

SANGSTAT MEDICAL CORP
Form 10-K
March 30, 2001

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, 2000

OR

**[] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 0-22890

SANGSTAT MEDICAL CORPORATION (Exact name of registrant as specified in
its charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

94-3076-069

(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 [X] NO []

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. []

The aggregate market value of voting stock held by non-affiliates of the Registrant, as of March 28, 2001 was approximately \$112,629,000 (based on the closing price for shares of the Registrant's Common Stock as reported by the Nasdaq National Market of \$8.50 on that date). Shares of Common Stock held by each officer, director, and holder of 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 28, 2001 approximately 19,474,360 shares of the Registrant's Common Stock, \$.001 par value, were outstanding.

Parts of the definitive Proxy Statement for Registrant's 2001 Annual Meeting of Stockholders to be filed with the Securities Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference into Part III of this Form 10-K.

SANGSTAT MEDICAL CORPORATION

FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000

TABLE OF CONTENTS

Part I.		Page
Item 1.	Business	<u>**</u>
Item 2.	Properties	<u>**</u>
Item 3.	Legal Proceedings	<u>**</u>
Item 4.	Submission of Matters to a Vote of Security Holders	<u>**</u>
Part II.		
Item 5.	Market for the Registrant's Common Equity and Related Stockholder Matters	<u>**</u>

Item 6.	Selected Consolidated Financial Data	<u>**</u>
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>**</u>
Item 7a.	Quantitative and Qualitative Disclosures About Market Risks	<u>**</u>
Item 8.	Financial Statements and Supplementary Data	<u>**</u>
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosures	<u>**</u>

Part III.

The information required by Items 10 through 13 is incorporated by reference from the registrant's proxy statement.

Part IV.

Item 14.	Exhibits, Consolidated Financial Statement Schedules and Reports on Form 8-K	<u>**</u>
----------	--	-----------

Signatures		<u>**</u>
-------------------	--	-----------

PART I

ITEM 1. BUSINESS

The following discussion and analysis should be read in conjunction with "Selected Consolidated Financial Data" and our Consolidated Financial Statements and Notes thereto included elsewhere in this Annual Report on Form 10-K. Except for the historical information contained herein, the discussion in this Annual Report on Form 10-K contains certain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. The cautionary statements made in this Annual Report on Form 10-K should be read as being applicable to all related forward-looking statements wherever they appear in this Annual Report on Form 10-K. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those discussed in "Risk Factors," as well as those discussed elsewhere herein. In particular, we have included forward-looking statements regarding the following: (i) our strategy; (ii) the anticipated timing of our regulatory filings and approvals; (iii) other product development efforts that we intend to undertake, including expanded uses and indications for existing products, and the related capital outlays; (iv) the growth of our product sales and markets; (v) the results of our litigation; (vi) our future revenue and expenses; and (vii) the anticipated timing of the sale of our division known as The Transplant Pharmacy.

Overview

SangStat is a global biotechnology company building on its foundation in transplantation to discover, develop and market high value therapeutic products in the transplantation, immunology and hematology/oncology areas. Since 1988, we have been dedicated to improving the outcome of organ and bone marrow transplantation through the development and marketing of products to address all phases of transplantation in the worldwide market. Our US headquarters are in Fremont, California. We also maintain a strong European presence, including direct sales and marketing forces in all major European markets and distributors throughout the rest of the world. Our stock is traded on the Nasdaq under the symbol "SANG". Our web site is located at www.sangstat.com.

Our business is currently organized into two segments: Pharmaceutical Products and Transplantation Services (see our Consolidated Financial Statements and Notes thereto). The Pharmaceutical Products segment consists of five marketed products, three principal product candidates and additional product candidates in various stages of research and development. We plan to capitalize on our products and product pipeline by developing relationships with key providers and managed care organizations to better integrate the management of transplant recipients' care to improve the outcomes and lower the costs of transplants.

In October 2000, we announced the implementation of a strategy to refocus the company. This strategy involves building on our foundation in transplantation to grow a core business in high value therapeutics. SangStat was a diagnostic/pharmaceutical company focused on solid organ transplantation, with particular emphasis on the cyclosporine market. The success of Thymoglobulin and its potential in areas beyond solid organ transplantation has provided us with an opportunity to pursue new markets. In addition, the changing nature of the cyclosporine market, including other generic entrants and the increased use of other chronic immunosuppressants, has reduced the overall potential in the solid organ transplantation market.

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 hematology and immunology.

We currently sell the following products:

- Thymoglobulin[®] (sold under the name Thymoglobuline[®] outside the US)
- Gengraf[®] cyclosporine capsule (co-promoted with Abbott Laboratories in the US)
- SangCya[®] Oral Solution - cyclosporine (outside the US)
- Lymphoglobuline[®] (outside the US)
- Celsior[®]

Our principal products under development include:

- A generic cyclosporine capsule
- ABX-CBL (anti-CD147 antibody in co-development with Abgenix, Inc.)
- RDP58

We also announced in October 2000 that we hoped to sell The Transplant Pharmacy (TTP), which comprises our transplantation services segment. In early March, we received several non-binding offers to purchase TTP, one of which we accepted on March 13, 2001, thus committing to a formal plan to sell this segment. We are currently in advanced negotiations with this bidder and expect to complete the sale of TTP by April 30, 2001. Consequently, the historical consolidated statements of operations and cash flows have been restated for all periods presented to account

for TTP as a discontinued operation.

Background

Organ Transplantation

Organ transplantation can save or improve the lives of patients with organ failures. Transplantation involves surgically replacing the failed organ of a transplant recipient with a healthy organ from a donor. Each year approximately 50,000 new patients receive donated organs. In order to prevent rejection of implanted organs, recipients must begin a life-long regimen of immunosuppressive therapy immediately upon receiving a donated organ. There are more than 240,000 patients in North America and Europe that need daily immunosuppressive therapy to prevent graft rejection and graft loss. Products that limit the need for immunosuppression and reduce the frequency and severity of rejection and infection episodes could significantly improve the cost-effectiveness and health benefits of transplantation.

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 lead to the recognition of the donor's organ as foreign matter by the recipient's immune system. Specifically, the donor organ antigens (HLA molecules) are recognized by the immune system of the graft recipient as being "non-self." When the recipient's immune system invades and attacks the donated organ, rejection and loss of the organ often occur.

Current therapies used to reduce the occurrence of rejection episodes involve the chronic use of immunosuppressants, which impair the entire immune system of the recipient. However, even with the use of immunosuppressants, rejection remains frequent. Chronic use of immunosuppressants can lead to serious side effects, including life-threatening infections, kidney or liver toxicity and cancers.

The Transplant Process

A typical transplant patient progresses through three phases:

- ◆ *The Pre-Transplant Phase*

A transplant candidate is registered on a national computerized waiting list. A candidate usually waits months or even years for a compatible organ. Organs harvested from donors are stored in a preservation solution such as Celsior to prevent deterioration. Each organ is cross-matched with potential recipients. The organ is then shipped in the same organ preservation solution to the recipient's transplant center. The length of storage time allowed before transplant varies among organ types and can severely limit the distance an organ can be shipped.

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

Transplant surgery has become a relatively safe and standardized procedure. After the transplant, however, the physician must prevent rejection for the transplant to be a success. Consequently, the success of the transplant is highly dependent on the immunosuppressive regimen that is initiated the day 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. Thymoglobulin and Lymphoglobuline are indicated for both prevention and treatment of rejection outside the US.

◆ *The Chronic Phase (Lifetime Post-Transplant)*

The use of immunosuppressants such as cyclosporine, initiated during the acute phase, is continued daily throughout the patient's lifetime to minimize or prevent the loss of the organ by rejection. These drugs impair the recipient's immune system in order to reduce the immune response against the graft. Even with the use of immunosuppressants, patients have an approximate 20% to 50% risk of losing a donated organ during the first three years following transplantation, and less than 50% of patients have functioning grafts after approximately ten years.

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 with damaged or defective bone marrow.

Immunosuppressive therapy, primarily anti-thymocyte globulin ("ATG") such as Lymphoglobuline and Thymoglobulin, chemotherapeutic agents, and/or irradiation are given as part of a conditioning regimen. The goals of this regimen are 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 ("GVHD"). This is a condition in which the graft (i.e. the new immune system) begins to reject the host (i.e. the body). ABX-CBL is initially being developed to treat steroid-resistant GVHD and may eventually be developed to prevent it.

Aplastic Anemia

Aplastic anemia is a disease in which the stem cells disappear from the bone marrow and primarily affects young people. Aplastic anemia has a high mortality rate and, even with treatment, quality of life is poor. Patients with this disease are dependent on weekly blood transfusions that require frequent visits to the physicians' offices and are expensive (\$10,000-15,000/year). Both Thymoglobulin and Lymphoglobuline are approved for treatment of aplastic anemia outside of the US and the majority of sales of Lymphoglobuline in Japan are for the treatment of aplastic anemia.

Myelodysplastic Syndrome (MDS)

MDS, also referred to as pre-leukemia, is a rare disease in which the bone marrow does not function normally and not enough normal blood cells are made. An estimated 30,000 to 40,000 people in the US suffer from MDS. Approximately 40% of patients will die from the consequences of ineffective blood cell production and 30% will progress to develop acute leukemia, a form of cancer where too many white blood cells are made. Supportive care with transfusions remains the principal therapy for less advanced types of MDS. Current treatments for the advanced types of the disease include chemotherapy and/or bone marrow transplantation, however these are ineffective or not

available in the majority of cases.

As with aplastic anemia, the outcomes are generally poor, the quality of life is reduced, and the patients are dependent on weekly blood transfusions. We have orphan drug status for Thymoglobulin for the treatment of MDS and have a clinical study on going to obtain FDA approval for this indication.

Crohn's Disease and Ulcerative Colitis

Crohn's disease and ulcerative colitis are similar diseases that are often grouped together as inflammatory bowel disease (IBD). Crohn's disease is a chronic inflammatory disease of the gastrointestinal (GI) tract. Crohn's disease usually causes diarrhea, abdominal pain, often fever, and can cause rectal bleeding. Ulcerative colitis is an inflammatory disease of the colon, the large intestine, which is characterized by inflammation and ulceration of the innermost lining of the colon. Symptoms include diarrhea with or without rectal bleeding and sometimes abdominal pain. Unlike Crohn's disease, which can involve all regions of the intestine, ulcerative colitis affects only the colon. It is estimated that there are up to 1,000,000 Americans with either ulcerative colitis or Crohn's disease, roughly half of that number for each disease. We are developing RDP58 for treatment for both diseases.

Products and Product Candidates

The following tables summarize our principal products and product candidates.

Marketed Products	
Product	Indications/Clinical Use
Thymoglobulin ^{®1}	Prevention and treatment of acute graft rejection, severe aplastic anemia and steroid resistant GVHD ¹
Gengraf ^{®2}	Chronic immunosuppression (prevents organ rejection)
Lymphoglobuline ^{®3}	Prevention and treatment of acute graft rejection, severe aplastic anemia and steroid resistant GVHD
Celsior [®]	Preserves organs prior to transplantation
SangCya [®] Oral Solution (cyclosporine) 4	Chronic immunosuppression (prevents organ rejection)

Principal Product Candidates	
Product Candidate	Description and Potential Clinical Use
Cyclosporine Capsule	Chronic immunosuppression (prevents organ rejection).
ABX-CBL	An anti-CD147 monoclonal antibody for the treatment of steroid resistant GVHD currently in a multicenter, randomized and controlled Phase II/III study. Licensed from and co-developed with Abgenix
RDP58 ⁵	

Product Candidate

A rationally designed peptide that inhibits TNF-alpha synthesis. We are investigating its use for treatment of various autoimmune disorders, particularly ulcerative colitis and Crohn's disease.

1

Approved in the US only for treatment of acute kidney rejection episodes.

2

Distributed only in the US. Gengraf is a registered trademark of Abbott Laboratories, Inc.

3

Not approved for sale in the US.

4

Withdrawn from the US market in July 2000. Being sold in a small number of countries outside the US.

5

Formerly known as Allotrap 1258.

Marketed Products

Thymoglobulin

Description

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 a transplant. While the exact mechanism is unknown, researchers believe Thymoglobulin antibodies may inactivate and kill these T-cells, thus reversing the rejection process.

Market

We (or our distributors) market Thymoglobulin in 56 countries, though our revenues from Thymoglobulin come primarily from Europe and North America. Our primary European subsidiary, IMTIX-SangStat S.A.S. (also known as SangStat-Europe) was formerly the IMTIX division of Pasteur Mérieux Connaught, now Aventis Pasteur, a subsidiary of Aventis S.A. ("Aventis"). IMTIX has sold the current formulation of Thymoglobulin in France since 1994 and its predecessor product since 1984. In Europe, Thymoglobulin has the following indications:

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

Description and Potential Clinical Use

In the US, we launched Thymoglobulin in February 1999. Thymoglobulin is indicated for treatment of acute rejection in kidney transplant recipients in the US. We intend to seek expanded indications for other organs within solid organ transplantation and seek new indications in hematological disorders such as MDS.

We market and sell Thymoglobulin outside Europe and North America through distributors. We have a distribution agreement with Aventis, which we are currently renegotiating, for most countries outside of Europe and North America. We have also entered into distribution agreements with distributors in certain Asian countries and are currently re-negotiating our distribution agreement with Aventis to obtain the right to distribute directly in certain territories. See "Strategic Relationships."

Clinical Studies

◆ *Induction/Prevention*

We have initiated a comparative induction study of Thymoglobulin versus Simulect, a monoclonal antibody marketed by Novartis Pharmaceuticals Inc. ("Novartis") in high-risk renal transplant recipients. The FDA has indicated that this trial will not be sufficient to support label indication changes or expansion. This is a prospective, randomized, open-label study conducted in 20 transplant centers with approximately 240 patients. Primary endpoints at 6 months will be graft survival, patient survival, incidence of acute rejection, and incidence of delayed graft function. We expect patient enrollment to be completed by year-end 2001.

◆ *Hematological Disorders and Malignancies*

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

MDS is a rare disorder of the bone marrow that often results in bone marrow failure in older people and results in the need for transfusions and supportive care. The endpoint in this trial is transfusion independence at six months post therapy. Patient enrollment began in October 2000. In part because this is a rare disease, as evidenced by its orphan drug status, to date patient enrollment has been relatively slow. While we have expanded the number of centers participating in the study with the aim of trying to meet the enrollment goal, which is completion of enrollment of 72 patients into the study by 2001 year end, enrollment may not be completed by that time.

Gengraf

® *Cyclosporine Capsules/ SangCya® Oral Solution*

Description

Cyclosporine is a potent immunosuppressive agent. Gengraf cyclosporine capsule, a product of Abbott Laboratories Inc. (Abbott) is a generic version of Neoral® capsules, which is marketed by Novartis. SangStat and Abbott co-promote and distribute Gengraf in the US. SangCya Oral Solution, which is a generic version of Neoral oral solution, was withdrawn from the US market in July 2000 and is currently being sold in a small number of countries

Description and Potential Clinical Use

outside the US.

Cyclosporine Market

Cyclosporine is the leading immunosuppressive drug used to prevent graft rejection in transplantation. There are approximately 140,000 transplant recipients in the US and 250,000 worldwide who will require daily lifelong immunosuppressive therapy. The majority of these patients are prescribed cyclosporine. Cyclosporine is also indicated for the treatment of rheumatoid arthritis and adult non-immunocompromised psoriasis patients. Worldwide sales of cyclosporine are greater than \$1 billion per year. The US market is approximately \$500 million.

We entered into an agreement with Abbott in May 1999 for the co-promotion, distribution, and research in the US of SangCya Oral Solution and Gengraf. See "Strategic Relationships." This agreement enables both companies to maximize their strengths by combining SangStat's transplant expertise with Abbott's pharmaceutical presence, especially in the managed care arena.

We launched Gengraf cyclosporine capsules in May 2000 in the US through our combined SangStat/Abbott sales force. Novartis has sued Abbott for patent infringement with respect to Gengraf. See "Item 3 - Legal Proceedings." 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.

We sell SangCya Oral Solution in the UK and Germany and we plan to file for marketing authorization for our cyclosporine capsule in the UK and US. See: "Principal Products in Development - Cyclosporine Capsules." In Europe, there are approximately 20,000 new transplant recipients per year concentrated in 250 transplant centers and over 100,000 transplant recipients in Europe who require daily lifelong immunosuppressive therapy from the time of transplant surgery.

Lymphoglobuline

®

Description

Lymphoglobuline is an anti-thymocyte equine immunoglobulin that induces immunosuppression as a result of t-cell depletion and immune modulation. Outside the US, it is approved for the prevention and treatment of rejection episodes in kidney, heart, pancreas, or liver transplantation. In hematology, Lymphoglobuline is approved for treatment of aplastic anemia and in the treatment of GVHD.

Market

Lymphoglobuline is marketed in over 45 countries. Our sales force markets it in Europe and Canada. Outside these countries, it is sold through our distribution agreement with Aventis or through other distributors. Aventis Pharma markets it in Japan, where a high percentage of sales occur for treatment of aplastic anemia. We have no plans to seek approval for Lymphoglobuline in the US.

Celsior

®

Description and Potential Clinical Use

Description

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 tissues during the recovery process and cold storage while the donor heart is transported to the recipient. Celsior is the first and only flush and cold storage solution approved by the FDA for cardiac transplantation. It was designed specifically for cardiac transplantation to minimize myocardial edema, oxygen free radical-induced reperfusion injury, and diastolic stiffness.

Market

Celsior is sold throughout Europe and was launched in the US in September 1999. It is indicated for cardiac transplantation in the US. We recently terminated our Celsior lung trial for financial reasons given the cost of the trial versus the sales of the product, but there is data from about seventy patients, which may result in a publication. Outside of Europe and North America, Celsior is sold through our distribution agreement with Aventis or through other distributors. There are approximately 5,000 cardiac and lung transplants each year worldwide.

Revenues from pharmaceutical products for 1998, 1999 and 2000 were \$11,294,000, \$44,303,000, and \$63,145,000 respectively. Revenues from Thymoglobulin were 69% of 1999 revenues and 60% of 2000 revenues, and revenues from Lymphoglobuline were 19% of 1999 revenues and 12% of 2000 revenues, respectively. Combined revenues of these two products were 66% of 1998 revenues. In addition, revenues from Gengraf were 18% of total revenues from pharmaceutical products in 2000, and revenues from SangCya Oral Solution were 16% of total revenues from pharmaceutical products in 1998 and were immaterial in 1999.

Principal Products In Development

We currently have three principal products in development. Our research and development expenses were \$17,688,000, \$14,470,000 and \$ 20,788,000 for 1998, 1999, and 2000 respectively.

Cyclosporine Capsules

We have exclusively licensed a novel cyclosporine capsule formulation, which uses a patented technology, from a small US research and development company. We are conducting a small pilot study in healthy volunteers to demonstrate the new capsule's bioequivalence to Neoral cyclosporine capsules in water. The other filing requirements include a larger bioequivalence trial and stability testing. If the results of the bioequivalence trial and stability testing are positive, we expect to file a Marketing Authorization Application (MAA) with the Medicines Control Agency (MCA) of the United Kingdom (UK) in 2001. We have withdrawn our MAA in the UK for our cyclosporine capsule product known as Sang-2000 in favor of this newer formulation. We intend to follow the European Community Mutual Recognition Procedure for obtaining regulatory approval in multiple Member States.

ABX-CBL

In August 2000, we entered into a global co-development, supply and license agreement for ABX-CBL with Abgenix under which we obtained an exclusive worldwide license for the marketing and sale of ABX-CBL. ABX-CBL is an anti-CD147 monoclonal antibody for the treatment of steroid resistant GVHD and is currently in a multi-center, randomized, and controlled Phase II/III study. The study is designed to demonstrate statistically significant efficacy of a single dose level of ABX-CBL in comparison to a control group of patients. We received orphan drug designation for ABX-CBL for the treatment of steroid resistant GVHD in November 2000.

In an earlier Phase II trial completed in the fall of 1999, 52% of patients receiving 0.1 - 0.3 mg/kg ABX-CBL survived at least 100 days following initiation of therapy, compared to 22% of patients receiving the presumed no effect dose of

Description and Potential Clinical Use

0.01 mg/kg. Approximately 25% of patients that undergo an allogeneic bone marrow transplant develop steroid resistant GVHD for which there is currently no standard approved therapy available.

RDP58

RDP58, a rationally designed peptide, is a novel inhibitor of TNF-alpha synthesis and is being investigated for treatment of various autoimmune disorders, particularly ulcerative colitis and Crohn's disease.

TNF-alpha is a cytokine released in excess in various autoimmune disorders. It triggers activation of immune responses and inflammation. Animal models, including studies in primates, suggest that RDP58 could decrease levels of TNF-alpha, reduce inflammation, and improve clinical outcomes. RDP58 is different from currently available TNF inhibitors in that it prevents the synthesis of TNF-alpha on a translational level as opposed to binding TNF-alpha to inhibit function. It is currently being tested in an oral formulation. We plan to file a Clinical Trial Experiment application (CTX) with the MCA in the UK and, following approval of the CTX, begin Phase I/II clinical trials studying RDP58 for both ulcerative colitis and Crohn's disease in the UK in 2001.

The Transplant Pharmacy®/TransplantRx.com™

We established The Transplant Pharmacy (TTP) in September of 1996. This program provides mail order distribution of drugs and other services for transplant patients. In November of 1999, we introduced TransplantRx.com, the first on-line pharmacy dedicated to organ transplantation. Designed as an extension to the mail order service, TransplantRx.com provides patients, their families and health care providers with a place to purchase all of their medications and access information and resources on transplantation on-line. We announced in October 2000 that we hoped to sell The Transplant Pharmacy (TTP), which comprises our transplantation services segment. In early March, we received several non-binding offers to purchase TTP, one of which we accepted on March 13, 2001, thus committing to a formal plan to sell this segment. We are currently in advanced negotiations with this bidder and expect to complete the sale of TTP by April 30, 2001. We are not including the accounts receivable and inventory in the sale, and we plan to liquidate these assets as soon as practicable following the closing of the sale. Consequently, the historical consolidated statements of operations and cash flows have been restated for all periods presented to account for TTP as a discontinued operation. See Note 15 of the Notes to Consolidated Financial Statements.

Sales and Marketing

In the US we market products through our direct sales force. As of March 5, 2001, we have 21 Transplant Account Managers, supervised by three regional sales directors, who call on or "detail" primarily to the approximately 250 transplant centers in the US. A number of the Account Managers have backgrounds in transplantation, either from detailing 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 and one open position for a national account director. Sales to McKesson HBOC and Cardinal Health Inc., accounted for 15% and 13%, respectively, of total revenues in 2000. Sales to McKesson HBOC accounted for approximately 11% of our total revenues in 1999. No customer accounted for more than 10% of our total revenues in 1998.

We reorganized our European sales and marketing departments in 2000 following the hiring of a new head of European operations and a new VP of Sales and Marketing in Europe. We have approximately 30 sales and marketing people spread throughout the major European markets. There are also approximately 250 transplant and hematology centers in Europe.

The marketing departments in the US and Europe work together in a coordinated, cohesive fashion with each other and with the sales force. Product concepts and market penetration programs are targeted to blend clinical data with proven marketing techniques. In 2000, the marketing departments conducted multiple faculty training meetings in

which academicians and researchers presented clinical data on our products to over 125 clinicians from transplant centers. We also use a variety of marketing techniques to promote our products, including sampling, journal advertising, promotional material, specialty publications, rebate coupons, product guarantees, educational conferences and exposure of our products on the Internet.

For certain territories and products, however, we have distributors. See "Strategic Relationships." To the extent we enter into co-promotion or other licensing arrangements, any revenues received by us will be dependent on the efforts of third parties, which may not be successful.

Revenues for sales outside of the US were \$8,022,000, \$26,209,000 and \$21,873,000 for 1998, 1999, and 2000 respectively, the majority of which have come from Europe since the acquisition of IMTIX in September 1998. Additional information regarding long-lived assets and revenues outside of the US can be found in Note 16 of the Notes to Consolidated Financial Statements.

Warehousing and Distribution

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

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. We may not be interested in or able to negotiate any additional collaborative arrangements. If we establish such relationships, they may not be successful.

Co-Promotion, Distribution and Research Agreement with Abbott

In May 1999, we signed a multi-year co-promotion, distribution and research agreement with Abbott for SangCya Oral Solution (which was withdrawn from the US market in July 2000) and Gengraf in the US. 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 products with Abbott. The agreement ends December 31, 2004 unless both companies agree to extend it. Pursuant to this agreement, Abbott made an equity investment of \$14 million during 1999 in exchange for approximately 894,000 shares of common stock, representing a premium to fair market value at that time aggregating to \$1.3 million. In addition, Abbott made a series of up-front and milestone payments totaling \$20.8 million, including \$1.9 million received in January 2000 and \$5.0 million received in May 2000, and a long-term loan of \$16 million to us received during 1999. In January 2000, we made a milestone payment of \$4.0 million to Abbott under the terms of the agreement. No further milestone payments are required from either company. All up-front and milestone payments received, net of milestone payments made, and the premium received on the sale of common stock to Abbott are recorded as deferred revenue and recognized ratably over the term of the agreement as revenue from collaborative agreements. In May 2000, Abbott and we launched Gengraf, the cyclosporine capsule developed by Abbott. In connection with the equity investment, Abbott and we entered into a Right of First Refusal Agreement and a Registration Rights Agreement, and amended and restated our existing Supply Agreement.

Co-Development, Supply and License Agreement with Abgenix, Inc.

In August 2000, we entered into a global co-development, supply and license agreement with Abgenix, Inc., for ABX-CBL, an antibody developed by Abgenix. Under the agreement, we have an exclusive worldwide license for the marketing and sale of ABX-CBL. ABX-CBL is an anti-CD 147 monoclonal antibody for the treatment of steroid

resistant graft versus host disease (GVHD) and is currently in a multicenter, randomized, and controlled Phase II/III study. Development costs will be shared equally, as would any potential profits from the sales of collaboration products. We share responsibility for product development with Abgenix, including the ongoing Phase II / III clinical trial. We will market any potential products and Abgenix will be responsible for manufacturing ABX-CBL. We also have the right, subject to the terms and conditions of the agreement, to commercialize other anti-CD147 antibodies developed by Abgenix.

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

If ABX-CBL receives regulatory approval and is launched, we will reimburse Abgenix for one-half of its development expenses incurred prior to January 1, 2000 up to a maximum reimbursement of \$6.1 million provided that we don't have any obligation to reimburse Abgenix until the first anniversary of the launch of ABX-CBL and the timing of reimbursement varies depending on ABX-CBL's sales. We have also agreed to reimburse Abgenix for one-half of the development costs for ABX-CBL from January 1, 2000 to August 8, 2000, with our share being approximately \$1.9 million. We must reimburse Abgenix for this amount over a two-year period commencing with a \$1 million payment, which has already been paid, and two equal payments of the remaining amount payable by the end of June 2001 and 2002. The license fee and the initial reimbursement of development expenses are recorded as research and development expenses.

Aventis Pasteur

We entered into a Distribution Agreement with Aventis in May 1999 that expires March 31, 2002. Aventis is our exclusive distributor for Thymoglobulin and Lymphoglobuline for most countries outside of North America, Europe and Japan (where Thymoglobuline and Lymphoglobuline are distributed by Aventis Pharma). The contract has minimum purchase requirements. If Aventis does not meet these minimums, the agreement becomes non-exclusive, which means we can sell to another distributor in the same country. Aventis sells these products either through its local subsidiary or through a distributor that often distributes other Aventis products. We are currently re-negotiating this distribution agreement to allow us to contract directly with distributors in countries in which Aventis has no direct presence (e.g. Israel and certain Asian countries). Aventis also performs certain steps in the manufacturing process of Thymoglobulin and Lymphoglobuline. See "Manufacturing". In addition, pursuant to the purchase of IMTIX on September 30, 1998, we pay Aventis royalties on Thymoglobulin and Lymphoglobuline contingent upon the sales of these products. In 1999 and 2000, royalty payments on Lymphoglobuline to Aventis totaled approximately \$646,000 and \$622,000 respectively. We expect these royalty payments to increase in future years since we will begin paying royalties on Thymoglobulin commencing on the third anniversary of the purchase of IMTIX (October 1, 2001).

Amgen, Inc.

Amgen, Inc. ("Amgen") is the exclusive distributor for our cyclosporine products in Australia, New Zealand, China and Taiwan. Amgen is responsible for obtaining the registrations and marketing the products. Amgen made an initial payment plus other milestone payments in 1998 and 1999. There are no more milestones due under the agreement. If Amgen is sued for patent infringement based upon its sales of our cyclosporine products in these countries, we will control and pay for such litigation.

Stanford University

We also have a worldwide, exclusive license from Stanford University to make, sell or otherwise distribute products covered by patents and patent applications on certain HLA peptides. Stanford University has no obligation to conduct any further research with respect to such peptides. Our exclusive right to these patents expires in October 2007.

Additionally, under the terms of this agreement, we pay Stanford University annual license fees and, if we obtain regulatory approval and start selling a product covered by the agreement, we will pay Stanford University a royalty on sales of this product.

University of North Carolina

We have been working with the University of North Carolina (UNC) since 1994. UNC does formulation work for us on cyclosporine formulations. Under the terms of our license agreement with UNC, we pay UNC a royalty on sales of SangCya Oral Solution in return for a worldwide exclusive license. Should UNC's work on other formulations result in a product, we may pay UNC a royalty for such products.

Novartis A.G.

We pay Novartis a royalty on sales of SangCya Oral Solution under the license agreement entered into as part of our settlement of the patent litigation involving SangCya Oral Solution.

Competition

The drug industry is very competitive. The drugs we market compete with existing and new drugs being created by pharmaceutical, biopharmaceutical, and biotechnology companies and universities. Many of these entities have significantly greater research and development capabilities, as well as substantial marketing, manufacturing, financial and managerial resources and represent significant competition for us. Many of the competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing the desired therapeutic effect than products we are developing or marketing and may be more effective and less costly. In addition, many of our competitors have significantly greater experience than we do in conducting clinical trials of pharmaceutical products and obtaining regulatory approvals of such products. This could cause our competitors to succeed in commercializing products more rapidly than we can. The principal factors upon which our products compete are:

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

We believe we compete favorably with respect to all of these factors. Gengraf, however, is a generic drug, which means we compete favorably against the branded drug, Neoral, on pricing, but some physicians may be reluctant to prescribe generic drugs.

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

<u>Our Products</u>	<u>Competitive Products</u>	<u>Competitor</u>
Thymoglobulin/Lymphoglobuline	Orthoclone OKT® 3	Ortho Biotech
	ATGAM®	Pharmacia & Upjohn Inc.

	Simulect®	Novartis AG
	Zenapax®	F. Hoffmann La-Roche Ltd.
Gengraf, SangCya Oral Solution, & cyclosporine capsules	Neoral	Novartis AG
	Sandimmune	Novartis AG
	Prograf®	Fujisawa Pharmaceutical Co. Ltd.
	Rapamune	American Home Products (AHP)
	Generic cyclosporine capsule	Eon Labs
	Generic cyclosporine capsule	Sidmak

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

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

Our cyclosporine products are generic and compete against the branded cyclosporine products as well as other generic cyclosporine products that have been or may be approved. These products also compete against Prograf, marketed by Fujisawa Pharmaceutical Co. Ltd, which was approved by the FDA to be taken instead of cyclosporine. Roche's Cellcept® is indicated as a conjunctive therapy, to be taken with cyclosporine rather than instead of cyclosporine. As noted above, Thymoglobulin competes with OKT3, ATGAM, Simulect, and Zenapax. In the US, Thymoglobulin has been successful in establishing a market share against these products, which were all previously on the market. In Europe, Novartis and Roche have just started selling Simulect and Zenapax, respectively, and we believe that the launch of these two products may impact sales of Thymoglobulin and Lymphoglobuline in Europe.

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

RDP58 is an inhibitor of TNF-alpha synthesis. TNF-alpha is a cytokine released in excess in various autoimmune disorders. For that reason, many companies are pursuing development of a TNF-alpha inhibitor and we believe there

could be substantial competition in this area. In addition, Immunex/AHP's Enbrel and Johnson & Johnson's Remicade are both TNF-alpha inhibitors that are currently approved for rheumatoid arthritis and Crohn's disease respectively.

Patents and Proprietary Technology

We have a number of issued patents and pending patent applications in the US and in corresponding countries with respect to the products we are selling, the products we have in development and our research areas. We aggressively seek patent protection on our inventions and our policy is to enforce our intellectual property rights. We have no issued patents covering Thymoglobulin and Lymphoglobuline and rely on our manufacturing know-how to protect these products. We have issued patents covering Celsior, SangCya Oral Solution and our cyclosporine capsules have formulation patent protection both issued and pending, but the cyclosporine compound is no longer patent-protected and there are several generics on the market in the US. We are pursuing patent protection for RDP58 and we believe that an issued patent may give us a competitive advantage.

We have twenty-nine issued patents and sixteen pending patent applications in the US and are pursuing corresponding patent applications in other countries.

- Two issued patents and three pending patent applications relating to our peptide program.
- Two issued patents and two pending patent applications in the heme oxygenase area.
- Two issued patents relating to Celsior.
- Three issued patents and four pending patent application in the general therapeutics area, including our complexine technology.
- One issued patent and two pending patent applications relating to Anti-LFA1.
- Four issued patents and three pending patent applications that cover our cyclosporine formulations technology for developing multiple formulations and dosage forms of cyclosporine.
- Fifteen issued patents and one pending patent application in the diagnostic or monitoring area.
- One pending patent application relating to the CycloTech device.

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

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

Patent applications in the US are maintained in secrecy until patents issue. 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. There can be no assurance that our pending patent applications will result in issued patents, that any of our issued patents will afford protection against a competitor or that our products will not infringe on other patents.

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

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

Manufacturing

Manufacturing pharmaceutical products is a highly regulated process. The FDA and other regulatory agencies require that manufacturing be done in accordance with current Good Manufacturing Practices ("GMP"). Additionally,

products can only be manufactured in facilities approved by the applicable regulatory authorities. Because of these and other factors, we may not be able to quickly and efficiently replace our manufacturing capacity in the event that we are unable to manufacture Thymoglobulin or Lymphoglobuline or one of our manufacturers is unable to manufacture one of our other products for us. See "Risk Factors - We may not be able to manufacture or obtain sufficient quantities of our products, which could lead to product shortages and harm our business," and "Risk Factors - Our reliance on third parties for manufacturing may delay product approval or once approved, result in a product shortage, which would reduce our revenues."

When we acquired IMTIX in 1998, we also acquired the manufacturing unit in Lyon, France that manufactured Thymoglobulin and Lymphoglobuline. Currently Aventis also performs certain steps in the manufacturing process of Thymoglobulin and Lymphoglobuline under contract to us. We perform the remaining manufacturing steps ourselves in manufacturing facilities that we lease from Aventis. These agreements with Aventis expire on dates ranging from 2008 to 2013. In 1999, partially in response to a letter from the FDA, we improved certain manufacturing processes at the Lyon facility and are continuing to improve these manufacturing processes in 2000 and 2001 as we move part of our operations to a new manufacturing building in the same location. Our manufacturing operations were not materially affected and we do not believe that they will be materially affected in the future. We believe that our facility currently complies with GMP.

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

Abgenix is responsible for the manufacturing of ABX-CBL. If the supplier they have chosen fails to perform, it would have the same results discussed above: 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 Sicom ("Sicom") and Abbott. Our Sicom agreement runs until October 31, 2013 and has an automatic five-year term renewal unless one party gives notice. Our Abbott agreement terminates December 31, 2004 and is automatically renewed until one party gives notice. Bulk cyclosporine is difficult to manufacture since it must be extracted from whole cells and carefully purified. We have an obligation to purchase a certain percentage of our future bulk cyclosporine requirements from Sicom and a minimum fixed amount from Abbott, subject to certain conditions being met. We believe we have sufficient quantities of bulk cyclosporine to meet our current needs. We believe we also have sufficient quantities of raw materials for our other products and product candidates.

Government Regulation

FDA and Other Regulatory Authorities

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 US and other countries ("Regulatory Agencies"). The US Federal Food, Drug, and Cosmetic Act (the "Act") and the regulations promulgated thereunder and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising, promotion, import and export of our products and product candidates. Preclinical study and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would harm our ability to commercialize any

product candidates we develop and our ability to receive product revenues. If regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed.

The steps ordinarily required before a drug or biological product may be marketed in the US include the following:

- preclinical studies,
- the submission to the FDA of an Investigational New Drug application ("IND"), which must become effective before human clinical trials may commence,
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug,
- the submission to the FDA of a New Drug Application ("NDA"), or Biological License Application ("BLA"), if applicable, and
- FDA approval of the application, including approval of all product labeling.

Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of each product. Laboratories that comply with FDA regulations regarding Good Laboratory Practice must conduct these preclinical safety tests. The results of the preclinical tests are submitted to the FDA as part of an IND and are reviewed by the FDA before the commencement of human clinical trials. Unless the FDA objects to an IND, the IND will become effective 30 days following its receipt by the FDA. Submission of an IND may not result in FDA authorization to commence clinical trials or the lack of an objection may not mean that the FDA will ultimately approve an application for marketing approval.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap.

- Phase I Phase I clinical trials involve the initial introduction of the drug into healthy human volunteers. In Phase I clinical trials, the drug is tested for safety (adverse effects), dosage tolerance, metabolism, distribution, excretion and pharmacodynamics (clinical pharmacology).
- Phase II Phase II clinical trials are conducted in a target patient population to gather evidence about the pharmacokinetics, safety and biological or clinical efficacy of the drug for specific indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks.
- Phase III When a compound has shown evidence of efficacy and an acceptable safety profile in Phase II evaluations, Phase III clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population.

Our products in clinical trials during 2001 may include Thymoglobulin for expanded labeling, ABX-CBL, RDP58, and bioequivalence studies for our cyclosporine capsule product.

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

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

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

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

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

Environmental Regulation

In connection with our research and development activities we are subject to 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. Although we believe that we have complied with these laws, regulations and policies in all material respects and have not been required to take any action to correct any noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and infectious biological specimens. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Third Party Reimbursement

Our operating results will depend in part on the availability of adequate reimbursement for our products from third-party payers, such as government entities, private health insurers and managed care organizations. Third-party payers increasingly are 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.

A number of legislative and regulatory proposals aimed at changing the US health care system have been proposed in recent years. While we cannot predict whether any such proposals will be adopted, or the effect that any such proposals may have, such proposals, if enacted, could harm our business operations.

Manufacturing

Product Liability Insurance

We face an inherent risk of exposure to product liability claims in the event that the use of our products is alleged to have resulted in adverse effects. Such risk exists even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise received regulatory approval for commercial sale. We could be subject to significant product liability claims. We currently have product liability insurance in the amount of \$25.0 million per claim and \$25.0 million in the aggregate on a claims-made basis. Many of our customers require that we maintain product liability insurance coverage as a condition to their conducting business with us. As the loss of such insurance coverage could result in a loss of such customers, we intend to take all reasonable steps necessary to maintain such insurance coverage. However, insurance coverage may not be available in the future on commercially reasonable terms. Such insurance may not be adequate to cover potential product liability claims and the loss of insurance coverage or the assertion of a product liability claim or claims could harm our operating results.

Employees

As of December 31, 2000, we employed 287 people worldwide, of which 133 are in the US and Canada and 154 are in Europe, which includes approximately 65 employees in our manufacturing facility in Lyon, France, most of whom are represented by labor unions. 31 of our US employees work at The Transplant Pharmacy, which we expect to sell by April 30, 2001. We believe that we maintain good relations with our employees.

Our Executive Officers

Jean-Jacques Bienaimé, 47, has been our President and Chief Operating Officer since June 1998 and became Chief Executive Officer on February 1, 1999. He was elected to the Board of Directors in March 1999. Mr. Bienaimé became Chairman of the Board of Directors in October 2000. From September 1992 to May 1998 Mr. Bienaimé was with Rhone Poulenc Rorer, Inc., a pharmaceutical company, rising to the position of Senior Vice President, Corporate Marketing and Business Development. He is currently a member of the board of Fox Chase Cancer Center and Aerogen Inc. Mr. Bienaimé received his degree in economics from Ecole Supérieure de Commerce de Paris in France and an M.B.A. from the Wharton School, University of Pennsylvania.

Christophe M. Bianchi, M.D., 39, has been the President of our IMTIX-SangStat subsidiary and our Senior Vice President, Global Marketing and Business Development since January 2000. From 1989 to December 1999, Dr. Bianchi held various positions with Rhône-Poulenc Rorer, Inc., serving most recently as Vice President and Head, Global Marketing. Dr. Bianchi received an M.D. from the University of Reims in France, a degree from Ecole De Hautes Etudes Commerciales (EDHEC graduate school of management), and a Masters of Business Administration from the Wharton School, University of Pennsylvania.

Steve Aselage, 49, has been our Senior Vice President, North American Sales since February 1999. From 1995 to January 1999, Mr. Aselage was the Director of Sales and Marketing at Advanced Tissue Sciences, a tissue engineering company. Mr. Aselage received a B.S. in biology from the University of Notre Dame.

Roland Buelow, Ph.D., 42, has been our Senior Vice President of Research and Development since April 2000 and was Vice President of Research and Development from 1993 until 2000. Dr. Buelow received a Ph.D. in Biology from the Max-Planck Institute for Biology in Tuebingen, Germany. Dr. Buelow visited the University of Texas as a Fulbright scholar and spent two years at Stanford Medical School.

Stephen G. Dance, 50, has been our Senior Vice President, Finance since April 1999. From July 1998 to April 1999, Mr. Dance was Director of Financial Accounting, Planning and Reporting at Plantronics, Inc., a telecommunications company. From 1983 to July 1998, Mr. Dance held various positions with Syntex Corporation, a pharmaceutical company, which was acquired by Roche Holding Ltd., also a pharmaceutical company, in 1994, serving most recently as Controller, Syntex Laboratories, Inc. Mr. Dance holds a B.A. in French from Leeds University in England, is a

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Certified Public Accountant in the State of California and a fellow of the Institute of Chartered Accountants in England and Wales.

Ralph E. Levy, 52, has been our Senior Vice President, Operations since 1995 and Vice President, Operations from 1990 until 1995. Mr. Levy received a B.S. in chemistry from the City College of New York and an M.S. in chemistry from Seton Hall University.

Carole L. Nuechterlein, 40, has been our Senior Vice President and General Counsel since February 2001 and was Vice-President and General Counsel from October 1998 to January 2001. From 1991 to October 1998, Ms. Nuechterlein held various positions with Roche Bioscience and Syntex Corporation, which was acquired by Roche Holding Ltd. in 1994, serving most recently as Director of Legal Affairs. Ms. Nuechterlein received a B.A. in 1983 from Valparaiso University and a J.D. in 1986 from the University of Michigan.

Raymond J. Tesi, M.D., 45, has been our Senior Vice President, Medical Affairs and Clinical Development since August 1999. From May 1997 to August 1999, Dr. Tesi served as our Senior Vice President of Marketing. From 1994 until 1997, Dr. Tesi was an associate professor of surgery and director of the extra-renal transplantation program at Tulane Medical School in New Orleans, Louisiana. He was a transplantation surgical fellow at the Ohio State University Hospital. Dr. Tesi received an M.D. from the Washington University School of Medicine in St. Louis, Missouri.

Randell J. Correia, Pharm.D, 42, has been Vice President, The Transplant Pharmacy® of SangStat Medical Corporation since 1995. Dr. Correia received a doctor of pharmacy degree from the University of the Pacific in Stockton, California.

Robert C. Floc'h, Ph.D., 53, has been the General Manager of our IMTIX-SangStat subsidiary since we acquired IMTIX in September 1998. In addition, Dr. Floc'h has been General Manager at SangStat Atlantique, our previous operating subsidiary in France, since 1992. Dr. Floc'h received a doctor of pharmacy degree and a Ph.D. in medical chemistry from the University of Nantes.

Risk Factors

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

We were incorporated in 1988 and have experienced significant operating losses since that date. As of December 31, 2000, our accumulated deficit was \$177,636,000. Our operating expenses from continuing operations have increased from approximately \$50.1 million to \$74.0 million to \$103.2 million over the three year period ended December 31, 2000. Total revenues from continuing operations have increased from approximately \$11.3 million to \$44.3 million to \$63.1 million, while losses from continuing operations decreased from approximately \$38.8 million to \$29.7 million and increased to \$40.0 million over the three year period ended December 31, 2000. We expect to continue to incur significant losses for the foreseeable future and we may not ever achieve significant revenues from product sales and we may not achieve profitable operations.

We may need to raise additional funds within the next 12 months and may not be able to secure adequate funds on terms acceptable to us.

Within the next twelve months, we may need to raise additional funds through financings and collaborative research and development arrangements with corporate partners. We may not be able to raise funds on favorable terms, if at all, and our discussions with potential collaborative partners may not result in any agreements. If adequate funds are not available, we may be required to delay, scale back or eliminate one or more of our development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain technologies, product candidates or products that we would not otherwise relinquish. To raise funds, we may also be

required to sell shares of our common stock, which may be at prices below the price at which you may have purchased shares. Such sales would also cause a dilution of your percent ownership of SangStat.

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 US. Our sales of Thymoglobulin began in the US in February 1999. We began distributing Gengraf in May 2000. We are marketing Gengraf in the US under a co-promotion agreement with Abbott Laboratories. We cannot guarantee that Abbott will be able to effectively market Gengraf, and its failure to do so may adversely impact sales of these products.

Any factor adversely affecting the sales of Thymoglobulin, Lymphoglobuline, and Gengraf individually or together, or regulatory approval of our cyclosporine capsule product would harm our business and results of operations. The following factors could adversely affect 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;
- the price of our products relative to alternative therapies;
- manufacturing or supply interruptions;
- competitive changes;
- regulatory issues;
- ease of use;
- changes in the prescribing practices of transplant physicians;
- the availability of third-party reimbursement; or
- product liability claims.

In particular, with respect to Gengraf, sales may be affected by the following:

- perceptions of both patients and physicians regarding use of a generic version of a critical, life-saving therapeutic;
- perception of bioequivalence;
- other generic competitors;
- number of contracts with managed care providers and group purchasing organizations;
- our recall of SangCya Oral Solution in July 2000; and
- intense competitive pressure from Novartis and Novartis' litigation with Abbott.

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

Our manufacturing facility in Lyon 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. If the FDA believes that we are not complying with its guidelines, it can issue a warning letter or prevent the import of Thymoglobulin into the US, which would reduce our revenues. In addition, Thymoglobulin and Lymphoglobuline are biologics and consequently difficult to manufacture. We acquired the IMTIX division of Aventis in 1998, including certain manufacturing capabilities with respect to Thymoglobulin and Lymphoglobuline. Before the acquisition, certain batches of Thymoglobulin did not meet manufacturing specifications, resulting in a shortage of Thymoglobulin for commercial sale. We still rely on Aventis for certain important manufacturing services, including quality assurance, quality control, and lyophilization. Aventis may not continue to effectively and continuously provide us these critical manufacturing services. In addition, we may experience manufacturing

difficulties with respect to Thymoglobulin or Lymphoglobuline in the future that may impair our ability to deliver products to our customers, which could reduce our revenues and harm our business.

If our products do not receive regulatory approvals, or if we do not otherwise comply with government regulations, our business would be harmed.

Our research, preclinical development, clinical trials, manufacturing, marketing and distribution of our products in the US and other countries are subject to extensive regulation by numerous governmental authorities including, but not limited to, the FDA. In order to obtain regulatory approval of a drug product, we must demonstrate to regulatory agencies, among other things, that the product is safe and effective for its intended uses and that the manufacturing facilities are in compliance with Good Manufacturing Practices requirements. The process of obtaining FDA and other required regulatory approvals is lengthy and will require the expenditure of substantial resources, and we do not know if we will obtain the necessary approvals for our product candidates. Moreover, for our approved products, the marketing, distribution and manufacture of our products remains subject to extensive regulatory requirements administered by the FDA and other regulatory bodies. Failure to comply with applicable regulatory requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval, withdrawal of approvals and criminal prosecution of SangStat and our employees.

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. There are three main risks associated with using third parties for manufacturing:

- The manufacturer may not pass a pre-approval inspection, or once approved, may not continue to manufacture to FDA's and other regulatory authorities' standards.
- The manufacturer may not deliver adequate supplies of a sufficiently high quality product in the time-line that we need to meet our clinical time-lines or to meet product demand.
- We may not be able to obtain commercial quantities of a product at an economically viable price.

In addition, we may not be able to enter into commercial scale manufacturing contracts on a timely or commercially reasonable basis, or at all, for our product candidates. Abgenix, from whom we have licensed ABX-CBL, remains responsible for entering into and maintaining the manufacturing agreement with a third party for the manufacturing of this product candidate. 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, any of which would impair our competitive position either because of the delays or because of a loss of revenues. Additionally, because our products can only be manufactured 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 their products.

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

We have significant amounts of bulk cyclosporine active ingredient inventory that we are not using to manufacture finished product in the amount anticipated. This inventory was originally purchased for use in cyclosporine finished products to be sold in the US and Europe. However, since we are now distributing Gengraf in the US and we have withdrawn SangCya Oral Solution from the US market, we are dependent on the European market to use this inventory. Although we plan to obtain marketing approval for a cyclosporine capsule product in Europe, the inherent uncertainty of the approval process makes it very difficult to forecast a launch date for this product. We currently expect approval of a cyclosporine capsule product in the UK in 2002. If the approval and product launch are delayed, we may not be able to convert all the inventory into finished product and sell it before its expiration date. As a result, we could write off portions of our bulk active ingredient in the future, which could significantly reduce the gross margin reported for that future period.

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

To achieve profitable operations, we must successfully develop, obtain regulatory approval for, manufacture, introduce and market new products and product candidates. We may not be able to successfully do this. Our product candidates will require extensive development and testing, as well as regulatory approval before marketing to the public. Our cyclosporine capsule product candidate in Europe has been delayed and we do not anticipate having approval of a cyclosporine capsule product in Europe until 2002. In addition, cost overruns and product approval delays could occur due to the following:

- ◆ unanticipated regulatory delays or demands;
- ◆ unexpected adverse side effects; or
- ◆ insufficient therapeutic efficacy.

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

Our recall of SangCya Oral Solution in the US in July 2000 could result in an FDA investigation and negative marketing by our competitors.

We recalled all lots of SangCya Oral Solution from the US wholesalers in July 2000 and at the same time announced its withdrawal from the US market. In addition to the loss of anticipated SangCya Oral Solution revenues, the FDA may conduct an investigation into the circumstances that led to the SangCya Oral Solution recall. Responding to an FDA investigation could be costly, time consuming, and may distract senior management from other tasks. Negative marketing may reduce sales of Gengraf or Thymoglobulin as competitors attempt to use the recall in marketing against our products and us. The FDA or other regulatory authorities may review our future drug approval applications more carefully, which may result in slower approval times. If approvals are delayed, revenues from these products would also be delayed.

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 results in adverse effects during research, clinical development or commercial use. We cannot guarantee we will avoid significant product liability exposure. Our product liability insurance coverage is currently limited to \$25 million, which may not be adequate to cover potential liability exposures. Moreover, we cannot assure you that adequate insurance coverage will be available at an acceptable cost, if at all, or that a product liability claim would not harm our results of operations.

Our inability to attract or retain key personnel could negatively affect our business

. 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 cannot assure you that we will be able to continue to attract or retain such people. 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 results of operations.

Operation of The Transplant Pharmacy may suffer while we are trying to sell the business, resulting in a lower sales price or inability to sell the business.

On October 16, 2000, we announced that we hoped to sell The Transplant Pharmacy, or TTP, our mail order pharmacy business. We have put a retention program in place to encourage employees to stay while we are selling the division. If we cannot successfully retain employees, it will be very difficult to replace employees and we may be forced to use temporary employees. Loss of employees or use of temporary employees could adversely affect operations of TTP. If TTP operations are disrupted, TTP would likely produce lower revenues and lower collections of accounts receivable, which, if either occurred, could result in a lower sale price for TTP or an inability to sell TTP. We are in advanced negotiations with a potential buyer and expect to complete the sale of TTP by April 30, 2001, however there can be no assurance that this sale will occur.

Our litigation with Novartis may be resolved adversely and will be a drain on time and resources.

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

Novartis' 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. Novartis' complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the US. The course of litigation is inherently uncertain: Novartis may choose to name us in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to our interests. Should we be named in this suit, we may incur expenses before reimbursement, if any, by Abbott who is obligated under our agreement to indemnify us against such suits. Should Novartis succeed in obtaining a preliminary or permanent injunction, Gengraf may be temporarily or permanently removed from the market. If Abbott or we were forced to remove Gengraf from the market before our co-promotion agreement with Abbott expires on December 31, 2004, our revenues would be decreased materially.

We may have a charge against earnings if we lose a breach of contract lawsuit.

In August 2000, two affiliated suppliers sued our French subsidiary, IMTIX-SangStat SAS, for breach of contract because we ordered lower quantities than were anticipated by the agreements. The suppliers are asking for damages of \$5 million for lost profits and reimbursement of capital expenditures. A hearing was held in late December 2000 and we currently anticipate a ruling in mid-April 2001. The course of litigation is inherently uncertain and we may not achieve a favorable outcome. If the court finds in the suppliers' favor, we would suffer a one-time charge against earnings, which could be material if these parties are awarded the full amount requested.

Our future success depends on our ability to successfully manage growth.

We continue to expand our operations, which places a strain upon our management, systems and resources. Our ability to compete effectively and to manage future growth, if any, will require us to continue to, on a timely basis,

improve our financial and management controls, reporting systems and procedures and expand, train and manage an increasing number of employees. Our failure to do so would harm our results of operations.

Failure to protect our intellectual property will adversely affect our business.

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 US and abroad. Some of our patents involve specific claims and thus do not provide broad coverage. There can be no assurance that our patent applications or any claims of these patent applications will be allowed, be 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. We have not conducted extensive patent and art searches with respect to our product candidates and technologies, and we do not know if third-party patents or patent applications exist or filed in the US, 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 US 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. We cannot guarantee these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known or independently developed by competitors.

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 a name has been selected for the product candidate. We have registered or applied for trademark registration of the names of most of our products under development or commercialized for research and development use. However, these trademark registrations may not be granted to us or may be challenged by competitors.

We face substantial competition, which could adversely affect our revenues and results of operations.

The drugs we develop compete 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.

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 and 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 and obtaining regulatory approvals of such products. Accordingly, our competitors may succeed in commercializing products more rapidly than we can.

Other treatments for the problems associated with transplantation that our products seek to address are currently available and under development. To the extent these therapeutics or monitoring products address the problems

associated with transplantation on which we have focused, they may represent significant competition.

We depend on collaborative relationships and any failure by our strategic partners to perform could adversely affect our competitive position

. We have a number of 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 US with Abbott. We are dependent upon Abbott for certain regulatory, manufacturing, marketing, and sales activities under the agreement. Abbott may not perform satisfactorily and any such failure may impair our ability to deliver products on a timely basis, or otherwise impair our competitive position, which would harm our business. We have also entered into a Co- Development, Supply and License Agreement with Abgenix, Inc. with respect to the development, marketing and sale of ABX-CBL. We are dependent upon Abgenix for certain development and manufacturing activities under the agreement. Abgenix may not perform satisfactorily and any such failure may delay regulatory approval, product launch, impair our ability to deliver products on a timely basis, or otherwise impair our competitive position, which would harm our business. We may enter into additional collaborative relationships with corporate and other partners to develop and commercialize certain of our potential products. We cannot assure you that we will be able to negotiate acceptable collaborative arrangements in the future, that such collaborations will be available to us on acceptable terms or that any such relationships, if established, will be scientifically or commercially successful.

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

Our quarterly and annual operating results may fluctuate due to a variety of factors. We therefore believe that quarter-to-quarter comparisons of our operating results may not be a good indication of our future performance, and you should not rely on them to predict our future performance or the future performance of our stock. Our operating losses have been substantial each year since inception. We also expect losses to continue in the near future as a result of a number of factors, including:

- the uncertainty in the timing and the amount of revenue we earn upon product sales;
- our achievement of research and development milestones;
- our funding obligations under collaborative research agreements; and
- expenses we incur for product development, clinical trials and marketing and sales activities.

Our operating results may also fluctuate significantly as a result of other factors, including:

- the introduction of new products by our competition;
- regulatory actions;
- market acceptance of our products;
- manufacturing capabilities;
- cost of litigation; and
- third-party reimbursement policies.

Fluctuations in our operating results have affected our stock price in the past and are likely to continue to do so in the future. In particular, the realization of any of the risks described herein could have a significant and adverse impact on the market price for our stock.

Our stock price as well as the stock prices for competitors in our industry has historically been volatile.

The market prices for securities of pharmaceutical and biotechnology companies, including ours, are highly volatile. 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;
- clinical trial results;
- developments in patent or other proprietary rights;
- public concern as to the safety of drugs developed by us or others;
- comments made by securities analysts; and
- general market conditions.

The uncertainty of pharmaceutical pricing and reimbursement may negatively impact our results of operations

. Our ability to successfully commercialize our products may depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. The pricing, availability of distribution channels and reimbursement status of newly approved healthcare products is highly uncertain and we cannot assure you that adequate third-party coverage will 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 US, 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, an increasing emphasis on managed care in the US has and will continue to increase the pressure on pharmaceutical pricing. While we cannot predict whether any such legislative or regulatory proposals will be adopted 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 results of operations. Further, to the extent that such proposals or efforts harm other pharmaceutical companies that are our prospective corporate partners, our ability to establish corporate collaborations may be adversely affected. In addition, third-party payers are increasingly challenging the prices charged for medical products and services. We do not know whether our products and product candidates, if approved, will be considered 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 research and development activities and operations, we are subject to 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. We cannot assure you that we will not incur significant costs to comply with environmental and health and safety regulations. Our research and development involves the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and infectious biological specimens. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. 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.

Our charter documents, stockholder rights plan and Delaware law may serve to deter a takeover.

Certain provisions of our Certificate of Incorporation and our Bylaws could delay or make more difficult a merger, tender offer or proxy contest, which could adversely affect the market price of our common stock. Our board of directors has the authority to issue up to 5 million shares of preferred stock and to determine the price, rights preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock could have

the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock. Further, 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, 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. In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which will prohibit us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, 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.

ITEM 2. PROPERTIES

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

Our European headquarters are located in Lyon, France. We lease approximately 38,300 square feet from Aventis in Marcy L'Etoile (just outside of Lyon), France for administration and manufacturing. The leases for non-manufacturing operations expire at various dates up to 2006 and may be renewed for subsequent years. The manufacturing lease expires in 2013 but may be terminated at our option upon giving one year's notice. In addition, we lease 12,400 square feet in Lyon, France for sales, marketing, finance, clinical, and administration, and lease administrative offices in various other countries.

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

ITEM 3. LEGAL PROCEEDINGS

The following is a description of our current litigation. The course of litigation is inherently uncertain and we may not achieve a favorable outcome. See "Item 1 - Risk Factors - Our litigation with Novartis may be resolved adversely and will be a drain on time and resources."

Novartis Patent Litigation

Novartis vs. SangStat

On July 27, 2000, we entered into a global settlement agreement with Novartis AG and Novartis Pharmaceuticals Corporation with respect to the patent infringement lawsuits filed against us regarding SangCya® Oral Solution, USP [MODIFIED] as well as the counterclaim we filed against Novartis Pharmaceuticals Corporation in the US. As part of the settlement, we have entered into a global license agreement pursuant to which Novartis shall license US patent #5,389,382 and its foreign counterparts to us and we shall pay Novartis a royalty on sales of SangCya Oral Solution. The settlement and license applies only to SangCya Oral Solution and does not apply to cyclosporine capsule products. We do not expect the terms of the settlement to have a material financial impact on us in the foreseeable future.

Novartis vs. Abbott

Novartis has sued Abbott claiming that Gengraf® (cyclosporine capsule, USP, MODIFIED), infringes certain Novartis patents. Novartis' complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the US, but to date they have not moved for a preliminary injunction. The trial date has been set for October 1, 2001. The discovery

schedule is still before the court pending resolution of differences between the parties' proposals. Abbott has informed us that it does not believe it infringes the Novartis patents. We have not been named a defendant in this lawsuit, and under our agreement with Abbott, Abbott is obligated to indemnify us against such suits. The course of litigation is inherently uncertain, however; Novartis may choose to name us in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to our interests. Should we be named in this suit, we may incur expenses prior to reimbursement (if any) by Abbott pursuant to its indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, Gengraf may be temporarily or permanently removed from the market.

Novartis Regulatory Litigation

US Regulatory Litigation

Novartis US sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia (case number 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral oral solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis asks that the court (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 parties have all filed motions for summary judgment with the Court and are awaiting a final ruling. The Court has dismissed the counts that relate specifically to the approval of SangCya Oral Solution, but Novartis may appeal this decision. Because we permanently withdrew SangCya Oral Solution from the US market in July 2000, we do not believe that this lawsuit will have any material impact on SangStat.

UK Regulatory Litigation - SangCya Oral Solution

On October 18, 1999, Novartis UK was granted leave to seek judicial review of the decision by the Medicines Control Agency (the "MCA") to approve SangCya Oral Solution (Case No. HC- 1969/99). On March 30, 2000, the High Court in London dismissed Novartis' 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 ("ECJ"). We estimate that the ECJ will issue its ruling in approximately eighteen to twenty four months. Following the ECJ ruling, the parties would go back to the Court of Appeal who will then apply the ECJ ruling on the law to the facts of this case.

UK 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 cyclosporine capsule application. 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 a marketing authorization for a cyclosporine capsule product, and 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' solicitors of capsule approval. The parties had 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 capsule. Because the High Court ruled in favor of the MCA with respect to the SangCya Oral Solution marketing authorization and the Court of Appeal has referred questions of law to the ECJ, 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 (approximately 2004).

Italian Regulatory/Trade Secret Litigation

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

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

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 because we ordered lower quantities than were anticipated by the agreements. They claim that the quantities set forth in the agreements were fixed orders; we believe that they were forecasts only. We believe that the agreements provide that if we purchased less than the forecast amounts, we would pay a penalty equal to a percentage of the difference between the amount ordered and the amount forecast. The suppliers claim this provision only applied during the first year of the agreement. The suppliers are asking for damages of 37 million French Francs (approximately \$5 million) for lost profits and reimbursement of capital expenditures. Under our interpretation, we would owe them 2.2 million French Francs (approximately \$300,000) for 2000 and 1.6 million French Francs (approximately \$200,000) in 2001, presuming no further orders are placed with these suppliers. The claim was filed under a "Fast Track" provision in the Lyon Commercial Courts and a hearing on the merits occurred at the end of December 2000. We currently anticipate a ruling in mid-April 2001. If the plaintiffs were to prevail, the court would likely appoint an expert to assess the exact amount of damages suffered by the plaintiffs.

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

None

PART II

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

Our common stock commenced trading publicly on the Nasdaq National Market on December 14, 1993 and is traded under the symbol SANG. The following table sets forth for the periods indicated the high and low daily closing prices for our common stock:

	HIGH	LOW
	-----	-----
Fiscal year ended December 31, 1999		
First Quarter.....	\$ 32.125	\$ 12.375
Second Quarter.....	17.438	11.813
Third Quarter.....	22.750	14.875
Fourth Quarter.....	30.625	18.438
Fiscal year ended December 31, 2000		
First Quarter.....	48.000	25.875
Second Quarter.....	33.813	21.813
Third Quarter.....	29.875	12.813
Fourth Quarter.....	14.500	6.500

On March 28, 2001 the closing sale price of our common stock as reported on the Nasdaq National Market was \$8.50 per share. As of March 28, 2001, there were approximately 100 holders of record of our common stock.

DIVIDEND POLICY

We have not declared or paid any cash dividends since our inception. We currently intend to retain all earnings, if any, for use in the expansion of our business and therefore do not anticipate paying any dividends in the foreseeable future. In addition, our Loan and Security Agreement with FINOVA Capital Corporation (FINOVA) precludes us from paying any dividends while any obligations are owed FINOVA. See Note 7 of the Notes to Consolidated Financial Statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources" regarding certain developments with respect to this Loan and Security Agreement.

SALE OF UNREGISTERED SECURITIES

Since January 1, 2000 until December 31, 2000, we have sold and issued the following unregistered securities and all were sold in reliance on the exemption from registration found in Section 4(2) of the Securities Act of 1933, as amended, as each placement was made by us as an issuer to only one investor in a transaction not constituting a public offering. The recipient of securities in each transaction represented its intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to share certificates and other instruments issued in such transactions. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

1. In February 2000, BioPharma Equities Holding NV, invested approximately \$15,000,000 in exchange for approximately 451,128 shares of our common stock.
2. In December 2000, Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, and SDS Capital Partners, LLC entered into an agreement to make an equity investment of approximately \$12,500,000 in exchange for approximately 1,315,800 shares of our common stock. Narragansett I. LP, Narragansett Offshore, Ltd., and Royal Bank of Canada acquired their shares on December 29, 2000 and S.A.C. Capital Associates, LLC and SDS Merchant Fund, LP (assignees of SDS Capital Partners, LLC) acquired their shares on January 5, 2001.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

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, 2000, and with respect to the balance sheets as of December 31, 2000 and 1999, are derived from our Consolidated Financial Statements, which are included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 1997 and 1996 and the balance sheet data as of December 31, 1998, 1997 and 1996, are derived from audited consolidated financial statements not included herein. The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our Consolidated Financial Statements and the Notes thereto included elsewhere in this Annual Report on Form 10-K. The table below has been restated to account for The Transplant Pharmacy as a discontinued operation. See Note 15 of the Notes to Consolidated Financial Statements.

	Year Ended December 31,				
	2000	1999	1998	1997	1996
(in thousands, except per share data)					
CONSOLIDATED STATEMENTS OF OPERATIONS DATA:					
Revenues:					
Net sales.....	\$ 60,447	\$ 42,243	\$ 10,202	\$ 2,456	\$ 2,266
Collaborative agreements.....	2,698	2,060	1,092	750	--
Total revenues.....	63,145	44,303	11,294	3,206	2,266
Operating expenses:					
Cost of sales.....	39,246	18,989	5,110	2,646	2,737
Research and development.....	20,788	14,470	17,688	16,210	8,330
Selling, general and administrative.....	41,766	39,170	23,707	9,442	5,652
Acquired in-process research and development.....	--	--	3,218	--	--
Amortization of intangible assets.....	1,392	1,398	351	--	--
Total operating expenses.....	103,192	74,027	50,074	28,298	16,719
Loss from continuing operations.....	(40,047)	(29,724)	(38,780)	(25,092)	(14,453)
Other income (expense), net.....	(1,602)	(913)	3,053	5,506	2,123
Loss from continuing operations before income taxes.....	(41,649)	(30,637)	(35,727)	(19,586)	(12,330)
Income taxes.....	(368)	(345)	(257)	--	--
Net loss from continuing operations..	(42,017)	(30,982)	(35,984)	(19,586)	(12,330)
Loss from operations of discontinued operation.....	(2,342)	(2,025)	(2,480)	(1,394)	(444)
Net loss.....	\$ (44,359)	\$ (33,007)	\$ (38,464)	\$ (20,980)	\$ (12,774)
Net loss per share - basic and diluted(1)					
Continuing operations.....	\$ (2.35)	\$ (1.83)	\$ (2.24)	\$ (1.27)	\$ (0.99)
Discontinued operation.....	(0.13)	(0.12)	(0.15)	(0.09)	(0.04)
	\$ (2.48)	\$ (1.95)	\$ (2.39)	\$ (1.36)	\$ (1.03)
Shares used in per share computations(1).....					
	17,910	16,888	16,080	15,376	12,405

December 31,

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

	2000	1999	1998	1997	1996
	(in thousands)				
CONSOLIDATED BALANCE SHEET DATA:					
Cash, cash equivalents and short-term investments.....	\$ 20,607	\$ 26,519	\$ 29,660	\$ 92,036	\$ 41,321
Working capital.....	39,774	63,991	46,828	93,812	40,727
Total assets.....	114,316	117,297	107,327	104,354	44,750
Long-term obligations, excluding current portion.....	44,689	49,496	16,402	1,557	1,100
Accumulated deficit.....	(177,636)	(133,277)	(100,270)	(61,806)	(40,826)
Total stockholders' equity.....	21,924	41,009	59,587	97,470	40,955

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

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

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

The following discussion and analysis should be read in conjunction with "Selected Consolidated Financial Data" and our Consolidated Financial Statements and Notes thereto included elsewhere in this Annual Report on Form 10-K. Except for the historical information contained herein, the discussion in this Annual Report on Form 10-K contains certain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. The cautionary statements made in this Annual Report on Form 10-K should be read as being applicable to all related forward-looking statements wherever they appear in this Annual Report on Form 10-K. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those discussed in "Risk Factors," as well as those discussed elsewhere herein. In particular, we have included forward-looking statements regarding the following: (i) our strategy; (ii) the anticipated timing of our regulatory filings and approvals; (iii) other product development efforts that we intend to undertake, including expanded uses and indications for existing products, and the related capital outlays; (iv) the growth of our product sales and markets; (v) the results of our litigation; (vi) our future revenue and expenses; and (vii) the anticipated timing of the sale of our division known as The Transplant Pharmacy.

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

Our business is currently organized into two segments: Pharmaceutical Products and Transplantation Services. The Pharmaceutical Products segment consists of five marketed products, three principal product candidates and additional product candidates in various stages of research and development. We plan to capitalize on our products and product pipeline by developing relationships with key providers and managed care organizations to better integrate the

management of transplant recipients' care to improve the outcomes and lower the costs of transplants. The Transplantation Services segment consists of The Transplant Pharmacy (TTP). In October 2000, we announced that we hoped to sell TTP. In early March, we received several non-binding offers to purchase TTP, one of which we accepted on March 13, 2001, thus committing to a formal plan to sell this segment. We are currently in advanced negotiations with this bidder and expect to complete the sale of TTP by April 30, 2001. Consequently, the historical consolidated statements of operations and cash flows have been restated for all periods presented to account for TTP as a discontinued operation. Unless otherwise indicated, the following discussion relates to our continuing operations.

Our accumulated deficit from inception through December 31, 2000 was \$177,636,000. Our operating loss has been substantial each year since inception and losses are expected to continue in the foreseeable future as a result of a number of factors, including the uncertainty in the timing and the amount of revenue to be earned upon product sales, and expenses required for product development, clinical trials and marketing and sales activities. In addition, our business is subject to significant risks, including but not limited to, the success of our research and development efforts, litigation by third parties regarding intellectual property, obtaining and enforcing patents important to our business, the lengthy and expensive regulatory approval process, reliance on third parties to manufacture products or product candidates, competition from other products and uncertainties associated with health care reform measures. Even if our products appear promising at various stages of development, they may not reach the market for a number of reasons. Such reasons include, but are not limited to, the possibilities that the product candidates will be found to be ineffective or unsafe, be difficult to manufacture on a large scale, be uneconomical to market, be precluded from commercialization by proprietary rights of third parties or be unacceptable to providers, payers or patients. Additional expenses, delays and losses of opportunities that may arise out of these and other risks could harm our business and results of operations.

Acquisition of IMTIX

On September 30, 1998, we completed the acquisition of Pasteur Mérieux Connaught's (Aventis) organ transplant business known as IMTIX. The acquisition was accounted for using the purchase method of accounting. The resulting wholly owned subsidiary, named IMTIX-SangStat (IMTIX), is dedicated to the research, development, manufacture and marketing of pharmaceuticals for transplantation. The aggregate gross purchase price of approximately \$31 million consisted of \$10 million paid upon closing and a non-interest bearing note of \$21 million payable over five years (see Liquidity and Capital Resources). The resulting aggregate net purchase price totaled \$28.7 million and was allocated to the net tangible assets acquired of \$11.1 million, based on their fair value on the date of acquisition, identifiable intangible assets of \$14.4 million and purchased in-process research and development of \$3.2 million. Approximately \$7.9 million of the purchase price was allocated to existing technology, and is being amortized over a period of fourteen years. The purchased in-process research and development of approximately \$3.2 million was charged to our operations in the third quarter of 1998 and represents the value of products that had not yet reached technological feasibility and had no alternative future use.

The purchased in-process technology acquired primarily consisted of a single drug, Anti-LFA1. Anti-LFA1 is a monoclonal, biologically manufactured immunosuppressant compound intended to be used in preventing the rejection of organ transplants. The estimated value for the in-process technology was determined using the income approach which discounted to present value the cash flows expected to be derived from the product as it was still in development at the date of acquisition. The projections were based on future expectations of the acquired company's revenue and expenses to be generated from the product still under development. Revenues and operating profit attributable to the in-process technology were estimated to total \$163.2 million and \$33.4 million, respectively, over a fourteen-year projection period. The resulting projected net cash flows were discounted to their present value of \$3.2 million using a discount rate of 25%, adjusted on a prorata basis for negative goodwill. The discount rate used was calculated based on the weighted average cost of capital and adjusted for the technology risk associated with development of the in-process product. The nature of the efforts required to develop the purchased in-process technology into a commercially viable product principally related to the completion of clinical trials to evaluate clinical efficacy and safety in an expanded patient population. Upon successful completion of the trials, FDA approval

would be required before marketing the product for a specified use. During 1999, following our evaluation of the outcome of the ongoing clinical studies, we decided to discontinue the development of Anti-LFA1.

The consolidated financial statements reflect the results of operations of IMTIX from October 1, 1998. Accordingly, the results of operations for 1999 and 2000 include a full year of IMTIX's results versus three months in 1998.

Results of Operations

Revenues.

Net sales of pharmaceutical products for the year ended December 31, 2000 were \$63,145,000, an increase of \$18,842,000 or 43% over net sales of \$44,303,000 for the year ended December 31, 1999. The increase was due primarily to sales of Gengraf, which was launched in the US in May 2000, and increased sales of Thymoglobulin in the US, which accounted for \$11,423,000 and \$10,563,000 of the increase, respectively. This increase was partially offset by lower sales outside the US. In particular, sales in Europe for the year ended December 31, 2000 were adversely affected by weakening currencies. Had average exchange rates remained the same as in fiscal 1999, net sales in fiscal 2000 would have been higher by \$3.1 million.

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

Net sales of pharmaceutical products for the year ended December 31, 1999 were \$44,303,000, an increase of \$33,009,000 or 292% over net sales of \$11,294,000 for the year ended December 31, 1998. The increase was due primarily to sales of Thymoglobulin in the US following the launch of that product in February 1999. In addition, net product sales in fiscal 1999 included a full year of sales of therapeutic products in Europe as a result of the acquisition of IMTIX, compared with only one quarter of sales in fiscal 1998. Included in net sales of pharmaceutical products was revenue from collaborative agreements of \$2,698,000 in 2000, an increase of \$638,000 or 31% over revenue from collaborative agreements of \$2,060,000 in 1999. Revenue from such agreements in fiscal 1999 represented an increase of \$968,000 or 89% over revenue of \$1,092,000 for the year ended December 31, 1998. In 2000 and 1999, we recognized revenue of \$2,698,000 and \$1,510,000 from milestone payments from Abbott Laboratories under the co-promotion agreement for cyclosporine. The unamortized portion of these milestone payments is shown as deferred revenue on our consolidated balance sheet and will be recognized as revenue on a straight-line basis over the remaining term of the co-promotion agreement. We also recognized revenue from milestone payments of \$550,000 and \$1,036,000 in 1999 and 1998 respectively from Amgen under the collaborative distribution agreement for our cyclosporine products in certain territories outside the US.

Cost of sales.

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

Cost of sales for pharmaceutical products of \$18,989,000 for the year ended December 31, 1999 represented an increase of \$13,879,000 or 272% over cost of sales of \$5,110,000 for the year ended December 31, 1998. The increase was primarily due to the increased sales of pharmaceutical products. Cost of sales in fiscal 1999 also included provisions of \$1,865,000 for short-dated SangCya Oral Solution finished goods inventory.

Research and development.

Research and development expenses were \$20,788,000 for the year ended December 31, 2000, an increase of \$6,318,000 or 44% over research and development expenses of \$14,470,000 for the year ended December 31, 1999. The increase in spending on research and development for the year ended December 31, 2000 mainly relates to charges for a license fee and reimbursement of development costs for ABX-CBL totaling \$3.9 million, clinical trials to pursue label expansion of Thymoglobulin and continued pre-clinical work on RDP58, a product in development that inhibits synthesis of TNF-alpha. The expenses for the year ended December 31, 2000 also included \$50,000 to cover the cost of terminating SangCya Oral Solution clinical trials following the previously discussed product recall.

Research and development expenses of \$14,470,000 for the year ended December 31, 1999 represented a decrease of \$3,218,000 or 18% over research and development expenses of \$17,688,000 for the year ended December 31, 1998. The decrease in fiscal 1999 was due primarily to a reduction in spending on clinical trials for Thymoglobulin and SangCya Oral Solution. Thymoglobulin was approved by the US Food and Drug Administration (FDA) on December 31, 1998 and was launched in the US in February 1999. Following its approval in the US by the FDA on October 31, 1998, SangCya Oral Solution was approved by the Medicines Control Agency in the United Kingdom in February 1999 and was launched in that country in April 1999.

Selling, general and administrative

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

Selling, general and administrative expenses of \$39,170,000 for the year ended December 31, 1999 represented an increase of \$15,463,000 or 65% over selling, general and administrative expenses of \$23,707,000 for the year ended December 31, 1998. The increase in expenses in fiscal 1999 reflects the inclusion of IMTIX expenses for the whole year and an increase in expenses incurred in the US. This increase was due primarily to sales and marketing expenses for Thymoglobulin and SangCya Oral Solution, as well as legal expenses relating to the Novartis lawsuits.

Acquired in-process research and development.

In connection with the acquisition of IMTIX, we recorded a charge of \$3,218,000 for purchased in-process research and development in 1998. This charge was primarily associated with the ongoing development of Anti-LFA1. During 1999, following our evaluation of the outcome of the ongoing clinical studies, we decided to discontinue the development of Anti-LFA1.

Amortization of intangible assets.

Amortization expense for the IMTIX acquisition-related intangible assets was \$1,392,000 for the year ended December 31, 2000, a decrease of \$6,000 over amortization expense of \$1,398,000 for the year ended December 31, 1999. Amortization expense for the year ended December 31, 1998 was \$351,000 since this expense occurred only in the fourth quarter of 1998.

Interest income.

Interest income for the year ended December 31, 2000 was \$2,016,000 compared to \$1,865,000 for the year ended December 31, 1999, and \$3,611,000 for the year ended December 31, 1998. For both fiscal 2000 and 1999, the change

in interest income versus the prior year primarily reflected the change in the average cash balance available for investment.

Interest expense.

Interest expense for the year ended December 31, 2000 was \$4,368,000 compared to \$3,034,000 for the year ended December 31, 1999 and \$404,000 for the year ended December 31, 1998. We recorded a full year of interest expense in fiscal 2000 on the notes payable to Aventis, Abbott Laboratories and the convertible note and eight months' expense on the FINOVA note payable compared to 12 months for Aventis, 6 months for Abbott and 10 months for the convertible debt in fiscal 1999. The increase in fiscal 1999 over 1998 reflected interest on the note payable to Aventis and Abbott Laboratories, and the convertible note issued in March 1999.

Other income (expense) - net

. Other income (expense) - net for the year ended December 31, 2000 was income of \$750,000 compared to \$256,000 for the year ended December 31, 1999 and an expense of \$154,000 for the year ended December 31, 1998. In fiscal 2000 and 1999, income was provided primarily by gains on the sale of equity securities of \$437,000 and \$223,000, respectively.

Income taxes.

For the years ended December 31, 2000 and 1999, we recorded a provision of \$368,000 and \$345,000 respectively, for European income taxes based upon income earned by our European affiliates. For the year ended December 31, 1998, we recorded a similar provision of \$257,000 based on income earned by our European affiliates for the fourth quarter of fiscal 1998.

Net loss from continuing operations.

Net loss from continuing operations for the year ended December 31, 2000 was \$42,017,000, an increase of \$11,035,000 or 36% compared to the net loss of \$30,982,000 for the year ended December 31, 1999. The increase in net loss for fiscal 2000 was due primarily to the product recall returns and charges of \$13,075,000 and increases in selling, general and administrative expenses, partially offset by the increase in net sales net of related cost of sales. Net loss from continuing operations for the year ended December 31, 1999 was \$30,982,000, a decrease of \$5,002,000 or 14% compared to the net loss of \$35,984,000 for the year ended December 31, 1998. The decrease in net loss was due primarily to the increase in net sales net of related cost of sales, partially offset by increases in selling, general and administrative expenses.

Net loss from operations of discontinued operation.

Net sales of transplantation services for the year ended December 31, 2000 were \$17,502,000, an increase of \$3,637,000 or 26% over sales of \$13,865,000 for the year ended December 31, 1999. Net sales of transplantation services in fiscal 1999 represented an increase of \$5,481,000 or 65% over sales of \$8,384,000 for the year ended December 31, 1998. The increase in net sales in both fiscal 2000 and 1999 was due primarily to an increase in the number of patients serviced by The Transplant Pharmacy. Net sales for all periods consisted entirely of drug sales to transplant patients.

Net loss for transplantation services for the year ended December 31, 2000 was \$2,342,000, an increase of \$317,000 or 16% compared to the net loss of \$2,025,000 for the year ended December 31, 1999. The increase in net loss was due primarily to the increase in operating expenses, partially offset by an increase in sales of The Transplant Pharmacy. Net loss for transplantation services for the year ended December 1999 was \$2,025,000, a decrease of \$455,000 or 18% compared to the net loss of \$2,480,000 for the year ended December 31, 1998. The decrease in net

loss was due primarily to the increase in sales of The Transplant Pharmacy.

Liquidity and Capital Resources

From inception through December 31, 2000, we financed our operations substantially from proceeds of approximately \$137,977,000 from public offerings of our Common Stock, \$57,398,000 from private placements of equity securities and \$25,550,000 from the convertible note and the note payable to Abbott Laboratories.

During the years ended December 31, 2000, 1999 and 1998, our net cash used in continuing operating activities was approximately \$25,610,000, \$39,885,000 and \$38,537,000 respectively. The decrease in net cash used in operating activities in fiscal 2000 was substantially due to a reduction in net inventories and increases in accounts payable and accrued liabilities, partially offset by an increase in net loss. The reduction in inventories is primarily due to provisions of \$11,774,000 relating to the SangCya Oral Solution product recall, which resulted in a corresponding increase in net loss for the year 2000. Net cash used in 2000 also included an increase in other current assets reflecting \$5,000,000 cash used as collateral for the note payable to FINOVA. In fiscal years 1999 and 1998, net cash used in operating activities was primarily due to the amount of net loss incurred, as well as an increase in inventories and a decrease in accounts payable over the prior year. In fiscal year 1999 these uses of cash were partially offset by the receipt of \$13,730,000 in milestone payments from Abbott Laboratories in connection with our co-promotion agreement with Abbott. The cash used in the discontinued operation approximated the net loss of the discontinued operation for the years ended December 31, 2000, 1999 and 1998. As of December 31, 2000, we had cash, cash equivalents and short-term investments of \$20,607,000 and total assets of \$114,316,000.

Net cash provided by investing activities totaled \$3,694,000, \$4,245,000 and \$6,489,000 during the years ended December 31, 2000, 1999 and 1998 respectively. In fiscals 2000 and 1999, cash was provided by maturities of short-term investments, partially offset by purchases of property and equipment and short-term investments. In fiscal 1998 net cash provided by investing activities was primarily from the maturity of short-term investments, partially offset by the use of cash for the purchase of IMTIX.

Net cash provided by financing activities totaled \$27,221,000, \$39,521,000 and \$29,000 during the years ended December 31, 2000, 1999 and 1998 respectively. In both fiscal years 2000 and 1999, cash was provided by the issuance of notes payable and the sale of common stock which are described in more detail in the following paragraphs. In fiscal year 1998 net cash was provided primarily by the sale of common stock, partially offset by repayments of notes and capital lease obligations.

On August 8, 2000, we entered into a global co-development, supply and license agreement with Abgenix, Inc. for ABX-CBL, an antibody developed by Abgenix. We will have an exclusive worldwide license for the marketing and sale of ABX-CBL, an anti-CD147 monoclonal antibody for the treatment of steroid resistant graft versus host disease (GVHD). ABX-CBL is currently in a multicenter, randomized, and controlled Phase II/III study. We made an initial license fee payment of \$1 million and an additional payment to Abgenix of \$1 million as partial reimbursement of one-half of the development costs incurred by Abgenix between January 1, 2000 and August 8, 2000. We will pay a further \$0.9 million as reimbursement of these development costs in two equal installments at the end of June 2001 and 2002. Development costs incurred after August 8, 2000 will be shared equally, as would any potential profits from future sales of collaboration products. We share responsibility for product development, including the ongoing clinical trial. Abgenix will be responsible for manufacturing ABX-CBL. We also have the right, subject to the terms and conditions of the agreement, to commercialize other anti-CD147 antibodies developed by Abgenix.

On April 21, 2000 we signed an agreement with FINOVA to provide a line of credit of up to \$30 million (the Loan Agreement). The Loan Agreement has a three year term and may be renewed annually thereafter if both parties agree. The line of credit consists of two elements: a \$15 million line of credit bearing interest at the prime rate (9.0% at December 31, 2000) and secured by a matching compensating cash balance, and a \$15 million line of credit bearing interest at the prime rate plus 1.5% and based on eligible domestic accounts receivable and inventory, as defined in the

Loan Agreement. Under the terms of the Loan Agreement, we are required to maintain a loan balance of at least \$5 million. As collateral for the line of credit, we have granted FINOVA a first priority security interest in certain of its tangible and intangible assets and have pledged the stock of our two French subsidiaries, IMTIX-SangStat SAS and SangStat Atlantique SA. In addition, we are required to meet certain financial covenants. At December 31, 2000 we had drawn down \$5.0 million under the line of credit and had set aside a corresponding compensating balance, which is included in Other Current Assets on our consolidated balance sheet. We have not drawn down any additional amounts under this line of credit and have no plans to do so. In connection with this financing, we issued a warrant to purchase 50,000 shares of our common stock at an exercise price of \$23.438. This warrant has been valued using the Black-Scholes pricing model with the following weighted average assumptions: expected life, five years; stock volatility, 72%; risk free interest rate, 6.0%; and no dividend payments during the expected term. The calculated value of the warrant of \$744,000 and the additional financing fees of \$750,000 have been included in Other Assets and are being amortized over the three year life of the Loan Agreement. As of December 31, 2000, we were in default of the Tangible Net Worth covenant under the Loan Agreement as a result of the reserve we took against inventory due to the SangCya Oral Solution recall. The Loan Agreement does not provide for a cure period for such a default. FINOVA has requested that the parties amend the Loan Agreement to terminate it as of September 30, 2001 and eliminate the portion of the line of credit collateralized by accounts receivable and inventory from the date of the amendment until termination of the Loan Agreement. In exchange, FINOVA would waive the default and all early termination penalties with respect to the Loan Agreement. We are currently in negotiations with FINOVA regarding this proposed amendment.

In March 1999, we issued a \$10 million convertible note due March 30, 2004. This note bears interest at the rate of 6.5% through March 30, 2004 and thereafter at the rate of 8.5% on any overdue amount. The interest is payable semi-annually in September and March. The note, or any portion thereof, is convertible at the option of the holder at any time on or after March 31, 2000 and before March 30, 2004 into shares of our common stock at the rate of 50.0773 shares of common stock for each \$1,000 principal amount. We received net proceeds of \$9,550,000.

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

Notes payable include \$13,293,000 and \$15,011,000 at December 31, 2000 and 1999, respectively, representing the current accreted value of the non-interest bearing note issued in connection with the acquisition of IMTIX. The note was discounted at a rate of 9.25% and the remaining unpaid balance of \$15 million at December 31, 2000 is payable as follows: \$6 million in 2001, \$5 million in 2002, and \$4 million in 2003.

In February 2000, we completed a private placement of approximately 450,000 shares of common stock with an institutional investor. The stock was issued at \$33.25, the closing price of the stock on February 14, 2000, for aggregate proceeds of \$15,000,000. On January 5, 2001, we completed a private placement of approximately 1.3 million shares of common stock for aggregate proceeds of approximately \$12.5 million with a group of institutional investors. Shares were purchased at a discount to the closing market price on the date the agreements were signed. The transaction occurred in two tranches of approximately \$8.5 million (894,800 shares) and \$4.0 million (421,000 shares) respectively, the first of which closed December 29, 2000, the second of which closed January 5, 2001. We did not pay any investment banking fees and did not issue any warrants with respect to this placement. We intend to use the proceeds to provide additional working capital to fund our anticipated future growth.

In fiscal years 2000, 1999 and 1998 we purchased \$3,790,000, \$4,020,000, and \$1,384,000, respectively, of new property and equipment. In fiscal years 2000 and 1999 this spending consisted primarily of manufacturing equipment, leasehold improvements for our new corporate headquarters in Fremont, California and expenditures associated with the implementation of a global enterprise resource planning (ERP) system. In fiscal year 1998 spending consisted primarily of manufacturing and other equipment.

At December 31, 2000, we had federal, state and foreign net operating loss ("NOL") carryforwards of approximately \$136,175,000, \$17,106,000 and \$1,913,000 respectively, available to reduce future taxable income. In addition, we had available research and experimentation credit carryforwards of approximately \$3,584,000 and \$1,968,000 for federal and state tax purposes. Our ability to realize the benefits of the NOL and credit carryforwards is dependent upon the generation of sufficient taxable income in the respective taxing jurisdictions prior to their expiration. There can be no assurance that we will be able to generate sufficient taxable income to avail ourselves of such benefits. Furthermore, utilization of the net operating losses and credits may be subject to an annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

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

Euro-Currency

The Single European Currency (Euro) was introduced on January 1, 1999 with complete transition to this new currency required by January 2002. We have made and expect to continue to make changes to our internal systems in preparation for the transition to the Euro. Changes made to date include changing the operating currency of our two French subsidiaries from the French franc to the Euro, which became effective during the second quarter of 2000. We expect to convert the other European subsidiaries that are affected by the Euro within the next twelve months.

We further expect that use of the Euro may affect our foreign exchange activities and may result in increased fluctuations in foreign currency results. Any delays in our ability to be Euro-compliant could have an adverse impact on our results of operations or financial position.

Recently Issued Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 133, *Accounting for Derivative Instruments and Hedging Activities*. This Statement requires companies to record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting. We adopted SFAS 133 effective January 1, 2001. We have completed our evaluation of the impact that will result from adopting SFAS 133 (as amended and interpreted) and have concluded that adoption of this Statement will not have a material effect on our financial position, results of operations or cash flows.

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*. SAB No. 101, as amended, was effective for us in the fourth quarter of 2000 and clarified the SEC's views on US GAAP for revenue recognition in financial statements. The requirements of SAB No. 101 did not have a significant impact on our financial position or results of operations.

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

other transfers of financial assets and collateral and requires certain disclosures, but it carries over most of SFAS No. 125's provisions without reconsideration. We have adopted the applicable disclosure requirements of SFAS No. 140 in our consolidated financial statements as of December 31, 2000. We are currently evaluating the impact of adopting the remaining provisions of SFAS No. 140, which will be effective for transactions entered into after March 31, 2001.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

Market Risk Disclosures.

The following discussion about our market risk disclosures involves forward-looking statements. Actual results could differ materially from those projected in the forward-looking statements. We are exposed to market risk related to changes in interest rates, equity security prices and foreign currency exchange rates.

Interest Rate Sensitivity.

We maintain a short-term investment portfolio consisting mainly of government and corporate bonds purchased with an average maturity of less than one year. These available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10 percent from levels at December 31, 2000, the fair value of the portfolio would decline by an immaterial amount, which is consistent with the estimated effects at December 31, 1999. We generally have the ability to hold fixed income investments until maturity and therefore do not expect operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

Substantially all of our long-term obligations bear interest at fixed rates which are not subject to future increases in interest rates. The fair value of these long-term obligations, including current portion, at December 31, 2000 was \$45.2 million compared to book value of \$47.5 million (see Note 8 to Consolidated Financial Statements). The corresponding fair value at December 31, 1999 was \$49.6 million compared to book value of \$44.4 million. We therefore do not expect operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates. If our notes payable and convertible debt were subject to rate fluctuation, a hypothetical interest rate increase of 1% would have added approximately \$475,000 to our interest expense for 2000 and \$440,000 for 1999.

Equity Price Risk.

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

Foreign Currency Risk.

Many of our foreign sales are invoiced in local currencies, creating receivables denominated in currencies other than the US dollar, primarily in the Euro and the Japanese yen. 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 intend to re-assess our hedging policy from time to time as our foreign operations change. A 10% movement in the currency exchange rates would not have a material impact on our financial position or the results of operations.

All of the potential changes noted above are based on sensitivity analyses performed on our financial positions at December 31, 2000 and 1999. Actual results may differ materially.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

PART III

The information required by Items 10 through 13 of Part III is incorporated by reference from the registrant's Proxy Statement, under the captions "*Nomination and Election of Directors*," "*Beneficial Stock Ownership*," "*Compensation of Executive Officers*" and "*Compensation Committee Interlocks and Insider Participation in Insider Participation and Certain Transactions*", which Proxy Statement will be mailed to stockholders in connection with the registrant's annual meeting of stockholders which is expected to be held in June 2001. Information on the Executive Officers is contained in Item 1 under the heading, "*Our Executive Officers*."

PART IV

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

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

1. Financial Statements.

Independent Auditors' Report	<u>43</u>
Consolidated Balance Sheets - December 31, 2000 and 1999	<u>44</u>
Consolidated Statements of Operations for the years ended December 31, 2000, 1999 and 1998	<u>45</u>
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2000, 1999 and 1998	<u>45</u>
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2000, 1999 and 1998	<u>L6</u>
Consolidated Statements of Cash Flows for the years ended December 31, 2000, 1999 and 1998	<u>L7</u>
Notes to Consolidated Financial Statements for the years ended December 31, 2000, 1999 and 1998	<u>L8</u>

2. Financial Statement Schedule.

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Schedule II - Valuation and Qualifying Accounts

N7

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

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

(b) Reports on Form 8-K.

Form 8-K filed October 6, 2000, reporting on Item 5 our license of a new cyclosporine capsule formulation.

Form 8-K filed on October 17, 2000, reporting on Item 5 our appointment of Jean-Jacques Bienaimé as Chairman of the Board of Director, as well as the refocus of our business.

(c) Exhibits.

Exhibits	Description of Exhibit
J.1 (5)	Agreement and Plan of Merger dated as of July 24, 1995 between SangStat Delaware, Inc. and SangStat Medical Corporation, a California corporation, as filed with the Delaware Secretary of State on August 11, 1995.
J.2 (7)	Master Agreement between SangStat Medical Corporation and Pasteur Merieux Serums & Vaccins, S.A. dated June 10, 1998, including Exhibit 8 thereto
K.2 (5)	Certificate of Incorporation of SangStat Delaware, Inc.
K.3 (12)	Certificate of Amendment of the Certification of Incorporation
K.4 (4)	Certificate of Designation for the Series A Junior Participating Preferred Stock, filed with the Delaware Secretary of State on August 16, 1995.
K.5 (11)	Second Amended and Restated Bylaws of the Registrant.
L.5 (3)	Specimen Common Stock Certificate of Registrant.
I0.7 (2)(3)	1993 Stock Option/Stock Issuance Plan.
I0.18 (5)	Form of Indemnification Agreement to be entered into between the Registrant and each of its officers and directors.
I0.19 (1)(3)	License Agreement, dated November 15, 1993, between the Registrant and the Board of Trustees of Leland Stanford Junior University
I0.25 (6)	Rights Agreement, dated as of August 14, 1995, between the Registrant and First National Bank of Boston.
10.26 (8)	Real Property Sub-Lease, dated March 8, 1999, between the Registrant and Kelley-Clarke, Inc. Real Property lease between Kelly-Clarke Inc. and Kaiser Development Company dated September 1, 1988 as amended on February 26,

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

1990, May 1, 1990, May 5, 1990, and April 19, 1995

- I0.27 (9) Call Option Agreement, dated as of May 7, 1999 between the Registrant and Abbott Laboratories, Inc.
- I0.28 (1)(9) Co-Promotion Agreement, dated as of May 7, 1999 between the Registrant and Abbott Laboratories, Inc.
- I0.29 (9) Right of First Refusal Agreement, dated as of May 7, 1999 between the Registrant and Abbott Laboratories, Inc.
- I0.30 (9) Registration Rights Agreement, dated as of May 7, 1999 between the Registrant and Abbott Laboratories, Inc
- I0.31 (10) Registration Rights Agreement, dated as of February 15, 2000 between the Registrant and BioPharma Equities Holdings NV.
- I0.32 (10) Convertible Promissory Note dated March 1999 for \$10,000,000 with Warburg Dillon Read LLC.
- I0.33 (11) Loan and Security Agreement dated as of April 21, 2000 between the Registrant and FINOVA Capital Corporation.
- I0.34 (1)(14) Co-Development, Supply and License Agreement dated as of August 8, 2000 between the Registrant and Abgenix, Inc.
- I0.35 (15) Securities Purchase Agreement dated December 29, 2000 between the Registrant and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, and SDS Capital Partners, LLC
- I0.36 (15) Registration Rights Agreement dated December 29, 2000 between the Registrant and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, and SDS Capital Partners, LLC
- I0.37 (13) Registration Rights Agreement dated March 19, 1999 by and between Registrant and Warburg Dillon Read LLC.
- J1.1 Subsidiaries of Registrant.
- J3.1 Independent Auditors' Consent.
- J4.1 Power of Attorney (reference is made to the signature page hereof)

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

(2) Management contract or compensatory plan or arrangement.

(3) Previously filed as an Exhibit to Registration Statement on Form S-1 (No. 33-70436).

(4) Previously filed as an Exhibit to Form 8-K filed August 14, 1995.

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

- (5) Previously filed as an Exhibit to Registration Statement on Form 8-B filed December 4, 1995.
 - (6) Previously filed as an Exhibit to Form 8-A filed August 25, 1995.
 - (7) Previously filed as Exhibits to Form 8-K filed on October 15, 1998 as amended on December 14, 1998.
 - (8) Previously filed as an Exhibit to our annual report on Form 10-K filed on March 31, 1999.
 - (9) Previously filed as an Exhibit to our Form 10-Q filed August 16, 1999. The SEC reviewed our request for confidential treatment for Exhibit 10.28 and we are re-filing a revised version with this Form 10-K to reflect the portions of the document for which the SEC has granted confidential treatment as noted in Footnote 1 above. The non-public information has been filed separately with the SEC.
 - (10) Previously filed as an Exhibit to our Report on Form 10-K for the fiscal year ended December 31, 1999.
 - (11) Previously filed as an Exhibit to our Form 10-Q filed May 15, 2000.
 - (12) Previously filed as an Exhibit to our Form 8-K filed August 28, 2000.
 - (13) Previously filed as an Exhibit to the Registration Statement on Form S-3 (No. 33-46578).
14. Previously filed as an Exhibit to our Form 10-Q filed November 14, 2000.
15. Previously filed as an Exhibit to our Form 8-K filed January 8, 2001.
-

INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying consolidated balance sheets of SangStat Medical Corporation and subsidiaries (collectively, the "Company") as of December 31, 2000 and 1999, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. Our audits also included the consolidated financial statement schedule listed in Item 14(a)2. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the

amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such consolidated financial statement schedule referenced above, when considered in relation to the basic consolidated financial statements as a whole, presents fairly, in all material respects, the information set forth therein.

DELOITTE & TOUCHE LLP

San Jose, California

February 13, 2001 (March 13, 2001 as to Note 15)

SANGSTAT MEDICAL CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2000	1999
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents.....	\$ 19,046	\$ 16,862
Short-term investments.....	1,561	9,657
Accounts receivable (net of allowance for doubtful accounts \$3,128 in 2000 and \$1,469 in 1999).....	17,569	12,782
Other receivables.....	2,333	2,906
Inventories.....	40,056	46,270
Prepaid expenses and other current assets.....	6,912	2,306
	-----	-----
Total current assets.....	87,477	90,783
PROPERTY AND EQUIPMENT -- net.....	6,539	5,574
INTANGIBLE ASSETS -- net of accumulated amortization of \$3,141 in 2000 and \$1,749 in 1999.....	11,142	12,534
OTHER ASSETS.....	9,158	8,406
	-----	-----
TOTAL.....	\$ 114,316	\$ 117,297
	=====	=====

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES:

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Accounts payable.....	\$ 17,553	\$ 11,851
Accrued liabilities.....	13,938	5,511
Capital lease obligations -- current portion....	257	700
Deferred revenue -- current portion.....	3,158	4,426
Notes payable -- current portion.....	12,797	4,304
	-----	-----
Total current liabilities.....	47,703	26,792
	-----	-----
CAPITAL LEASE OBLIGATIONS.....	535	125
DEFERRED REVENUE.....	9,475	9,304
NOTES PAYABLE.....	34,679	40,067
COMMITMENTS AND CONTINGENCIES (Notes 9 and 18)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$.001 par value, 5,000 shares authorized; none outstanding.....	--	--
Common stock, \$.001 par value, 35,000,000 shares authorized; outstanding: 2000, 18,942 shares; 1999, 17,354 shares.....	201,766	174,990
Accumulated deficit.....	(177,636)	(133,277)
Accumulated other comprehensive loss.....	(2,206)	(704)
	-----	-----
Total stockholders' equity.....	21,924	41,009
	-----	-----
TOTAL.....	\$ 114,316	\$ 117,297
	=====	=====

See notes to consolidated financial statements.

SANGSTAT MEDICAL CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2000	1999	1998
REVENUES:			
Net sales.....	\$ 61,319	\$ 42,243	\$ 10,202
Product recall returns.....	(872)	--	--
Revenue from collaborative agreements (Note 9).....	2,698	2,060	1,092
	-----	-----	-----
Total revenues.....	63,145	44,303	11,294
	-----	-----	-----

COSTS AND OPERATING EXPENSES:

Cost of sales:

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Cost of product sales and manufacturing expenses.....	27,472	18,989	5,110
Product recall charges.....	11,774	--	--
Research and development (including product recall expenses of \$50 for the year ended December 31, 2000).....	20,788	14,470	17,688
Selling, general and administrative (including product recall expenses of \$379 for the year ended December 31, 2000).....	41,766	39,170	23,707
Acquired in-process research and development.....	--	--	3,218
Amortization of intangible assets.....	1,392	1,398	351
	-----	-----	-----
Total costs and operating expenses.....	103,192	74,027	50,074
	-----	-----	-----
Loss from continuing operations.....	(40,047)	(29,724)	(38,780)
	-----	-----	-----
OTHER INCOME (EXPENSE):			
Interest income.....	2,016	1,865	3,611
Interest expense.....	(4,368)	(3,034)	(404)
Other income (expense), net.....	750	256	(154)
	-----	-----	-----
Other income (expense), net.....	(1,602)	(913)	3,053
	-----	-----	-----
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES.....	(41,649)	(30,637)	(35,727)
INCOME TAX PROVISION.....	(368)	(345)	(257)
	-----	-----	-----
NET LOSS FROM CONTINUING OPERATIONS.....	(42,017)	(30,982)	(35,984)
	-----	-----	-----
NET LOSS FROM OPERATIONS OF DISCONTINUED OPERATION.....	(2,342)	(2,025)	(2,480)
	-----	-----	-----
NET LOSS.....	\$ (44,359)	\$ (33,007)	\$ (38,464)
	=====	=====	=====
NET LOSS PER SHARE - basic and diluted (Note 1):			
Continuing operations.....	\$ (2.35)	\$ (1.83)	\$ (2.24)
Discontinued operation.....	(0.13)	(0.12)	(0.15)
	-----	-----	-----
	\$ (2.48)	\$ (1.95)	\$ (2.39)
	=====	=====	=====
WEIGHTED AVERAGE COMMON SHARES.....	17,910	16,888	16,080
	=====	=====	=====

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2000	1999	1998
Net loss.....	\$ (44,359)	\$ (33,007)	\$ (38,464)
Reversal of unrealized gain on marketable securities sold during the period.....	(644)	--	--
Unrealized gains (losses) on marketable securities classified as available for sale in the current period.....	40	1,078	(494)
Foreign currency translation adjustments.....	(898)	(1,388)	89
Total comprehensive loss.....	\$ (45,861)	\$ (33,317)	\$ (38,869)

See notes to consolidated financial statements.

SANGSTAT MEDICAL CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)

	Common Stock		Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount			
Balances, January 1, 1998.....	16,009,531	\$ 159,265	\$ (61,806)	\$ 11	\$ 97,470
Exercise of stock options.....	205,320	869	--	--	869
Stock option compensation expense.....	--	117	--	--	117
Accumulated translation adjustment....	--	--	--	89	89
Unrealized loss on investments.....	--	--	--	(494)	(494)
Net loss.....	--	--	(38,464)	--	(38,464)
Balances, December 31, 1998.....	16,214,851	160,251	(100,270)	(394)	59,587
Issuance of common stock.....	893,996	12,661	--	--	12,661
Exercise of stock options.....	244,927	1,859	--	--	1,859
Issuance of stock for services.....	--	160	--	--	160
Stock option compensation expense.....	--	59	--	--	59
Accumulated translation adjustment....	--	--	--	(1,388)	(1,388)
Unrealized gain on investments.....	--	--	--	1,078	1,078
Net loss.....	--	--	(33,007)	--	(33,007)
Balances, December 31, 1999.....	17,353,774	174,990	(133,277)	(704)	41,009
Issuance of common stock.....	1,345,928	23,401	--	--	23,401

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Exercise of stock options.....	242,644	2,631	--	--	2,631
Warrant issued in connection with financing.....	--	744	--	--	744
Accumulated translation adjustment....	--	--	--	(898)	(898)
Reversal of unrealized gain on marketable securities sold during the period, net.....	--	--	--	(604)	(604)
Net loss.....	--	--	(44,359)	--	(44,359)
	-----	-----	-----	-----	-----
Balances, December 31, 2000.....	18,942,346	\$ 201,766	\$ (177,636)	\$ (2,206)	\$ 21,924
	=====	=====	=====	=====	=====

See notes to consolidated financial statements.

SANGSTAT MEDICAL CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2000	1999	1998
	-----	-----	-----
OPERATING ACTIVITIES:			
Net loss from continuing operations.....	\$ (42,017)	\$ (30,982)	\$ (35,984)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization.....	3,780	2,921	1,873
Non-cash interest expense.....	1,365	1,476	--
Acquired in-process research and development..	--	--	3,218
Loss on disposal of property and equipment....	836	167	--
Stock compensation expense.....	--	219	117
Deferred income taxes.....	130	88	257
Changes in assets and liabilities:			
Accounts receivable.....	(4,787)	(1,819)	(4,163)
Other receivables.....	573	(465)	(656)
Inventories.....	6,214	(12,895)	(18,980)
Prepaid expenses.....	(4,606)	(579)	1,465
Accounts payable.....	5,702	(13,973)	15,132
Accrued liabilities.....	8,297	2,227	(816)
Deferred revenue.....	(1,097)	13,730	--
	-----	-----	-----
Net cash used in continuing operating activit	(25,610)	(39,885)	(38,537)
Net cash used in discontinued operation.....	(2,223)	(1,917)	(2,415)
	-----	-----	-----
Net cash used in operating activities.....	(27,833)	(41,802)	(40,952)
	-----	-----	-----
INVESTING ACTIVITIES:			
Purchases of property and equipment.....	(3,790)	(4,020)	(1,384)
Maturities of short-term investments.....	7,492	8,517	34,210

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Purchase of short-term investments.....	--	(3,721)	(6,674)
Business acquired in purchase transaction, net of cash acquired.....	--	--	(10,737)
Other assets.....	(8)	3,469	(8,926)
	-----	-----	-----
Net cash provided by investing activities .	3,694	4,245	6,489
	-----	-----	-----
FINANCING ACTIVITIES:			
Sale of common stock.....	26,032	14,520	869
Note payable borrowings.....	6,574	28,513	216
Notes payable repayments.....	(4,834)	(3,079)	(676)
Repayment of capital lease obligations.....	(551)	(433)	(380)
	-----	-----	-----
Net cash provided by financing activities...	27,221	39,521	29
	-----	-----	-----
EFFECT OF EXCHANGE RATE CHANGES ON CASH.....	(898)	(1,388)	89
	-----	-----	-----
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS.....	2,184	576	(34,345)
CASH AND CASH EQUIVALENTS, Beginning of year.....	16,862	16,286	50,631
	-----	-----	-----
CASH AND CASH EQUIVALENTS, End of year.....	\$ 19,046	\$ 16,862	\$ 16,286
	=====	=====	=====
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for interest.....	\$ 1,158	\$ 1,401	\$ 225
	=====	=====	=====
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Warrants issued in connection with financing....	\$ 744	\$ --	\$ --
	=====	=====	=====
Property acquired under capital leases.....	\$ 518	\$ 493	\$ 291
	=====	=====	=====
Unrealized gain (loss) on investments.....	\$ 604	\$ 1,078	\$ (494)
	=====	=====	=====
On September 30, 1998, the Company acquired IMTIX (see Note 2).			
In conjunction with the acquisition, liabilities were assumed as follows:			
Fair value of assets acquired.....			\$ 35,139
Acquired in-process research and development..			3,218
Cash paid.....			(11,662)
Discounted note payable.....			(16,208)

Liabilities assumed.....			\$ 10,487
			=====

See notes to consolidated financial statements.

SANGSTAT MEDICAL CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2000, 1999 and 1998

(in thousands)

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Organization

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

Principles of Consolidation

-The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, including IMTIX from September 30, 1998 (See Note 2). Intercompany accounts and transactions are eliminated.

Revenue Recognition

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

Research and Development

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

Advertising Expenses

- Advertising costs, which also include promotional expenses, are expensed as incurred. Advertising expenses for the years ended December 31, 2000, 1999 and 1998 were approximately \$4.5 million, \$3.2 million and \$1.8 million, respectively.

Cash and Cash Equivalents

-The Company considers all highly liquid debt instruments purchased with an original maturity date of three months or less to be cash equivalents.

Short-Term Investments

-The Company has classified all of its investments as available-for-sale securities. While the Company's practice is to hold debt securities to maturity, the Company has classified all debt securities as available-for-sale securities, as the sale of such securities may be required prior to maturity to implement management strategies. The carrying value of

Our Executive Officers

all securities is adjusted to fair market value, with unrealized gains and losses, net of deferred taxes, being excluded from earnings and reported as a separate component of stockholders' equity and included in accumulated other comprehensive loss. Cost is based on the specific identification method for purposes of computing realized gains or losses.

Inventories

-Inventories are stated at the lower of cost (first-in, first-out) or market.

Property and Equipment

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

Valuation of Long-lived Assets

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

Other Assets

-At December 31, 2000 and 1999 Other Assets included \$1.0 million paid to Gensia Sicor as an advance against future cyclosporine purchases from Gensia Sicor, one of the Company's suppliers of bulk cyclosporine. At December 31, 2000 and 1999, Other Assets also included \$6.0 million of restricted cash that serves as collateral for the note payable to Aventis (see Note 2) and \$303,000 and \$301,000 respectively, of deferred income tax benefits.

Foreign Currency Translation

-Operations for the majority of the Company's foreign subsidiaries are measured using local currency as the functional currency. Assets and liabilities of such subsidiaries are translated into US dollars at the exchange rates in effect as of the balance sheet dates, and results of operations for each subsidiary are translated using average rates in effect for the periods presented. Gains or losses resulting from foreign currency translation are included as a component of accumulated other comprehensive loss.

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

Stock-Based Compensation

-The Company accounts for stock-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board (APB) No. 25, *Accounting for Stock Issued to Employees* ("APB 25"). The Company accounts for stock based awards to non-employees in accordance with Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, and its interpretations. In March 2000, the Financial Accounting Standards Board issued (FASB) Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation - An Interpretation of APB Opinion No. 25* ("FIN 44"). FIN 44 clarifies the application of APB

25, and among other issues clarifies the following: the definition of an employee for purposes of applying APB 25; the criteria for determining whether a plan qualifies as a non-compensatory plan; the accounting consequence of various modifications to the terms of previously fixed stock options or awards; and the accounting for an exchange of stock compensation awards in a business combination. FIN 44 became effective July 1, 2000, but certain conclusions in FIN 44 cover specific events that occurred after either December 15, 1998 or January 12, 2000. Adoption of this Interpretation did not have a material effect on the Company's financial position.

Net Loss Per Share

-Basic EPS excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted into common stock. Common share equivalents including stock options and convertible notes payable, aggregating 1,215,203 shares, 1,011,247 shares and 931,396 shares for the years ended December 31, 2000, 1999 and 1998, respectively, have been excluded from diluted EPS, as their effect would be antidilutive.

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

	Year Ended December 31,		
	2000	1999	1998
Net loss (numerator)			
Continuing operations.....	\$ (42,017)	\$ (30,982)	\$ (35,984)
Discontinued operation.....	(2,342)	(2,025)	(2,480)
	-----	-----	-----
	\$ (44,359)	\$ (33,007)	\$ (38,464)
	=====	=====	=====
Shares (denominator)			
Weighted average common shares outstanding.....	17,910	16,888	16,080
	=====	=====	=====
Net loss per share - basic and diluted:			
Continuing operations.....	\$ (2.35)	\$ (1.83)	\$ (2.24)
Discontinued operation.....	(0.13)	(0.12)	(0.15)
	-----	-----	-----
	\$ (2.48)	\$ (1.95)	\$ (2.39)
	=====	=====	=====

Certain Significant Risks and Uncertainties

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

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

The Company participates in the dynamic biopharmaceutical industry. The Company believes that changes in any of the following areas could have a negative impact on the Company in terms of its future financial position and results of operations: ability to obtain additional financing; successful product development; manufacturing and marketing capabilities; ability to negotiate acceptable collaborative relationships; obtaining necessary FDA and foreign regulatory approvals; ability to attract and retain key personnel; litigation and other claims against the Company, including, but not limited to, patent claims; increased competition; uncertainty regarding health care reimbursement and reform; and potential exposure for product liability and hazardous materials.

Accumulated Other Comprehensive Loss

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

	December 31,		
	2000	1999	1998
Unrealized gain (loss) on investments....	\$ 6	\$ 609	\$ (469)
Accumulated translation adjustments.....	(2,212)	(1,313)	75
Total.....	\$ (2,206)	\$ (704)	\$ (394)

Recently Issued Accounting Pronouncements- In June 1998, the FASB issued SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. This Statement requires companies to record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting. The Company adopted SFAS No. 133 effective January 1, 2001. The Company has completed its evaluation of the impact that will result from adopting SFAS No.133 (as amended and interpreted) and has concluded that adoption of this Statement will not have a material effect on the Company's financial position, results of operations or cash flows.

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*. SAB No. 101, as amended, was effective for the Company in the fourth quarter of 2000 and clarified the SEC's views on US GAAP for revenue recognition in financial statements. The requirements of SAB No. 101 did not have a significant impact on the Company's financial position or results of operations.

In September 2000, the FASB issued SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. SFAS No. 140 replaces SFAS No. 125, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. It revises the standards for accounting for securitizations and other transfers of financial assets and collateral and requires certain disclosures, but carries over most of SFAS No. 125's provisions without reconsideration. The Company has adopted the applicable disclosure requirements of SFAS No. 140 in its consolidated financial statements as of December 31, 2000. The Company is currently evaluating the impact of adopting the remaining provisions of SFAS No. 140, which will be effective for transactions entered into after March 31, 2001.

2. ACQUISITION

On September 30, 1998, the Company completed the acquisition of Pasteur Mérieux Connaught's (Aventis) transplant business known as IMTIX. The acquisition was accounted for using the purchase method of accounting. The resulting wholly owned subsidiary of the Company, named IMTIX-SangStat (IMTIX), is dedicated to the research, development, manufacture and marketing of pharmaceuticals for transplantation. The aggregate gross purchase price

of approximately \$31 million consisted of \$10 million paid upon closing and a non-interest bearing note of \$21 million payable over five years (see Note 7). In addition, the Company will pay Aventis certain royalties on IMTIX product sales and had approximately \$6.0 million of restricted cash at December 31, 2000 and 1999, that serves as collateral for a standby letter of credit in favor of Aventis.

The resulting aggregate net purchase price totaled \$28.7 million (including acquisition costs of approximately \$2.5 million) and was allocated to the net tangible assets acquired of \$11.1 million, based on their fair value on the date of acquisition, identifiable intangible assets of \$14.4 million and purchased in-process research and development of \$3.2 million. Intangible assets based on the appraised values consisted of the following amounts: developed technology of \$7.9 million, avoided royalties of \$2.4 million, assembled workforce of \$1.6 million, distribution rights and trademarks of \$1.5 million and customer list of \$1.0 million. Such intangibles are being amortized on a straight line basis over their estimated useful lives ranging from five to fourteen years.

The purchased in-process research and development of approximately \$3.2 million was charged to the Company's operations in the third quarter of 1998 and represents the value of products that had not yet reached technological feasibility and had no alternative future use. The purchased in-process technology primarily consisted of a single drug, Anti-LFA1, a monoclonal, biologically manufactured immunosuppressant compound intended to be used in preventing the rejection of organ transplants. The estimated value for the in-process technology was determined using the income approach which discounted to present value the cash flows expected to be derived from the product as it was still in development at the date of acquisition. The projections were based on future expectations of the acquired business' revenue and expenses to be generated from the product still under development. The nature of the efforts required to develop the purchased in-process technology into a commercially viable product principally related to the completion of clinical trials to evaluate clinical efficacy and safety in an expanded patient population. Upon successful completion of the trials, FDA approval would have been required before marketing the product for a specified use. During 1999, following the Company's evaluation of the outcome of the ongoing clinical studies, the Company decided to discontinue the development of Anti-LFA1.

3. INVESTMENTS

Available-for-sale securities consist of the following (in thousands):

	December 31, 2000			
	Amortized Cost	Unrealized Gain on Investments	Unrealized Loss on Investments	Estimated Fair Value
Corporate bonds	\$ 1,415	\$ 6	\$ --	\$ 1,421
One year CD	140	--	--	140
Total.....	\$ 1,555	\$ 6	--	1,561
	=====	=====	=====	=====
	December 31, 1999			
	Amortized Cost	Unrealized Gain on Investments	Unrealized Loss on Investments	Estimated Fair Value
Corporate bonds	\$ 6,040	\$ --	\$ 33	\$ 6,007
Commercial paper....	1,002	--	2	1,000

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

One year CD	140	--	--	140
Short-term investments.....	7,182	--	35	7,147
Corporate equity securities.....	1,866	644	--	2,510
Total.....	\$ 9,048	\$ 644	\$ 35	\$ 9,657

Corporate equity securities represented the Company's investment in Gensia Sicor and were included in short-term investments at December 31, 1999. These securities were sold during the year ended December 31, 2000.

The contractual maturities of available-for-sale debt securities at December 31, 2000 are within one year.

4. INVENTORIES

Inventories consist of (in thousands):

	December 31,	
	2000	1999
Raw materials.....	\$ 18,860	\$ 26,710
Work in process.....	14,107	9,498
Finished goods.....	7,089	10,062
Total.....	\$ 40,056	\$ 46,270

5. PROPERTY AND EQUIPMENT

Property and equipment consist of (in thousands):

	December 31,	
	2000	1999
Machinery and equipment.....	\$ 8,072	\$ 7,779
Capitalized software.....	3,011	--
Furniture and fixtures.....	392	555
Projects in process.....	107	881
Leasehold improvements.....	1,440	1,415
Total.....	13,022	10,630
Accumulated depreciation and amortization..	(6,483)	(5,056)
Property and equipment--net.....	\$ 6,539	\$ 5,574

Included in machinery and equipment at December 31, 2000 and 1999 are assets leased under capital leases of \$2,287,000 and \$1,413,000 (net of accumulated amortization of \$1,584,000 and \$1,042,000), respectively. Depreciation and amortization expense of property and equipment totaled \$2,507,000, \$1,412,000 and \$1,587,000 for

the years ended December 31, 2000, 1999 and 1998, respectively.

6. ACCRUED LIABILITIES

Accrued liabilities consist of (in thousands):

	December 31,	
	2000	1999
Salaries and related benefits.....	\$ 3,689	\$ 3,814
Interest payable.....	1,894	178
Research and development expenses (Note 9).	2,420	--
Marketing and development expenses (Note 9)	2,436	--
Other taxes payable.....	475	363
Deferred rent.....	359	153
Other accrued liabilities.....	2,665	1,003
	-----	-----
Total.....	\$ 13,938	\$ 5,511
	=====	=====

7. NOTES PAYABLE

Notes payable consist of (in thousands):

	December 31,	
	2000	1999
Note payable to Aventis.....	\$ 15,000	\$ 18,000
Discount on note payable to Aventis.....	(1,707)	(2,989)
Convertible note.....	9,691	9,609
Note payable to Abbott Laboratories.....	16,000	16,000
Note payable to FINOVA.....	5,000	--
Other debt.....	3,492	3,751
	-----	-----
Total.....	47,476	44,371
Less current portion.....	(12,797)	(4,304)
	-----	-----
Long-term.....	\$ 34,679	\$ 40,067
	=====	=====

In connection with the acquisition of IMTIX (see Note 2), the Company issued a \$21 million non-interest bearing note payable over five years as follows: \$3 million in 1999, \$3 million in 2000, \$6 million in 2001, \$5 million in 2002 and \$4 million in 2003. The note payable was discounted at a rate of 9.25%, which the Company believes was consistent with its normal borrowing rate. The resulting discount of approximately \$4.8 million is being accreted as an addition to interest expense over the term of the note. During the years ended December 31, 2000 and 1999, \$1,282,000 and \$1,418,000 of amortization was recognized.

In March 1999, the Company issued a \$10 million convertible note due March 30, 2004. This note bears interest at the rate of 6.5% through March 30, 2004 and thereafter at the rate of 8.5% on any overdue amount. The interest is payable

semi-annually in September and March. The note, or any portion thereof, is convertible at the option of the holder at any time on or after March 31, 2000 and before March 30, 2004 into shares of common stock of the Company at the rate of 50.0773 shares of common stock for each \$1,000 principal amount. The net proceeds received by the Company were \$9,550,000. The note is being accreted to its face amount over the five year term.

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

On April 21, 2000 the Company entered into an agreement with FINOVA Capital Corporation ("FINOVA") to provide a line of credit of up to \$30 million (the Loan Agreement). The Loan Agreement has a three year term and may be renewed annually thereafter if both parties agree. The line of credit consists of two elements: a \$15 million line of credit bearing interest at the prime rate (9.0% at December 31, 2000) and secured by a matching compensating cash balance, and a \$15 million line of credit bearing interest at the prime rate plus 1.5% and based on eligible domestic accounts receivable and inventory, as defined in the Loan Agreement. Under the terms of the Loan Agreement, the Company is required to maintain a loan balance of at least \$5 million. As collateral for the line of credit, the Company has granted FINOVA a first priority security interest in certain of its tangible and intangible assets and has pledged the stock of its two French subsidiaries, IMTIX-SangStat SAS and SangStat Atlantique SA. The net book value of the assets subject to such security interest was approximately \$67 million at December 31, 2000. In addition, the Company is required to meet certain financial covenants and is precluded from paying any dividends while any obligations are owed FINOVA. At December 31, 2000 the Company had drawn down \$5.0 million under the line of credit and had set aside a corresponding compensating balance, which is included in Other Current Assets on the consolidated balance sheet. The Company has not drawn down any additional amounts under this line of credit and has no plans to do so. In connection with this financing, the Company issued a warrant to purchase 50,000 shares of the Company's common stock at an exercise price of \$23.438. This warrant has been valued using the Black-Scholes pricing model with the following weighted average assumptions: expected life, five years; stock volatility, 72%; risk free interest rate, 6.0%; and no dividend payments during the expected term. The calculated value of the warrant of \$744,000 and additional financing fees of \$750,000 have been included in Other Assets on the consolidated balance sheet and are being amortized over the three year life of the Loan Agreement. As of December 31, 2000, the Company was in default of the Tangible Net Worth covenant under the Loan Agreement as a result of the reserve the Company took against inventory due to the SangCya Oral Solution recall. The Loan Agreement does not provide for a cure period for such a default. FINOVA has requested that the parties amend the Loan Agreement to terminate it as of September 30, 2001 and to eliminate the portion of the line of credit collateralized by accounts receivable and inventory from the date of the amendment until termination of the Loan Agreement. In exchange, FINOVA would waive the default and all early termination penalties with respect to the Loan Agreement. The Company is currently in negotiations with FINOVA regarding this proposed amendment. Because of this, the amount of \$5 million payable to FINOVA has been classified as short-term.

Other debt at December 31, 2000 consisted primarily of borrowings by IMTIX against four revolving lines of credit from French banks. These lines of credit, which are renegotiable annually, bear interest at variable rates based on Eonia (Euro Over Night Index Average) plus 0.5% to 1.0%, and are secured by accounts receivable from unaffiliated customers. At December 31, 2000, accounts receivable subject to such security totaled approximately \$4,027,000. At December 31, 2000, approximately \$1.7 million remained available for borrowing under these credit lines. Interest rates on other debt at December 31, 2000 range between 3.55% and 8.25%.

As of December 31, 2000, future principal payments of notes payable (net of discounts) are as follows (in thousands):

Years Ending December 31,

2001.....	\$	12,797
2002.....		4,930

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

2003.....	3,756
2004.....	25,993

Total.....	\$ 47,476
	=====

8. FINANCIAL INSTRUMENTS

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

Short-term investments and corporate equity securities are recorded at fair value based on quoted market prices (see Note 3).

The fair value of the convertible note is based on market quotations, the major element of which is a comparison of the fixed conversion price and the closing price of the Company's common stock at December 31, 2000 and 1999. The fair value of the notes payable to Aventis and Abbott Laboratories is based on the present value of future cash flows discounted at an interest rate of 10.0% at December 31, 2000 and 1999, respectively. These estimates are approximate since no liquid market exists for these notes. The fair value of the Company's other debt is based on carrying value as those obligations have short-term variable interest rates.

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

	December 31, 2000		December 31, 1999	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
	-----	-----	-----	-----
Note payable to Aventis.....	\$ 13,293	\$ 12,592	\$ 15,011	\$ 14,175
Note payable to Abbott Laboratories.....	16,000	15,366	16,000	15,242
Note payable to FINOVA.....	5,000	5,000	--	--
Convertible debt.....	9,691	8,796	9,609	16,400
Other debt.....	3,492	3,492	3,751	3,751
	-----	-----	-----	-----
Total.....	\$ 47,476	\$ 45,246	\$ 44,371	\$ 49,568
	=====	=====	=====	=====

9. COLLABORATIVE AGREEMENTS

In May 1999, the Company and Abbott Laboratories ("Abbott") signed a multi-year co-promotion, distribution and research agreement for SangCya Oral Solution and cyclosporine capsules (the products) in the US. The Company is the exclusive distributor for the products and shares marketing, promotional and development expenses as well as the profits from the co-promotion of the products with Abbott. The agreement ends December 31, 2004 unless both parties agree to extend it. Pursuant to this agreement, Abbott made an equity investment of \$14 million during 1999 in exchange for approximately 894,000 shares of common stock, representing a premium to fair market value at that time aggregating to \$1.3 million. In addition, Abbott made a series of up-front and milestone payments totaling \$20.8 million through May 2000, and a long-term loan of \$16 million (see Note 7) to the Company. In January 2000, the Company made a milestone payment to Abbott of \$4 million under the terms of the agreement. No further milestone payments are required from either party. All up-front and milestone payments received, net of milestone payments made, and the premium received on the sale of the common stock to Abbott are recorded as deferred revenue and are being recognized ratably over the term of the agreement. For the years ended December 31, 2000 and 1999, the

Company amortized \$2.7 million and \$1.5 million, respectively, to revenue. In May 2000, the Company and Abbott launched the cyclosporine capsule developed by Abbott under the brand name Gengraf®. In connection with the equity investment, Abbott and the Company entered into a Right of First Refusal Agreement and a Registration Rights Agreement, and amended and restated their existing Supply Agreement.

On August 8, 2000, the Company entered into a global co-development, supply and license agreement with Abgenix, Inc. for ABX-CBL, an antibody developed by Abgenix. The Company will have an exclusive worldwide license for the marketing and sale of ABX-CBL. ABX-CBL is an anti-CD 147 monoclonal antibody for the treatment of steroid resistant graft versus host disease (GVHD) and is currently in a multicenter, randomized, and controlled Phase II/III study. Future development costs will be shared equally, as would any potential profits from the sales of collaboration products. The Company and Abgenix will share responsibility for product development, including the ongoing Phase II / III clinical trial. The Company will market any potential products and Abgenix will be responsible for manufacturing ABX-CBL. The Company also has the right, subject to the terms and conditions of the Agreement, to commercialize other anti-CD147 antibodies developed by Abgenix.

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

If ABX-CBL receives regulatory approval and is launched, the Company shall reimburse Abgenix for one-half of the development expenses incurred by Abgenix prior to January 1, 2000 up to a maximum reimbursement by the Company of \$6.1 million, provided that the Company shall have no obligation to reimburse Abgenix until the first anniversary of the launch of ABX-CBL and the timing of reimbursement varies depending on the amount of net sales of ABX-CBL. The Company has also agreed to reimburse Abgenix for one-half of the development costs incurred by Abgenix from January 1, 2000 to August 8, 2000, with the Company's share being approximately \$1.9 million. The Company must reimburse Abgenix for this amount over a two-year period commencing with a \$1 million payment made during fiscal 2000 and the remaining amount payable in two equal installments by the end of June 2001 and 2002. The license fee and the initial reimbursement of development expenses are recorded as research and development expenses.

The Company entered into a Distribution Agreement with Aventis in May 1999 that expires on March 31, 2002. Aventis is the exclusive distributor for Thymoglobulin and Lymphoglobuline for most countries outside of North America, Europe, and Japan (where Thymoglobuline and Lymphoglobuline are distributed by Aventis Pharma). The contract has minimum purchase requirements. If Aventis does not meet those minimums, the agreement becomes non-exclusive, which means that the Company can sell to another distributor in the same country. Aventis sells these products either through its local subsidiary or through a distributor that often distributes other Aventis products. The Company is currently re-negotiating this distribution agreement to allow it to contract directly with distributors in countries in which Aventis has no direct presence (e.g. Israel and certain Asian countries). Aventis also performs certain steps in the manufacturing process of some of the Company's products. In addition, pursuant to the purchase of IMTIX, the Company pays Aventis royalties on Thymoglobulin and Lymphoglobuline contingent upon the sales of these products. In the years ended December 31, 2000 and 1999, royalty payments on Lymphoglobuline to Aventis totaled approximately \$622,000 and \$646,000, respectively. The Company will begin paying royalties on sales of Thymoglobulin commencing on the third anniversary of the purchase of IMTIX (October 1, 2001).

In December 1997, the Company signed an agreement with Amgen Inc. ("Amgen") for the exclusive registration, marketing and distribution of its cyclosporine products in selected territories in the Asia/Pacific Rim region. Under the terms of the agreement, Amgen will have exclusive rights to market the Company's cyclosporine products under the Company's branded trademark in Australia, New Zealand, China and Taiwan. The licensing agreement includes an initial \$750,000 payment to the Company, which was received in 1997, and other milestone and reimbursement payments based on key regulatory submissions and approvals. Payments and reimbursements under the agreement of

\$550,000 and \$1,036,000 were received in the years ended December 31, 1999 and 1998, respectively, and are included in revenue from collaborative agreements in the Consolidated Statements of Operations.

10. LEASING ARRANGEMENTS

The Company leases administrative facilities under operating leases and machinery and equipment under capital leases expiring through 2006. As of December 31, 2000, future minimum annual payments under capital and operating leases are as follows (in thousands):

Years Ending December 31,	Capital Leases	Operating Leases
-----	-----	-----
2001.....	\$ 305	\$ 1,626
2002.....	204	1,621
2003.....	168	1,591
2004.....	166	1,397
2005.....	--	990
Thereafter.....	--	4,466
	-----	-----
Total minimum lease payments.....	843	\$ 11,691
Less amounts representing interest.....	(51)	=====

Present value of minimum lease payments.....	792	
Less current portion.....	(257)	

Capital lease obligations.....	\$ 535	
	=====	

The Company also leases manufacturing facilities from Aventis in Lyon, France under a lease that expires in 2013. This lease may be terminated at the Company's option with one year's notice. Annual payments, which have not been included in the above table, are approximately \$500,000.

Rent expense for the years ended December 31, 2000, 1999 and 1998 was \$1,493,000, \$1,047,000 and \$761,000, respectively.

11. STOCKHOLDERS' EQUITY

Issuance of Common Stock

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

Stockholder Rights Plan-

In August 1995, the Company's Board of Directors approved a plan to protect stockholders' rights in the event of a proposed takeover of the Company. Under the plan a preferred share purchase right (Right) is attached to each share of common stock. The Rights are exercisable only if a person or group acquires 15% or more of the Company's common stock or announces a tender offer, the consummation of which would result in ownership by a person or group of 15% or more of the Company's common stock. Each Right will entitle stockholders to buy one

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

one-hundredth of a share of a new series of junior participating preferred stock at an exercise price of \$45 upon certain events. If, after the Rights become exercisable, the Company is acquired in a merger or other business combination transaction, or sells 50% or more of its assets or earnings power, each Right will entitle its holder to purchase, at the Right's then-current price, a number of the acquiring company's common shares having a market value at the time of twice the Right's exercise price. If a person or group acquires 15% or more of the Company's outstanding common stock, each Right will entitle its holder (other than such person or members of such group) to purchase, at the Right's then-current exercise price, a number of the Company's common shares (or cash, other securities or property) having a market value twice the Right's exercise price. At any time within ten days after a person or group has acquired beneficial ownership of 15% or more of the Company's common stock, the Rights are redeemable for \$.01 per Right at the option of the Board of Directors. The Rights expire on August 25, 2005, unless earlier redeemed or exchanged.

Stock Option Plans

The Company has two stock option plans: the 1993 Stock Option Plan (the 1993 Plan) and the 1996 Non-Employee Directors Stock Option Plan (the Directors Plan). Under the Company's stock option plans, incentive or non-statutory stock options to purchase up to 4,792,200 shares of common stock may be granted to employees, directors, and consultants. Incentive and non-statutory options must be granted at not less than fair market value at the date of grant.

A summary of stock option activity is as follows:

	Number of Shares		Weighted Average Exercise Price
Balances, January 1, 1998.....	1,501,189	\$	11.78
Options granted (weighted average fair value of \$16.43)..	1,363,757		25.64
Options exercised.....	(205,320)		4.24
Options canceled.....	(103,983)		22.31
Balances, December 31, 1998 (1,308,819 vested at a weighted average exercise price of \$17.34).....	2,555,643		19.32
Options granted (weighted average fair value of \$19.16)..	913,394		18.11
Options exercised.....	(244,927)		7.59
Options canceled.....	(413,151)		25.19
Balances, December 31, 1999 (1,258,563 vested at a weighted average exercise price of \$19.62).....	2,810,959		19.43
Options granted (weighted average fair value of \$18.11)..	1,331,725		21.19
Options exercised.....	(242,644)		10.84
Options canceled.....	(702,266)		23.15
Balances, December 31, 2000.....	3,197,774	\$	19.97

Under the 1993 Plan, options to purchase common stock generally vest over a period of four years, are exercisable upon vesting and expire ten years from the date of grant. As of December 31, 2000, 212,163 shares were available under the 1993 Plan for future grants. During 1999, the Company recorded a charge of \$160,000 related to certain fully vested non-employee options.

Under the Directors Plan, up to a total 500,000 options to purchase shares of the Company's common stock may be issued. Also in accordance with the Directors' Option Plan, during 2000, 1999 and 1998, each of the non-employee Directors was granted options to purchase 4,000, 4,000 and 3,000 shares of the Company's common stock, respectively. In addition, in 1998, each of the non-employee directors was granted options to purchase 10,000 shares of the Company's common stock. All options granted under the Directors Plan are immediately exercisable, but the

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Company may repurchase at the exercise price any unvested shares held by a non-employee Board member when his or her service terminates. The first 25% of the shares acquired under the Directors Plan vest when the non-employee director completes the first 12 months of service after the date of grant, and the balance vests in equal monthly installments as the non-employee director completes each of the next 36 months of service. The shares vest in full if the non-employee Board member's service terminates due to death or permanent disability or if the Company is subject to a change in control or a party to a merger or certain other transactions. In addition, the Directors Plan permits non-employee directors to convert their annual cash retainer into additional options to purchase shares of common stock. As of December 31, 2000, there were no outstanding shares subject to repurchase rights and 341,632 shares were available under the Directors Plan for future grants. Options granted under the Directors Plan are also included in the above table.

Additional information regarding options outstanding as of December 31, 2000 is as follows:

Options Outstanding and Exercisable				Vested Options	
Range of Exercise Prices	Number Outstanding	Weighted Avg. Remaining Contractual Life (yrs)	Weighted Average Exercise Price	Number Vested	Weighted Average Exercise Price
\$0.00 - \$5.00	116,050	1.4	\$ 3.72	116,050	\$ 3.72
5.01 - 10.00	176,874	5.2	6.77	88,415	5.96
10.01 - 15.00	502,407	8.4	11.73	101,775	13.48
15.01 - 20.00	865,137	5.6	19.04	461,791	19.64
20.01 - 25.00	848,806	8.0	22.79	225,604	22.35
25.01 - 30.00	392,567	7.4	27.23	160,759	27.29
30.01 - 35.00	272,933	4.7	32.46	150,643	32.96
35.01 - 45.00	23,000	9.2	42.84	--	--
	3,197,774	6.7	\$ 19.97	1,305,037	\$ 19.77

Additional Stock Plan Information-

SFAS No. 123, requires the disclosure of pro forma net income (loss) and earnings (loss) per share as though the Company had adopted the fair value method. Under SFAS No. 123, the fair value of stock-based awards to employees is calculated through the use of option pricing models, even though such models were developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. These models also require subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. The Company's calculations were made using the Black-Scholes option pricing model with the following weighted average assumptions: expected life, five and a half years; stock volatility, 108% in 2000, 72% in 1999 and 69% in 1998; risk free interest rate, approximately 5.50% in 2000 and 1999 and 5.25% in 1998; and no dividend payments during the expected term. The Company's calculations are based on a single option valuation approach and forfeitures are recognized as they occur. If the computed fair values of the plan awards had been amortized to expense over the vesting period of the awards, pro forma net loss would have been approximately as follows:

	Year Ended December 31,		
	2000	1999	1998
Net loss (numerator)			
Continuing operations.....	\$ 44,418	\$ 36,148	\$ 42,188
Discontinued operation.....	2,704	2,158	2,601
	\$ 47,122	\$ 38,306	\$ 44,789

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Shares (denominator)			
Weighted average common shares			
outstanding.....	17,910	16,888	16,080
	=====	=====	=====
Net loss per share - basic and diluted:			
Continuing operations.....	\$ 2.48	\$ 2.14	\$ 2.62
Discontinued operation.....	0.15	0.13	0.16
	-----	-----	-----
	\$ 2.63	\$ 2.27	\$ 2.79
	=====	=====	=====

12. INCOME TAXES

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

	December 31,		
	-----	-----	-----
	2000	1999	1998
	-----	-----	-----
Loss from continuing operations			
before income taxes:			
Domestic.....	\$ (38,448)	\$ (28,023)	\$ (33,137)
Foreign.....	(3,201)	(2,614)	(2,590)
Net loss from operations of			
discontinued operation:			
Domestic.....	(2,342)	(2,025)	(2,480)
Provision for income taxes:			
Domestic.....	--	--	--
Foreign.....	368	345	257
	-----	-----	-----
Net loss.....	\$ (42,017)	\$ (30,982)	\$ (35,984)
	=====	=====	=====

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

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

	December 31,	
	-----	-----
	2000	1999
	-----	-----
Deferred tax assets:		
Net operating loss carryforwards.....	\$ 47,999	\$ 36,122
General business credits.....	5,604	4,312
Deferred revenue.....	5,032	6,494
Capitalized research and		
development.....	3,299	3,227
Accruals and reserves deductible		

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

in different periods.....	8,524	2,361
Depreciation.....	2,584	932
	-----	-----
	73,042	53,448
Valuation allowance.....	(72,739)	(53,147)
	-----	-----
Total.....	\$ 303	\$ 301
	=====	=====

Based on its history of US operating losses, the Company has placed a valuation allowance of \$72,739,000 and \$53,147,000 against its otherwise recognizable domestic net deferred tax assets at December 31, 2000 and 1999, respectively, due to the uncertainty surrounding the realizability of these benefits.

At December 31, 2000, the Company had federal, California and foreign net operating loss carryforwards of approximately \$136,175,000, \$17,106,000 and \$1,913,000 respectively, available to reduce future taxable income. Such carryforwards expire beginning in 2001 through 2020.

Also at December 31, 2000, the Company had research and experimentation credit carryforwards available of approximately \$3,584,000 and \$1,968,000 for federal and state tax purposes, respectively. The federal tax credit carryforwards expire beginning in 2004 and the state tax credit carryforwards have no expiration date.

Included in the deferred tax assets at December 31, 2000 is approximately \$4,093,000 of cumulative tax benefit related to equity transactions which will be credited to stockholders' equity, if and when realized after the other tax deductions in the carryforwards have been realized.

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

13. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) tax-deferred savings plan, whereby eligible employees may contribute a portion of their eligible compensation. Company contributions are discretionary and through December 31, 2000 the Company had not made any contributions.

14. MAJOR CUSTOMERS

For the year ended December 31, 2000, the Company had two customers that accounted for approximately 15% and 13%, respectively, of total revenues. For the year ended December 31, 1999, the Company had one customer that accounted for approximately 11% of total revenues. No customer accounted for more than 10% of total revenues for the year ended December 31, 1998.

15. DISCONTINUED OPERATION

In October 2000, the Company announced that it hoped to sell The Transplant Pharmacy (TTP). In early March, the Company received several non-binding offers to purchase TTP, one of which the Company accepted on March 13, 2001, thus committing to a formal plan to sell this segment. The Company is currently in advanced negotiations with this bidder and expects to complete the sale of TTP by April 30, 2001. The Company is not including the accounts receivable and inventory in the sale, and plans to liquidate these assets as soon as practicable following the closing of the sale.

The historical consolidated statements of operations and cash flows have been restated for all periods presented to account for TTP as a discontinued operation. The financial data of TTP reflects the historical sales and expenses of the transplantation services segment. Discontinued operations include TTP net sales which totaled \$17,502,000, \$13,865,000 and \$8,384,000 for the years ended December 31, 2000, 1999 and 1998, respectively. Net loss from the operations of TTP was \$2,342,000, \$2,025,000 and \$2,480,000 for the years ended December 31, 2000, 1999 and 1998, respectively.

The Company expects that the net results of future operations of TTP, together with the anticipated sale proceeds and costs associated with the sale, will result in a net gain to the Company, therefore no provision has been made in these consolidated financial statements regarding the future operations of TTP.

16. BUSINESS SEGMENT DATA

As stated in Note 15, the Company has presented the results of TTP, which represents its previously reported transplantation services segment, as a discontinued operation. As a result, the Company's continuing operations are organized and operate in one business segment: pharmaceutical products. Pharmaceutical products consist primarily of products for patient monitoring and therapeutic products for preventing and treating organ rejection. The company's segment information has been restated to reflect the results of such decision. The following information is presented in accordance with the requirements of SFAS No. 131, "*Disclosures about Segments of an Enterprise and Related Information.*"

The Company is engaged in the business of developing and marketing products and services for use in transplantation. The Company's operations in Europe primarily relate to the manufacture, marketing and selling, research and development and clinical study of therapeutic products for transplantation. The Company's operations in the rest of the world are principally sales and marketing related.

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

	United States	Europe	Canada	Rest of the World	Consolidated
Year ended December 31, 2000:					
Sales to unaffiliated customers.....	\$ 41,272	14667	\$ 1,289	\$ 5,917	\$ 63,145
Long-lived assets.....	\$ 5,003	\$ 12,669	\$ 9	\$ --	\$ 17,681
Year ended December 31, 1999:					
Sales to unaffiliated customers.....	\$ 18,094	\$ 22,428	\$ 1,401	\$ 2,380	\$ 44,303
Long-lived assets.....	\$ 4,909	\$ 13,184	\$ 15	\$ --	\$ 18,108
Year ended December 31, 1998:					
Sales to unaffiliated customers.....	\$ 3,272	\$ 4,885	\$ 1,356	\$ 1,781	\$ 11,294

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Long-lived assets.....	\$	2,295	\$	14,957	\$	33	\$	--	\$	17,285
		=====		=====		=====		=====		=====

17. RECALL OF SANGCYA ORAL SOLUTION

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

In the UK, the Company is selling SangCya Oral Solution on a named patient only basis subject to an amendment to the labeling. The Company is working with the Medicines Control Agency ("MCA") to complete a labeling change that must be approved by the other member states to permit the Company to obtain authorization to sell SangCya Oral Solution in these other countries.

The Company included in its financial results for the year ended December 31, 2000, charges to cover the losses resulting from the recall. These charges, which are reported in the consolidated statements of operations under revenues, cost of sales, research and development expenses and selling, general and administrative expenses, include \$872,000 for sales returns, \$11,774,000 for the write-off of all SangCya Oral Solution and CycloTech finished goods and components and a partial write-down of bulk cyclosporine inventories, and \$429,000 for costs to terminate ongoing marketing and clinical programs, and to administer the recall. The inventory reserves are non-cash in nature since the inventories in question have already been paid for. The amounts remaining unpaid at December 31, 2000 were not significant.

18. LITIGATION

Novartis Patent Litigation

Novartis vs. SangStat

On July 27, 2000, the Company entered into a global settlement agreement with Novartis AG and Novartis Pharmaceuticals Corporation with respect to the patent infringement lawsuits filed against the Company regarding SangCya[®] Oral Solution, USP [**MODIFIED**] as well as the counterclaim the Company filed against Novartis Pharmaceuticals Corporation in the US. As part of the settlement, the Company has entered into a global license agreement pursuant to which Novartis shall license US patent #5,389,382 and its foreign counterparts to the Company and the Company shall pay Novartis a royalty on sales of SangCya Oral Solution. The settlement and license applies only to SangCya Oral Solution and does not apply to cyclosporine capsule products. The Company does not expect the terms of the settlement to have a material financial impact on the Company in the foreseeable future.

Novartis vs. Abbott

Novartis has sued Abbott claiming that Gengraf[®] (cyclosporine capsule, USP, MODIFIED), infringes certain Novartis patents. Novartis' complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the US, but to date Novartis has not moved for a preliminary injunction. The trial date has been set for October 1, 2001. The discovery schedule is still before the court pending resolution of differences between the parties' proposals. Abbott has informed the Company that it does not believe it infringes the Novartis patents. The Company has not been named a defendant

in this lawsuit, and under the Company's agreement with Abbott, Abbott is obligated to indemnify the Company against such suits. The course of litigation is inherently uncertain, however; Novartis may choose to name the Company in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to the Company's interests. Should the Company be named in this suit, the Company may incur expenses prior to reimbursement (if any) by Abbott pursuant to its indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, Gengraf may be temporarily or permanently removed from the market.

Novartis Regulatory Litigation

US Regulatory Litigation

Novartis US sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia (case number 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral oral solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis asks that the Court (i) allow Novartis to keep its microemulsion labeling; (ii) declare microemulsion to be a separate dosage form; and (iii) rescind the AB rating that was given to SangCya Oral Solution. The Company intervened in this lawsuit. The parties have all filed motions for summary judgment with the Court and are awaiting a final ruling. The Court has dismissed the counts that relate specifically to the approval of SangCya Oral Solution, but Novartis may appeal this decision. Because the Company permanently withdrew SangCya Oral Solution from the US market in July 2000, the Company does not believe that this lawsuit will have any material impact on its financial position or results of operations.

UK Regulatory Litigation - SangCya Oral Solution

On October 18, 1999, Novartis UK was granted leave to seek judicial review of the decision by the Medicines Control Agency (the "MCA") to approve SangCya Oral Solution (Case No. HC- 1969/99). On March 30, 2000, the High Court in London dismissed Novartis' 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 ("ECJ"). The Company estimates that the ECJ will issue its ruling in approximately eighteen to twenty four months. Following the ECJ ruling, the parties would go back to the Court of Appeal who will then apply the ECJ ruling on the law to the facts of this case.

UK 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 cyclosporine capsule application. 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 a marketing authorization for a cyclosporine capsule product; in return, the Company agreed that the Company would not launch or commence mutual recognition procedures in relation to the cyclosporine capsule marketing authorization (including a request to MCA to prepare an assessment report) for a period of 28 days commencing on the day on which the Company notify Novartis' solicitors of capsule approval. The parties have agreed to continue the stay until the appeal of the High Court decision with respect to the judicial review of SangCya Oral Solution. The stay of this application for judicial review will remain in place pending the ECJ ruling on the questions of law and resulting Court of Appeal judgment.

Novartis has also indicated that it will seek an injunction to prevent the Company's cyclosporine capsule from being sold in the United Kingdom until final resolution of the judicial review relating to its cyclosporine capsule. Because the High Court ruled in favor of the MCA with respect to the SangCya Oral Solution marketing authorization and the Court of Appeal has referred questions of law to the ECJ, the Company believes that it is unlikely that a court would

grant Novartis a preliminary injunction with respect to its cyclosporine capsule marketing authorization. If the Court of Appeals reverses the High Court's ruling following the ECJ's decisions on questions of law, either the MCA could still approve its cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve its cyclosporine capsule marketing authorization until the expiration of the ten year data exclusivity period for Neoral capsules (approximately 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 subsidiary of the Company, and IMTIX SangStat Ltd. with a summons to the Milan Tribunal. Novartis Italy alleges that by requesting mutual recognition from the Italian Health Authorities of the SangCya Oral Solution dossier approved by the MCA, the Company implicitly requested that the Italian Health Authorities review the Neoral dossier. Novartis alleges that this request is an act of unfair competition in that (i) the Neoral data has ten year exclusivity and (ii) the data is secret and by requesting mutual recognition, the Company is responsible for the Health Authorities act of unfair competition following use of the Neoral dossier in reviewing the SangCya Oral Solution dossier. While the summons acknowledges that the UK High Court did not invalidate the SangCya Oral Solution marketing authorization, it does not acknowledge that the High Court ruled that the MCA could review the Neoral data. To the best of the Company's knowledge, Novartis Italy has not filed suit against the Italian Health Authorities. The initial appearance of the parties before the Milan Tribunal was scheduled for January 2001. The Company filed its response to the complaint at that time and the hearing was postponed until September 2001.

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

Breach of Contract Suit

In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes, sued the Company's French subsidiary, IMTIX-SangStat SAS, for breach of contract because the Company ordered lower quantities than was anticipated by the agreements. Those suppliers claim that the quantities set forth in the agreements were fixed orders; the Company believes that these were forecasts only. The Company believes that the agreements provide that if it purchased less than the forecast amounts, the Company would pay a penalty equal to a percentage of the difference between the amount ordered and the amount forecast. The suppliers claim this provision only applied during the first year of the agreements. The suppliers are asking for damages of 37 million French Francs (approximately \$5 million) for lost profits and reimbursement of capital expenditures. Under its interpretation, the Company would owe the suppliers 2.2 million French Francs (approximately \$300,000) for 2000, which was accrued in fiscal 2000, and 1.6 million French Francs (approximately \$200,000) for 2001, presuming no further orders are placed with these suppliers. The claim was filed under a "Fast Track" provision in the Lyon Commercial Courts and a hearing on the merits occurred at the end of December 2000. The Company currently anticipates a ruling in mid-April 2001. If the plaintiffs were to prevail, the Court would likely appoint an expert to assess the exact amount of damages suffered by the plaintiffs.

Summary

The Company believes that these lawsuits are without merit and that it will prevail in these matters. Although the Company is optimistic that these disputes will ultimately be resolved in its favor, the course of litigation is inherently uncertain and there can be no assurance of a favorable outcome. With respect to Novartis' lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, the Company's revenues would be reduced. With respect to the regulatory and trade secret lawsuits, Novartis' requested relief, if granted, could have a

negative economic impact on the Company depending on how the MCA would proceed with the Company's Marketing Authorization Application (MAA) for its capsule product. The MCA could approve the Company's MAA for cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve the Company's MAA for its cyclosporine capsule until the expiration of the ten year data exclusivity period for Neoral capsules (approximately 2004). If the Company cannot obtain approval of its cyclosporine capsule in Europe until 2004, this could have a material impact on the Company's future revenues and results of operations. With respect to the FDA lawsuit, Novartis' requested relief would mean that Gengraf and all other generic cyclosporine products would lose their AB rating. If Gengraf was no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would harm revenues. With respect to the breach of contract lawsuit, the requested relief would be a one-time charge against earnings. None of these lawsuits involves significant time or resources of the Company at the current stage of litigation. The UK regulatory litigation will require additional time and expense towards the end of 2001 or early 2002 as the Company prepares for a hearing before the ECJ. The litigation, if not resolved favorably to the Company, could have a material adverse effect on the Company's business, financial condition, cash flows and results of operations.

19. UNAUDITED QUARTERLY FINANCIAL INFORMATION

Selected Quarterly Consolidated Financial Data:

(in thousands, except per share data)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	-----	-----	-----	-----
Year ended December 31, 2000:				
Net revenues.....	11,978	15,991	16,894	18,282
Gross profit.....	7,509	(3,519)	10,578	9,331
Net loss:				
Continuing operations.....	7,094	19,836	10,366	4,721
Discontinued operation.....	695	382	512	753
	-----	-----	-----	-----
	7,789	20,218	10,878	5,474
	=====	=====	=====	=====
Net loss per share - basic and diluted:				
Continuing operations.....	0.40	1.11	0.58	0.26
Discontinued operation.....	0.04	0.02	0.03	0.04
	-----	-----	-----	-----
	0.44	1.13	0.60	0.30
	=====	=====	=====	=====
Year ended December 31, 1999:				
Net revenues.....	7,475	11,108	11,116	14,604
Gross profit.....	4,273	6,520	6,408	8,113
Net loss:				
Continuing operations.....	9,211	8,199	7,252	6,320
Discontinued operation.....	512	384	501	628
	-----	-----	-----	-----
	9,723	8,583	7,753	6,948
	=====	=====	=====	=====

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Net loss per share - basic and diluted:				
Continuing operations.....	0.56	0.49	0.42	0.39
Discontinued operation.....	0.03	0.02	0.03	0.04
	-----	-----	-----	-----
	0.60	0.51	0.45	0.43
	=====	=====	=====	=====

Schedule II

SANGSTAT MEDICAL CORPORATION
Valuation and Qualifying Accounts

(In thousands)

	Balance at beginning of period	Additions charged to costs and expenses	Deductions	Other	Balance at end of period
	-----	-----	-----	-----	-----
1998					
Allowance for doubtful account \$	139	\$ 773	\$ 231 (1)	\$ 248 (2)	\$ 929
1999					
Allowance for doubtful account \$	929	\$ 1,126	\$ 586 (1)		\$ 1,469
2000					
Allowance for doubtful account \$	1,469	\$ 3,789	\$ 2,130 (1)		\$ 3,128

(1) Accounts written off, net of recoveries

(2) Allowances added from the acquisition of IMTIX

SANGSTAT MEDICAL CORPORATION

SIGNATURES

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

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

SANGSTAT MEDICAL CORPORATION

By: _

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

POWER OF ATTORNEY

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Jean-Jacques Bienaimé</u>	CEO & Chairman of the Board of Directors	March 29, 2001
Jean-Jacques Bienaimé		
<u>/s/ Stephen G. Dance</u>	Chief Financial Officer (Principal Accounting Officer)	March 29, 2001
Stephen G. Dance, CPA, FCA.		
<u>/s/ Fredric J. Feldman</u>	Director	March 29, 2001
Fredric J. Feldman, Ph.D.		
<u>/s/ Elizabeth M. Greetham</u>	Director	March 29, 2001
Elizabeth M. Greetham		
<u>/s/ Richard D. Murdock</u>	Director	March 29, 2001

Richard D. Murdock

/s/ Andrew Perlman

Director

March 29, 2001

Andrew Perlman, M.D., Ph.D

/s/ Vincent Worms

Director

March 29, 2001

Vincent Worms

EXHIBIT INDEX

Exhibits	Description of Exhibit
J.1 (5)	Agreement and Plan of Merger dated as of July 24, 1995 between SangStat Delaware, Inc. and SangStat Medical Corporation, a California corporation, as filed with the Delaware Secretary of State on August 11, 1995.
J.2 (7)	Master Agreement between SangStat Medical Corporation and Pasteur Merieux Serums & Vaccins, S.A. dated June 10, 1998, including Exhibit 8 thereto
K.2 (5)	Certificate of Incorporation of SangStat Delaware, Inc.
K.3 (12)	Certificate of Amendment of the Certification of Incorporation
K.4 (4)	Certificate of Designation for the Series A Junior Participating Preferred Stock, filed with the Delaware Secretary of State on August 16, 1995.
K.5 (11)	Second Amended and Restated Bylaws of the Registrant.
L.5 (3)	Specimen Common Stock Certificate of Registrant.
I0.7 (2)(3)	1993 Stock Option/Stock Issuance Plan.
I0.18 (5)	

Edgar Filing: SANGSTAT MEDICAL CORP - Form 10-K

Form of Indemnification Agreement to be entered into between the Registrant and each of its officers and directors.

- I0.19 (1)(3) License Agreement, dated November 15, 1993, between the Registrant and the Board of Trustees of Leland Stanford Junior University
- I0.25 (6) Rights Agreement, dated as of August 14, 1995, between the Registrant and First National Bank of Boston.
- 10.26 (8) Real Property Sub-Lease, dated March 8, 1999, between the Registrant and Kelley-Clarke, Inc. Real Property lease between Kelly-Clarke Inc. and Kaiser Development Company dated September 1, 1988 as amended on February 26, 1990, May 1, 1990, May 5, 1990, and April 19, 1995
- I0.27 (9) Call Option Agreement, dated as of May 7, 1999 between the Registrant and Abbott Laboratories, Inc.
- I0.28 (1)(9) Co-Promotion Agreement, dated as of May 7, 1999 between the Registrant and Abbott Laboratories, Inc.
- I0.29 (9) Right of First Refusal Agreement, dated as of May 7, 1999 between the Registrant and Abbott Laboratories, Inc.
- I0.30 (9) Registration Rights Agreement, dated as of May 7, 1999 between the Registrant and Abbott Laboratories, Inc
- I0.31 (10) Registration Rights Agreement, dated as of February 15, 2000 between the Registrant and BioPharma Equities Holdings NV.
- I0.32 (10) Convertible Promissory Note dated March 1999 for \$10,000,000 with Warburg Dillon Read LLC.
- I0.33 (11) Loan and Security Agreement dated as of April 21, 2000 between the Registrant and FINOVA Capital Corporation.
- I0.34 (1)(14) Co-Development, Supply and License Agreement dated as of August 8, 2000 between the Registrant and Abgenix, Inc.
- I0.35 (15) Securities Purchase Agreement dated December 29, 2000 between the Registrant and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, and SDS Capital Partners, LLC
- I0.36 (15) Registration Rights Agreement dated December 29, 2000 between the Registrant and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, and SDS Capital Partners, LLC
- I0.37 (13) Registration Rights Agreement dated March 19, 1999 by and between Registrant and Warburg Dillon Read LLC.
- J1.1 Subsidiaries of Registrant.
- J3.1 Independent Auditors' Consent.

J4.1

Power of Attorney (reference is made to the signature page hereof)

-
- (1) Confidential treatment has been granted for the deleted portions of this document. The non-public information has been filed separately with the SEC.
 - (2) Management contract or compensatory plan or arrangement.
 - (3) Previously filed as an Exhibit to Registration Statement on Form S-1 (No. 33-70436).
 - (4) Previously filed as an Exhibit to Form 8-K filed August 14, 1995.
 - (5) Previously filed as an Exhibit to Registration Statement on Form 8-B filed December 4, 1995.
 - (6) Previously filed as an Exhibit to Form 8-A filed August 25, 1995.
 - (7) Previously filed as Exhibits to Form 8-K filed on October 15, 1998 as amended on December 14, 1998.
 - (8) Previously filed as an Exhibit to our annual report on Form 10-K filed on March 31, 1999.
 - (9) Previously filed as an Exhibit to our Form 10-Q filed August 16, 1999. The SEC reviewed our request for confidential treatment for Exhibit 10.28 and we are re-filing a revised version with this Form 10-K to reflect the portions of the document for which the SEC has granted confidential treatment as noted in Footnote 1 above. The non-public information has been filed separately with the SEC.
 - (10) Previously filed as an Exhibit to our Report on Form 10-K for the fiscal year ended December 31, 1999.
 - (11) Previously filed as an Exhibit to our Form 10-Q filed May 15, 2000.
 - (12) Previously filed as an Exhibit to our Form 8-K filed August 28, 2000.
 - (13) Previously filed as an Exhibit to the Registration Statement on Form S-3 (No. 33-46578).
 - (14) Previously filed as an Exhibit to our Form 10-Q filed November 14, 2000.
 - (15) Previously filed as an Exhibit to our Form 8-K filed January 8, 2001.
-