immune systems of transgenic animals. THP is a private research stage company that was formed by two scientists, one of whom, Dr. Roland Buelow, was our Senior Vice President of Discovery Research from April 1, 2000 to November 8, 2002. Dr. Buelow is transitioning from his employment with us to become the full-time Chief Scientific Officer of THP.

THP was formed to develop animals whose immune systems have been genetically altered so that they would produce antibodies that contain human, instead of animal, sequences. The engineered animals would then be injected with proteins called antigens that are found primarily on disease-producing cells, viruses or other pathogenic (disease-causing) materials. For example, antigens that mark certain cancer cells could be injected. The animal s altered immune system would then produce antibodies that react against the antigen and, hence, against the disease target (for example, the cancer cell). These antibodies would be extracted from the animal s blood and purified for human use. THP s first genetic engineering effort is focused on rabbits, which produce high quantities

(titers) of antibodies. Our primary marketed product, Thymoglobulin, is a rabbit antibody product made in a similar fashion from non-engineered rabbits. Consequently, our expertise in producing pharmaceutical-grade polyclonal antibodies from rabbits fits well with THP s plans to develop antibodies from transgenic rabbits. Animal antibodies generally have limited utility, since they normally produce an immune reaction against them when injected into humans. By humanizing the antibodies, THP hopes to reduce or eliminate these reactions.

Current humanized antibody products such as Rituxan® and Herceptin® are monoclonal antibodies. The antibodies in these products are all identical and identify only a single point (epitope) on the antigen. By contrast, the antibodies produced directly by live animals have significant variability and react against many epitopes of the antigen. These antibodies are called polyclonal antibodies. Because they react to many epitopes, polyclonal antibodies have the potential to be more effective than monoclonal antibodies, since disease targets may contain different epitopes.

Another potential advantage of the THP system is that commercial quantities of the antibodies are produced directly from colonies of rabbits, which we anticipate will be very similar to production of our Thymoglobulin product. By contrast, current humanized monoclonal antibody products must first be developed from a mouse or synthetic system, and then cloned into a production cell line. The commercial quantities of humanized monoclonal antibody products are made in complex and expensive bioreactor factories where the cells lines are cultivated.

Antibodies have two different components: the constant region that is the same for each antibody, and the variable region that varies and codes for a specific antigen. Currently, THP has produced rabbits that produce antibodies with part of the constant region that is human. THP s first objective is to develop a proof-of-principle rabbit that produces antibodies with fully human constant regions within a year. Because the research is at an early stage, clinical products from the technology are not expected to reach the market for years, if ever.

We have options from THP to obtain exclusive licenses to the THP technology to produce humanized polyclonal antibody products. One option is for a humanized version of our current Thymoglobulin product. We also have options to obtain exclusive licenses to products to treat hematology (blood related) diseases, such as leukemia and lymphoma. The options have an exercise period that commences when THP has produced a genetically engineered rabbit capable of producing commercial-grade humanized antibodies. Each license would have an up-front

fee, milestone payments based on progression through clinical trials to product approval, and royalties. THP has the right to contribute to the development costs for hematology products and receive a commensurate share of profits from commercial sales. We share antibody purification know-how with THP. In November 2002, we made a one-time technology access fee payment to THP of $500,000 under the terms of the agreement.

Additionally, we have made an equity investment of $3.2 million in THP and are committed to make a second investment of $3.2 million when THP has produced the proof-of-principle engineered rabbit, unless that milestone is unduly delayed. The total of these investments would represent ownership of approximately twenty percent (20%) of the issued share capital of THP. Our investments are made in conjunction with investments by Research Corporation Technologies, Inc., which provided start-up financing for THP and is the majority shareholder of THP. When THP has produced the commercial-grade engineered rabbit, we have an option to make an additional equity investment of $15.0 million, which would give us ownership of approximately 40% of THP s issued share capital. We do not have the right to acquire full ownership of THP.

Abbott Laboratories

In May 1999, we signed a multi-year co-promotion, distribution and research agreement with Abbott for 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 for Gengraf involves only sales in the U.S. 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 $16.0 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. We have repaid $11.0 million of the loan and $5.0 million remains outstanding. Our ability to continue marketing Gengraf may be limited as a result of a recent judgment that Gengraf infringed a Novartis patent.

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. We made an initial license fee payment of $1.0 million to Abgenix. 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 are shared equally. We also have the right, subject to the terms and conditions of the agreement, to commercialize other anti-CD147 antibodies developed by Abgenix.

In February 2003, preliminary results of the Phase II/III study showed no survival advantage with ABX-CBL compared to the control arm of the study. Consequently, we and Abgenix decided to discontinue further development of ABX-CBL. As a result, we will not have to pay Abgenix two additional payments of $1.0 million that were contingent on achievement of certain milestones. We also do not have to reimburse Abgenix for development expenses incurred prior to January 1, 2000 since that reimbursement was payable only after product launch. The amount had not been determined, but the agreement limited our obligation to $6,100,000. We were required to 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 paid Abgenix $1.4 million as of December 31, 2001 and the remaining $0.5 million was paid in 2002. The license fee and the reimbursement of development expenses are recorded as research and development expenses.

Aventis

We entered into a Distribution Agreement with Aventis in May 1999 that appointed Aventis as our exclusive distributor outside North America and Western Europe. The agreement automatically extends for additional annual periods unless either party gives notice of termination, and the current expiration date is March 31, 2004. Aventis sells our products either through its local subsidiaries or through third party distributors that often distribute other Aventis products. We are in the process of renegotiating the Aventis contract to remove territories from the contract. We then would contract directly with a local distributor in that territory, which may be the local Aventis subsidiary in that territory. We have contracted directly with local distributors in Israel and certain countries in Eastern Europe, South and Central America, and Asia.

Aventis also performs some of the steps in the manufacturing process of Thymoglobulin and Lymphoglobuline. In addition, we pay Aventis royalties on Thymoglobulin and Lymphoglobuline contingent upon the sales of these products. In 2000, 2001 and 2002, royalty payments on Lymphoglobuline and Thymoglobulin to Aventis totaled approximately $622,000, $2.2 million and $7.6 million, respectively. 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 SangStat-Synt:em agreement builds on earlier development efforts between SangStat and Synt:em with Allotrap peptides that led to the original discovery of RDP58. Under the terms of the agreement, 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.

In late 2001, the European Community, or EC issued a research contract to a consortium consisting of our wholly owned French subsidiary, Imtix-SangStat SAS, and seven academic research centers. The grant covered a term of

three years and would provide up to approximately $2,755,600 (2,628,567 Euros) to the consortium to fund research in the role of heme oxygenase-1, or HO-1, in inflammation. Since RDP58 regulates HO-1, the research was of interest to Imtix-SangStat. A consortium agreement is being negotiated under which it is anticipated that the academic members of the consortium would convey to Imtix-SangStat the rights to commercialize any inventions arising in the course of the research. Under the EC research contract, Imtix-SangStat committed to funding approximately $471,500 (450,000 Euros) of research, with the EC matching that amount. Imtix-SangStat intended that a portion of its research would be subcontracted to Synt:em. Since the research of Synt:em currently being conducted under the SangStat-Synt:em Agreement is included under the EC contract, we are working with Imtix-SangStat and Synt:em to assign the SangStat-Synt:em Agreement to Imtix-SangStat.

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 generally compete favorably with respect to these factors. However, Thymoglobulin is the price leader in the U.S. and thus is exposed to competition from lower-priced products as pressures increase on health providers to contain costs.

Thymoglobulin and Lymphoglobuline compete with various products in the U.S. and worldwide. In the U.S., Thymoglobulin has been successful in establishing a market share against these products, most of which were all previously on the market. In the U.S. there is no competitor selling a rabbit antibody product similar to Thymoglobulin while in Europe there are a number of rabbit antibody competitors. Thymoglobulin has recently experienced increased competition from the off-label use of a newly introduced product. Increased competition from this or other products could affect the future sales or price of Thymoglobulin, which could have a material adverse effect on our business

and operating results.

Gengraf and our cyclosporine capsule in development are generic and compete against the branded cyclosporine product (Neoral®, produced by Novartis AG) 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, and Rapamune®, marketed by Wyeth, which were approved by the FDA to be taken instead of cyclosporine.

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. For example, 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 several issued patents in the U.S. that pertain to previous products and technologies that we do not intend to commercialize. Of our products, only Celsior is covered by issued patents. We have several pending patent applications on RDP58 and intend to vigorously pursue patent coverage for RDP58 and related products. We have no issued patents covering Thymoglobulin and Lymphoglobuline, and rely on our manufacturing know-how to protect these products. With respect to our cyclosporine capsules, we have in-licensed a pending formulation patent application from Tris Pharma.

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.

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. Our ability to continue marketing Gengraf may be limited as a result of a recent judgment that Gengraf infringed a Novartis patent.

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.

We acquired the unit near Lyon, France that manufactures Thymoglobulin and Lymphoglobuline in 1998. The FDA, as well as the Canadian and French health authorities, inspected this facility in February and March 2002 to ensure compliance with current regulatory standards. Currently Aventis performs some of the 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. The agreements with Aventis expire on dates ranging from 2008 to 2013.

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.

With respect to raw materials, we have agreements for commercial scale production of cyclosporine bulk material with Gensia Sicor and Abbott Laboratories. Our Gensia Sicor agreement runs until December 31, 2005 and has an automatic one-year term renewal unless either party gives

notice. Our Abbott agreement terminates December 31, 2004 and is automatically renewed unless either party gives notice. Bulk cyclosporine is difficult to manufacture since it must be extracted from whole cells and carefully purified. 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 in the U.S. from one central warehousing location in

Memphis, Tennessee. When our 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 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 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 the remainder of 2003 may include Thymoglobulin for expanded labeling and RDP58.

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. Also 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 an 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 certain 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 the regulatory agencies. In addition, the 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, 2002, we employed 299 people worldwide, of which 110 are in the U.S. and Canada and 189 are in Europe, which includes approximately 74 employees in our manufacturing facility near Lyon, France. Most of our employees in our French facilities are represented by labor unions. We believe that we maintain good relations with our employees.

Available Information

Our Internet address is http://www.sangstat.com/. Information contained on our website is not part of this annual report on Form 10-K. We make available free of charge on http://www.sangstat.com/ our annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Statements of changes in beneficial ownership of our securities on Form 4 by our executive officers and directors are made available on our web site by the end of the business day following the submission of such filings to the SEC.

In addition, you may request a copy of these filings (excluding exhibits) at no cost by writing or telephoning us at the following address or telephone number:

SangStat Medical Corporation
6300 Dumbarton Circle
Fremont, CA 94555
Attention: Investor Relations
Telephone: (800) 298-1738

Code of Ethics

We have adopted a Financial Code of Ethics for our chief executive officer, chief financial officer, controller and finance director, Europe. A copy of the Financial Code of Ethics is available on our web site at http://www.sangstat.com/. We intend to post on our web site any material changes to, or waiver from our code of business conduct, if any, within five business days of such event.

Risk Factors

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

We were incorporated in 1988 and have experienced significant operating losses since that date. As of December 31, 2002, our accumulated deficit was $180.7 million. While the 2002 year was a profitable year, we may recognize losses in subsequent periods for a variety of reasons, particularly if we are unable to sell Gengraf in the future or if we increase our research and development expenditures directly or through investment or partnering arrangements with others. We expect to continue the development of our existing products and to enter into license or partnering arrangements in the future.

To date, our product revenues have been primarily derived from sales of Thymoglobulin, Lymphoglobuline, and Gengraf. Revenues from Thymoglobulin were 60%, 54% and 58% of total revenues in 2000, 2001 and 2002, respectively. Revenues from Lymphoglobuline were 12%, 8% and 7% of total revenues in 2000, 2001 and 2002, respectively. In addition, revenues from Gengraf were 18%, 31% and 31% of total revenues in 2000, 2001 and 2002, respectively. If Abbott were required to obtain a license from Novartis to continue the sale of Gengraf, Abbott s cost of sales for Gengraf may increase, and Gengraf sales may fall dramatically if this increased cost renders Gengraf less competitive in the marketplace. We believe that under our agreement with Abbott, any royalties due to Novartis should be paid by Abbott solely from Abbott s share of Gengraf profits, but Abbott may contest this. If Gengraf were withdrawn from the market due to the Novartis patent lawsuit against Abbott, these revenues would be lost entirely.

While we experienced our first profitable year in 2002, we may not be able to maintain or increase our financial reporting profitability on a quarterly or annual basis. Our operating results will be significantly dependent upon our success in, among other things:

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

Abbott s ability and willingness to continue marketing Gengraf despite the recent judgment that Gengraf infringes a Novartis patent;

successfully commercializing our product candidates, especially 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 investments in or acquisition of products or 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. In this regard, our recent collaboration with and investment in Human Therapeutic Polyclonals decreased our level of profitability in 2002.

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 securities analysts. This could cause the trading price of our common stock to decline substantially. 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.

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, including seasonal fluctuations;

our ability to continue marketing Gengraf in light of pending litigation between Novartis and Abbott and a judgment in favor of Novartis, and Abbott s willingness to continue marketing Gengraf;

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 products or other companies;

increased competition by existing or new products;

regulatory action;

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.

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. We expect to announce the results of our Phase II trials of RDP58 for patients with mild-to-moderate ulcerative colitis or Crohn s disease in the second quarter of 2003. As our lead and primary product in development, adverse or inconclusive results from these trials would have a significant and material adverse effect on our research and development program and our prospects. In any event, 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 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. Similarly, we recently announced preliminary results from our PhaseII/III study of ABX-CBL indicating that survival with ABX-CBL was similar to ATGAM. Based on these results, we do not plan to pursue further development of ABX-CBL. 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 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 could be required or could elect to discontinue or curtail marketing of Gengraf in light of the recent judgment that Gengraf infringes a Novartis patent.

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 this regard, Thymoglobulin has recently experienced increased competition from the off-label use of a newly introduced product. Increased competition from this or other products could affect the future sales or price of Thymoglobulin, which could have a material adverse effect on our business and operating 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; and

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; and

competitive pressures from competing products.

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

Abbott s ability and willingness to continue marketing Gengraf despite the recent judgment that Gengraf infringes a Novartis patent;

Reaction of patients, physicians, pharmacies, distributors and medical institutions to possible disruptions in the supply of Gengraf due to fears that Gengraf may be removed from the market because of the Novartis patent lawsuit against Abbott;

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 U.S. 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.

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. Additionally, our increasing sales of Thymoglobulin are attracting competition. Thymoglobulin has recently experienced increased competition from the off-label use of a newly introduced product. Increased competition from this or other products could affect the future sales or price of Thymoglobulin, which could have a material adverse effect on our business and operating results.

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 us.

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.

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. On August 19, 2002 a judgment was entered in U.S. District Court finding that Gengraf infringed one of the Novartis patents and awarding Novartis $5.0 million in damages. Novartis has filed for injunctive relief to prevent the sale of Gengraf in the U.S. The course of litigation is inherently uncertain: Novartis may choose to sue us directly, Abbott may not prevail, Abbott may withdraw Gengraf from the market or Abbott may choose to settle on terms adverse to our interests. If Novartis sues us directly, 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. 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 are forced or elect to remove Gengraf from the market before our co-promotion agreement with Abbott expires on December 31, 2004, our customers might return unsold inventory to us for credit or refund and we could be holding inventory of Gengraf that we are unable to sell. In that event, our revenues would

decrease significantly and our operating results would be materially adversely affected.

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 approximately $17.5 million of bulk cyclosporine active ingredient inventory classified as other assets in the balance sheet 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 no longer sell SangCya Oral Solution, we are dependent on our capsule product under development to use this inventory. Although we plan to obtain marketing approval for the 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 filed for marketing approval of the cyclosporine capsule product in a European country in January 2003. 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 or all of our bulk active ingredient in the future, which could significantly reduce the gross margin reported for that future period. If our cyclosporine capsule product is not launched by mid to late 2004, or if sales do not meet our expectations, we may have to write off additional amounts for expired inventory, which would adversely impact our operating results.

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. Sales to Cardinal Health Inc., McKesson Corporation, Bergen Brunswig Drug Company and AmeriSource accounted for approximately 28%, 19%, 15% and 14% respectively, of total revenues in 2002. Bergen Brunswig Drug Company acquired AmeriSource in 2002. We expect that we will continue to derive a substantial portion of our revenue from these wholesalers. The loss of any 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 near 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. While the FDA may inspect our facilities at any time, we do not expect an FDA inspection until 2004. If in the future the FDA or Canadian authority believes that we are not complying with its guidelines, it can issue a warning letter or prevent the import and sale of Thymoglobulin into the U.S. or Canada, and/or order a recall of these products, 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. 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 that resulted in a judgment against us of approximately $3.6 million plus interest, which was recorded as a charge to other income (expense) - net for the year ended December 31, 2001. Our preferred rabbit suppliers are reaching full capacity and we are negotiating arrangements with them to expand capacity to meet our future needs. If this expansion is delayed or fails to materialize, we may incur shortages of an essential raw material. We have drawn upon our inventory of rabbit serum and our current inventory represents approximately 2.5 months supply.

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 Sicor for the manufacture of bulk cyclosporine for the capsule product that is pending regulatory review in Europe. Abbott Laboratories also manufactures Gengraf, which would be a competing product with our cyclosporine capsule in Europe. It is possible that this competitive relationship could result in Abbott being an unreliable supplier for bulk cyclosporine for us. 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. 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 requires the expenditure of substantial resources. We do not know if we will obtain the necessary approvals for any of 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 could 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 elect to in-license or partner the development of new products from others, or we may elect to acquire products or 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, quality problems, declining reimbursement, and integration risks related to new products, technology and human resources. 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 realized 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. Accounting rules require us to periodically evaluate our investments in products, technologies or collaborators, such as our investment in Therapeutic Human Polyclonals, Inc. A reduction in appraised value due to technology delays or failures or other reasons would require us to record loss, that would adversely affect our financial results.

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.

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 did not file for approval until January 2003. Similarly, we recently announced preliminary results from our PhaseII/III study of ABX-CBL indicating that survival with ABX-CBL was similar to ATGAM. Based on these results, we do not plan to pursue further development of ABX-CBL. 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, our product candidates under development may not prove to be safe, effective or capable of being manufactured in commercial quantities at an economical cost, and our products could infringe the proprietary rights of others or may not be accepted in the marketplace.

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 $20.0 million per claim and $20.0 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. We are in the process of searching for a new Chief Executive Officer and may be unable to find a qualified new Chief Executive Officer on a timely basis, and the inability to do so could harm our business. There is risk that changes in management will disrupt our operations or lead to further resignations. Additionally, new and proposed laws, rules and regulations increasing the liability of directors and officers may make it more difficult to recruit for these positions.

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. 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 our cyclosporine capsule product candidate 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.

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, or the patents of our collaborators. In this regard our ability to continue marketing Gengraf may be limited as a result of a recent judgment that Gengraf infringed a Novartis patent. 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. However, we may fail to obtain these trademark registrations or our competitors may challenge them.

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

We have 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 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 2002, the price of our common stock ranged from $10.20 to $27.49 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;
- departures or changes in key personnel;
- financial or other disclosure irregularities;
- public concern as to the safety of drugs developed by us or others;

comments or recommendations made by securities analysts; and

general market conditions.

Adverse economic conditions, terrorism, war and geopolitical actions could affect our business.

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. The continued threat of terrorism in the U.S. and elsewhere 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. Geopolitical actions by governments, companies or individuals resulting in trade restrictions, embargos, boycotts or other actions could affect our business. We are unable to predict whether terrorism, or the military, geopolitical or other 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.

Financial disclosure and other compliance requirements present a risk of liability or government investigation

New laws, rules and regulations by the federal and state legislatures, Securities and Exchange Commission and NASDAQ will increase the requirements for review and disclosure of financial and other information. The Office of Inspector General of the Department of Health and Human Services has issued new compliance guidelines for the pharmaceutical industry relating to the marketing of pharmaceutical products and the federal government is increasingly active in investigating and enforcing laws and regulations on improper promotion of pharmaceutical products. These and other laws, rules and regulations create uncertainty and risk in our industry, particularly for smaller companies such as ours that must rely on external resources for guidance. Risks include government investigation (which can be time consuming and divert management attention), fines and civil and criminal liability. The increased potential for liability also may make it more difficult to attract and retain candidates for our board of directors.

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 involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals, infectious biological specimens and radiological materials. 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. Additionally, recent developments in California may make it more difficult or impossible to close facilities where radiological materials have been used. While we do not plan to close such facilities in the near future, if such restrictions are not eased, we could encounter difficulties expanding our research facilities or in establishing collaborations with third parties, and could incur expenses to retain facilities that cannot be closed.

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 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.

We may not be able to find a tenant for vacant space

We lease vacant office space in Newark, California that housed our discontinued operation, The Transplant Pharmacy. Due to the depressed real estate market, we may not succeed in finding a tenant for this property for a subrental in an amount that will prevent us from recognizing a further loss on our lease.

Some of our facilities in California are located near an earthquake fault, and an earthquake or other types of natural disasters or resource shortages could disrupt our operations and adversely effect results.

Our corporate headquarters is located at a single location in the Fremont area of California near active earthquake zones. This location houses various functions and related infrastructure to support our international operations in France. In the event of a natural disaster, such as an earthquake, drought or flood, or localized extended outages of critical utilities or transportation systems, we do not have a formal business continuity or disaster recovery plan, and could therefore experience a significant business interruption. California from time to time has experienced shortages of water, electric power and natural gas; future shortages and conservation measures could disrupt our operations and cause expense, thus adversely affecting our business and financial results.

Legacy computer systems may be vulnerable to failure or breaches of security

We use computer systems, including our enterprise-wide financial system that may not include the most advanced security and reliability features available. There is a risk of breakdown and unauthorized access to computer systems, including our financial systems. While management makes efforts to assess risks and prevent and detect such security breaches, our financial results, and our ability to accurately report such results, could be impacted if such unauthorized access were to occur and not be detected within our normal internal control procedures, or breakdowns were to occur and not be promptly remedied.

ITEM 2. PROPERTIES

Our global headquarter is 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 June 2005. We are negotiating with the landlord for an extension to this lease.

Our European headquarter is 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 approximately 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 in United States District Court in Delaware claiming that Gengraf® infringes its patents. On August 19, 2002 a judgment was entered finding that Gengraf infringed one of the Novartis patents and awarding Novartis $5.0 million in damages. Novartis filed for an injunction to prevent the sale of Gengraf in the U.S., but the judge has not yet ruled on the injunction. We have not been named a defendant in this lawsuit and we are not liable for the damages awarded by the jury. 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, Novartis may choose to sue us directly, Abbott may not prevail on its motions or on appeal, Abbott may elect to withdraw Gengraf from the market or Abbott may choose to settle on terms adverse to our interests. Should

Novartis, sue us, 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, If Abbott or we are forced or elect to remove Gengraf from the market before our co-promotion agreement with Abbott expires on December 31, 2004, our customers might return unsold inventory to us for credit or refund and we could be holding inventory of Gengraf that we are unable to sell. In that event, our revenues would decrease significantly and our operating results would be materially adversely affected. We might also be required to write-off all or a portion of our Gengraf inventory.

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 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. On July 11, 2002, the judge ordered Novartis, the FDA and us to file motions for summary judgment and set a schedule for briefs to be filed through December 20, 2002. We permanently withdrew SangCya Oral Solution from the U.S. market in July 2000, and receive no revenue from SangCya, but if the court were to declare microemulsion to be a separate dosage form, this ruling would require rescission of the AB rating for Gengraf, which would have a material adverse effect on our 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. 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. The ECJ hearing was held on November 7, 2002, and the Advocate General issued an opinion in January 2003. We expect the ECJ s decision approximately six to twelve 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. We no longer market SangCya Oral Solution, but the outcome of the case may affect the timing of regulatory approvals for our cyclosporine capsule product.

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 in a lawsuit concerning our application for approval by the Italian Health Authorities of the SangCya Oral Solution. In December 2002, Novartis Italy agreed to withdraw the lawsuit and we agreed not to file for approval of a cyclosporine oral solution before May 2004. Consequently, we do not expect any adverse consequences from this lawsuit.

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 in the Commercial Court of Lyon, France. The suppliers won in the trial court and appeals court and we paid approximately $3.6 million in damages plus interest. IMTIX-SangStat recorded charges of $3,250,000 and $204,000 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. We appealed the case to the French Cours de Cassation, and are negotiating with the parent of the suppliers to settle the lawsuit in return for a refund of some of the damages paid.

Summary

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 loss of Gengraf sales would have a significant and material adverse effect on our business and operating results. We might also be required to write-off all or a portion of our cyclosporine inventory. With respect to the European regulatory and trade secret lawsuits, Novartis s requested relief, if granted, could have a negative material adverse effect on us if the European Court of Justice ruling prevents us from filing for marketing authorization of our cyclosporine capsule product currently under development until after the expiration of the data exclusivity period for Novartis Neoral cyclosporine product. (That data exclusivity period expires in May 2004 for most European countries, including Germany, France, Italy and the United Kingdom.) If we cannot obtain approval of our cyclosporine capsule in Europe until 2004, this could have a material adverse impact on our future operating results because of (i) the loss of potential revenue and (ii) need to write-off some or all of our bulk cyclosporine inventory. With respect to the FDA lawsuit, Novartis s requested relief, if granted could 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 our operating results. The litigation, if not resolved favorably to us, could have a material adverse effect on our business and operating results. Of the foregoing litigation matters, only the Novartis patent lawsuit against Abbott is likely to require significant time and expense to the extent we become involved in the dispute.

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

No matters were submitted to a vote of our stockholders during the fourth quarter of 2002.

PART II

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

Our common stock is traded on the Nasdaq National Market under the symbol SANG. The table below sets forth, during the periods indicated, the high and low per share bid prices for our common stock as reported on the Nasdaq National Market.

	2002		2001	
	High	Low	High	Low
First Quarter	$ 27.490	$ 17.000	$ 13.188	$ 7.500
Second Quarter	27.470	18.790	17.000	8.875
Third Quarter	25.270	16.040	19.060	12.350
Fourth Quarter	22.780	10.200	24.870	15.880

As of March 14, 2003, there were approximately 77 holders of record of our common stock.

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.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth, as of December 31, 2002, the number of securities outstanding under each of our stock option plans, the weighted average exercise price of such options, and the number of options available for grant under such plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)

Equity compensation plans approved by security holders	3,626,846	$	18.22	2,133,303
Equity compensation plans not approved by security holders.	N/A		N/A	N/A
Total	3,626,846	$	18.22	2,133,303

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, 2002, and our balance sheets as of December 31, 2002 and 2001, are derived from our audited consolidated financial statements, which are included elsewhere in this Report on Form 10-K. The statement of operations data for the years ended December 31, 1999 and 1998 and the balance sheet data as of December 31, 2000, 1999 and 1998, 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 Report on Form 10-K. The table below has been restated to account for The Transplant Pharmacy as a discontinued operation pursuant to the sale of this operation in April 2001.

	Year Ended December 31,				
	2002	**2001**	**2000 (2)**	**1999**	**1998**
	(in thousands, except per share data)				
Consolidated Statements of Operations Data					
Revenues:					
Net product sales	$ 116,849	$ 91,302	$ 60,447	$ 42,243	$ 10,202
Revenue from collaborative agreements	3,208	3,207	2,698	2,060	1,092
Total revenues	120,057	94,509	63,145	44,303	11,294
Costs and operating expenses:					
Cost of product sales	56,723	42,816	39,246	18,989	5,110
Research and development	18,913	17,863	20,788	14,470	17,688
Selling, general and administrative	35,797	33,782	41,766	39,170	23,707
Acquired in-process research and development					3,218
Amortization of intangible assets	1,000				