SANGSTAT MEDICAL CORP
Form 10-Q
May 15, 2001

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

FORM 10-Q

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

For the quarterly period ended March 31, 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	**94-3076-069**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification Number)

6300 Dumbarton Circle
Fremont, California 94555
(Address of principal executive offices)

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

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 [X] NO [ ]

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

CLASS	NUMBER OF SHARES
Common Stock	19,478,055*

* As of April 30, 2001

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FORM 10-Q
For the Quarterly Period Ended March 31, 2001
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PART I. FINANCIAL INFORMATION

PART I -- FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2001	December 31, 2000
	(unaudited)	(1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,985	$ 19,046
Short-term investments	1,454	1,561
Accounts receivable (net of allowance for doubtful accounts of $3,514 in 2001 and $3,128 in 2000)	20,006	17,569
Other receivables	2,097	2,333
Inventories	38,488	40,056
Prepaid expenses and other current assets	7,784	6,912

Total current assets	84,814	87,477
PROPERTY AND EQUIPMENT -- net	6,104	6,539
INTANGIBLE ASSETS (net of accumulated amortization of $3,489 in 2001 and $3,141 in 2000)	10,794	11,142
OTHER ASSETS	6,923	9,158
TOTAL	$ 108,635	$ 114,316
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 14,848	$ 17,553
Accrued liabilities	17,192	13,938
Capital lease obligations -- current portion	174	257
Deferred revenue -- current portion	3,158	3,158
Notes payable -- current portion	12,551	12,797
Total current liabilities	47,923	47,703
CAPITAL LEASE OBLIGATIONS	454	535
DEFERRED REVENUE	8,685	9,475
NOTES PAYABLE	32,245	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 - 19,475 shares; 2000 - 18,942 shares	206,359	201,766
Accumulated deficit	(184,108)	(177,636)
Accumulated other comprehensive loss	(2,923)	(2,206)
Total stockholders' equity	19,328	21,924
TOTAL	$ 108,635	$ 114,316

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

See notes to Condensed Consolidated Financial Statements.

SANGSTAT MEDICAL CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31,	
	2001	2000
REVENUES:		
Net sales	$ 19,535	$ 11,216
Revenue from collaborative agreements	790	582
Total revenues	20,325	11,798
COSTS AND OPERATING EXPENSES:		
Cost of product sales and manufacturing	8,621	4,288
Research and development	4,545	3,978
Selling, general and administrative	8,725	9,896
Amortization of intangible assets	348	348
Total costs and operating expenses	22,239	18,510
Loss from continuing operations	(1,914)	(6,712)
OTHER EXPENSE - NET	(3,795)	(321)
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	(5,709)	(7,033)
INCOME TAX PROVISION	--	(61)
NET LOSS FROM CONTINUING OPERATIONS	(5,709)	(7,094)
NET LOSS FROM OPERATIONS OF DISCONTINUED OPERATION	(763)	(695)
NET LOSS	$ (6,472)	$ (7,789)
NET LOSS PER SHARE -basic and diluted (Note 2)		
Continuing operations	$ (0.29)	$ (0.40)
Discontinued operation	(0.04)	(0.04)
	$ (0.33)	$ (0.44)
Shares Used in Per Share Computations (Basic and diluted)	19,414	17,635

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

	Three Months Ended March 31,	
	2001	2000

Net loss	$ (6,472)	$ (7,789)
Unrealized gains and losses on marketable securities classified as available for sale in the current period	1	(642)
Foreign currency translation adjustments	(718)	(347)
Total comprehensive loss	$ (7,189)	$ (8,778)

See notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2001	2000
OPERATING ACTIVITIES:		
Net loss from continuing operations	$ (5,709)	$ (7,094)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	882	895
Non-cash interest expense	326	398
Loss on disposal of property and equipment	177	--
Deferred income taxes	--	94
Changes in assets and liabilities:		
Accounts receivable	(2,437)	220
Other receivables	236	1,558
Inventories	1,568	519
Prepaid expenses	(872)	(261)
Accounts payable	(2,705)	409
Accrued liabilities	3,254	1,228
Deferred revenue	(790)	(2,682)
Net cash used in continuting operating activities	(6,070)	(4,716)
Net cash used in discontinued operation	(763)	(695)
Net cash used in operating activities	(6,833)	(5,411)

INVESTING ACTIVITIES:		
Purchases of property and equipment	(276)	(437)
Maturities of short-term investments	358	1,893
Purchase of short-term investments	(250)	(913)
Other assets	2,235	(289)
Net cash provided by investing activities	2,067	254
FINANCING ACTIVITIES:		
Sale of common stock	4,593	16,622
Note payable borrowings	246	177
Note payable repayments	(3,252)	(1,951)
Repayment of capital lease obligations	(164)	(152)
Net cash provided by financing activities	1,423	14,696
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(718)	(347)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(4,061)	9,192
CASH AND CASH EQUIVALENTS, Beginning of period	19,046	16,862
CASH AND CASH EQUIVALENTS, End of period	$ 14,985	$ 26,054
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during the period for interest, net of interest capitalized	$ 1,782	$ 305
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Property acquired under capital leases	$ --	$ 631
Unrealized loss on investments	$ 1	$ (642)

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 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. 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 659,123 shares and 1,757,194 shares as of March 31, 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 March 31,	
	2001	2000
Net loss (numerator):		
Continuing operations	$ 5,709	$ 7,094
Discontinued operation	763	695
	$ 6,472	$ 7,789
Shares (denominator)		
Weighted average common shares outstanding	19,414	17,635
Net loss per share - basic and diluted		
Continuing operations	$ 0.29	$ 0.40
Discontinued operation	0.04	0.04
	$ 0.33	$ 0.44

3. *Comprehensive Loss*

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

	March 31, 2001	December 31, 2000
Unrealized gain (loss) on investments	$ 6	$ 6
Accumulated translation		

adjustments	(2,929)	(2,212)
Total.....	$ (2,923)	$ (2,206)

4. *Inventories*

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

	March 31, 2001	December 31, 2000
Raw materials.....	$ 18,855	$ 18,860
Work-in-progress.....	13,371	14,107
Finished goods.....	6,262	7,089
Total.....	$ 38,488	$ 40,056

5. *Notes Payable*

Notes payable consist of (in thousands):

	March 31, 2001	December 31, 2000
Note payable to Aventis.....	$ 12,000	15,000
Discount on note payable to Aventis.....	(1,403)	(1,707)
Convertible note.....	9,713	9,691
Note payable to Abbott Laboratories.....	16,000	16,000
Note payable to FINOVA.....	5,000	5,000
Other debt.....	3,486	3,492
Total.....	44,796	47,476
Less current portion.....	(12,551)	(12,797)
Long-term.....	$ 32,245	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). As of March 31, 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 have entered into an Amendment dated May 11, 2001, which provides 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. Because of this, the amount of $5 million payable to FINOVA and the corresponding $5 million compensating balance have been classified as short-term.

6. *Issuance of Common Stock*

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

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 will retain the inventory and accounts receivable related to the business and plans to convert these assets into cash during the next several months. 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. Revenue from discontinued operations was $4,199,000 and $4,142,000 for the three months ended March 31, 2001, and 2000, respectively. Net loss from the operations of TTP was $763,000, and $695,000 for the three months ended March 31, 2001 and 2000, respectively. 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, therefore no provision has been made in these condensed consolidated financial statements regarding the future operations of TTP.

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 products for patient monitoring and therapeutic products for preventing and treating organ rejection. The Company's segment information has been restated to reflect the results of such decision.

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 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 formally 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 Company is currently evaluating the impact of adopting the remaining provisions of SFAS No. 140, which will be effective for transactions entered into after March 31, 2001.

10. *Litigation*

Novartis Patent Litigation re Gengraf

Novartis has sued Abbott claiming that Gengraf® (cyclosporine capsule, USP, MODIFIED), infringes certain Novartis patents. Novartis' complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the US, but to date Novartis has not moved for a preliminary injunction. The trial date has been set for October 1, 2001. The discovery schedule is still before the court pending resolution of differences between the parties' proposals. Abbott has informed the Company that it does not believe it infringes the Novartis patents. The Company has not been named a defendant in this lawsuit, and under the Company's agreement with Abbott, Abbott is obligated to indemnify the Company against such suits. The course of litigation is inherently uncertain, however; Novartis may choose to name the Company in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to the Company's interests. Should the Company be named in this suit, the Company may incur expenses prior to reimbursement (if any) by Abbott pursuant to its indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, Gengraf may be temporarily or permanently removed from the market.

Novartis Regulatory Litigation

US Regulatory Litigation

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

UK Regulatory Litigation - SangCya Oral Solution

On October 18, 1999, Novartis UK was granted leave to seek judicial review of the decision by the Medicines Control Agency (the "MCA") to approve SangCya Oral Solution (Case No. HC- 1969/99). On March 30, 2000, the High Court in London dismissed Novartis' application for judicial review and ruled that the MCA acted properly in granting the SangCya Oral Solution marketing authorization. Novartis appealed the High Court's decision and the hearing was held before the Court of Appeal on November 13 and 14, 2000. The Court of Appeal has stayed ruling on this matter pending the answer of certain questions of law to be submitted to the European Court of Justice ("ECJ"). The Company estimates that the ECJ will issue its ruling in approximately eighteen to twenty four months. Following the ECJ ruling, the parties would go back to the Court of Appeal who will then apply the ECJ ruling on the law to the facts of this case.

UK Regulatory Litigation - Cyclosporine Capsules

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

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

Italian Regulatory/Trade Secret Litigation

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

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

Summary

The Company believes that these lawsuits are without merit and that it will prevail in these matters. Although the Company is optimistic that these disputes will ultimately be resolved in its favor, the course of litigation is inherently uncertain and there can be no assurance of a favorable outcome. With respect to Novartis' lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, the Company's revenues would be reduced. With respect to the regulatory and trade secret lawsuits, Novartis' requested relief, if granted, could have a negative economic impact on the Company depending on how the MCA would proceed with the Company's Marketing Authorization Application (MAA) for its capsule product. The MCA could approve the Company's MAA

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

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 to other expense - net of $3,148,000 in the three months ended March 31, 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 plans to appeal the decision.

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 in this Quarterly Report on Form 10-Q contains certain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. The cautionary statements made in this Quarterly Report on Form 10-Q should be read as being applicable to all related forward-looking statements wherever they appear in this Quarterly Report on Form 10-Q. 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.

Results of Operations - Three Months Ended March 31, 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 US headquarters are in Fremont, California. We also maintain a strong European presence, including direct sales and marketing forces in all major European markets and distributors throughout the rest of the world.

Our business is currently organized into two segments: Pharmaceutical Products and Transplantation Services. The Pharmaceutical Products segment consists of five marketed products, three principal product candidates and additional product candidates in various stages of research and development. The Transplantation Services segment consists of The Transplant Pharmacy (TTP). On April 5, 2001 we signed a binding agreement with Chronimed for the sale for cash of TTP. The transaction closed on April 20, 2001. Consequently, the historical consolidated statements of operations and cash flows have been restated for all periods presented to account for TTP as a discontinued operation. Unless otherwise indicated, the following discussion relates to our continuing operations.

In June 1998, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 133, *Accounting for Derivative Instruments and Hedging Activities*. This Statement requires companies to record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting. We adopted SFAS 133 effective January 1, 2001. 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.

Revenues.

Net sales of pharmaceutical products for the three months ended March 31, 2001 were $20,325,000, an increase of $8,527,000 or 72% over net sales of $11,798,000 for the three months ended March 31, 2000. The increase was due primarily to sales of Gengraf, which was launched in the US in May 2000, and increased sales of Thymoglobulin in both the US and overseas markets.

Included in net sales of pharmaceutical products was revenue from collaborative agreements of $790,000 for the three months ended March 31, 2001, an increase of $208,000 or 36% over revenue from collaborative agreements of $582,000 for the three months ended March 31, 2000. For both 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 the Company's 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 sales for pharmaceutical products were $8,621,000 for the three months ended March 31, 2001, an increase of $4,333,000 or 101% over cost of sales of $4,288,000 for the three months ended March 31, 2000. The increase in cost of sales was primarily due to the increase in sales of pharmaceutical products combined with the higher cost of Gengraf as compared to our other products.

Research and development

. Research and development expenses were $4,545,000 for the three months ended March 31, 2001, an increase of $567,000 or 14% over research and development expenses of $3,978,000 for the three months ended March 31, 2000. The increase in spending on research and development mainly relates to reimbursement of development costs for ABX-CBL totaling $1.1 million, 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 March 31, 2001 were $8,725,000, a decrease of $1,171,000 or 12% over selling, general and administrative expenses of $9,896,000 for the three months ended March 31, 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 March 31, 2001 was $3,795,000, compared to $321,000 for the three months ended March 31, 2000. The increase in other expense - net in the first three months of 2001 is attributable to:

- $3,148,000 charge related to a breach of contract suit;
- $437,000 gain on sale of marketable securities which was recognized in 2000;
- $260,000 net increase in unrealized foreign exchange losses; and
- $485,000 net increases in interest and other miscellaneous expenses.

These amounts were partially offset by an $856,000 reimbursement claim we received from a supplier.

Income taxes

. For the three months ended March 31, 2001, we recorded zero provision for European income taxes compared to $61,000 for the three months ended March 31, 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 March 31, 2001 was $5,709,000, a decrease of $1,385,000 or 20% compared to the net loss of $7,094,000 for the three months ended March 31, 2000. The decrease in net loss was due primarily to the increase in sales net of related cost of sales, partially offset by the provision of $3,148,000 for the breach of contract suit.

Net loss from operations of discontinued operation.

Net sales of transplantation services for the three months ended March 31, 2001 was $4,199,000, an increase of $57,000 or 1% over sales of $4,142,000 for the three months ended March 31, 2000. Net loss for transplantation services for the three months ended March 31, 2001 was $763,000, an increase of $68,000 or 10% compared to the net loss of $695,000 for the three months ended March 31, 2000.

Liquidity and Capital Resources

During the first three months of 2001 and 2000, the net cash used in continuing operating activities was approximately $6,070,000 and $4,716,000, respectively. The increase in net cash used in operating activities in the first three months of fiscal 2001 was due substantially to a reduction of accounts payable and an increase in accounts receivable, partially offset by a reduction in net inventories and an increase in accrued liabilities. The cash used in the discontinued operation approximated the net loss of the discontinued operation for the three months ended March 31, 2001 and 2000. As of March 31, 2001, we had cash, cash equivalents and short-term investments of $16,439,000 and total assets of $108,635,000.

Net cash provided by investing activities for the three months ended March 31, 2001 was $2,067,000 as compared to $254,000 for the comparable quarter in 2000. The amount in 2001 is primarily the result of the maturity of short-term investments and a decrease in other assets, partially offset by purchases of property and equipment. In 2000, cash provided was primarily by the maturity of short-term investments, partially offset by purchases of property and equipment and an increase in other assets.

Net cash provided by financing activities for the three months ended March 31, 2001 was $1,423,000 as compared to $14,696,000 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 January 2001, we completed a private placement of 421,000 shares of common stock with a group of institutional investors. The shares were issued at a discount to the closing market price on the date the agreements were signed, for aggregate proceeds of $3,999,500. We intend to use the proceeds to fund working capital requirements. In February 2000, we completed a private placement of 451,128 shares of common stock with an institutional investor. The stock was issued at $33.25, the closing price of the stock on February 14, 2000, for aggregate proceeds of $15,000,006.

In April 2000, we signed an agreement with FINOVA Capital Corporation to provide a line of credit of up to $30 million. The agreement is for three years and may be renewed annually thereafter if both parties agree. The line of credit consists of two elements: a $15 million line of credit bearing interest at the prime rate and secured by a matching compensating cash balance, and a $15 million line of credit bearing interest at the prime rate plus 1.5% and based on eligible domestic accounts receivable and inventory. As 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 have entered into an Amendment dated May 11, 2001, which provides 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.

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 million and an additional payment to Abgenix of $1 million as partial reimbursement of one-half of the development costs incurred by Abgenix between January 1, 2000 and August 8, 2000. We will pay a further $0.9 million as reimbursement of these development costs in two equal installments at the end of June 2001 and 2002. Development costs incurred after August 8, 2000 will be shared equally, as would any potential profits from future sales of collaboration products. We share responsibility for product development, including the ongoing clinical trial. Abgenix will be responsible for manufacturing ABX-CBL. We also have the right, subject to the terms and conditions of the agreement, to commercialize other anti-CD147 antibodies developed by Abgenix.

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 our two French subsidiaries from the French franc to the Euro, which became effective during the second quarter of 2000. We expect to convert the other European subsidiaries that are affected by the Euro within the next twelve months.

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

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 March 31, 2001, our accumulated deficit was $184,108,000. Our operating expenses from continuing operations have increased from approximately $50.1 million to $74.0 million to $103.2 million over the three year period ended December 31, 2000, and were approximately $22.2 million for the three months ended March 31, 2001. Total revenues from continuing operations have increased from approximately $11.3 million to $44.3 million to $63.1 million over the three year period ended December 31, 2000, and were approximately $20.3 million for the three months ended March 31, 2001, while losses from continuing operations have decreased from approximately $38.8 million to $29.7 million and increased to $40.0 million over the three year period ended December 31, 2000, and were approximately $5.7 million for the three months ended March 31, 2001. We cannot guarantee that we will ever achieve significant revenues from product sales or that we will achieve profitable operations. To date, our product revenues have been primarily derived from sales of Thymoglobulin, Lymphoglobuline, and Gengraf®.

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 constitute a dilution of your percent ownership of SangStat.

Our future growth depends on sales of key products.

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

Any factor adversely affecting the sales of Thymoglobulin, Lymphoglobuline, and Gengraf individually or together, or regulatory approval of our cyclosporine capsule product would harm our business and results of operations. The following factors could adversely affect the sale or approval of these products:

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

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

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

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

Our manufacturing facility in Lyon must meet FDA standards of Good Manufacturing Practices and other regulatory guidelines. The FDA and other regulatory authorities inspect our manufacturing facility to ensure that it meets regulatory standards. If the FDA believes that we are not complying with its guidelines, it can issue a warning letter or prevent the import of Thymoglobulin into the US, which would reduce our revenues. In addition, Thymoglobulin and Lymphoglobuline are biologics 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 experience manufacturing difficulties with respect to Thymoglobulin or Lymphoglobuline in the future that may impair our ability to deliver products to our customers, which could reduce our revenues and harm our business.

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

Our research, preclinical development, clinical trials, manufacturing, marketing and distribution of our products in the US and other countries are subject to extensive regulation by numerous governmental authorities including, but not limited to, the FDA. In order to obtain regulatory approval of a drug product, we must demonstrate to regulatory agencies, among other things, that the product is safe and effective for its intended uses and that the manufacturing facilities are in compliance with Good Manufacturing Practices requirements. The process of obtaining FDA and other required regulatory approvals is lengthy and will require the expenditure of substantial resources, and we do not know if we will obtain the necessary approvals for our product candidates. Moreover, for our approved products, the marketing, distribution and manufacture of our products remains subject to extensive regulatory requirements administered by the FDA and other regulatory bodies. Failure to comply with applicable regulatory requirements can

result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval, withdrawal of approvals and criminal prosecution of SangStat and our employees.

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

Except for Thymoglobulin and Lymphoglobuline, third parties manufacture all of our products and product candidates. There are three main risks associated with using third parties for manufacturing:

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

In addition, we may not be able to enter into commercial scale manufacturing contracts on a timely or commercially reasonable basis, or at all, for our product candidates. Abgenix, from whom we have licensed ABX-CBL, remains responsible for entering into and maintaining the manufacturing agreement with a third party for the manufacturing of this product candidate. For some of our potential products, we will need to develop our production technologies further for use on a larger scale to conduct human clinical trials and produce such products for sale at an acceptable cost.

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

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

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

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

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

delays could occur due to the following:

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

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

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

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

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

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

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

. Our ability to develop our business depends in part upon our attracting and retaining qualified management and scientific personnel. As the number of qualified personnel is limited, competition for such personnel is intense. We cannot assure you that we will be able to continue to attract or retain such people. The loss of our key personnel or the failure to recruit additional key personnel could significantly impede attainment of our objectives and harm our financial condition and results of operations.

Conversion of Accounts Receivable and Inventory to Cash from The Transplant Pharmacy may be difficult.

We closed the sale of The Transplant Pharmacy, or TTP, our mail order pharmacy business, on April 20, 2001. We have approximately $4 million in accounts receivable and $1 million 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 on the disposal of the business.

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

While we have settled our patent litigation with Novartis regarding SangCya Oral Solution, we are involved in litigation with Novartis in the US and the UK, which could potentially harm sales of Gengraf in the US (due to the US

regulatory litigation which would impact the labeling for all generic cyclosporine products), and SangCya Oral Solution and our cyclosporine capsule product candidates in Europe. The course of litigation is inherently uncertain and we may not achieve a favorable outcome. The litigation, whether or not resolved favorably to us, is likely to be expensive, lengthy and time consuming, and divert management's attention.

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

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

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

We continue to expand our operations, which places a strain upon our management, systems and resources. Our ability to compete effectively and to manage future growth, if any, will require us to continue to, on a timely basis, improve our financial and management controls, reporting systems and procedures and expand, train and manage an increasing number of employees. Our failure to do so would harm our results of operations.

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

Our success depends in part on our ability to obtain and enforce patent protection for our products and to preserve our trade secrets. We hold patents and pending patent applications in the US and abroad. Some of our patents involve specific claims and thus do not provide broad coverage. There can be no assurance that our patent applications or any claims of these patent applications will be allowed, be valid or enforceable. These patents or claims of these patents may not provide us with competitive advantages for our products. Our competitors may successfully challenge or circumvent our issued patents and any patents issued under our pending patent applications. We have not conducted extensive patent and art searches with respect to our product candidates and technologies, and we do not know if third-party patents or patent applications exist or filed in the US, Europe or other countries. This would have an adverse effect on our ability to market our products. We do not know if claims in our patent applications would be allowed, be valid or enforceable, or that any of our products would not infringe on others' patents or proprietary rights in the US or abroad. We also have patent licenses from third parties whose patents and patent applications are subject to the same risks as ours.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements with our employees and consultants. We cannot guarantee these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known or independently developed by competitors.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- announcements of new therapeutic products by us or our competitors;
- announcements regarding collaborative agreements;
- governmental regulations;
- clinical trial results;
- developments in patent or other proprietary rights;
- public concern as to the safety of drugs developed by us or others;
- comments made by securities analysts; and
- general market conditions.

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

. Our ability to successfully commercialize our products may depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. The pricing, availability of distribution channels and reimbursement status of newly approved healthcare products is highly uncertain and we cannot assure you that adequate third-party coverage will be available for us to maintain price levels sufficient for realization of an appropriate return on our investment in product development. In certain foreign markets, pricing or profitability of healthcare products is subject to government control. In the US, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. In addition, an increasing emphasis on managed care in the US has and will continue to increase the pressure on pharmaceutical pricing. While we cannot predict whether any such legislative or regulatory proposals will be adopted or the effect such proposals or managed care efforts may have on our business, the announcement of such proposals or efforts could harm our ability to raise capital, and the adoption of such proposals or efforts could harm our results of operations. Further, to the extent that such proposals or efforts harm other pharmaceutical companies that are our prospective corporate partners, our ability to establish corporate collaborations may be adversely affected. In addition, third-party payers are increasingly challenging the prices charged for medical products and services. We do not know whether our products and product candidates, if approved, will be considered cost effective or that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive basis.

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

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

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

Certain provisions of our Certificate of Incorporation and our Bylaws could delay or make more difficult a merger, tender offer or proxy contest, which could adversely affect the market price of our common stock. Our board of directors has the authority to issue up to 5 million shares of preferred stock and to determine the price, rights preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock. Further, we have adopted a stockholder rights plan. Under this plan we may issue a dividend to stockholders who hold rights to acquire our shares or, under certain circumstances, an acquiring corporation, at less than half their fair market value. The plan could have the effect of delaying, deferring or preventing a change in control. In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which will prohibit us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The application of Section 203 also could have the effect of delaying or preventing a change of control.

ITEM 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 has sued Abbott claiming that Gengraf® (cyclosporine capsule, USP, MODIFIED), infringes certain Novartis patents. Novartis' complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the US, but to date they have not moved for a preliminary injunction. The trial date has been set for October 1, 2001. The discovery schedule is still before the court pending resolution of differences between the parties' proposals. Abbott has informed us that it does not believe it infringes the Novartis patents. We have not been named a defendant in this lawsuit, and under our agreement with Abbott, Abbott is obligated to indemnify us against such suits. The course of litigation is inherently uncertain, however; Novartis may choose to name us in this suit, Abbott may not prevail, or Abbott may

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

Novartis Regulatory Litigation

US Regulatory Litigation

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

UK Regulatory Litigation - SangCya Oral Solution

On October 18, 1999, Novartis UK was granted leave to seek judicial review of the decision by the Medicines Control Agency (the "MCA") to approve SangCya Oral Solution (Case No. HC- 1969/99). On March 30, 2000, the High Court in London dismissed Novartis' application for judicial review and ruled that the MCA acted properly in granting the SangCya Oral Solution marketing authorization. Novartis appealed the High Court's decision and the hearing was held before the Court of Appeal on November 13 and 14, 2000. The Court of Appeal has stayed ruling on this matter pending the answer of certain questions of law to be submitted to the European Court of Justice ("ECJ"). We estimate that the ECJ will issue its ruling in approximately eighteen to twenty four months. Following the ECJ ruling, the parties would go back to the Court of Appeal who will then apply the ECJ ruling on the law to the facts of this case.

UK Regulatory Litigation - Cyclosporine Capsules

In November 1999, Novartis filed a request with the High Court in London for judicial review of the refusal by MCA to state that it would not reference Neoral data in approving any cyclosporine capsule application. An agreement was reached between the parties in which Novartis agreed to stay the judicial review until the earlier of (i) the decision on the judicial review of SangCya Oral Solution or (ii) MCA's approval of a marketing authorization for a cyclosporine capsule product, and in return, we agreed that we would not launch or commence mutual recognition procedures in relation to the cyclosporine capsule marketing authorization (including a request to MCA to prepare an assessment report) for a period of 28 days commencing on the day on which we notify Novartis' solicitors of capsule approval. The parties had agreed to continue the stay until the appeal of the High Court decision with respect to the judicial review of SangCya Oral Solution. The stay of this application for judicial review will remain in place pending the ECJ ruling on the questions of law and resulting Court of Appeal judgment.

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

exclusivity period for Neoral capsules (approximately 2004).

Italian Regulatory/Trade Secret Litigation

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

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

Breach of Contract Suit

In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes, sued our French subsidiary, IMTIX-SangStat SAS, for breach of contract. 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 to other expense - net of $3,148,000 in the three months ended March 31, 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 plans to appeal the decision.

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 January 5, 2001 we sold 210,500 shares of our common stock to S.A.C. Capital Associates, LLC and 210,500 shares of our common stock to SDS Merchant Fund, LP at a price of $9.50 per share pursuant to an agreement entered into on December 29, 2000. The aggregate offering price was $3,999,500 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

None

ITEM 5. Other Information

None

ITEM 6. Exhibits and Reports on Form 8-K

(a) EXHIBITS - The following exhibit is attached hereto and filed herewith:

Exhibits	Description
10.38	First Amendment to Loan and Security Agreement between us and Finova Capital Corporation dated as of May 11, 2001

(b) We filed a Current Report on Form 8-K on January 8, 2001 and February 27, 2001.

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: May 15, 2001

By: /s/ STEPHEN G. DANCE

Stephen G. Dance
Senior Vice President, Finance
(Principal Financial Officer)