

SANGSTAT MEDICAL CORP  
Form 10-Q  
August 14, 2001

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

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FORM 10-Q

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

**For the quarterly period ended June 30, 2001**

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)

**510-789-4300**

(Registrant's telephone number, including area code)

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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 reports), and (2) has been subject to such filing requirements for the past 90 days. YES

NO

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

<u>CLASS</u>	<u>NUMBER OF SHARES</u>
Common Stock	20,857,215*

\* As of July 31, 2001

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**SANGSTAT MEDICAL CORPORATION**  
**FORM 10-Q**  
**For the Quarterly Period Ended June 30, 2001**  
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**PART I -- FINANCIAL INFORMATION**

Item 1. Financial Statements

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

	June 30, 2001	December 31, 2000
	----- (unaudited)	----- (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents.....	\$ 30,544	\$ 19,046
Short-term investments .....	1,753	1,561
Accounts receivable (net of allowance for doubtful accounts of \$3,306 in 2001 and \$3,128 in 2000) ..	18,647	17,569

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Other receivables.....	736	2,333
Inventories.....	24,930	40,056
Prepaid expenses and other current assets.....	1,540	6,912
	-----	-----
Total current assets.....	78,150	87,477
PROPERTY AND EQUIPMENT -- net.....	5,657	6,539
INTANGIBLE ASSETS (net of accumulated amortization of \$3,836 in 2001 and \$3,141 in 2000).....	10,447	11,142
OTHER ASSETS.....	21,032	9,158
	-----	-----
TOTAL.....	\$ 115,286	\$ 114,316
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable.....	\$ 17,158	\$ 17,553
Accrued liabilities.....	16,447	13,938
Capital lease obligations -- current portion.....	171	257
Deferred revenue -- current portion.....	3,158	3,158
Notes payable -- current portion.....	6,465	12,797
	-----	-----
Total current liabilities.....	43,399	47,703
	-----	-----
CAPITAL LEASE OBLIGATIONS.....	395	535
DEFERRED REVENUE.....	7,896	9,475
NOTES PAYABLE.....	32,565	34,679
STOCKHOLDERS' EQUITY:		
Preferred stock, \$.001 par value 5,000 shares authorized; none outstanding.....	--	--
Common stock, \$.001 par value, 35,000 shares authorized; outstanding: 2001 - 20,850 shares; 2000 - 18,942 shares.....	221,301	201,766
Accumulated deficit.....	(186,730)	(177,636)
Accumulated other comprehensive loss.....	(3,540)	(2,206)
	-----	-----
Total stockholders' equity.....	31,031	21,924
	-----	-----
TOTAL.....	\$ 115,286	\$ 114,316
	=====	=====

(1) Derived from the Company's audited consolidated financial statements at December 31, 2000.

See notes to Condensed Consolidated Financial Statements.

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**SANGSTAT MEDICAL CORPORATION  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

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(in thousands, except per share data)  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2001	2000	2001	2000
<b>REVENUES:</b>				
Net sales.....	\$ 20,995	\$ 16,079	\$ 40,530	\$ 27,295
Product recall returns.....	--	(722)	--	(722)
Revenue from collaborative agreements.....	789	634	1,579	1,216
Total revenues.....	21,784	15,991	42,109	27,789
<b>COSTS AND OPERATING EXPENSES:</b>				
Cost of sales:				
Cost of product sales and manufacturing expenses .....	9,322	7,950	17,943	12,239
Product recall charges.....	--	11,561	--	11,561
Research and development (including product recall expenses of \$50 in 2000).....	4,203	4,017	8,748	7,995
Selling, general and administrative (including product recall expenses of \$379 in 2000).....	8,781	11,385	17,506	21,571
Amortization of intangible assets....	347	353	695	701
Total costs and operating expenses.....	22,653	35,266	44,892	54,067
Loss from continuing operations...	(869)	(19,275)	(2,783)	(26,278)
OTHER EXPENSE - NET.....	(1,502)	(411)	(5,297)	(732)
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES.....	(2,371)	(19,686)	(8,080)	(27,010)
INCOME TAX (PROVISION) BENEFIT.....	(251)	141	(251)	80
NET LOSS FROM CONTINUING OPERATIONS....	(2,622)	(19,545)	(8,331)	(26,930)
NET LOSS FROM OPERATIONS OF DISCONTINUED OPERATION.....	--	(673)	(763)	(1,077)
NET LOSS.....	\$ (2,622)	\$ (20,218)	\$ (9,094)	\$ (28,007)
<b>NET LOSS PER SHARE - Basic and diluted (Note 2)</b>				
Continuing operations.....	\$ (0.13)	\$ (1.09)	\$ (0.43)	\$ (1.52)
Discontinued operation.....	--	(0.04)	(0.04)	(0.06)
	\$ (0.13)	\$ (1.13)	\$ (0.47)	\$ (1.59)
<b>Shares Used in Per Share Computations (Basic and diluted).....</b>				
	19,632	17,932	19,523	17,660

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
(in thousands)  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2001	2000	2001	2000
Net loss.....	\$ (2,622)	\$ (20,218)	\$ (9,094)	\$ (28,007)
Reversal of unrealized gains and (losses) on marketable securities sold during the current period.....	--	--	--	(644)
Unrealized gains and losses on marketable securities classified as available for sale in the current period.....	(1)	22	--	22
Foreign currency translation adjustments.....	(616)	66	(1,334)	(279)
Total comprehensive loss.....	\$ (3,239)	\$ (20,130)	\$ (10,428)	\$ (28,908)

See notes to Condensed Consolidated Financial Statements.

**SANGSTAT MEDICAL CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)  
(unaudited)

	Six Months Ended June 30,	
	2001	2000
<b>OPERATING ACTIVITIES:</b>		
Net loss from continuing operations.....	\$ (8,331)	\$ (26,930)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization.....	1,857	1,793
Non-cash interest expense.....	590	701
Loss on disposal of property and equipment.....	203	114
Changes in assets and liabilities:		
Accounts receivable.....	(1,078)	(4,736)
Other receivables.....	1,597	778
Inventories.....	(204)	9,583
Prepaid expenses and other current assets.....	5,372	(5,380)
Accounts payable.....	(395)	4,919

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Accrued liabilities.....	2,509	4,294
Deferred revenue.....	(1,579)	1,684
	-----	-----
Net cash provided by (used in)		
continuing operating activities.....	541	(13,180)
Net cash used in discontinued operation.....	(763)	(1,077)
	-----	-----
Net cash used in operating activities.....	(222)	(14,257)
	-----	-----
INVESTING ACTIVITIES:		
Purchases of property and equipment.....	(483)	(1,208)
Maturities of short-term investments.....	58	3,989
Purchase of short-term investments.....	(250)	(51)
Other assets.....	3,456	(1,177)
	-----	-----
Net cash provided by investing activities.....	2,781	1,553
	-----	-----
FINANCING ACTIVITIES:		
Sale of common stock.....	19,535	17,292
Note payable borrowings.....	355	5,986
Note payable repayments.....	(9,391)	(2,298)
Repayment of capital lease obligations.....	(226)	(273)
	-----	-----
Net cash provided by financing activities.....	10,273	20,707
	-----	-----
EFFECT OF EXCHANGE RATE CHANGES ON CASH.....	(1,334)	(279)
	-----	-----
NET INCREASE IN CASH AND CASH EQUIVALENTS .....	11,498	7,724
CASH AND CASH EQUIVALENTS, Beginning of period.....	19,046	16,862
	-----	-----
CASH AND CASH EQUIVALENTS, End of period.....	\$ 30,544	\$ 24,586
	=====	=====
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during the period for interest,		
net of interest capitalized.....	\$ 2,446	\$ 424
	=====	=====
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Property acquired under capital leases.....	\$ --	\$ 1,164
	=====	=====
Warrants issued in connection with financing.....	\$ --	\$ 744
	=====	=====
Unrealized loss on investments.....	\$ --	\$ (622)
	=====	=====

See notes to Condensed Consolidated Financial Statements.

## SANGSTAT MEDICAL CORPORATION

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. *Basis of Presentation*

The condensed consolidated financial statements include the accounts of SangStat Medical Corporation and its wholly owned subsidiaries. Intercompany accounts and transactions have been eliminated.

The condensed consolidated financial statements presented are unaudited and in the opinion of management reflect all adjustments (consisting of normal recurring accruals) which the Company considers necessary for a fair presentation of the financial condition and results of operations as of and for the interim periods presented. Certain reclassifications to June 30, 2000 condensed consolidated financial statements were made in order to conform to the current quarter condensed consolidated financial statements presentation. The results for interim periods are not necessarily indicative of the results to be expected for the full year. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's 2000 Annual Report on Form 10-K.

2. *Net Loss Per Share*

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share 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 677,822 shares and 1,281,009 shares as of June 30, 2001 and 2000, respectively, have been excluded from diluted net loss per share, 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 (amounts in thousands, except per share figures):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2001	2000	2001	2000
Net loss (numerator):				
Continuing operations.....	\$ 2,622	\$ 19,545	\$ 8,331	\$ 26,930
Discontinued operation.....	--	673	763	1,077
	=====	=====	=====	=====
	\$ 2,622	\$ 20,218	\$ 9,094	\$ 28,007
Shares (denominator)				
Weighted average common shares outstanding.....	19,632	17,932	19,523	17,660
	=====	=====	=====	=====
Net loss per share - basic and diluted				
Continuing operations.....	\$ 0.13	\$ 1.09	\$ 0.43	\$ 1.52
Discontinued operation.....	--	0.04	0.04	0.06
	=====	=====	=====	=====
	\$ 0.13	\$ 1.13	\$ 0.47	\$ 1.59
	=====	=====	=====	=====



3. *Comprehensive Loss*

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

	June 30, 2001	December 31, 2000
	-----	-----
Unrealized gain (loss) on investments .....	\$ 5	\$ 6
Accumulated translation adjustments .....	(3,545)	(2,212)
	-----	-----
Total.....	\$ (3,540)	\$ (2,206)
	=====	=====

4. *Inventories*

Inventories, valued at the lower of cost (first-in, first-out) or market consist of (in thousands):

	June 30, 2001	December 31, 2000
	-----	-----
Raw materials.....	\$ 3,042	\$ 18,860
Work-in-progress.....	13,896	14,107
Finished goods.....	7,992	7,089
	-----	-----
Total.....	\$ 24,930	\$ 40,056
	=====	=====

In addition to these inventories, the Company has classified approximately \$15,330,000 of raw materials inventory as other assets in the accompanying consolidated balance sheet at June 30, 2001, as it is not expected to be utilized in operations during the next twelve months.

5. *Notes Payable*

Notes payable consist of (in thousands):

	June 30, 2001	December 31, 2000
	-----	-----
Note payable to Aventis.....	\$ 12,000	\$ 15,000
Discount on note payable to Aventis.....	(1,160)	(1,707)
Convertible note.....	9,735	9,691
Note payable to Abbott Laboratories.....	16,000	16,000
Note payable to FINOVA.....	--	5,000
Other debt.....	2,455	3,492
	-----	-----
Total.....	39,030	47,476
Less current portion.....	(6,465)	(12,797)
	-----	-----
Long-term.....	\$ 32,565	\$ 34,679
	=====	=====

As of December 31, 2000 the Company had an agreement with FINOVA Capital Corporation ("FINOVA") to provide a line of credit of up to \$30 million (the "Loan Agreement"). At December 31, 2000 and through May 11, 2001, 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 during 2000 due to the SangCya Oral Solution recall. The Loan Agreement does not provide for a cure period for such a default. The parties entered into an Amendment dated May 11, 2001, which provided that the Loan Agreement would terminate as of December 31, 2001, the portion of the line of credit collateralized by accounts receivable and inventory would be eliminated and FINOVA would waive the default and all early termination penalties with respect to the Loan Agreement. Subsequently, the Company repaid the loan balance of \$5 million on June 29, 2001, thereby terminating the Loan Agreement. Since the loan has been repaid, the \$5 million compensating balance previously classified as other current assets has now been classified as cash in the accompanying condensed consolidated balance sheet.

#### 6. Issuance of Common Stock

On June 20, 2001, the Company completed a private placement of approximately 1.36 million shares of common stock for aggregate proceeds of approximately \$15 million with a group of institutional investors. The shares were purchased at a discount to the closing market price on the date the agreements were signed. 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 and to make scheduled loan repayments.

#### 7. Discontinued Operation

On March 13, 2001, the Company committed to a formal plan to sell its division known as The Transplant Pharmacy ("TTP"). On April 20, 2001, the Company closed the sale of TTP to Chronimed for \$1.8 million in cash. The Company retained the inventory and accounts receivable related to the business and is in the process of converting these assets into cash. The disposition of TTP has been accounted for as a discontinued operation in accordance with Accounting Principles Board ("APB") Opinion No. 30, and prior period consolidated statements of operations and cash flows have been restated to account for TTP as a discontinued operation. The Company expects that the sale proceeds, together with the transaction expenses and costs incurred as a result of the sale, will result in a net gain to the Company, however no gain has been recorded in these condensed consolidated financial statements pending the successful conversion of the remaining inventory and accounts receivable.

The condensed consolidated balance sheets at June 30, 2001 and December 31, 2000, include the remaining assets and liabilities of TTP as follows (in thousands):

	June 30, 2001	December 31, 2000
	-----	-----
Accounts receivable - net.....	\$ 1,462	\$ 3,986
Inventories.....	103	1,137
Other assets.....	--	96
Accounts payable and accrued expenses.....	(316)	(601)
	-----	-----
Net assets of discontinued operation.....	\$ 1,249	\$ 4,618
	=====	=====

#### 8. Business Segment Data

As stated in Note 7, the Company has presented the results of TTP, which represents its previously reported transplantation services segment, as a discontinued operation. As a result, the Company's continuing operations are

organized and operate in one business segment: pharmaceutical products. Pharmaceutical products consist primarily of therapeutic products for preventing and treating organ rejection. The Company's segment information has been restated to reflect the results of such decision.

#### 9. *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. The Company adopted SFAS No. 133 effective January 1, 2001. The adoption of this statement did not have an effect on the Company's financial position, results of operations or cash flows as the Company had no stand-alone or embedded derivatives at December 31, 2000 and had not historically entered into any derivative transactions to hedge currency or other exposures.

As a matter of policy, the Company does not currently enter into transactions involving derivative financial instruments. In the event the Company does enter into such transactions in the future, such items will be accounted for in accordance with SFAS No. 133, in which case the Company will document all relationships between hedging instruments and hedged items, as well as its risk- management objective and strategy for undertaking such hedge transactions.

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. The Company adopted the applicable disclosure requirements of SFAS No. 140 in its consolidated financial statements as of December 31, 2000. The remaining provisions of SFAS No. 140, which became effective for transactions entered into after March 31, 2001 had no effect on the Company's consolidated financial statement.

In June 2001, the FASB issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired outside of a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives not be amortized, but will rather be tested at least annually for impairment. The Company will adopt SFAS No. 142 for its fiscal year beginning January 1, 2002. Upon adoption of SFAS No. 142, the Company will stop the amortization of goodwill with an expected net carrying value of \$ 9,750,000 at the date of adoption and annual amortization of \$1,392,000 that resulted from business combinations completed prior to the adoption of SFAS No. 141. The Company will evaluate goodwill under the transitional impairment test in SFAS No. 142 and, accordingly, has not yet determined whether or not there will be an impairment loss. Any transitional impairment loss will be recognized as a change in accounting principle.

#### 10. *Litigation*

##### Novartis Patent Litigation re Gengraf

Novartis 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 U.S., but to date Novartis has not moved for a preliminary injunction. The trial date has been set for October 1, 2001. Abbott 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

##### U.S. Regulatory Litigation

Novartis U.S. sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia (case number 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis asks the Court to (i) allow Novartis to keep its microemulsion labeling; (ii) declare microemulsion to be a separate dosage form; and (iii) rescind the AB rating that was given to SangCya Oral Solution. The Company intervened in this lawsuit. The 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 U.S. market in July 2000, the Company does not believe that this lawsuit will have any material impact on SangCya revenues but if the court declares microemulsion to be a separate dosage form, this ruling would rescind the AB rating for Gengraf, which would have a material impact on Gengraf revenues.

##### U.K. Regulatory Litigation - SangCya Oral Solution

On October 18, 1999, Novartis U.K. was granted leave to seek judicial review of the decision by the Medicines Control Agency (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"). No date has been set for the ECJ hearing, but it is likely to be scheduled sometime in late 2001 or early 2001, with a ruling approximately six months thereafter. Following the ECJ ruling, the parties would go back to the Court of Appeal, which will then apply the ECJ ruling on the law to the facts of this case.

##### U.K. Regulatory Litigation - Cyclosporine Capsules

In November 1999, Novartis filed a request with the High Court in London for judicial review of the refusal by MCA to state that it would not reference Neoral data in approving any 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 notifies 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 (May 2004).

#### Italian Regulatory/Trade Secret Litigation

On May 5, 2000, Novartis Farma S.p.A. ("Novartis Italy") served IMTIX SangStat S.r.l., an Italian 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 U.K. High Court did not invalidate the SangCya Oral Solution marketing authorization, it does not acknowledge that the High Court ruled that the MCA could review the Neoral data. To the best of the Company's knowledge, Novartis Italy has not filed suit against the Italian Health Authorities. The initial appearance of the parties before the Milan Tribunal was scheduled for January 2001. The Company filed its response to the complaint at that time, and the hearing 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 U.K. regulatory litigation, since the MCA's actions are the basis for the Italian lawsuit.

#### 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. 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 European 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 (May 2004). If the Company cannot obtain approval of its cyclosporine capsule in Europe until 2004, this could have an adverse impact on the Company's future revenues and results of operations. With respect to the FDA lawsuit, Novartis' requested relief would mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would harm revenues. The litigation, if not resolved favorably to the Company, could have a material adverse effect on the Company's business, financial condition, cash flows and results of operations.

#### Breach of Contract Suit

In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes, sued the Company's French subsidiary, IMTIX-SangStat SAS, for breach of contract. On May 2, 2001 the Company and IMTIX-SangStat were notified that the Commercial Court of Lyon ruled against IMTIX-SangStat in the breach of contract suit and the court awarded the suppliers 26.5 million French Francs (approximately \$3.6 million) for lost profits and reimbursement of capital expenditures. IMTIX-SangStat recorded a charge of \$3,250,000 to other expense - net for the six months ended June 30, 2001, which, combined with reserves recorded in fiscal 2000, fully provide for the court award. IMTIX-SangStat believes that the ruling was in error and has appealed the decision. The hearing for the appeal is scheduled for November 2001.

The supply agreements provided that IMTIX-SangStat could reduce orders if it paid up to a maximum penalty of 3.8 million French Francs (approximately \$525,000). When IMTIX-SangStat reduced orders, the suppliers sued for breach of contract claiming that this provision did not apply. The court agreed, holding that the penalty provision applied only in the first year of the agreements and since IMTIX-SangStat reduced orders in the second year of the agreements, it was liable for additional damages. IMTIX-SangStat maintains it should be able to invoke the penalty throughout the term of the agreements. IMTIX-SangStat's rabbit serum requirements are currently being met by its other suppliers.

## ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our Condensed Consolidated Financial Statements and Notes thereto included elsewhere in this Quarterly Report on Form 10-Q, as well as the Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2000. Except for the historical information contained herein, the discussion contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. The cautionary statements should be read as being applicable to all related forward-looking statements wherever they appear. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those discussed in "Risk Factors," as well as those discussed elsewhere herein. In particular, we have included forward-looking statements regarding the following: (i) our 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) expected results of our on-going litigation; (vi) our future revenue and expenses, including expectations regarding liquidity; and (vii) the anticipated conversion into cash of inventory and accounts receivable following the sale of our division known as The Transplant Pharmacy.

*We disclaim any obligation to update these forward-looking statements for subsequent events.*

### Results of Operations - Three and Six Months Ended June 30, 2001 and 2000

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 U.S. headquarters are in Fremont, California. We also maintain a strong European presence, including direct sales and marketing forces in the major European markets and distributors throughout the rest of the world.

Our business is currently organized into one segment: Pharmaceutical Products. This segment consists of five marketed products and three principal product candidates. In prior periods, we also operated a second segment,

Transplantation Services, which consisted of The Transplant Pharmacy (TTP). On April 20, 2001, we sold TTP to Chronimed for cash proceeds of \$1,800,000. 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 and excludes our discontinued operation.

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

In June 2001, the FASB issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired outside of a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives not be amortized, but will rather be tested at least annually for impairment. We will adopt SFAS No. 142 for its fiscal year beginning January 1, 2002. Upon adoption of SFAS No. 142, we will stop the amortization of goodwill with an expected net carrying value of \$ 9,750,000 at the date of adoption and annual amortization of \$1,392,000 that resulted from business combinations completed prior to the adoption of SFAS No. 141. We will evaluate goodwill under the transitional impairment test in SFAS No. 142 and, accordingly, have not yet determined whether or not there will be an impairment loss. Any transitional impairment loss will be recognized as a change in accounting principle.

#### Revenues.

Net sales of pharmaceutical products for the three months ended June 30, 2001 were \$21,784,000, an increase of \$5,793,000 or 36% over net sales of \$15,991,000 for the three months ended June 30, 2000. Net sales of pharmaceutical products for the six months ended June 30, 2001 were \$42,109,000, an increase of \$14,320,000 or 52% over net sales of \$27,789,000 for the six months ended June 30, 2000. The increase for the three months ended June 30, 2001 was due to higher sales of Gengraf, which was launched in the U.S. in May 2000, and increased sales of Thymoglobulin in the U.S. These same factors were the primary reason for the increase for the six months ended June 30, 2001, however sales of Thymoglobulin and Lymphoglobuline outside the U.S. were also higher than the prior period.

Included in net sales of pharmaceutical products was revenue from collaborative agreements of \$789,000 for the three months ended June 30, 2001, an increase of \$155,000 or 24% over revenue from collaborative agreements of \$634,000 for the three months ended June 30, 2000. Revenue from collaborative agreements was \$1,579,000 for the six months ended June 30, 2001, an increase of \$363,000 or 30% over revenue from collaborative agreements of \$1,216,000 for the six months ended June 30, 2000. For all periods, this revenue relates to 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 condensed consolidated balance sheet and will be recognized as revenue on a straight-line basis over the remaining term of the co-promotion agreement.

#### Cost of sales.

Cost of product sales and manufacturing expenses were \$9,322,000 for the three months ended June 30, 2001, an increase of \$1,372,000 or 17% over cost of sales of \$7,950,000 for the three months ended June 30, 2000. Cost of sales and manufacturing expenses were \$17,943,000 for the six months ended June 30, 2001, an increase of \$5,704,000 or 47% over cost of product sales of \$12,239,000 for the six months ended June 30, 2000. For both periods, the increase in cost of product sales and manufacturing expenses was primarily due to increased sales of pharmaceutical products combined with the higher cost of Gengraf as compared to our other products. We anticipate an increase in our cost of product sales for Thymoglobulin to occur starting October 1, 2001 due to initiation of royalties to Aventis on sales of Thymoglobulin.

Total cost of sales for the three and six months ended June 30, 2000 included a product recall reserve of \$11,561,000 for SangCya Oral Solution that was taken in the second quarter of fiscal year 2000. No such reserve has been recorded in fiscal year 2001.

#### Research and development

. Research and development expenses were \$4,203,000 for the three months ended June 30, 2001, an increase of \$186,000 or 5% over research and development expenses of \$4,017,000 for the three months ended June 30, 2000. Research and development expenses were \$8,748,000 for the six months ended June 30, 2001, an increase of \$753,000 or 9% over research and development expenses of \$7,995,000 for the six months ended June 30, 2000. The increase in spending on research and development mainly relates to reimbursement of development costs for ABX-CBL totaling \$1,200,000 and \$2,300,000 for the three and six month periods ended June 30, 2001, respectively, partially offset by the elimination of spending on SangCya Oral Solution and related products.

#### Selling, general and administrative

. Selling, general and administrative expenses for the three months ended June 30, 2001 were \$8,781,000, a decrease of \$2,604,000 or 23% over selling, general and administrative expenses of \$11,385,000 for the three months ended June 30, 2000. Selling, general and administrative expenses for the six months ended June 30, 2001 were \$17,506,000, a decrease of \$4,065,000 or 19% over selling, general and administrative expenses of \$21,571,000 for the six months ended June 30, 2000. The overall reduction in expenses reflects the results of SangStat's cost control efforts through the continuation of its cost containment program.

#### Other expense - net

. Other expense - net for the three months ended June 30, 2001 was \$1,502,000, compared to \$411,000 for the three months ended June 30, 2000. Other expense - net for the six months ended June 30, 2001 was \$5,297,000, compared to \$732,000 for the six months ended June 30, 2000. The increase in other expense - net for the three months ended June 30, 2001 was due to the write down of the balance of the value of the warrant and the loan origination fees of \$1,128,000 related to repayment and subsequent termination of the FINOVA loan agreement.

The increase in other expense - net for the six months ended June 30, 2001 is attributable to the following:

- \$3,250,000 charge related to a breach of contract suit;
- \$437,000 gain on sale of marketable securities which was recognized in 2000;
- \$287,000 net increase in fixed asset disposal / retirement losses; and
- \$591,000 net increases in interest and other miscellaneous expenses (including the effects of the FINOVA loan termination agreement, partially offset by an \$856,000 reimbursement claim we received from a supplier).

#### Income taxes



. For the three and six months ended June 30, 2001, we recorded a provision for European income taxes of \$251,000 as compared to a benefit of \$141,000 for the three months ended June 30, 2000 and a benefit of \$80,000 for the six months ended June 30, 2000. The change in provision is attributable to the net loss position of our European subsidiaries in the current period as compared to income in the prior period.

Net loss from continuing operations.

Net loss from continuing operations for the three months ended June 30, 2001 was \$2,622,000, a decrease of \$16,923,000 or 87% compared to the net loss of \$19,545,000 for the three months ended June 30, 2000. Net loss from continuing operations for the six months ended June 30, 2001 was \$8,331,000, a decrease of \$18,599,000 or 69% compared to the net loss of \$26,930,000 for the six months ended June 30, 2000. The decrease in net loss for the three and six month periods ended June 30, 2001 was due primarily to expenses of \$12,708,000 relating to the SangCya Oral Solution product recall, as well as the increase in sales net of related cost of sales and the reduction in selling, general and administrative expenses.

Net loss from operations of discontinued operation.

Net loss for transplantation services for the three months ended June 30, 2001 was zero compared to a net loss of \$673,000 for the three months ended June 30, 2000. Net loss for transplantation services for the six months ended June 30, 2001 was \$763,000 compared to a net loss of \$1,077,000 for the six months ended June 30, 2000. For both periods, the change in net loss reflects the sale of our transplantation services business that closed on April 20, 2001.

Impact of Litigation

The cyclosporine products that we sell are involved in litigation. We believe that these lawsuits are without merit and that we or Abbott will prevail in these matters. Although we are optimistic that these disputes will ultimately be resolved in our or Abbott's favor, the course of litigation is inherently uncertain. With respect to Novartis' patent infringement lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, our revenues would be reduced. With respect to the European regulatory and trade secret lawsuits, Novartis' requested relief, if granted, could have a negative economic impact on us depending on how the MCA would proceed with our Marketing Authorization Application (MAA) for its capsule product. The MCA could approve our MAA for cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve our MAA for its cyclosporine capsule until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004). If we cannot obtain approval of our cyclosporine capsule in Europe until 2004, this could have an adverse impact on our future revenues and results of operations. With respect to the FDA lawsuit, Novartis' requested relief would mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would harm revenues. The litigation, if not resolved favorably to us, could have a material adverse effect on the Company's business, financial condition, cash flows and results of operations. Currently, none of these lawsuits involves significant time, resources or expense. The U.K. regulatory litigation will require additional time and expense towards the end of 2001 or early 2002 as we prepare for the European Court of Justice hearing.

Liquidity and Capital Resources

During the first six months of 2001 and 2000, the net cash provided by continuing operating activities was approximately \$541,000 in 2001 and net cash used in continuing operating activities of approximately \$13,180,000 in 2000. The net cash provided by operating activities in the first six months of fiscal 2001 was due substantially to a reduction in other current assets due to the reclassification of \$5,000,000 to cash and cash equivalents. This cash had previously been treated as restricted since it served as collateral for the loan with FINOVA. However, the loan was repaid in June 2001 and the cash is no longer restricted. Other factors contributing to the net cash provided by

operating activities included an increase in accrued liabilities and a decrease in other receivables, offset by the net loss for the six months ended June 30, 2001. Net cash used in continuing operating activities during the first six months of 2000 was due to the net loss for the period and an increase in other current assets following the establishment of a collateral account for the FINOVA loan, partially offset by a reduction in inventories, and increases in accounts payable and accrued liabilities. For both periods presented, the cash used in the discontinued operation approximated the net loss of the discontinued operation. As of June 30, 2001, we had cash, cash equivalents and short-term investments of \$32,297,000 and total assets of \$115,286,000.

Net cash used in investing activities for the six months ended June 30, 2001 was \$2,781,000 as compared to \$1,553,000 for the same period in 2000. The amount in 2001 is primarily the result of an increase in other assets, purchases of property and equipment and short-term investments. In 2000, cash used was primarily due to purchases of property and equipment, partially offset by maturities of short-term investments.

Net cash provided by financing activities for the six months ended June 30, 2001 was \$10,273,000 as compared to \$20,707,000 for the same period in 2000. In both fiscal periods, cash provided by the sale of common stock was partially offset by the repayment of notes and capital lease obligations. In addition, we borrowed \$5,000,000 from FINOVA in 2000, which was repaid in June 2001. We completed two private placements in January and June 2001 for aggregate proceeds of \$18,999,485. In January 2001, we issued 421,000 shares of common stock with a group of institutional investors for aggregate proceeds of \$3,999,500 pursuant to an agreement signed in December 2000. In June 2001, we issued 1,363,635 shares of common stock with a group of institutional investors for aggregate proceeds of \$14,999,985. In both cases, the shares were issued at a discount to the closing market price on the date the agreements were signed. We intend to use the proceeds to fund working capital requirements and meet scheduled loan repayment obligations. In 2000, we issued 451,128 shares of common stock to an institutional investor in February 2000 for aggregate proceeds of \$15,000,006 and in December 2000, we issued 894,800 shares of common stock with a group of institutional investors for aggregate proceeds of \$8,500,600.

In April 2000, we signed an agreement with FINOVA Capital Corporation to provide a line of credit of up to \$30,000,000. The agreement was for three years. The line of credit consisted of two elements: a \$15,000,000 line of credit bearing interest at the prime rate and secured by a matching compensating cash balance, and a \$15,000,000 line of credit bearing interest at the prime rate plus 1.5% and based on eligible domestic accounts receivable and inventory. As additional security for the line of credit, we granted FINOVA a first priority security interest in certain of our tangible and intangible assets and have pledged the stock of our two French subsidiaries, IMTIX-SangStat SAS and SangStat Atlantique SA. The parties entered into an Amendment dated May 11, 2001, which provided that the Loan Agreement would terminate as of December 31, 2001, the portion of the line of credit collateralized by accounts receivable and inventory would be eliminated, and FINOVA would waive the existing default and all early termination penalties with respect to the Loan Agreement. Subsequently, we repaid the loan balance of \$5,000,000 on June 29, 2001, thereby terminating the Loan Agreement. Since the loan has been repaid, the \$5,000,000 compensating balance has been classified as cash.

In August 2000, we entered into a global co-development, supply and license agreement with Abgenix, Inc. for ABX-CBL, an antibody developed by Abgenix. We 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 \$1,000,000 and an additional payment to Abgenix of \$1,000,000 as partial reimbursement of one-half of the development costs incurred by Abgenix between January 1, 2000 and August 8, 2000. We will pay a further \$900,000 as reimbursement of these development costs in two equal installments at the end of June 2001 and 2002, the first of which installments has been paid. Development costs incurred after August 8, 2000 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. If ABX-CBL receives regulatory approval and is launched, we will be required to pay

Abgenix \$6,100,000 for our share of development expenses incurred prior to January 1, 2000, provided that we do not have any obligation to reimburse Abgenix until the first anniversary of the launch of ABX-CBL and the timing of reimbursement varies depending on ABX-CBL's sales.

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

#### Euro-Currency

The Single European Currency (Euro) was introduced on January 1, 1999 with complete transition to this new currency required by January 2002. We have 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 the European subsidiaries that are affected by the Euro from the national currency to the Euro, which became effective during fiscal year 2000. We expect to complete the conversion of all financial aspects of these subsidiaries by December 31, 2001.

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.

#### 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 June 30, 2001, our accumulated deficit was \$186.7 million. We have not yet had a profitable quarter. To become profitable and maintain profitability, we will have to increase revenues sufficient to cover current operating losses and expected increases in development costs as we move our pipeline products through the development process to approval.

To date, our product revenues have been primarily derived from sales of Thymoglobulin, Lymphoglobuline, and Gengraf. Revenues from Thymoglobulin were 69% and 60% of 1999 and 2000 total revenues from pharmaceutical products, respectively. Revenues from Lymphoglobuline were 19% and 12% of 1999 and 2000 total revenues from pharmaceutical products, respectively. Combined revenues of Thymoglobulin and Lymphoglobuline were 66% of 1998 total revenues from pharmaceutical products. 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 and 2000.

Our expectations with respect to achieving positive cash flows and financial reporting profitability are subject to much risk and uncertainty. Even if we do achieve positive cash flows or financial reporting profitability, we may not be able to maintain or increase our positive cash flows or financial reporting profitability on a quarterly or annual basis. Our ability to achieve positive cash flows and financial reporting profitability will be significantly dependent upon our success in:

- maintaining and increasing revenue from Thymoglobulin, Lymphoglobuline and Gengraf, particularly Thymoglobulin;
- successfully commercializing our product candidates, especially ABX-CBL;
- limiting our manufacturing and selling, general and administrative expenses; and
- controlling research and development expenses

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

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

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 financing 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 U.S. Our sales of Thymoglobulin began in the U.S. in February 1999. We began distributing Gengraf in May 2000. We are marketing Gengraf in the U.S. under a co-promotion agreement with Abbott Laboratories. Abbott may not effectively market Gengraf, and its failure to do so may adversely impact sales of these products.

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

- the timing of regulatory approval and market entry relative to competitive products;
- the availability of alternative therapies;
- perceived clinical benefits and risks;
- competitive changes;
- regulatory issues;
- ease of use;
- changes in the prescribing practices of transplant physicians;
- the availability of third-party reimbursement; or
- product liability claims.

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

- the price of our products relative to alternative therapies;
- manufacturing or supply interruptions; or
- competitive pressures from Novartis and Roche.

With respect to Gengraf and our generic capsules, the following factors may decrease revenue:

- perceptions of both patients and physicians regarding use of a generic version of a critical, life-saving therapeutic;
- perception of bioequivalence;
- number of contracts with managed care providers and group purchasing organizations;
- our recall of SangCya Oral Solution in July 2000 from the U.S. despite continued marketing in the U.K. and Germany;
- pricing pressure from other generic competitors;
- intense competitive pressure from Novartis; and
- Novartis's 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. We expect the FDA to inspect our Lyon facility again in October 2001 as part of its regular inspection process. 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 U.S., which would reduce our revenues. In addition, Thymoglobulin and Lymphoglobuline are biological products, which are more difficult to manufacture than chemical compounds. 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, a step in the manufacturing process which involves removing the water from the product, similar to freeze-drying. Aventis may not continue to effectively and continuously provide us these critical manufacturing services. In addition, we may have difficulties manufacturing Thymoglobulin or Lymphoglobuline in the future that may impair our ability to deliver products to our customers, which could reduce our revenues.

Although we use our own facilities, to manufacture Thymoglobulin and Lymphoglobuline, we rely on third parties to supply us with raw materials. These third parties may stop supplying us with the materials we need at any time, and we may have to find new suppliers. We have nine suppliers of rabbit serum used for the manufacturing of Thymoglobulin, but recently had a dispute with two of these suppliers. These two affiliated suppliers sued our French subsidiary, IMTIX-SangStat SAS, for breach of contract after we reduced our orders of rabbit serum from them. As a result of a court ruling against us in this lawsuit, IMTIX-SangStat recorded a charge to other expense - net of \$3,250,000 in the six months ended June 30, 2001 which, combined with reserves recorded in fiscal 2000, fully provide for the court award of \$3,600,000. Although we believe the ruling was in error and have appealed the decision, we may lose this appeal.

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

Our research, preclinical development, clinical trials, manufacturing, marketing and distribution of our products in the U.S. and other countries are subject to extensive regulation by numerous governmental authorities including, but not limited to, the FDA. In order to obtain regulatory approval of a drug product, we must demonstrate to regulatory agencies, among other things, that the product is safe and effective for its intended uses and that the manufacturing facilities are in compliance with Good Manufacturing Practices requirements. The process of obtaining FDA and other required regulatory approvals is lengthy and will require the expenditure of substantial resources, and we do not know if we will obtain the necessary approvals for our product candidates. Further, for our approved products, the marketing, distribution and manufacture of our products remains subject to extensive 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. We rely on Abbott and Gensia Sicor for the manufacture of Gengraf and SangCya Oral Solution. Fresenius Kabi France manufactures Celsior for us. 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, has entered into and is responsible for maintaining the manufacturing agreement with Lonza Biologics PLC, the third party manufacturer of this product candidate. Similarly, we rely on Accucaps Industries Limited to supply us with cyclosporine capsules and UCB S.A. to supply us with bulk RDP58 for research purposes. For some of our potential products, we will need to develop our production technologies further for use on a larger scale to conduct human clinical trials and produce such products for sale at an acceptable cost.

If our manufacturers fail to perform their obligations effectively and on a timely basis, these failures may delay clinical development or submission of products for regulatory approval, or once a product is approved, result in product shortages, any of which would impair our competitive position either because of the delays or because of a

loss of revenues. Additionally, because our manufacturers can only manufacture our products in facilities approved by the applicable regulatory authorities, we may not be able to replace our manufacturing capacity quickly or efficiently in the event that our manufacturers are unable to manufacture our products.

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

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

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

A substantial portion of demand for our products is from customers such as hospitals and pharmacies who purchase our products from wholesalers, McKesson HBOC and Cardinal Health Inc. Approximately 15% and 13%, respectively, of total revenues in 2000 were derived from sales to customers who place orders through these wholesalers. We expect that we will continue to derive a substantial portion of our revenue from McKesson HBOC and Cardinal Health for the foreseeable future. Difficulties in collecting from these wholesalers could harm our financial results. No other customer accounts for more than 10% of revenues.

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

We have significant amounts of bulk cyclosporine active ingredient inventory that we are not using to manufacture finished product in the amount anticipated. This inventory was originally purchased for use in cyclosporine finished products to be sold in the U.S. and Europe. However, since we are now distributing Gengraf in the U.S. and we have withdrawn SangCya Oral Solution from the U.S. market, we are dependent on the European market to use this inventory. We recalled SangCya Oral Solution from the U.S. in July 2000 in response to a study in healthy volunteers that identified that SangCya is not bioequivalent to Neoral oral solution when mixed with apple juice as recommended in its labeling. In addition, since our CycloTech product is only intended for use with the SangCya Oral Solution, we have discontinued the distribution of CycloTech in the U.S. 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 U.K. 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 U.S. 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 U.S. wholesalers in July 2000 and at the same time announced its withdrawal from the U.S. 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. Delayed approvals would lead to a delay in revenues from these products.

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. Our product liability insurance coverage is currently limited to \$25 million, which may not be adequate to cover potential liability exposures. In addition, adequate insurance coverage may not be available in the future at an acceptable cost, if at all, and a product liability claim could harm our results of operations.

We may be unable to attract or retain key personnel.

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

Failure to convert The Transplant Pharmacy's accounts receivable and inventory to cash may result in a loss recognition.

We closed the sale of The Transplant Pharmacy, or TTP, our mail order pharmacy business, on April 20, 2001. As of June 30, 2001, we had approximately \$1.5 million in accounts receivable, net of reserves and \$103,000 in inventory that we expect to convert to cash. If we are unable to return all of the inventory or if we have difficulties collecting accounts receivable, we may have to recognize a loss.

Our litigation with Novartis may be resolved adversely and could 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 U.S. and the U.K., which could potentially harm sales of Gengraf in the U.S. (due to the U.S. regulatory litigation which would impact the labeling for all generic cyclosporine products), and 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. The trial is scheduled for October 1, 2001. Novartis' complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the U.S. The course of litigation is inherently uncertain: Novartis may choose to name us in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to our interests. If Novartis names us in this suit, we may incur expenses before reimbursement, if any, by Abbott who is obligated under our agreement to indemnify us against such suits. Should Novartis succeed in obtaining a preliminary or permanent injunction, this injunction may temporarily or permanently remove Gengraf from the market. If Abbott or we were forced to remove Gengraf from the market before our co-promotion agreement with Abbott expires on December 31, 2004, our revenues would decrease materially.

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

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

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

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

We face substantial competition.

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 products address the problems associated with transplantation on which we have focused, they may represent significant competition.

Competitive products with respect to our key 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

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

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

Our stock price 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. For example, during 2000, the price of our common stock ranged from \$6.50 to \$48.00 per share. The stock market has from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. The market price for our common stock may fluctuate as a result of factors such as:

- announcements of new therapeutic products by us or our competitors;
- announcements regarding collaborative agreements;
- governmental regulations;
- our clinical trial results or clinical trial results from our competitors;
- 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 decrease the commercial potential of our products.

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. As a result, adequate third-party coverage may not be available for us to maintain price levels sufficient for realization of an appropriate return on our investment in product development. In certain foreign markets, pricing or profitability of healthcare products is subject to government control. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. In addition, an increasing emphasis on managed care in the U.S. has and will continue to increase the pressure on pharmaceutical pricing. While we cannot predict the adoption of any such legislative or regulatory proposals or the effect such proposals or managed care efforts may have on our business, the announcement of such proposals or efforts could harm our ability to raise capital, and the adoption of such proposals or efforts could harm our results of operations. Further, to the extent that such proposals or efforts harm other pharmaceutical companies that are our prospective corporate partners, this may

reduce our ability to establish corporate collaborations. In addition, third-party payers are increasingly challenging the prices charged for medical products and services. We do not know whether consumers, third-party payers and others will consider our products and product candidates, if approved, cost effective or that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive basis.

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

. In connection with our 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. As a result, we may 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, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our ability to pay.

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

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

- limit the right of stockholders to call special meetings of stockholders;
- limit the right of stockholders to present proposals, nominate directors for election or otherwise raise matters at annual meetings of stockholders without giving advance notice;
- eliminate the ability of stockholders to take action by written consent;
- prohibit cumulative voting in any election of directors, which may make it more difficult for a third party to gain control of our Board of Directors; and
- authorize our Board of Directors to issue up to five million shares of preferred stock in one or more series and to determine the price, rights, preferences, privileges, and restrictions of those shares without any further vote or action on the part of stockholders.

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

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

ITEM 3. Quantitative And Qualitative Disclosures About Market Risk

Reference is made to part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report on Form 10-K for the year ended December 31, 2000.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

Novartis Patent Litigation

Novartis vs. Abbott

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

U.S. Regulatory Litigation

Novartis U.S. sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia (case number 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis asks the court to (i) allow Novartis to keep its microemulsion labeling; (ii) declare microemulsion to be a separate dosage form; and (iii) rescind the AB rating that was given to SangCya Oral Solution. We intervened in this lawsuit. The 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 U.S. market in July 2000, we do not believe that this lawsuit will have any material impact on SangCya revenues but if the court declares microemulsion to be a separate dosage form, this ruling would rescind the AB rating for Gengraf, which would have a material impact on Gengraf revenues.

U.K. Regulatory Litigation - SangCya Oral Solution

On October 18, 1999, Novartis U.K. was granted leave to seek judicial review of the decision by the Medicines Control Agency (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"). No date has been set for the ECJ hearing, but it is likely to be scheduled sometime in late 2001 or early 2001, with a ruling approximately six months thereafter. Following the ECJ ruling, the parties would go back to the Court of Appeal, which will then apply the ECJ ruling on the law to the facts of this case.

#### U.K. Regulatory Litigation - Cyclosporine Capsules

In November 1999, Novartis filed a request with the High Court in London for judicial review of the refusal by MCA to state that it would not reference Neoral data in approving any 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 (May 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 U.K. High Court did not invalidate the SangCya Oral Solution marketing authorization, it does not acknowledge that the High Court ruled that the MCA could review the Neoral data. To the best of our knowledge, Novartis Italy has not filed suit against the Italian Health Authorities. The initial appearance of the parties before the Milan Tribunal was scheduled for January 2001. We filed our response to the complaint at that time, and the hearing 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 U.K. 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. On May 2, 2001, IMTIX-SangStat and we were notified that the Commercial Court of Lyon ruled against IMTIX-SangStat in the breach of contract suit and the court awarded the suppliers 26.5 million French Francs (approximately \$3.6 million) for lost profits and reimbursement of capital expenditures. IMTIX-SangStat recorded a charge of \$3,250,000 to other expense - net for the six months ended June 30, 2001, which, combined with reserves recorded in fiscal 2000, fully provide for the court award. IMTIX-SangStat believes that the ruling was in error and has appealed the decision. The hearing for the appeal is scheduled for November 2001.

The supply agreements provided that IMTIX-SangStat could reduce orders if it paid up to a maximum penalty of 3.8 million French Francs (approximately \$525,000). When IMTIX-SangStat reduced orders, the suppliers sued for breach of contract claiming that this provision didn't apply. The court agreed, holding that the penalty provision applied only in the first year of the agreements and since IMTIX-SangStat reduced orders in the second year of the agreements, it was liable for additional damages. IMTIX-SangStat maintains it should be able to invoke the penalty throughout the term of the agreements. IMTIX-SangStat's rabbit serum requirements are currently being met by its other suppliers.

#### ITEM 2. Changes In Securities And Use Of Proceeds

On June 20, 2001 we sold 450,000 shares of our common stock to S.A.C. Capital Associates, LLC, 330,000 shares of our common stock to Royal Bank of Canada, 330,000 shares of our common stock to Narragansett Offshore, Ltd., 170,000 shares of our common stock to Narragansett I, LP and 83,635 shares of our common stock to Société Générale. The shares were sold at a price of \$11.00 per share pursuant to an agreement entered into on June 20, 2001. The aggregate offering price was \$14,999,985 and was paid in cash. The shares sold in this offering from us in a private placement exempt from registration under the Securities Act of 1933 pursuant to the exemption from registration set forth in Section 4(2) of the Securities Act . This transaction did not involve an underwriter, underwriter's discount or commissions.

#### ITEM 3. Defaults Upon Senior Securities

None

#### ITEM 4. Submission Of Matters To A Vote Of Security Holders

We distributed our Definitive Proxy Statement, Proxy and Annual Report to Shareholders on or about May 11, 2001 to each stockholder of record as of April 16, 2001, for our Annual Meeting of Stockholders held June 13, 2001. At our Annual Meeting, the stockholders were asked to consider four proposals.

The first proposal involved the election of directors. The existing Board of Directors selected six nominees, all of whom ran unopposed and all of whom were then serving as our directors. The nominees of the Board, and the voting results with respect thereto, were:

Name	Votes For	Withheld
Jean-Jacques Bienaimé	12,558,934	3,058,497

Fredric Feldman	15,392,340	225,091
Elizabeth Greetham	15,391,630	225,801
Richard Murdock	15,392,570	224,861
Andrew Perlman	15,392,570	224,861
Vincent Worms	15,392,470	224,961

The second proposal was a proposal to amend and restate our 1993 Stock Option Plan to (i) increase the number of shares of Common Stock authorized for issuance thereunder by 250,000 shares and (ii) increase the number of shares of Common Stock authorized for issuance under the automatic annual increase program from 400,000 to 800,000 shares commencing January 1, 2002. The number of shares cast for, against and abstentions were 3,312,442, 7,684,067, and 11,228 respectively. The affirmative vote of a majority of the shares of Common Stock outstanding as of the record date was required for approval of this proposal. The percent of shares voted in favor of this proposal was 17% of the shares of Common Stock outstanding. Therefore, proposal two was not approved by the stockholders.

The third proposal was a proposal to amend and restate our 1996 Non-Employee Directors Stock Option Plan (the "Directors Plan"), to increase the number of shares of Common Stock automatically granted to directors annually from 4,000 to 8,000. The number of shares cast for, against and abstentions were 13,594,485, 2,012,548, and 10,398 respectively. The affirmative vote of a majority of the shares of Common Stock outstanding as of the record date was required for approval of this proposal. The percent of shares voted in favor of this proposal was 70% of the shares of Common Stock outstanding. Therefore, proposal three was approved by the stockholders.

The fourth and final proposal was the ratification of our independent auditors, Deloitte & Touche LLP, for the fiscal year ending December 31, 2001. The number of shares cast for, against, and the number of abstentions were 15,524,134, 86,592, and 6,705, respectively. The affirmative vote of a majority of the shares of Common Stock outstanding as of the record date was required for approval of this proposal. The percent of shares voted in favor of this proposal was 80% of the shares of Common Stock outstanding. Therefore, proposal four was approved by the stockholders.

#### ITEM 5. Other Information

None

#### ITEM 6. Exhibits and Reports on Form 8-K

(a) EXHIBITS - The following exhibits are attached hereto and filed herewith:

<u>Exhibits</u>	<u>Description</u>
10.39(1)	Securities Purchase Agreement dated as of June 20, 2001 between the Company and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, S.A.C. Capital Associates, LLC, and Société Générale
10.40(1)	



Registration Rights Agreement dated as of June 20, 2001 between the Company and Narragansett I. LP, Narragansett Offshore, Ltd., Royal Bank of Canada, S.A.C. Capital Associates, LLC, and Société Générale
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(1) Previously filed as an Exhibit to our Form 8-K filed June 21, 2001.

(b) We filed a Current Report on Form 8-K on April 5, 2001, April 23, 2001, May 2, 2001, May 4, 2001, and June 21, 2001.

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**SIGNATURES**

Pursuant to the requirements 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  
*(Registrant)*

Dated: August 14, 2001

By: /s/ Jean-Jacques Bienaimé

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Jean-Jacques Bienaimé  
*Chairman, CEO, & President*