SANGSTAT MEDICAL CORP
Form 10-Q
May 14, 2003

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, 2003

OR

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

Commission File Number: 0-22890

SANGSTAT MEDICAL CORPORATION

(Exact name of registrant as specified in its charter)

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

6300 Dumbarton Circle, Fremont, California 94555

(Address of principal executive offices, including zip code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

x Yes o No

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

x Yes o 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	26,463,055*

* As of April 30, 2003

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PART I. FINANCIAL INFORMATION

SANGSTAT MEDICAL CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except par values)

	March 31, 2003	December 31, 2002 (1)
	(unaudited)	
ASSETS		

CURRENT ASSETS:		
Cash and cash equivalents	$ 74,203	$ 85,412
Short-term investments	20,386	12,100
Accounts receivable (net of allowances of $4,077 in 2003 and $4,150 in 2002)	22,864	22,847
Other receivables	2,622	1,948
Inventories	24,412	27,161
Prepaid expenses and other current assets	6,927	7,501
Total current assets	151,414	156,969
PROPERTY AND EQUIPMENT -- net	5,645	5,824
INVESTMENT IN AFFILIATE	2,632	3,036
INTANGIBLE ASSETS (net of accumulated amortization of $4,500 in 2003 and $4,250 in 2002)	7,392	7,642
OTHER ASSETS	18,792	18,966
TOTAL	$ 185,875	$ 192,437
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 17,217	$ 22,447
Accrued liabilities	12,532	13,485
Capital lease obligations -- current portion	240	235
Deferred revenue -- current portion	3,158	3,158
Notes payable -- current portion	11,843	4,114
Total current liabilities	44,990	43,439
CAPITAL LEASE OBLIGATIONS	436	448
DEFERRED REVENUE	2,368	3,158
NOTES PAYABLE	5,493	15,472
STOCKHOLDERS EQUITY:		
Preferred stock, $.001 par value 5,000 shares authorized; none outstanding		
Common stock. $.001 par value, 40,000 shares authorized; outstanding: 2003, 26,463 shares; 2002, 26,443 shares	310,608	310,495
Accumulated deficit	(178,842)	(180,666)
Accumulated other comprehensive income	822	91
Total stockholders equity	132,588	129,920
TOTAL	$ 185,875	$ 192,437

(1) Derived from the Company s audited consolidated financial statements at December 31, 2002.

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,	
	2003	**2002**
REVENUES:		
Net product sales	$ 28,738	$ 23,355

Revenue from collaborative agreements	790	789
Total revenues	29,528	24,144
COSTS AND OPERATING EXPENSES:		
Cost of product sales	13,684	10,623
Research and development	4,426	4,318
Selling, general and administrative	9,252	7,953
Amortization of intangible assets	250	250
Total costs and operating expenses	27,612	23,144
Income from operations	1,916	1,000
OTHER INCOME - NET	734	111
EQUITY IN NET LOSS OF AFFILIATE	(404)	
Income from operations before income taxes	2,246	1,111
INCOME TAX PROVISION	422	433
NET INCOME	$ 1,824	$ 678
NET INCOME PER COMMON SHARE - BASIC	$ 0.07	$ 0.03
NET INCOME PER COMMON SHARE - DILUTED	$ 0.07	$ 0.03
Shares Used in Per Share Computations - Basic	26,445	24,032
Shares Used in Per Share Computations - Diluted	26,521	24,766

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

	Three Months Ended March 31,	
	2003	**2002**
Net income	$ 1,824	$ 678
Unrealized gains and losses on marketable securities classified as available for sale in the current period	36	
Foreign currency translation adjustments	695	(111)
Total comprehensive income	$ 2,555	$ 567

See notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2003	**2002**
OPERATING ACTIVITIES:		

Net income	$ 1,824	$ 678
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	693	634
Non-cash interest expense	111	210
Equity in net loss of affiliate	404	
Loss on disposal of property and equipment	49	7
Changes in assets and liabilities:		
Accounts receivable	(17)	(826)
Other receivables	(674)	(1,719)
Inventories	2,749	201
Prepaid expenses and other current assets	574	548
Accounts payable	(5,230)	1,396
Accrued liabilities	(953)	(1,120)
Deferred revenue	(790)	(789)
Net cash used in operating activities	(1,260)	(780)
INVESTING ACTIVITIES:		
Purchases of property and equipment	(239)	(442)
Maturities of short-term investments	12,100	
Purchases of short-term investments	(20,350)	
Other assets	174	262
Net cash used in investing activities	(8,315)	(180)
FINANCING ACTIVITIES:		
Sale of common stock	113	87,201
Notes payable borrowings		156
Notes payable repayments	(2,361)	(10,550)
Repayment of capital lease obligations	(7)	(51)
Net cash (used) provided by financing activities	(2,255)	76,756
EFFECT OF EXCHANGE RATE CHANGES ON CASH	621	(78)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(11,209)	75,718
CASH AND CASH EQUIVALENTS, Beginning of period	85,412	32,822
CASH AND CASH EQUIVALENTS, End of period	$ 74,203	$ 108,540
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during the period for interest	$ 788	$ 449

See notes to Condensed Consolidated Financial Statements

SANGSTAT MEDICAL CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. ***Basis of Presentation***

The condensed consolidated financial statements include the accounts of SangStat Medical Corporation and its wholly owned subsidiaries (the Company). 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 only of normal recurring adjustments) necessary for a fair presentation of the financial condition and results of operations as of and for the interim periods presented. These condensed consolidated financial statements should be read in conjunction with the Company s audited consolidated financial statements for the year ended December 31, 2002 and notes thereto included in the Company s 2002 Annual Report on Form 10-K filed with the SEC on March 26, 2003. The results of operations for the first quarter 2003 are not necessarily indicative of the results to be expected for any other interim period or for the year ending December 31, 2003.

2. ***Net Income Per Share***

Basic EPS excludes dilution and is computed by dividing net income by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted into common stock. For the three months ended March 31, 2003 and 2002 common share equivalents for stock options aggregating 75,475 and 734,045, as determined using the treasury stock method, are included in the diluted EPS calculation.

The following table presents the calculation of the basic and diluted net income per share (amounts in thousands, except per share amounts):

	Three Months Ended March 31,	
	2003	**2002**
Net income	$ 1,824	$ 678
Basic:		
Weighted average number of common shares outstanding	26,445	24,032
Diluted:		
Weighted average number of common shares outstanding	26,445	24,032
Common share equivalents - stock options	76	734
Weighted average number of common shares and common share equivalents	26,521	24,766
Basic net income per share	$ 0.07	$ 0.03
Diluted net income per share	$ 0.07	$ 0.03

3. ***Accumulated Other Comprehensive Income***

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

	March 31, 2003	**December 31, 2002**
Unrealized gain (loss) on investments	$ 30	$ (6)
Accumulated translation adjustments	792	97
Total	$ 822	$ 91

4. ***Inventories***

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

	March 31, 2003	December 31, 2002
Raw materials	$ 1,093	$ 830
Work in process	17,283	16,896
Finished goods	6,036	9,435
Total	$ 24,412	$ 27,161

In addition to these inventories, the Company has classified at March 31, 2003 and December 31, 2002 approximately $17,527,000 of raw materials inventory as other assets in the accompanying condensed consolidated balance sheets as it is not expected that any significant portion of the inventory will be utilized in operations during the next twelve months.

5. ***Notes Payable***

Notes payable consist of (in thousands):

	March 31, 2003	December 31, 2002
Note payable to Aventis	$ 2,000	$ 4,000
Discount on note payable to Aventis	(89)	(176)
Convertible note	9,898	9,874
Note payable to Abbott Laboratories	5,000	5,000
Other debt	527	888
Total	17,336	19,586
Less current portion	(11,843)	(4,114)
Long-term	$ 5,493	$ 15,472

6. Stock-Based Compensation

The Company has stock-based compensation plans under which stock options are granted to employees and directors at the market price on the date of grant. Grants were issued during the three months ended March 31, 2003 under these stock-based compensation plans. Pursuant to SFAS No. 123, Accounting for Stock-Based Compensation, the Company has elected to account for its employee stock option plans under APB Opinion No. 25, Accounting for Stock Issued to Employees, which recognizes expense based on the intrinsic value at date of grant. As stock options have been issued with exercise prices equal to grant date fair value, no compensation cost has resulted. Had compensation cost for all options granted been determined based on the fair value at grant date consistent with SFAS No. 123, the Company s net earnings and earnings per share would have been as follows:

	Three Months Ended March 31,	
	2003	2002
Net earnings:		
Net income - as reported	$ 1,824	$ 678
Stock option compensation expense	(198)	(507)
Net income - pro forma	$ 1,626	$ 171
Net earnings per common share:		

Basic net income per share - as reported	$	0.07	$	0.03
Diluted net income per share- as reported	$	0.07	$	0.03
Basic net income per share - pro forma	$	0.06	$	0.01
Diluted net income per share- pro forma	$	0.06	$	0.01

7. ***Recently Issued Accounting Pronouncements***

In July 2001, the FASB issued SFAS No.143, *Accounting for Asset Retirement Obligations*. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development, and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The provisions of SFAS No. 143 were effective for fiscal years beginning after June 15, 2002. The Company has adopted the provisions of SFAS No. 143. Adoption of this statement did not have an impact on the Company s financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated With Exit or Disposal Activities.* SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3 *Liability Recognition for Certain Employer Termination Benefits and other Costs to an Exit Activity (Including Certain Costs in a Restructuring).* SFAS No. 146 requires that the liability for costs associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue No. 94-3, a liability for an exit cost was recognized at the date of the Company s commitment to an exit plan. SFAS No.146 also establishes that the liability should initially be measured and recorded at fair value. The Company adopted the provisions of SFAS No. 146 for restructuring activities initiated after December 31, 2002.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation* to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*, to require more prominent disclosures about the method of accounting for stock-based employee compensation and the effect of the method used on reported results in both annual and interim financial statements. The Company adopted the disclosure provisions of SFAS No. 148 for its fiscal year ended December 31, 2002 and quarter ended March 31,2003.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 requires that upon issuance of a guarantee, a guarantor must recognize a liability for the fair value of an obligation assumed under a guarantee. FIN 45 also requires additional disclosures by a guarantor in its interim and annual financial statements about the obligations associated with guarantees issued. The recognition provisions of FIN 45 are effective for any guarantees issued or modified after December 31, 2002. The disclosure requirements were effective for financial statements of interim or annual periods ending after December 15, 2002. The Company has adopted the disclosure requirements for its financial statements for the period ended December 31, 2003. Adoption of the recognition provisions of FIN 45 did not have an impact on the Company s financial position or results of operations.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*. FIN 46 requires that the assets, liabilities and results of the activity of variable interest entities be consolidated into the financial statements of the company that has controlling

financial interest. It also provides the framework for determining whether a variable interest entity should be consolidated based on voting interest or significant financial support provided to it. This Interpretation is effective July 1, 2003. The Company is currently evaluating the effects of FIN 46, however the adoption of this statement is not expected to have an impact on the Company s financial position or results of operations.

8. ***Litigation***

Novartis Patent Litigation with Respect to Gengraf

Novartis sued Abbott in United States District Court in Delaware claiming that Gengraf® infringes its patents. While a judgment was entered finding that Gengraf infringed one of the Novartis patents on August 19, 2002 the judge reversed the judgment and ruled that Abbott had not infringed the Novartis patents on March 27, 2003. Novartis is appealing the decision. The Company has not been named a defendant in this lawsuit. Under the Company s agreement with Abbott, Abbott is obligated to indemnify the Company against such suits, but their indemnity may not cover lost sales, if any. The course of litigation is inherently uncertain. Novartis may choose to sue the Company directly, Abbott may not prevail on appeal, Abbott may elect to withdraw Gengraf from the market or Abbott may choose to settle on terms adverse to the Company s

interests. Should the Company be sued by Novartis, it 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, Abbott and the Company may be forced or elect to remove Gengraf from the market before the Company s co-promotion agreement with Abbott expires on December 31, 2004, the Company s customers might return unsold inventory to the Company for credit or refund and the Company could then be holding inventory of Gengraf that it may be unable to sell. In that event, the Company s revenues would decrease significantly and its operating results would be materially adversely affected. The Company might also be required to write-off all or a portion of its Gengraf inventory.

Novartis Regulatory Litigation

U.S. Regulatory Litigation. Novartis U.S. sued the Food and Drug Administration or FDA on February 11, 1999 in the United States District Court for the District of Columbia alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis initially asked the Court to (i) allow Novartis to keep its microemulsion labeling; (ii) declare microemulsion to be a separate dosage form; and (iii) rescind the AB rating that was given to SangCya Oral Solution. The Company intervened in this lawsuit. The Court granted the Company s motion to dismiss the counts that relate specifically to the approval of SangCya Oral Solution, but Novartis may appeal this decision. The Company remains a party in the case. On July 11, 2002, the judge ordered Novartis, the FDA and the Company to file motions for summary judgment and set a schedule for briefs to be filed through December 20, 2002. The Company permanently withdrew SangCya Oral Solution from the U.S. market in July 2000, and receives no revenue from SangCya, but if the court were to declare microemulsion to be a separate dosage form, this ruling would require rescission of the AB rating for Gengraf, which would have a material adverse effect on its Gengraf revenues.

U.K. Regulatory Litigation SangCya Oral Solution. On October 18, 1999, Novartis U.K. was granted leave to seek judicial review of the decision by the Medicines Control Agency, or MCA, to approve SangCya Oral Solution. On March 30, 2000, the High Court in London dismissed Novartis s application for judicial review and ruled that the MCA acted properly in granting the SangCya Oral Solution marketing authorization. Novartis appealed the High Court s decision, and the hearing was held before the Court of Appeal on November 13 and 14, 2000. The Court of Appeal has stayed ruling on this matter pending the answer of certain questions of law to be submitted to the European Court of Justice, or ECJ. The ECJ hearing was held on November 7, 2002, and the Advocate General issued an opinion in January 2003. The Company expects the ECJ s decision approximately six to twelve months thereafter. Following the ECJ ruling, the parties would go back to the Court of Appeal, which will then apply the ECJ ruling on the law to the facts of this case. The Company no longer markets SangCya Oral Solution, but the outcome of the case may affect the timing of regulatory approvals for its cyclosporine capsule product.

U.K. Regulatory Litigation Cyclosporine Capsules. In November 1999, Novartis filed a request with the High Court in London for judicial review of the refusal by MCA to state that it would not reference Neoral data in approving any generic copies of Novartis s cyclosporine capsule. An agreement was reached between the parties in which Novartis agreed to stay the judicial review until the earlier of (i) the decision on the judicial review of SangCya Oral Solution or (ii) MCA s approval of SangStat s marketing authorization for its cyclosporine capsule product; in return, the Company agreed that it would not launch or commence mutual recognition procedures in relation to the cyclosporine capsule marketing authorization (including a request to MCA to prepare an assessment report) for a period of 28 days commencing on the day on which the Company notifies Novartis s solicitors of capsule approval. The parties have agreed to continue the stay until the appeal of the High Court decision with respect to the judicial review of SangCya Oral Solution. The stay of this application for judicial review will remain in place pending the ECJ ruling on the questions of law and subsequent 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 oral solution. Because the High Court ruled in favor of the MCA with respect to the SangCya Oral Solution marketing authorization and the Court of Appeal has referred questions of law to the ECJ, the Company believes that it is unlikely that a court would grant Novartis a preliminary injunction with respect to its cyclosporine capsule marketing authorization. If the Court of Appeals reverses the High Court s ruling following the ECJ s decisions on questions of law, either the MCA could still approve the cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve the Company s cyclosporine capsule marketing authorization until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004).

Italian Regulatory/Trade Secret Litigation. On May 5, 2000, Novartis Farma S.p.a. (Novartis Italy) served IMTIX-SangStat S.r.l., an Italian SangStat subsidiary, and IMTIX-SangStat Ltd. with a summons to the Milan Tribunal in a lawsuit concerning our application for approval by the Italian Health Authorities of the SangCya Oral Solution. In December 2002, Novartis Italy agreed to withdraw the lawsuit and the Company agreed not to file for approval of a cyclosporine oral solution before May 2004. Consequently, the Company does not expect any adverse consequences from this lawsuit.

IFFA CREDO and Elevage Scientifique des Dombes Breach of Contract Suit

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In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes (ESD), sued the Company s French subsidiary, IMTIX-SangStat SAS, for breach of contract in the Commercial Court of Lyon, France. The suppliers won in the trial court and appeals court and the Company paid approximately $3.6 million in damages plus interest. IMTIX-SangStat recorded charges of $3,250,000 and $204,000 to other expense net for the year ended December 31, 2001, which, combined with reserves recorded in fiscal 2000, fully provided for the court award. The Company appealed the case to the French Cours de Cassation. In March 2003, the Company settled the lawsuit in return for a payment by IFFA CREDO and ESD of 800,000 Euros (approximately $864,000) and this amount is recorded in other income (expense) net. The Company received these amounts in April 2003.

Summary

The course of litigation is inherently uncertain. With respect to Novartis s lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds despite the recent ruling of non-infringement, the loss of Gengraf sales would have a significant and material adverse effect on the Company s business and operating results. The Company might also be required to write-off all or a portion of its cyclosporine inventory. With respect to the European regulatory lawsuits, Novartis s requested relief, if granted, could have a material adverse effect on the Company if the European Court of Justice ruling prevents the Company from filing for marketing authorization of its cyclosporine capsule product currently under development until after the expiration of the data exclusivity period for Novartis Neoral cyclosporine product. (That data exclusivity period expires in May 2004 for most European countries, including Germany, France, Italy and the United Kingdom.) If the Company cannot obtain approval of its cyclosporine capsule in Europe until 2004, this could have a material adverse impact on the Company s future operating results because of (i) the loss of potential revenue and (ii) the need to write-off some or all of its bulk cyclosporine inventory. With respect to the FDA lawsuit, Novartis s requested relief, if granted could mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would have a material adverse effect on the Company. Currently, none of the foregoing litigation matters require the Company to expend significant time or expense.

9. Subsequent Event

Effective April 1, 2003, the Company and Abbott Laboratories agreed to amend their co-promotion agreement for Gengraf for the remaining 21 months of its term. The amendment relieves Abbott of its obligations to provide physician details and maintain a minimum number of managed care organization account representatives. SangStat will continue to provide physician details but is relieved of its obligation to maintain a minimum number of sales representatives. In addition, SangStat will assume sole responsibility for all Gengraf marketing and promotional expenses, which were previously shared by both companies, and Abbott will pay a quarterly fee to SangStat if certain sales thresholds are met.

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

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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, 2002. Except for the historical information contained herein, the discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to the safe harbor created by those sections. The forward-looking statements are based on the Registrant s current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as may, will, should, could, predicts, potential, continue, expects, anticipates, future, intends, plans, believes, estimates, and similar expressions. In particular, we have included forward-looking statements regarding the following: (i) our anticipated financial results for 2003; (ii) the timeline and potential results of preclinical development and clinical trials; (iii) the timeline and potential outcomes of our pending litigation; (iv) our plans for marketing a cyclosporine capsule in Europe; (v) anticipated expenditures and timing relating to FDA and foreign approval of our products and facilities; and (vi) anticipated potential strategic collaborations with others. These forward-looking statements are made as of the date of this Report on Form 10-Q. These forward-looking statements are based on current beliefs, expectations and assumptions and involve certain risks and uncertainties that could cause actual results, levels of activity, performance, achievements and events to differ materially from those implied by such forward-looking statements. The cautionary statements made in this Report on Form 10-Q should be read as being applicable to all related forward-looking statements wherever they appear. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those discussed in Risk Factors, as well as those discussed elsewhere herein. The Registrant disclaims any obligation to update these forward-looking statements.

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

Our primary marketed product, Thymoglobulin, a treatment for acute rejection of a kidney transplant, was launched in the U.S. in February 1999. Thymoglobulin achieved worldwide sales of $37.9 million in 2000, $51.4 million in 2001 and $69.5 million in 2002. The success of Thymoglobulin and its potential in areas beyond solid organ transplantation have provided us with the ability to examine and develop new therapeutic opportunities outside of transplantation.

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

On November 8, 2002, we entered into a strategic collaboration with Therapeutic Human Polyclonals, Inc. (THP) to develop and commercialize humanized polyclonal antibodies. Humanized polyclonal antibodies build upon the current clinical successes of humanized monoclonal antibodies. Our financial commitments to THP under the collaboration agreements

consist of product licensing fees, clinical milestone payments and royalties. As part of the transaction, we made an equity investment in THP of $3.2 million, with a commitment to invest an additional $3.2 million if certain technical milestones are met. These two equity investments are co-investments with Research Corporation Technologies, a technology management company. We also have an option to make a substantial additional equity investment in THP as its technology matures.

Critical Accounting Policies

In December 2001, the SEC issued Financial Reporting Release No. 60, Cautionary Advice Regarding Disclosure About Critical Accounting Policies, or FR 60, suggesting that companies provide additional disclosure and commentary on those accounting policies considered most critical. FR 60 considers an accounting policy to be critical if it is important to a company s financial condition and results and requires significant judgment and estimates on the part of management in its application. Our critical accounting estimates and the related assumptions are evaluated periodically as conditions warrant, and changes to such estimates are recorded as new information or changed conditions require revision. Application of the critical accounting policies requires management s significant judgments, often as the result of the need to make estimates of matters that are inherently uncertain. If actual results were to differ materially from the estimates made, the reported results could be materially affected. Our senior management has reviewed these critical accounting policies and estimates with our audit committee. We believe that the following represents our critical accounting policies as contemplated by FR 60.

Revenue Recognition

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

Revenue from sales of Gengraf, which we co-promote with Abbott Laboratories, is recorded on a gross basis, in accordance with Emerging Issues Task Force Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent.* Abbott s share of the gross profit, as defined, resulting from the sale is recorded as cost of product sales.

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

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market. We classify inventory not expected to be utilized within the next twelve months as long-term assets. We evaluate our inventory levels based on our estimates of marketing approval and forecasts of future sales, among other things. If these estimates or forecasts change at some time in the future we may be required to record additional charges for the write-down of excess or obsolete inventories. At March 31, 2003 we classified approximately $17.5 million of bulk cyclosporine raw materials inventory, net of reserves, as other long-term assets. We filed for marketing approval of the cyclosporine capsule product in a European country in January 2003. We intend to follow the European Community Mutual Recognition Procedure for obtaining marketing authorization in multiple member states following initial approval and to launch in these countries shortly after obtaining approval. The use of such inventory is dependent upon the successful approval and launch of the cyclosporine capsule in the major European markets.

Foreign currency gains and losses

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

Income taxes

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

We have substantial deferred tax assets that relate to prior-period losses, primarily in the United States. We evaluate these deferred tax assets in each tax jurisdiction by estimating the likelihood of generating future profits to realize these assets. In most cases, we have assumed that we will not be able to generate sufficient future taxable income to realize these assets and have created valuation reserves to reduce the net asset values to zero. If these estimates and assumptions change in the future, we may be required to record additional valuation allowances against the net deferred tax assets resulting in additional income tax expense in our consolidated statement of operations. Conversely, we may be able to reverse the valuation allowances in future periods should the Company generate taxable income. At December 31, 2002, we had approximately $71.0 million of valuation allowances related to our net deferred tax assets.

Recently Issued Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board, or FASB issued Statement of Financial Accounting Standards, or SFAS No. 143, *Accounting for Asset Retirement Obligations*. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the

acquisition, construction, development, and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The provisions of SFAS No. 143 were effective for fiscal years beginning after June 15, 2002. We adopted the provisions of SFAS No. 143. Adoption of this statement did not have an impact on our financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated With Exit or Disposal Activities.* SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3 *Liability Recognition for Certain Employer Termination Benefits and other Costs to an Exit Activity (Including Certain Costs in a Restructuring).* SFAS No. 146 requires that the liability for costs associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue No. 94-3, a liability for an exit cost was recognized at the date of the Company s commitment to an exit plan. SFAS No.146 also establishes that the liability should initially be measured and recorded at fair value. We adopted the provisions of SFAS No. 146 for restructuring activities initiated after December 31, 2002.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation* to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*, to require more prominent disclosures about the method of

accounting for stock-based employee compensation and the effect of the method used on reported results in both annual and interim financial statements. We adopted the disclosure provisions of SFAS No. 148 for our fiscal year ended December 31, 2002 and quarter ended March 31,2003.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 requires that upon issuance of a guarantee, a guarantor must recognize a liability for the fair value of an obligation assumed under a guarantee. FIN 45 also requires additional disclosures by a guarantor in its interim and annual financial statements about the obligations associated with guarantees issued. The recognition provisions of FIN 45 are effective for any guarantees issued or modified after December 31, 2002. The disclosure requirements were effective for financial statements of interim or annual periods ending after December 15, 2002. We adopted the disclosure requirements for our financial statements for the period ended December 31, 2003. Adoption of the recognition provisions of FIN 45 did not have an impact on our financial position or results of operations.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*. FIN 46 requires that the assets, liabilities and results of the activity of variable interest entities be consolidated into the financial statements of the company that has controlling financial interest. It also provides the framework for determining whether a variable interest entity should be consolidated based on voting interest or significant financial support provided to it. This Interpretation is effective July 1, 2003. We are currently in the process of evaluating the impact of this Statement on our financial condition and operating results. However the adoption of this statement is not expected to have an impact on our financial position or results of operations.

Results of Operations Three Months Ended March 31, 2003 and 2002

Revenues. Total revenues for the three months ended March 31, 2003 were $29,528,000, an increase of $5,384,000 or 22% over total revenues of $24,144,000 for the three months ended March 31, 2002. The increase for the three months ended March 31, 2003 was primarily due to higher sales of Thymoglobulin and Gengraf.

Included in total revenues was revenue from collaborative agreements of $790,000 and $789,000 for the three months ended March 31, 2003 and 2002, respectively. For both periods, this revenue relates to recognition of milestone payments from Abbott Laboratories under the co-promotion agreement for Gengraf. 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 which expires December 31, 2004.

Cost of product sales. Cost of product sales was $13,684,000 for the three months ended March 31, 2003, an increase of $3,061,000 or 29% over cost of sales of $10,623,000 for the three months ended March 31, 2002. The increase in cost of product sales for the three months ended March 31, 2003 was due to the overall increase in sales and the higher relative cost of Gengraf as compared to our other products.

Research and development. Research and development expenses were $4,426,000 for the three months ended March 31, 2003, an increase of $108,000 or 3% over research and development expenses of $4,318,000 for the three months ended March 31, 2002. These expenditures were necessary to support the advancement of potential drug candidates in all stages of development programs.

While we allocate scientists and track resources when required pursuant to the terms of a partnering or similar arrangement, members of our research team typically work on a number of products concurrently, and our equipment and intellectual property resources often are deployed over a range of products with a view to maximizing the benefit of our investment. Accordingly, we have not and do not intend to separately track the costs incurred to date for each of our research projects on a product-by-product basis. For the three months ended March 31, 2003, however, we estimate that the majority of research and development expense was associated with our two product candidates: RDP58 and cyclosporine capsules. The balance of our expense was associated primarily with ongoing development of our marketed products, clinical trials for Thymoglobulin, and early-stage product candidates.

In Europe, we recently completed Phase IIa clinical trials for RDP58 and announced preliminary results on April 9, 2003. The Phase II trials were prospective, randomized, blinded trials in patients with mild-to-moderate ulcerative colitis (UC) or Crohn s disease. Endpoints in each disease were response and remission. In UC, RDP58 achieved statistically significant response and remission compared with a placebo. In Crohn s disease, there was no statistically significant response or remission compared with a placebo. We consider the RDP58 UC results to be a significant milestone event for us with a number of important implications which may result in changes to our corporate strategy. Because the UC results indicate that RDP58 has promise as a therapeutic agent, we may be able to license rights to RDP58, and possible follow-on molecules, for significant payments and commitments. We also are working to determine the optimum path for further clinical and toxicology studies of RDP58, which could lead to an eventual application

to market RDP58 and benefits from potential development and marketing partners. We are also studying the implications for manufacturing (such as scale-up, cost reduction and formulations), including a capsule version of RDP58, and for marketing in the gastrointestinal arena. Future efforts for developing RDP58 could result in significant expense which may or may not be offset by revenues from licensing or partnering.

We conducted a multi-center, randomized, and controlled Phase II/III study of ABX-CBL. In this study, patients were randomized to receive the polyclonal equine antibody, ATGAM, in the control group versus patients who received ABX-CBL in the treatment arm. Our primary endpoint of this study was patient survival at 180 days. On February 18, 2003, we announced preliminary results from this study that indicated that survival with ABX-CBL was similar to ATGAM. Based on these results, we do not plan to pursue further development of ABX-CBL.

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

We intend to initiate three new clinical studies involving Thymoglobulin in 2003. One study would investigate the use of Thymoglobulin to *prevent* rejection of a kidney transplanted from an unrelated donor. Currently, Thymoglobulin is approved by the FDA only for treatment of an acute rejection of a donated kidney, in conjunction with concomitant immunosuppression.

The second study would investigate the effect of Thymoglobulin on prevention of graft-versus-host disease in bone marrow transplant patients using matched related donors. The third trial would investigate the use of Thymoglobulin to treat rejection of a transplanted liver.

Of course, our timelines are estimates that are subject to change. Due to the inherent risks and uncertainties associated with the development of our proposed drugs, we are unable to further specify with meaningful certainty the estimated completion date or estimated cost of completion of our proposed products, or whether any of our products will eventually be successfully developed. For a discussion of the risks and uncertainties surrounding the development and cost of these products, see Risk Factors - If we do not develop and market new products, our business will be harmed and Risk Factors - If our preclinical and clinical testing of potential products is unsuccessful, our business will be harmed.

Selling, general and administrative. Selling, general and administrative expenses for the three months ended March 31, 2003 were $9,252,000, an increase of $1,299,000 or 16% over expenses of $7,953,000 for the three months ended March 31, 2002. The increase in expenses for the three months ended March 31, 2003 over the comparable period in 2002 was primarily due to increased selling and marketing costs related to promotional programs and unrestricted grant costs to support new and existing products.

Other income - net. Other income - net for the three months ended March 31, 2003 was $734,000, compared to $111,000 for the three months ended March 31, 2002. The following table shows the components of other income (expense) net (in thousands).

	Three Months Ended March 31,	
	2003	**2002**
Interest income (expense) - net	$ (121)	$ (318)
Net gains on sales of fixed assets		300
Compensation received for a termination of manufacturing agreement		375
Income related to a lawsuit settlement	864	
Foreign exchange effects resulting from the impact of currency movements	(6)	(175)
Other, net	(3)	(71)
Other income - net	$ 734	$ 111

The interest income (expense) net reported a lower net expense in the first quarter 2003 than in the comparable period in 2002, due primarily to a reduction in long term-debt combined with the higher interest earnings on our cash equivalents and marketable securities. Other income-net for the three months ended March 31, 2003 also included a one-time income of $864,000 related to the settlement of the IMTIX-SangStat rabbit supplier litigation (See Note 8 to the condensed consolidated financial statements).

Equity in net loss of affiliate. Equity in net loss of affiliate for the three months ended March 31, 2003 includes SangStat s proportionate share of the net loss of THP and the amortization of intangible assets, representing the difference between the Company s carrying value and its interest in the underlying net assets of THP. These intangible assets are being amortized on a straight-line basis over two years.

Income taxes. For the three months ended March 31, 2003 and 2002, we recorded a provision of $422,000 and $433,000, respectively. The income tax provision primarily relates to our European operations.

Net income. Net income from operations for the three months ended March 31, 2003 was $1,824,000, an increase of $1,146,000 or 169% as compared to $678,000 for the three months ended March 31, 2002. The increase in net income for the three months ended March 31, 2003 was primarily due to higher product sales, partially offset by higher cost of product sales, resulting primarily from the higher product sales, and increased selling and marketing costs related to promotional programs and unrestricted grant costs to support new and existing products. In addition, other income-net for the three months ended March 31, 2003 included a one-time income of $864,000 related to the settlement of the IMTIX-SangStat rabbit supplier litigation (See Note 8 to the condensed consolidated financial statements).

Impact of Litigation

The cyclosporine product that we sell is involved in litigation. Novartis sued Abbott, claiming that Abbott s Gengraf product (which is co-marketed and distributed by us) violates Novartis patents, a judgment that was entered finding that Gengraf infringes one of the Novartis patents was reversed by the trial judge and is on appeal. The course of litigation is inherently uncertain. With respect to Novartis s lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, the loss of Gengraf sales would have a significant and material

adverse effect on our business and operating results. We might also be required to write-off all or a portion of our cyclosporine inventory. With respect to the European regulatory lawsuits, Novartis s requested relief, if granted, could have a negative material adverse effect on us if the European Court of Justice ruling prevents us from filing for marketing authorization of our cyclosporine capsule product currently under development until after the expiration of the data exclusivity period for Novartis s Neoral cyclosporine product. (That data exclusivity period expires in May 2004 for most European countries, including Germany, France, Italy and the United Kingdom.) If we cannot launch our cyclosporine capsule in Europe until after 2004, this could have a material adverse impact on our future operating results because of (i) the loss of potential revenue and (ii) need to write-off some or all of our bulk cyclosporine inventory. With respect to the FDA lawsuit, Novartis s requested relief, if granted could mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would harm our operating results. The litigation, if not resolved favorably to us, could have a material adverse effect on our business and operating results. Currently, none of the foregoing litigation matters require us to expend significant time or expense.

Liquidity and Capital Resources

As of March 31, 2003, we had cash, cash equivalents and short-term investments of $94,589,000 and total assets of $185,875,000.

During the three months ended March 31, 2003, the net cash used in operating activities was $1,260,000 as compared to $780,000 in the same period of 2002.

Net cash used in investing activities for the three months ended March 31, 2003 was $8,315,000, as compared to $180,000 for the same period in 2002. The amount in 2003 is primarily the result of purchases of short-term investments and property and equipment partially offset by maturities of short-term investments. The amount in 2002 was primarily the result of purchases of property and equipment.

Net cash used in financing activities for the three months ended March 31, 2003 was $2,255,000, as compared to net cash provided by financing activities of $76,756,000 for the same period in 2002. In both periods, cash provided by the sale of common stock was partially offset by the repayment of notes and capital lease obligations. On February 20, 2002, we completed the issuance of 5,175,000 shares of common stock in a public offering for proceeds net of underwriting discounts of $84,145,500. Subsequently, we repaid $11,000,000 of a note payable to Abbott Laboratories.

Effective April 1, 2003, Abbott Laboratories and we agreed to amend their co-promotion agreement for Gengraf for the remaining 21 months of its term. The amendment relieves Abbott of its obligations to provide physician details and maintain a minimum number of managed care organization account representatives. We will continue to provide physician details but is relieved of our obligation to maintain a minimum number of sales representatives. In addition, we will assume sole responsibility for all Gengraf marketing and promotional expenses, which were previously shared by both companies, and Abbott will pay a quarterly fee to us if certain sales thresholds are met. We anticipate that the net effect of this amendment will be to favorably affect quarterly net income (loss) by approximately $350,000 through the term of the

agreement which expires December 31, 2004.

We believe that our current cash position, together with cash flows from operations, will be sufficient to meet our cash flow requirements for at least the next 12 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.

Properties

We sublease our U.S. headquarters in Fremont, California for a term expiring June 30, 2005. We do not have an option to extend the sublease but we are currently negotiating with the landlord to extend our tenancy. We lease additional vacant office space in Newark, California, which housed our discontinued operation, The Transplant Pharmacy. While we are seeking to obtain a tenant for this property, to date we have not succeeded in doing so due to the depressed real estate market. We have reserved approximately $95,000 against this lease, which expires March 31, 2005. Our lease payments currently are $11,000 per month.

Risk Factors

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

We were incorporated in 1988 and have experienced significant operating losses since that date. As of March 31, 2003, our accumulated deficit was $178.8 million. While Fiscal year 2002 was a profitable year, we may recognize losses in subsequent periods for a variety of reasons, particularly if we increase our research and development expenditures directly or through investment or partnering arrangements with others. We expect to continue the development of our existing products and to enter into license or partnering arrangements in the future.

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

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

- maintaining and increasing revenues from Thymoglobulin, Lymphoglobuline and Gengraf, particularly Thymoglobulin;
- Abbott s ability and willingness to continue marketing Gengraf despite the current litigation by Novartis alleging that Gengraf infringes Novartis patents;
- successfully commercializing our product candidates, especially RDP58;
- limiting our manufacturing and selling, general and administrative expenses; and
- controlling research and development expenses.

Our operating results may also be affected by the licensing of complementary products or the investments in or acquisition of products or companies we may effect in the future. Any such acquisition or licensing could have the immediate effect of causing an operating loss in future periods. In this regard, our recent collaboration with and investment in Human Therapeutic Polyclonals decreased our level of profitability in 2002.

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

Our quarterly and annual operating results may fluctuate due to a variety of factors, and these fluctuations may not match our expectations or the expectations of investors and securities analysts. This could cause the trading price of our common stock to decline substantially. We therefore believe that quarter-to-quarter comparisons of our operating results may not be a good indication of our future performance, and you should not rely on them to predict our future performance or the future performance of our stock.

We also expect our operating results to fluctuate significantly as a result of a number of factors, including:

- the uncertainty in the timing and the amount of revenue we earn from product sales, including seasonal fluctuations;
- our ability to continue marketing Gengraf in light of pending litigation between Novartis and Abbott, and Abbott s willingness to continue marketing Gengraf;
- our achievement of research and development milestones;
- expenses we incur for product development, clinical trials and marketing and sales activities;
- the licensing of new products or the acquisition of products or other companies;
- increased competition by existing or new products;
- regulatory action;
- market acceptance of our products;
- manufacturing capabilities;
- cost of litigation; and
- third-party reimbursement policies.

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

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

Before obtaining regulatory approval for the sale of any of our product candidates, we must subject these product candidates to extensive preclinical and clinical testing to establish their safety and efficacy. If these tests are unsuccessful, we will be unable to commercialize these products. We recently announced the results of our Phase II trials of RDP58 for patients with mild-to-moderate ulcerative colitis or Crohn s disease, and clinical trials of RDP58 are expected to be ongoing. As our lead and primary product in development, adverse or inconclusive results from these trials would have a significant and material adverse effect on our research and development program and our prospects. In any event, interim results of trials do not necessarily predict final results, and acceptable results in early trials may not be repeated in later trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, we delayed our expected filing for our cyclosporine capsule by approximately six months due to unanticipated results on an initial clinical trial for that product, and we could experience further delays in the future for this and other products. Similarly, we recently announced preliminary results from our PhaseII/III study of ABX-CBL indicating that survival with ABX-CBL was similar to that with ATGAM. Based on these results, we do not plan to pursue further development of ABX-CBL. Moreover, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be repeated or a program to be terminated. We typically rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to perform data collection and analysis and, as a result, we may face additional delaying factors outside our control. The rate of completion of clinical trials depends, in part, on the enrollment of patients, which in turn depends on many factors such as the size of the patient population, the proximity of target patients to clinical sites, the eligibility criteria for the trial, the trial design, perceived risks and benefits, availability of the study drug and the existence of competitive experimental or approved therapies. Any delay in planned patient enrollment in our current or future clinical trials may result in increased costs, trial delays or both. Our product development costs will increase if we have delays in testing or approval or if we need to perform more or larger clinical trials than planned. If the delays are significant, our financial results and the commercial prospects for our products will be harmed.

Our future growth depends on sales of key products.

We expect to derive most of our future revenues from sales of Thymoglobulin, Lymphoglobuline, and Gengraf. We have limited experience selling our products in the U.S. Our sales of Thymoglobulin began in the U.S. in February 1999. We began distributing Gengraf in May 2000. We are marketing Gengraf in the U.S. under a co-promotion agreement with Abbott Laboratories. Abbott could be required or could elect to discontinue or curtail marketing of Gengraf in light of the Novartis patent litigation. Because we expect Thymoglobulin, Lymphoglobuline and Gengraf to be key revenue-generating products, any factor decreasing sales of these products, particularly Thymoglobulin, would harm our financial results. In this regard, Thymoglobulin has recently experienced increased competition from the off-label use of a newly introduced product and increased marketing efforts by competitors. Increased competition from this or other products could affect the future sales or price of Thymoglobulin, which could have a material adverse effect on our business and operating results. In addition, a delay in regulatory approval of our cyclosporine capsule product would harm our future financial results. The following factors could harm the sale or approval of these products:

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

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

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

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

Abbott s ability and willingness to continue marketing Gengraf despite the Novartis patent litigation;
Reaction of patients, physicians, pharmacies, distributors and medical institutions to possible disruptions in the supply of Gengraf due to fears that Gengraf may be removed from the market because of the Novartis patent lawsuit against Abbott;
perceptions of both patients and physicians regarding use of a generic version of a critical, life-saving therapeutic;
perception of bioequivalence;
number of contracts with managed care providers and group purchasing organizations;
pricing pressure from other generic competitors;
intense competitive pressure from Novartis; and
Novartis s litigation with the U.S. Food and Drug Administration, the Medicines Control Agency in the U.K. and Abbott.

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

We face substantial competition.

Each of the drugs we develop competes with existing and new drugs being created by pharmaceutical, biopharmaceutical, biotechnology companies and universities. Many of these entities have significantly greater research and development capabilities, as well as substantial marketing, manufacturing, financial and managerial resources and represent significant competition. The principal factors upon which our products compete are product utility, therapeutic benefits, ease of use, effectiveness, marketing, distribution and price. With respect to our products, we are competing against large companies that have significantly greater financial resources and established marketing and distribution channels for competing products. Additionally, our increasing sales of Thymoglobulin are attracting competition. Thymoglobulin has recently experienced increased competition from the off-label use of a newly introduced product and increased marketing efforts by competitors. Increased competition from this or other products could affect the future sales or price of Thymoglobulin, which could have a material adverse effect on our business and operating results.

The drug industry is intensely price competitive, and we expect we will face this and other forms of competition. Developments by others may render our products or technologies obsolete or noncompetitive, and we may not be able to keep pace with technological developments. Many of our competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for products that compete with our own. Some of these products may have an entirely different approach or means of accomplishing the desired therapeutic effect than

do our products and may be more effective, more convenient or less costly. In addition, many of these competitors have significantly greater experience than we do in undertaking preclinical testing and human clinical trials of pharmaceutical products, obtaining regulatory approval of such products and manufacturing them. Accordingly, our competitors may succeed in commercializing products more rapidly than us.

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

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

Novartis sued Abbott in August 2000 claiming that Gengraf infringes certain Novartis patents. While a judgment was entered in U.S. District Court finding that Gengraf infringed one of the Novartis patents on August 19, 2002 the judge reversed the judgment and ruled that Abbott had not infringed the Novartis patents on March 27, 2003. The course of litigation is inherently uncertain: Novartis may choose to sue us directly, Abbott may not prevail, Abbott may withdraw Gengraf from the market or Abbott may choose to settle on terms adverse to our interests. If Novartis sues us directly, we may incur expenses before reimbursement, if any, by Abbott, which is obligated under our agreement to indemnify us against such suits but its indemnity may not cover lost sales. Should Novartis succeed in obtaining a preliminary or permanent injunction, this injunction may temporarily or permanently remove Gengraf from the market. If Abbott or the Company is forced or elects to remove Gengraf from the market before our co-promotion agreement with Abbott expires on December 31, 2004, our customers might return unsold inventory to us for credit or refund and we could be holding inventory of Gengraf that we may be unable to sell. In that event, our revenues would decrease significantly and our operating results would be materially adversely affected.

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

We have approximately $17.5 million of bulk cyclosporine active ingredient inventory classified as other assets in the balance sheet that we are not using to manufacture finished product in the amount anticipated. This inventory was originally purchased for use in cyclosporine finished products to be sold in the U.S. and Europe. However, since we are now distributing Gengraf in the U.S. and no longer sell SangCya Oral Solution, we are dependent on our capsule product under development to use this inventory. Although we plan to obtain marketing approval for the cyclosporine capsule product in Europe, the inherent uncertainty of the approval process makes it very difficult to forecast a launch date for this product. We filed for marketing approval of the cyclosporine capsule product in a European country in January 2003. If the approval and product launch are delayed, we may not be able to convert all the inventory into finished product and sell it before its expiration date. As a result, we could write off portions or all of our bulk cyclosporine active ingredient in a future period, which could significantly reduce the gross margin reported for that future period. If our cyclosporine capsule product is not launched by mid to late 2004, or if sales do not meet our expectations, we may have to write off additional amounts for expired inventory, which would adversely impact our operating results.

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

A substantial portion of demand for our products is from customers such as hospitals and pharmacies who purchase our products from wholesalers. Sales to Cardinal Health Inc., McKesson Corporation, Bergen Brunswig Drug Company and AmeriSource accounted for approximately 28%, 19%, 15% and 14%, respectively, of total revenues in 2002. Bergen Brunswig Drug Company acquired AmeriSource in 2002. We expect that we will continue to derive a substantial portion of our revenue from these wholesalers. The loss of any of these wholesalers could harm our business and operating results.

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

Our manufacturing facility near Lyon, France, must meet FDA standards of Good Manufacturing Practices and other regulatory guidelines. The FDA and other regulatory authorities inspect our manufacturing facility to ensure that it meets regulatory standards. The FDA, as well as the Canadian and French health authorities, inspected our Lyon facility in February and March 2002. While the FDA may inspect our facilities at any time, we do not expect an FDA inspection until 2004. If in the future the FDA or Canadian authority believes that we are not complying with its guidelines, it can issue a warning letter or prevent the import and sale of Thymoglobulin into the U.S. or Canada, and/or order a recall of these products, which would cause an immediate and significant adverse effect on our business and operating results. In addition, Thymoglobulin and Lymphoglobuline are biological products, which are more difficult to manufacture than chemical compounds. We rely on Aventis for certain important manufacturing services, including quality assurance, quality control, and lyophilization, a step in the manufacturing process which involves removing the water from the product. Aventis may not continue to effectively and continuously provide us these critical manufacturing services. In addition, we may have difficulties manufacturing Thymoglobulin or Lymphoglobuline in the future that may impair our ability to deliver products to our customers, which could reduce our revenues.

Although we primarily use our own facilities to manufacture Thymoglobulin and Lymphoglobuline, we rely on third parties to supply us with raw materials. These third parties may stop supplying us with the materials we need at any time, and we may have to find new suppliers. We have six suppliers of rabbit serum used for the manufacturing of Thymoglobulin. We recently had a dispute with two former suppliers of rabbit serum that resulted in a judgment against us of approximately $3.6 million plus interest, which was recorded as a charge to other income (expense) - net for the year ended December 31, 2001. We appealed the case to the French Cours de Cassation. In March 2003, we settled the lawsuit in return for a payment of 800,000 Euros (approximately $864,000). Our preferred rabbit suppliers are reaching full capacity and we have negotiated arrangements with them to expand capacity to meet our future needs. If this expansion is delayed or fails to materialize, we may incur shortages of an essential raw material. We have drawn upon our inventory of rabbit serum and our current inventory represents approximately 2.5 months supply.

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

Except for Thymoglobulin and Lymphoglobuline, third parties manufacture all of our products and product candidates. We rely on Abbott Laboratories and Sicor for the manufacture of bulk cyclosporine for the capsule product that is pending regulatory review in Europe. Abbott Laboratories also manufactures Gengraf, which would be a competing product with our cyclosporine capsule in Europe. It is possible that this competitive relationship could result in Abbott being an unreliable supplier of bulk cyclosporine for us. Federa (Fresenius Kabi France) manufactures Celsior for us. Some of the risks associated with using third parties for manufacturing are as follows:

- the manufacturer may not pass a pre-approval inspection or, once approved, may not continue to manufacture to the FDA s and other regulatory authorities standards;
- the manufacturer may not timely deliver adequate supplies of a sufficiently high quality product in the timeline necessary to meet product demand; and
- we may not be able to obtain commercial quantities of a product at an economically viable price.

In addition, we may not be able to enter into commercial scale manufacturing contracts on a timely or commercially reasonable basis, or at all, for our product candidates. We rely on Accucaps Industries Limited to supply us with cyclosporine capsules and UCB S.A. to supply us with bulk RDP58 for research and clinical purposes. For some of our potential products, we will need to develop our production technologies further for use on a larger scale to conduct human clinical trials and produce such products for sale at an acceptable cost.

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

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

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

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

We may elect to in-license or partner the development of new products from others, or we may elect to acquire products or other companies. We expect that the licensing or acquisition of products or companies in an early stage of development would require substantial additional investment prior to yielding anticipated returns. Moreover, we may fail to ultimately realize any anticipated benefits for a variety of reasons including risks inherent to the research and development of early-stage products, competition, quality problems, declining reimbursement, and integration risks related to new products, technology and human resources. Integration of new products or companies may strain our existing financial and managerial controls, reporting systems and procedures. This may result in the diversion of management and financial resources from our core business objectives and needs. Because we only recently realized quarterly profitability, we would expect that any such acquisition or licensing could have the immediate effect of causing an operating loss in future periods. Furthermore, the licensing or acquisition of new products or companies for cash could limit our financial resources, and the issuance of our stock in such a transaction could result in substantial dilution to existing stockholders. Accounting rules require us to periodically evaluate our investments in products, technologies or collaborators, such as our investment in Therapeutic Human Polyclonals, Inc. A reduction in appraised value due to technology delays or failures or other reasons would require us to record losses that would adversely affect our financial results.

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

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

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

To maintain profitable operations, we must successfully develop, obtain regulatory approval for, manufacture, introduce and market new products and product candidates. We may not be able to successfully do this. Our product candidates will require extensive development and testing, as well as regulatory approval before marketing to the public. Our cyclosporine capsule product candidate in Europe has been delayed and we did not file for approval until January 2003. We recently announced preliminary results from our PhaseII/III study of ABX-CBL indicating that survival with ABX-CBL was similar to ATGAM. Based on these results, we do not plan to pursue further development of ABX-CBL. In addition, cost overruns and product approval delays could occur due to the following:

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

These events would prevent or substantially slow down the development effort and ultimately would harm our business. Furthermore, our product candidates under development may not prove to be safe, effective or capable of being manufactured in commercial quantities at an economical cost, and our products could infringe the proprietary rights of others or may not be accepted in the marketplace.

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

We face an inherent business risk of exposure to product liability claims in the event that the use of our products is alleged to have resulted in adverse effects. Such risk exists even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise received regulatory approval for commercial sale. We could be subject to significant product liability claims. We currently have product liability insurance in the amount of $20.0 million per claim and $20.0 million in the aggregate on a claims-made basis, which may not be adequate to cover potential liability exposures. In addition, adequate insurance coverage may not be available in the future on commercially reasonable terms, if at all. The loss of insurance coverage or the assertion of a product liability claim or claims could harm our operating results.

We may be unable to attract or retain key personnel.

Our ability to develop our business depends in part upon our attracting and retaining qualified management and scientific personnel. As the number of qualified personnel is limited, competition for such personnel is intense. We may not be able to continue to attract or retain such people on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and nonprofit research institutions. The loss of our key personnel or the failure to recruit additional key personnel could significantly impede attainment of our objectives and harm our financial condition and operating results. There is risk that changes in management will disrupt our operations or lead to further resignations. Additionally, new and proposed laws, rules and regulations increasing the liability of directors and officers may make it more difficult to recruit for these positions.

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

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

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

Our success depends in part on our ability to obtain and enforce patent protection for our products and to preserve our trade secrets. We hold patents and pending patent applications in the U.S. and abroad. Some of our patents involve specific claims and thus do not provide broad coverage. Our patent applications or any claims of these patent applications may not be allowed, valid or enforceable. These patents or claims of these patents may not provide us with

competitive advantages for our products. Our competitors may successfully challenge or circumvent our issued patents and any patents issued under our pending patent applications, or the patents of our collaborators. Further, we do not have patents on Thymoglobulin or Lymphoglobuline. Therefore, we are primarily dependent upon our trade secrets for these products. We have not conducted extensive patent and prior art searches with respect to our product candidates and technologies, and we do not know if third-party patents or patent applications exist or have been filed in the U.S., Europe or elsewhere. This would have an adverse effect on our ability to market our products. We do not know if claims in our patent applications would be allowed, be valid or enforceable, or that any of our products would not infringe on others patents or proprietary rights in the U.S. or abroad. We also have patent licenses from third parties whose patents and patent applications are subject to the same risks as ours.

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

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

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

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

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

The market prices for securities of pharmaceutical and biotechnology companies, including ours, are highly volatile. For example, during 2002, the price of our common stock ranged from $10.20 to $27.49 per share. The stock market has from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. The market price for our common stock may fluctuate as a result of factors such as:

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

- announcements regarding collaborative agreements;
- governmental regulations;
- our clinical trial results or clinical trial results from our competitors;
- fluctuations in our revenues or profitability;
- the licensing or acquisition of new products or other companies;
- developments in patent or other proprietary rights;
- departures or changes in key personnel;
- financial or other disclosure matters;
- public concern as to the safety of drugs developed by us or others;
- comments or recommendations made by securities analysts; and
- general market conditions.

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

A recession or other downturn in the U.S. or other regional economy could adversely affect our customers, including wholesalers, which could reduce our sales or make it more difficult to collect payments from them on a timely basis. Epidemics such as the recent incidence of Severe Acute Respiratory Syndrome (SARS) can adversely affect our business. For example, SARS has disrupted at least one of our transplant center customers, resulting in reduction of our sales to that customer. The continued threat of terrorism in the U.S. and elsewhere and any ongoing military action and heightened security measures in response to this threat may cause significant disruption to commerce throughout the world. To the extent that this disruption results in delays or cancellations of orders, a general decrease in spending on pharmaceutical products or our inability to effectively market and ship our products, our business and operating results could be harmed. In particular, our Thymoglobulin and Lymphoglobuline products are perishable and require express shipping, which may be curtailed or delayed because of security restrictions and border inspections. Geopolitical actions by governments, companies or individuals resulting in trade restrictions, embargos, boycotts or other

actions could affect our business. We are unable to predict whether economic conditions, epidemics, terrorism, or the military, geopolitical or other responses thereto will result in any long-term commercial disruptions or if such activities or responses will have a long-term adverse effect on our business or operating results.

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

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

management attention.

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

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

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

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

In connection with our manufacturing, research and development activities and operations, we are subject to foreign, federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. As a result, we may incur significant costs to comply with environmental and health and safety regulations. Our manufacturing, research and development involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals, infectious biological specimens and radiological materials.

Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by foreign, state and federal regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our ability to pay. Additionally, recent developments in California may make it more difficult or impossible to close facilities where radiological materials have been used. While we do not plan to close such facilities in the near future, if such restrictions are not eased, we could encounter difficulties expanding our research

facilities or in establishing collaborations with third parties, and could incur expenses to retain facilities that cannot be closed.

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

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

These provisions, among other things:

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

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

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

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

We lease vacant office space in Newark, California that housed our discontinued operation, The Transplant Pharmacy. Due to the depressed real estate market, we may not succeed in finding a

tenant for this property for a subrental in an amount that will prevent us from recognizing a further loss on our lease.

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

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

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

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

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risks has not changed materially since December 31, 2002. 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 fiscal year ended December 31, 2002.

ITEM 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures. The Company s Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the Company s disclosure controls and procedures (as such term is defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date). Based on such evaluation, such officers have concluded that, as of the Evaluation Date, the Company s disclosure controls and procedures are effective in alerting them on a timely basis to material information relating to the Company (including its consolidated subsidiaries) required to be included in the Company s reports filed or submitted under the Exchange Act.

(b) Changes in Internal Controls. Since the Evaluation Date, there have not been any significant changes in the Company s internal controls or in other factors that could significantly affect such controls.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

Novartis Patent Litigation with Respect to Gengraf

Novartis sued Abbott in United States District Court in Delaware claiming that Gengraf® infringes its patents. While a judgment was entered finding that Gengraf infringed one of the Novartis patents on August 19, 2002 the judge reversed the judgment and ruled that Abbott had not infringed the Novartis patents on March 27, 2003. Novartis is appealing the decision. We have not been named a defendant in this lawsuit. Under our agreement with Abbott, Abbott is obligated to indemnify us against such suits, but their indemnity may not cover lost sales, if any. The course of litigation is inherently uncertain, Novartis may choose to sue us directly, Abbott may not prevail on appeal, Abbott may elect to withdraw Gengraf from the market or Abbott may choose to settle on terms adverse to our interests. Should Novartis sue us, we may incur expenses prior to reimbursement, if any, by Abbott pursuant to its indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, Abbott or we may be forced or elect to remove Gengraf from the market before our co-promotion agreement with Abbott expires on December 31, 2004, our customers might return unsold inventory to us for credit or refund and we could then be holding inventory of Gengraf that we may be unable to sell. In that event, our revenues would decrease significantly and our operating results would be materially adversely affected. We might also be required to write-off all or a portion of our Gengraf inventory.

Novartis Regulatory Litigation

U.S. Regulatory Litigation. Novartis U.S. sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis initially asked the Court to (i) allow Novartis to keep its microemulsion labeling; (ii) declare microemulsion to be a separate dosage form; and (iii) rescind the AB rating that was given to SangCya Oral Solution. We intervened in this lawsuit. The Court granted our motion to dismiss the counts that relate specifically to the approval of SangCya Oral Solution, but Novartis may appeal this decision. We remain a party in the case. On July 11, 2002, the judge ordered Novartis, the FDA and us to file motions for summary judgment and set a schedule for briefs to be filed through December 20, 2002. We permanently withdrew SangCya Oral Solution from the U.S. market in July 2000, and receive no revenue from SangCya, but if the court were to declare microemulsion to be a separate dosage form, this ruling would require rescission of the AB rating for Gengraf, which would have a material adverse effect on our Gengraf revenues.

U.K. Regulatory Litigation SangCya Oral Solution. On October 18, 1999, Novartis U.K. was granted leave to seek judicial review of the decision by the Medicines Control Agency, or MCA, to approve SangCya Oral Solution. On March 30, 2000, the High Court in London dismissed Novartis s application for judicial review and ruled that the MCA acted properly in granting the SangCya Oral Solution marketing authorization. Novartis appealed the High Court s decision, and the hearing was held before the Court of Appeal on November 13 and 14, 2000. The Court of Appeal has stayed ruling on this matter pending the answer of certain questions of law to be

submitted to the European Court of Justice, or ECJ. The ECJ hearing was held on November 7, 2002, and the Advocate General issued an opinion in January 2003. We expect the ECJ s decision approximately six to twelve months thereafter. Following the ECJ ruling, the parties would go back to the Court of Appeal, which will then apply the ECJ ruling on the law to the facts of this case. We no longer market SangCya Oral Solution, but the outcome of the case may affect the timing of regulatory approvals for our cyclosporine capsule product.

U.K. Regulatory Litigation Cyclosporine Capsules. In November 1999, Novartis filed a request with the High Court in London for judicial review of the refusal by MCA to state that it would not reference Neoral data in approving any generic copies of Novartis s cyclosporine capsule. An agreement was reached between the parties in which Novartis agreed to stay the judicial review until the earlier of (i) the decision on the

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

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

Italian Regulatory/Trade Secret Litigation. On May 5, 2000, Novartis Farma S.p.a. (Novartis Italy) served IMTIX-SangStat S.r.l., an Italian SangStat subsidiary, and IMTIX-SangStat Ltd. with a summons to the Milan Tribunal in a lawsuit concerning our application for approval by the Italian Health Authorities of the SangCya Oral Solution. In December 2002, Novartis Italy agreed to withdraw the lawsuit and we agreed not to file for approval of a cyclosporine oral solution before May 2004. Consequently, we do not expect any adverse consequences from this lawsuit.

IFFA CREDO and Elevage Scientifique des Dombes Breach of Contract Suit

In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes (ESD), sued our French subsidiary, IMTIX-SangStat SAS, for breach of contract in the Commercial Court of Lyon, France. The suppliers won in the trial court and appeals court and we paid approximately $3.6 million in damages plus interest. IMTIX-SangStat recorded charges of $3,250,000 and $204,000 to other expense net for the year ended December 31, 2001, which, combined with reserves recorded in fiscal 2000, fully provided for the court award. We appealed

the case to the French Cours de Cassation. In March 2003, we settled the lawsuit in return for a payment by IFFA CREDO and ESD of 800,000 Euros (approximately $864,000).

Summary

The course of litigation is inherently uncertain. With respect to Novartis s lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds despite the recent ruling of non-infringement, the loss of Gengraf sales would have a significant and material adverse effect on our business and operating results. We might also be required to write-off all or a portion of our cyclosporine inventory. With respect to the European regulatory lawsuits, Novartis s requested relief, if granted, could have a material adverse effect on us if the European Court of Justice ruling prevents us from filing for marketing authorization of our cyclosporine capsule product currently under development until after the expiration of the data exclusivity period for Novartis Neoral cyclosporine product. (That data exclusivity period expires in May 2004 for most European countries, including Germany, France, Italy and the United Kingdom.) If we cannot obtain approval of our cyclosporine capsule in Europe until 2004, this could have a material adverse impact on our future operating results because of (i) the loss of potential revenue and (ii) need to write-off some or all of our bulk cyclosporine inventory. With respect to the FDA lawsuit, Novartis s requested relief, if granted could mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would have a material adverse effect on us. Currently, none of the foregoing litigation matters require us to expend significant time or expense.

ITEM 2. Changes in Securities and Use of Proceeds
None

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 exhibits are attached hereto and filed herewith:

Exhibits	Description
10.1	Second Amendment to Co-Promotion Agreement dated as of April 1, 2003 between the Registrant and Abbott Laboratories, Inc.*
99.1	Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Confidential treatment was requested for a portion of this exhibit.

(b) We filed a Current Report on Form 8-K on April 28, 2003.

SANGSTAT MEDICAL CORPORATION

SIGNATURES

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

Date: May 14, 2003

SANGSTAT MEDICAL CORPORATION

By: /s/ RICHARD D. MURDOCK
Richard D. Murdock
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ STEPHEN G. DANCE
Stephen G. Dance, CPA, FCA.
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

CERTIFICATIONS
CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Richard D. Murdock, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SangStat Medical Corporation;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) Evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Signature	Title	Date
/s/ Richard D. Murdock Richard D. Murdock	Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)	May 14, 2003

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Stephen G. Dance, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SangStat Medical Corporation;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) Evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Signature	Title	Date
/s/ Stephen G. Dance Stephen G. Dance, CPA, FCA.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	May 14, 2003