SANGSTAT MEDICAL CORP
Form 10-Q
August 14, 2002

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2002

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 of incorporation)	(IRS Employer Identification No.)

6300 Dumbarton Circle
Fremont, CA 94555
(Address of principal executive office, Zip Code)

Registrant s telephone number, including area code: **510-789-4300**

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.

ý Yes 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	26,423,815*

* As of July 31, 2002

SangStat Medical Corporation

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PART I. FINANCIAL INFORMATION

SANGSTAT MEDICAL CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	June 30, 2002 (unaudited)	December 31, 2001 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 84,108	$ 32,822
Short-term investments	21,524	
Accounts receivable (net of allowances of $3,645 in 2002 and $4,072 in 2001)	24,573	19,872
Other receivables	1,628	480
Inventories	21,935	22,942
Prepaid expenses and other current assets	1,840	2,494
Total current assets	155,608	78,610
PROPERTY AND EQUIPMENT net	5,615	5,469
GOODWILL	578	
INTANGIBLE ASSETS (net of accumulated amortization of $3,750 in 2002 and $4,324 in 2001)	8,142	9,220
OTHER ASSETS	22,863	21,260
TOTAL	$ 192,806	$ 114,559
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 26,587	$ 22,019
Accrued liabilities	12,681	14,375
Capital lease obligations current portion	185	177
Deferred revenue current portion	3,158	3,158
Notes payable current portion	4,127	5,615
Total current liabilities	46,738	45,344
CAPITAL LEASE OBLIGATIONS	290	326
DEFERRED REVENUE	4,738	6,317
NOTES PAYABLE	17,389	30,213
STOCKHOLDERS EQUITY:		
Preferred stock, $.001 par value, 5,000 shares authorized; none outstanding		
Common stock, $.001 par value, 40,000 shares authorized; outstanding: 2002, 26,399 shares; 2001, 20,961 shares	310,084	222,521
Accumulated deficit	(184,529)	(187,015)
Accumulated other comprehensive loss	(1,904)	(3,147)

Total stockholders equity			123,651	32,359
TOTAL		$	192,806	$ 114,559

(1) Derived from the Company s audited consolidated financial statements at December 31, 2001.

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 June 30,		Six Months Ended June 30,	
	2002	**2001**	**2002**	**2001**
REVENUES:				
Net product sales	$ 30,127	$ 20,995	$ 53,482	$ 40,530
Revenue from collaborative agreements	790	789	1,579	1,579
Total revenues	30,917	21,784	55,061	42,109
COSTS AND OPERATING EXPENSES:				
Cost of product sales	15,266	9,322	25,889	17,943
Research and development	5,110	4,203	9,428	8,748
Selling, general & administrative	8,677	8,781	16,630	17,506
Amortization of intangible assets	250	347	500	695
Total costs and operating expenses	29,303	22,653	52,447	44,892
Income (loss) from continuing operations	1,614	(869)	2,614	(2,783)
OTHER INCOME (EXPENSE) - NET	763	(1,502)	874	(5,297)
INCOME (LOSS) FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	2,377	(2,371)	3,488	(8,080)
INCOME TAX PROVISION	(569)	(251)	(1,002)	(251)
NET INCOME (LOSS) FROM CONTINUING OPERATIONS	1,808	(2,622)	2,486	(8,331)
NET LOSS FROM OPERATIONS OF DISCONTINUED OPERATION				(763)
NET INCOME (LOSS)	$ 1,808	$ (2,622)	$ 2,486	$ (9,094)
NET INCOME (LOSS) PER SHARE - BASIC				
Continuing operations	$ 0.07	$ (0.13)	$ 0.10	$ (0.43)
Discontinued operation				(0.04)
Net income (loss)	$ 0.07	$ (0.13)	$ 0.10	$ (0.47)
NET INCOME (LOSS) PER SHARE - DILUTED				
Continuing operations	$ 0.07	$ (0.13)	$ 0.10	$ (0.43)
Discontinued operation				(0.04)
Net income (loss)	$ 0.07	$ (0.13)	$ 0.10	$ (0.47)
Shares Used in Per Share Computations - Basic	26,376	19,632	25,210	19,523
Shares Used in Per Share Computations - Diluted	27,305	19,632	26,034	19,523

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Net income (loss)	$ 1,808	$ (2,622)	$ 2,486	$ (9,094)
Unrealized losses on short-term investments classified as available for sale in the current period	(42)	(1)	(42)	
Foreign currency translation adjustments	1,396	(616)	1,285	(1,334)
Total comprehensive income (loss)	$ 3,162	$ (3,239)	$ 3,729	$ (10,428)

See notes to Condensed Consolidated Financial Statements.

SANGSTAT MEDICAL CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2002	**2001**
OPERATING ACTIVITIES:		
Net income (loss) from continuing operations	$ 2,486	$ (8,331)
Adjustments to reconcile net income (loss) to cash (used in) provided by operating activities:		
Depreciation and amortization	1,302	1,857
Non-cash interest expense	370	590
Loss on disposal of property and equipment	7	203
Changes in assets and liabilities:		
Accounts receivable	(4,701)	(1,078)
Other receivables	(1,148)	1,597
Inventories	(1,098)	(204)
Prepaid expenses and other current assets	654	5,372
Other assets	502	3,456
Accounts payable	4,568	(395)
Accrued liabilities	(1,694)	2,509
Deferred revenue	(1,579)	(1,579)
Net cash (used in) provided by continuing operating activities	(331)	3,997
Net cash used in discontinued operation		(763)
INVESTING ACTIVITIES:		
Purchases of property and equipment	(712)	(483)
Maturities of short-term investments		58
Purchases of short-term investments	(21,566)	(250)
Net cash used in investing activities	(22,278)	(675)
FINANCING ACTIVITIES:		
Sale of common stock	87,563	19,535
Notes payable borrowings	156	355
Notes payable repayments	(14,838)	(9,391)
Repayment of capital lease obligations	(28)	(226)
Net cash provided by financing activities	72,853	10,273
EFFECT OF EXCHANGE RATE CHANGES ON CASH	1,042	(1,334)
NET INCREASE IN CASH AND CASH EQUIVALENTS	51,286	11,498
CASH AND CASH EQUIVALENTS, Beginning of period	32,822	19,046

CASH AND CASH EQUIVALENTS, End of period	$	84,108	$	30,544
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Cash paid during the period for interest	$	561	$	2,446
NONCASH INVESTING AND FINANCING ACTIVITIES:				
Unrealized loss on investments	$	(42)	$	

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 the Company and its wholly owned subsidiaries. Intercompany accounts and transactions have been eliminated.

The condensed consolidated financial statements presented are unaudited and in the opinion of management reflect all adjustments (consisting only of normal recurring adjustments), which the Company considers necessary for a fair presentation of the financial condition and results of operations as of and for the interim periods presented. Certain reclassifications to the June 30, 2001 condensed consolidated financial statements were made in order to conform to the current quarter condensed consolidated financial statements presentation. The results for interim periods are not necessarily indicative of the results to be expected for the full year. These condensed consolidated financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto included in the Company s 2001 Annual Report on Form 10-K.

2. ***Net Income (Loss) Per Share***

Basic and diluted net income (loss) per share amounts have been computed using the weighted average number of common shares outstanding during the periods presented. For the three and six month periods ended June 30, 2002, calculation of diluted net income per share also includes the dilutive effect of outstanding stock options, and does not include the effect of outstanding convertible notes and warrants of 550,773 shares as these would be anti-dilutive for the periods presented. For the three and six month periods ended June 30, 2001, we incurred a net loss and as such we did not include the effect of outstanding stock options of 158,350 shares and the effect of outstanding convertible notes and warrants of 550,773 shares in the diluted net loss per share calculation as their effect would be anti-dilutive.

The following is a reconciliation of the numerators and denominators of the basic and diluted net income (loss) per share computations (amounts in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Numerator:				
Net income (loss)				
Continuing operations	$ 1,808	$ (2,622)	$ 2,486	$ (8,331)
Discontinued operation				(763)
Net income (loss)	$ 1,808	$ (2,622)	$ 2,486	$ (9,094)
Denominator:				
Basic:				
Weighted average number of common shares outstanding	26,376	19,632	25,210	19,523
Diluted:				
Weighted average number of common shares outstanding	26,376	19,632	25,210	19,523
Common share equivalents - stock options	929		824	
Weighted average number of common shares and common share equivalents	27,305	19,632	26,034	19,523
Basic net income (loss) per share				
Continuing operations	$ 0.07	$ (0.13)	$ 0.10	$ (0.43)
Discontinued operation				(0.04)
Net income (loss) per share	$ 0.07	$ (0.13)	$ 0.10	$ (0.47)
Diluted net income (loss) per share				
Continuing operations	$ 0.07	$ (0.13)	$ 0.10	$ (0.43)
Discontinued operation				(0.04)
Net income (loss) per share	$ 0.07	$ (0.13)	$ 0.10	$ (0.47)

3. ***Accumulated Other Comprehensive Loss***

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

	June 30, 2002	December 31, 2001
Unrealized loss on investments	$ (42)	$
Accumulated foreign currency translation adjustments	(1,862)	(3,147)
Total	$ (1,904)	$ (3,147)

4. ***Inventories***

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

	June 30, 2002	December 31, 2001
Raw materials	$ 739	$ 2,976
Work in process	15,970	13,868
Finished goods	5,226	6,098
Total	$ 21,935	$ 22,942

In addition to these inventories, the Company has classified at June 30, 2002 and December 31, 2001 approximately $17,369,000 and $15,263,000, respectively, 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. ***Goodwill and Intangible Assets***

The Company adopted Statement of Financial Accounting Standard (SFAS) No. 142, *Goodwill and Other Intangible Assets* on January 1, 2002. SFAS No. 142 required that the net book value of assembled workforce intangibles be reclassified to goodwill on January 1, 2002. Further, as required by SFAS No. 142, the Company performed a transitional impairment test as of January 1, 2002 and concluded that no impairment of goodwill was indicated. Intangible assets consist of the following (in thousands):

		June 30, 2002			December 31, 2001		
	Amortization Period (years)	Gross Carrying Amount	Accumulated Amortization	Net Amount	Gross Carrying Amount	Accumulated Amortization	Net Amount
Developed technology	14	$ 7,613	$ 2,039	$ 5,574	$ 7,613	$ 1,767	$ 5,846
Avoided royalties	14	2,514	673	1,841	2,514	584	1,930
Trademarks	10	763	286	477	763	248	515
Customer list	5	1,002	752	250	1,002	651	351
Assembled workforce	5				1,652	1,074	578
Total		$ 11,892	$ 3,750	$ 8,142	$ 13,544	$ 4,324	$ 9,220

Following the adoption of SFAS No. 142 all of the Company s identifiable intangible assets are subject to amortization. The Company evaluated the useful lives of its acquired intangible assets in connection with the adoption of SFAS No. 142 and determined that no changes to the useful lives were necessary. Had the provisions of SFAS No. 142 been applied for the three and six months ended June 30, 2001, net loss for those periods would have decreased by $83,000 and $165,000 respectively, with no effect on the reported net loss per share for the three months ended June 30, 2001. For the six months ended June 30, 2001 the net loss per share would have decreased by $0.01. Estimated annual amortization expense for the next five fiscal years ending December 31 is as follows (in thousands): 2002-$1,000; 2003-$950; 2004-$800; 2005-$800 and 2006-$800.

6. ***Notes Payable***

Notes payable consist of (in thousands):

	June 30, 2002	December 31, 2001
Note payable to Aventis	$ 6,500	$ 9,000
Discount on note payable to Aventis	(403)	(727)
Convertible note	9,826	9,779
Note payable to Abbott Laboratories	5,000	16,000
Other debt	593	1,776
Total	21,516	35,828
Less current portion	(4,127)	(5,615)
Long-term	$ 17,389	$ 30,213

7. ***Issuance of Common Stock***

On February 20, 2002, the Company completed the issuance of 5,175,000 shares of common stock in a public offering for proceeds net of underwriting discounts of approximately $84.1 million. The Company intends to use the proceeds for repayment of existing debt and general corporate purposes, including in-licensing and partnering opportunities. In addition, the Company may use a portion of the net proceeds to acquire complementary products, product candidates or businesses.

8. Stock Option Plans

On May 14, 2002, the stockholders approved the Company s 2002 Stock Option Plan (the 2002 Plan) which was adopted by the Board of Directors effective March 6, 2002. The 2002 Plan serves as the successor to the Company s 1993 Stock Option Plan (the Predecessor Plan). The Predecessor Plan terminated upon stockholder approval of the 2002 Plan, and no further stock option grants were or will be made from the Predecessor Plan from and after the date of stockholder approval of the 2002 Plan. All options outstanding under the Predecessor Plan immediately prior to the termination of the Predecessor Plan were incorporated into the 2002 Plan and are treated as outstanding options under the 2002 Plan. However, each outstanding option so incorporated will continue to be governed solely by the express terms and conditions of the instrument evidencing such grant, and no provision of the 2002 Plan will be deemed to affect or otherwise modify the rights or obligations of the holders of such incorporated options with respect to their acquisition of shares under such options.

9. Discontinued Operation

On March 13, 2001, the Company committed to a formal plan to sell its division known as The Transplant Pharmacy (TTP). On April 20, 2001, the Company closed the sale of TTP to Chronimed for $1.8 million in cash. The Company retained the inventory and accounts receivable related to the business and has converted these assets into cash. The disposition of TTP has been accounted for as a discontinued operation in accordance with Accounting Principles Board (APB) Opinion No. 30. Net sales and net loss from the discontinued operation of TTP was $4,199,000 and $763,000, respectively, for the six months ended June 30, 2001.

10. ***Recently Issued Accounting Pronouncements***

In July 2001, the Financial Accounting Standards Board (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 will be effective for the Company s fiscal year beginning January 1, 2003, however early application is permitted. The Company is currently in the process of evaluating the impact of adoption of this Statement on its financial position and results of operations.

In August 2001, the FASB issued SFAS No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*. SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, and addresses financial accounting and reporting for the impairment or disposal of long-lived assets. The Company adopted SFAS No. 144 on January 1, 2002. 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,* which addresses accounting for restructuring and similar costs. SFAS No. 146 supersedes previous guidance, principally *Emerging Issues Task Force Issue* No. 94-3. The Company will adopt the provisions of SFAS No. 146 for restructuring activities initiated after December 31, 2002. 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 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. Accordingly, SFAS No. 146 may affect the timing of recognizing future restructuring costs as well as the amounts recognized.

11. ***Litigation***

Novartis Patent Litigation with Respect to Gengraf

Novartis sued Abbott in United States District Court in Delaware claiming that Gengraf® infringes its patents. On July 30, 2002, a jury found that Gengraf infringed one of the Novartis patents and awarded Novartis $5 million in damages. Abbott has requested the judge to enter a judgment in its favor, but to date, a judgment has not been entered. Novartis is expected to move for an injunction to prevent the sale of Gengraf in the U.S. Abbott informed the Company that it believes the jury s verdict is inconsistent and that it intends to appeal any adverse judgment. The Company has not been named a defendant in this lawsuit and is not liable for the damages awarded by the jury. 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 its motions or 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, the Company may incur expenses prior to reimbursement, if any, by Abbott pursuant to Abbott s indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, the Company and Abbott may be required to negotiate a license on unfavorable terms, or Gengraf may be temporarily or

permanently removed from the market, which would decrease the Company s revenues significantly and the Company s operating results would be adversely affected. However, should Gengraf be removed from the market, we estimate that the impact on earnings per share (EPS) for 2003 would be a reduction in EPS by approximately 11-15 cents.

Novartis Regulatory Litigation

U.S. Regulatory Litigation. Novartis U.S. sued the U.S. Food and Drug Administration (the FDA) on February 11, 1999 in the United States District Court for the District of Columbia (Case No. 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis 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. Because the Company permanently withdrew SangCya Oral Solution from the U.S. market in July 2000, the Company does not believe that this lawsuit will have any material impact on SangCya revenues but if the court declares microemulsion to be a separate dosage form, this ruling would require rescission of the AB rating for Gengraf, which would have a material impact on Gengraf revenues.

U.K. Regulatory Litigation SangCya Oral Solution. On October 18, 1999, Novartis U.K. was granted leave to seek judicial review of the decision by the Medicines Control Agency, or MCA, to approve SangCya Oral Solution (Case No. HC-1969/99). 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 is scheduled for November 7, 2002, with a ruling approximately six months thereafter. Following the ECJ ruling, the parties would go back to the Court of Appeal, which will then apply the ECJ ruling on the law to the facts of this case.

U.K. Regulatory Litigation Cyclosporine Capsules. In November 1999, Novartis filed a request with the High Court in London for judicial review of the refusal by MCA to state that it would not reference Neoral data in approving any 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 resulting Court of Appeal judgment.

Novartis has also indicated that it will seek an injunction to prevent the Company s cyclosporine capsule from being sold in the United Kingdom until final resolution of the judicial review relating to the Company s 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 Company s 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. Novartis Italy alleges that by requesting mutual recognition from the Italian Health Authorities of the SangCya Oral Solution dossier approved by the MCA, the Company implicitly requested that the Italian Health Authorities review the Neoral dossier. Novartis alleges that this request is an act of unfair competition in that (i) the Neoral data has ten year exclusivity and (ii) the data is secret and by requesting mutual recognition, the Company is responsible for the Health Authorities act of unfair competition following use of the Neoral dossier in reviewing the SangCya Oral Solution dossier. While the summons acknowledges that the U.K. High Court did not invalidate the SangCya Oral Solution marketing authorization, it does not acknowledge that the High Court ruled that the MCA could review the Neoral data. To the best of the Company s knowledge, Novartis Italy has not filed suit against the Italian Health Authorities. The initial appearance of the parties before the Milan Tribunal was scheduled for January 2001. The Company filed its response to the complaint at that time, and the hearing has been postponed until February 2003.

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

Summary

The 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 the Company s operating results. With respect to the European regulatory and trade secret lawsuits, Novartis s requested relief, if granted, could have a negative economic impact on the Company depending on how the MCA would proceed with the Company s Marketing Authorization Application (MAA) for its capsule product. The MCA could approve the Company s MAA for its cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve the Company s MAA for its cyclosporine capsule until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004). If the Company cannot obtain approval of its cyclosporine capsule in Europe before the end of 2004, this could have a material adverse impact on the

Company s future operating results. With respect to the FDA lawsuit, Novartis s requested relief would mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would harm the Company s operating results. The litigation, if not resolved favorably to the Company, could have a material adverse effect on the Company s business, financial condition, cash flows and operating results. Currently, none of these lawsuits involves significant time, resources or expense. The U.S. and U.K. regulatory litigation may require additional time and expense in 2002 as the Company prepares for the European Court of Justice hearing and prepares motions for summary judgment in the U.S. FDA litigation.

IFFA CREDO and Elevage Scientifique des Dombes Breach of Contract Suit

In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes, sued the Company s French subsidiary, IMTIX-SangStat SAS, for breach of contract. On May 2, 2001 the Company was notified that the Commercial Court of Lyon ruled against IMTIX-SangStat in the breach of contract suit and the court awarded the suppliers 26.5 million French Francs (approximately $3.6 million) for lost profits and reimbursement of capital expenditures. IMTIX-SangStat recorded a charge of $3,250,000 to other expense net for the year ended December 31, 2001, which, combined with reserves recorded in fiscal 2000, fully provided for the court award. On March 22, 2002, the appeals court upheld the lower court decision and assessed interest against the Company of approximately $204,000 which was recorded as a charge to other income (expense) - net for the year ended December 31, 2001.

The Company s rabbit serum requirements are currently being met by its other suppliers.

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our Condensed Consolidated Financial Statements and Notes thereto included elsewhere in this Quarterly Report on Form 10-Q, as well as the Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2001. Except for the historical information contained herein, the discussion in this Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, intentions and future results. In particular, we have included forward-looking statements regarding the following: (i) our anticipated financial results for 2002; (ii) the timeline and potential results of preclinical development and clinical trials; (iii) potential outcomes of our and Abbott s litigation with Novartis; (iv) our plans for marketing a cyclosporine capsule in Europe; (v) anticipated expenditures and timing relating to FDA and foreign approval of our products and facilities; and (vi) anticipated potential strategic collaborations with others. The cautionary statements appearing under the caption Risk Factors in this Quarterly Report on Form 10-Q and our other documents filed with the Securities and Exchange Commission should be read as being applicable to all related forward-looking statements wherever they appear in this Quarterly Report on Form 10-Q. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those discussed in Risk Factors in these documents as well as those discussed elsewhere herein. These forward-looking statements are based on our current

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expectations, and we disclaim any obligation to update these forward-looking statements for subsequent events or to explain why actual results differ.

SangStat is a global biotechnology company expanding on its transplantation foundation to discover, develop and market high value therapeutic products in immunology, hematology/oncology and auto-immune disease. 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 to address all phases of 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 and the U.S. and distributors throughout the rest of the world.

Historically, our business was comprised of two segments: pharmaceutical products and transplantation services. In October 2000, we implemented a new strategy focused on growing a core business in high value therapeutics that builds on our expertise in transplantation but extends into new therapeutic areas. As a result of this new strategy, we decided to dedicate significant resources to our pharmaceutical products segment, which consists of four marketed products and three principal product candidates. On April 20, 2001, we sold our transplantation services segment, The Transplant Pharmacy, to Chronimed, for cash proceeds of $1.8 million. Consequently, the historical consolidated statements of operations and cash flows have been restated for all periods presented to account for the transplantation services segment business as a discontinued operation. Unless otherwise indicated, the following discussion relates to our continuing operations and excludes our discontinued operation.

Critical Accounting Policies

We have identified the policies below as critical to our business operations and the understanding of our results of operations.

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 royalties that are recorded in the same period as the related revenue. While we believe we can make reliable estimates for these revenue adjustments, the actual amounts realized could vary from our estimates and the amounts of such changes could affect our operating results.

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 either ratably over the life of the agreement where significant obligations for future services or the Company s 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 inventories 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 June 30, 2002 and December 31, 2001, we classified approximately $17 million and $15 million respectively, of bulk cyclosporine raw materials inventory, net of writedowns, as other long term assets.

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 and to alter our expectations as to future operating results.

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 the Company 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 June 30, 2002 and December 31, 2001, we had approximately $75 million of valuation allowances related to our net deferred tax assets.

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 will be effective for our fiscal year beginning January 1, 2003; however early application is permitted. We are currently in the process of evaluating the impact of this Statement on our financial position and operating results.

In August 2001, the FASB issued SFAS No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*. SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, and addresses financial accounting and reporting for the impairment or disposal of long-lived assets. We adopted SFAS No. 144 on January 1, 2002. The 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,* which addresses accounting for restructuring and similar costs. SFAS No. 146 supersedes previous guidance, principally *Emerging Issues Task Force Issue* No. 94-3. We will adopt the provisions of SFAS No. 146 for restructuring activities initiated after December 31, 2002. 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 94-3, a liability for an exit cost was recognized at the date of the Company s commitment to an exit plan. SFAS 146 also establishes that the liability should initially be measured and recorded at fair value. Accordingly, SFAS No. 146 may affect the timing of recognizing future restructuring costs as well as the amounts recognized.

Results of Operations Three and Six Months Ended June 30, 2002 and 2001

Revenues. Total revenues for the three months ended June 30, 2002 were $30,917,000, an increase of $9,133,000 or 42% over total revenues of $21,784,000 for the three months ended June 30, 2001. Total revenues for the six months ended June 30, 2002 were $55,061,000, an increase of $12,952,000 or 31% over total revenues of $42,109,000 for the six months ended June 30, 2001. The increase for the three and six months ended June 30, 2002 was due to higher sales of Gengraf and increased sales of Thymoglobulin in the U.S. However for the three months ended June 30, 2002, sales of Thymoglobulin and Lymphoglobuline outside the U.S. were also higher than the prior period.

Included in total revenues was revenue from collaborative agreements of $790,000 and $789,000 for the three months ended June 30, 2002 and 2001, respectively. Revenue from collaborative agreements was $1,579,000 for both the six month periods ended June 30, 2002 and 2001, respectively. For all 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.

Cost of sales. Cost of sales was $15,266,000 for the three months ended June 30, 2002, an increase of $5,944,000 or 64% over cost of sales of $9,322,000 for the three months ended June 30, 2001. Cost of sales was $25,889,000 for the six months ended June 30, 2002, an increase of $7,946,000 or 44% over cost of sales of $17,943,000 for the six months ended June 30, 2001. The increase in cost of sales for the three and six months ended June 30, 2002 was due to the overall increase in sales and the higher relative cost of Gengraf as compared to our other

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products and also due to initiation of royalties to Aventis on sales of Thymoglobulin starting October 1, 2001.

Research and development. Research and development expenses were $5,110,000 for the three months ended June 30, 2002, an increase of $907,000 or 22% from research and development expenses of $4,203,000 for the three months ended June 30, 2001. Research and development expenses were $9,428,000 for the six months ended June 30, 2002, an increase of $680,000 or 8% over research and development expenses of $8,748,000 for the six months ended June 30, 2001. The increase in spending for the three and six months ended June 30, 2002 on research and development mainly relates to spending on RDP58 and the ongoing stability studies for our cyclosporine capsule. For both periods this increase in spending was partially offset by lower expenses relating to SangStat s negotiated share of development costs incurred by Abgenix for ABX-CBL.

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 for each of our research projects so as to enable accurate disclosure of the actual costs incurred to date on a product by product basis. For the three and six months ended June 30, 2002, however, we estimate that the majority of our research and development expense was associated with our three leading product candidates: RDP58, ABX-CBL and cyclosporine capsules. The balance of our expense was associated primarily with ongoing development of our marketed products, primarily clinical trials for Thymoglobulin, and early-stage product candidates.

We completed Phase I clinical trials for RDP58 and subsequently started a Phase IIa trial in October 2001. We currently expect to complete enrollment of this trial by the end of 2002. We are also conducting a Phase II / III trial for ABX-CBL. We completed enrollment of this trial and we now expect to announce results in the first half of 2003. We are conducting bioequivalence and stability studies for a cyclosporine capsule. If the results from these studies are favorable, we expect to file for marketing approval for this product in a major European country, which we currently estimate will occur in late 2002. We also have under way two clinical trials involving Thymoglobulin. One trial compares Thymoglobulin with Simulect. The study was closed early in March 2002, with a total enrollment of 279 participants out of a planned 340, after an interim analysis revealed significantly fewer acute rejections of implanted kidneys in patients treated with Thymoglobulin versus Simulect. The second trial investigates the use of Thymoglobulin in myelodysplastic syndrome. We aim to complete enrollment of patients into this study in 2003. The primary end-point is 180 days after enrollment. Of course, our timelines are estimate that are subject to change from time to time. 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 and effectively precluding such disclosure, see Risk Factors - If we do not develop and market new products, our business will be harmed.

Selling, general and administrative. Selling, general and administrative expenses for the three months ended June 30, 2002 were $8,677,000, a decrease of $104,000 or 1% from selling, general and administrative expenses of $8,781,000 for the three months ended June 30, 2001.

Selling, general and administrative expenses for the six months ended June 30, 2002 were $16,630,000, a decrease of $876,000 or 5% from selling, general and administrative expenses of $17,506,000 for the six months ended June 30, 2001. The decrease in expenses for the three and six months ended June 30, 2002 reflects a reduction in SangStat s share of Phase IV Gengraf study expenses, and a reduction in legal expenses.

Other income (expense) - net. Other income (expense) - net for the three months ended June 30, 2002 was an income of $763,000, compared to an expense of ($1,502,000) for the three months ended June 30, 2001. Other income (expense) - net for the six months ended June 30, 2002 was an income of $874,000, compared to an expense of ($5,297,000) for the six months ended June 30, 2001.The following table shows the components of other income (expense) net.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	**2001**	**2002**	**2001**
Interest expense - net	$ (22)	$ (1,822)	(340)	(2,520)
Net gains/(losses) on sales of fixed assets		4	300	(173)
Compensation received for a termination of manufacturing agreement			375	
Reimbursement claim received from a supplier				856
Charge related to a breach of contract suit		(102)		(3,250)
Foreign exchange effects resulting from the impact of currency movements	784	362	609	(158)
Other, net	1	56	(70)	(52)
Other income (expense) - net	$ 763	$ (1,502)	$ 874	$ (5,297)

Income taxes. For the three and six months ended June 30, 2002, we recorded a provision of $569,000 and $1,002,000, respectively, for European income taxes compared to a provision of $251,000 for the three and six months ended June 30, 2001. For the three and six months ended June 30, 2002 the change in provision is attributable to the change in net income position of our European subsidiaries as compared to the three and six months ended June 30, 2001.

Net income (loss) from continuing operations. Net income from continuing operations for the three months ended June 30, 2002 was $1,808,000, an increase of $4,430,000 or 169% as compared to the net loss of $2,622,000 for the three months ended June 30, 2001. Net income from continuing operations for the six months ended June 30, 2002 was $2,486,000, an increase of $10,817,000 or 130% as compared to the net loss of $8,331,000 for the six months ended June 30, 2001. The increase in net income for the three and six months ended June 30, 2002 was primarily due to higher product sales, including sales of Gengraf, partially offset by higher cost of sales, resulting primarily from the higher product sales. In addition, the interest expense-net for the three and six months ended June 30, 2001 included a one-time charge of $1,128,000 due to the write down of the balance of the value of the warrant and the loan origination fees related to the repayment and subsequent termination of the FINOVA loan agreement. The six months ended June 30, 2001 included a one-time charge of $3,250,000 related to the IMTIX-SangStat rabbit supplier litigation (discussed in Note 11).

Net loss from operations of discontinued operation. Net sales of transplantation services for the three and six months ended June 30, 2001 were zero and $4,199,000 and the net loss from transplantation services for the three and six months ended June 30, 2001 was zero and $763,000, respectively. The change in the net loss reflects the sale of our transplantation services business

that closed on April 20, 2001. There were no additional sales or losses incurred during the three and six months ended June 30, 2002.

Impact of Litigation

The cyclosporine products that we sell are involved in litigation. Novartis sued Abbott, claiming that Abbott s Gengraf product (which is co-marketed and distributed by us) violates Novartis patents, and a jury has entered a verdict finding that Gengraf infringes one of the Novartis patents. The course of litigation is inherently uncertain. With respect to Novartis s patent infringement 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 operating results. With respect to the European regulatory and trade secret lawsuits, Novartis s requested relief, if granted, could have a negative economic impact on us depending on how the U.K. Medicines Control Agency would proceed with our Marketing Authorization Application for our capsule product. The Medicines Control Agency could approve our Marketing Authorization Application for our cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data, or the agency could decide not to approve the application for our cyclosporine capsule until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004). If we cannot obtain approval of our cyclosporine capsule in Europe until 2004, this could have a material adverse impact on our future operating results. With respect to the FDA lawsuit, Novartis s requested relief would mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would harm our operating results. The litigation, if not resolved favorably to us, could have a material adverse effect on our business, financial condition, cash flows and operating results. Currently, none of these lawsuits involves significant time, resources or expense. The U.S. and U.K. regulatory litigation may require additional time and expense in 2002 as we prepare for the European Court of Justice hearing and prepare motions for summary judgment in the U.S. FDA litigation.

Liquidity and Capital Resources

As of June 30, 2002, we had cash, cash equivalents and short-term investments of $105,632,000 and total assets of $192,806,000.

During the six months ended June 30, 2002, the net cash used in continuing operating activities was $331,000 as compared to net cash provided by continuing operating activities of $3,997,000 in the same period of 2001. The increase in net cash used in operating activities in the six months ended June 30, 2002 compared to net cash provided by operating activities in the same period in 2001 is primarily due to the following:

i) accrued liability decreases in 2002, compared to accrued liability increases in 2001;

ii) smaller decreases in prepaid expenses and other current assets in 2002, compared to 2001 as we reclassified $5.0 million from other current assets to cash and cash equivalents in 2001. This cash had previously been treated as restricted as it served as collateral for our loan with FINOVA; and

iii) an increase in accounts and other receivables for 2002, compared to a decrease in other receivables for 2001.

These amounts were partially offset by a net income realized in the six months ended June 30, 2002, compared to a net loss for the same period in 2001, and an increase in accounts payable for the six months ended June 30, 2002, compared to a decrease in accounts payable for the same period of 2001.

Net cash used in investing activities for the six months ended June 30, 2002 was $22,278,000, as compared to $675,000 for the same period in 2001. The amount in 2002 is primarily the result of purchases of short-term investments and property and equipment. The amount in 2001 was primarily the result of purchases of property and equipment and short-term investments, partially offset by maturity of short-term investments.

Net cash provided by financing activities for the six months ended June 30, 2002 was $72,853,000, as compared to $10,273,000 for the same period in 2001. 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. We completed two private placements in January and June 2001 for aggregate proceeds of $18,999,485. In addition, we borrowed $5,000,000 from FINOVA in 2000, which was repaid in June 2001.

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

Euro-Currency

The Single European Currency (Euro) was introduced on January 1, 1999 with complete transition to this new currency required by January 2002. We have completed all necessary changes to our internal systems and have fully transitioned to the Euro. We expect that use of the Euro may affect our foreign exchange activities and may result in increased fluctuations in foreign currency results.

Risk Factors

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

We were incorporated in 1988 and have experienced significant operating losses since that date. As of June 30, 2002, our accumulated deficit was $184.5 million. While the quarter ended June 30, 2002 was a profitable quarter, we may recognize losses in subsequent quarters for a variety of reasons, particularly if we are unable to sell Gengraf in the future or if we increase our research and development expenditures directly

or through investment or partnering arrangements with others. We expect to continue the development of our existing products and to enter into license or partnering

arrangements in the future. If we are unable to maintain or increase sales of our existing products, particularly Thymoglobulin, and develop and subsequently market our products in development, our business and operating results will be adversely affected.

To date, our product revenues have been primarily derived from sales of Thymoglobulin, Lymphoglobuline, and Gengraf. Revenues from Thymoglobulin were 69%, 60% and 54% of total revenues in 1999, 2000 and 2001, respectively. Revenues from Lymphoglobuline were 19%, 12% and 8% of total revenues in 1999, 2000 and 2001, respectively. In addition, revenues from Gengraf were 18% and 31% of total revenues in 2000 and 2001, respectively. Gengraf sales comprised 32% of our total revenues for the six months ended June 30, 2002. 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 is withdrawn from the market due to the Novartis patent lawsuit against Abbott, these revenues would be lost entirely.

Our expectations with respect to achieving and maintaining positive cash flow and financial reporting profitability are subject to risk and uncertainty. While we recently experienced our first profitable quarters, we may not be able to establish positive cash flow or to maintain or increase our financial reporting profitability on a quarterly or annual basis. Our ability to achieve positive cash flow and financial reporting profitability will be significantly dependent upon our success in, among other things:

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

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

successfully commercializing our product candidates, especially ABX-CBL and 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 acquisition of strategic 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.

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

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

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

the uncertainty in the timing and the amount of revenue we earn upon product sales, including seasonal fluctuations;

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

our achievement of research and development milestones;

expenses we incur for product development, clinical trials and marketing and sales activities;

the licensing of new products or the acquisition of other companies;

the introduction of new products by our competition;

regulatory actions;

market acceptance of our products;

manufacturing capabilities;

cost of litigation; and

third-party reimbursement policies.

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

Our future growth depends on sales of key products.

We expect to derive most of our future revenues from sales of Thymoglobulin, Lymphoglobuline, and Gengraf. We have limited experience selling our products in the U.S. Our sales of Thymoglobulin began in the U.S. in February 1999. We began distributing Gengraf in May 2000. We are marketing Gengraf in the U.S. under a co-promotion agreement with Abbott Laboratories. Abbott may not effectively market Gengraf, and its failure to do so may adversely impact sales of these products. Abbott could be required or could elect to discontinue or curtail marketing of Gengraf in light of the recent jury verdict that Gengraf infringes a Novartis patent.

Because we expect Thymoglobulin, Lymphoglobuline and Gengraf to be key revenue-generating products, any factor decreasing sales of these products, particularly Thymoglobulin, would harm our financial results. In 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 Novartis, Pharmacia and Roche.

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

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

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

perceptions of both patients and physicians regarding use of a generic version of a critical, life-saving therapeutic;

perception of bioequivalence;

number of contracts with managed care providers and group purchasing organizations;

pricing pressure from other generic competitors;

intense competitive pressure from Novartis; and

Novartis s litigation with the U.S. Food and Drug Administration, the Medicines Control Agency in the U.K. and Abbott.

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

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, including Cardinal Health Inc. and McKesson Corporation. Approximately 13% and 15%, respectively, of total revenues in 2000 were derived from sales to customers who place orders through these two wholesalers, and in 2001, sales to Cardinal Health Inc., McKesson Corporation, AmeriSource and Bergen Brunswig Drug Company accounted for approximately 26%, 18%, 12% and 11%, respectively, of total revenues. We expect that we will continue to derive a substantial portion of our revenue from

Cardinal Health Inc. and McKesson Corporation. The loss of either 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 in 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, and we do not expect another FDA inspection for another two years. 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 of Thymoglobulin into the U.S. or Canada, 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, similar to freeze-drying. Aventis may not continue to effectively and continuously provide us these critical manufacturing services. In addition, we may have difficulties manufacturing Thymoglobulin or Lymphoglobuline in the future that may impair our ability to deliver products to our customers, which could reduce our revenues.

Although we 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 which resulted in a judgment against us of approximately $3.6 million, which was recorded as a charge to other income (expense) - net for the year ended December 31, 2001.

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 Gensia Sicor for the manufacture of bulk cyclosporine. Abbott Laboratories manufactures Gengraf, and 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. Abgenix, from

whom we have licensed ABX-CBL, is responsible for maintaining the manufacturing agreement for ABX-CBL with Lonza Biologics PLC, the third party manufacturer of this product candidate. Similarly, we rely on Accucaps Industries Limited to supply us with cyclosporine capsules and UCB S.A. to supply us with bulk RDP58 for research 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 will require the expenditure of substantial resources, and we do not know if we will obtain the necessary approvals for our product candidates. Further, for our approved products, the marketing, distribution and manufacture of our products remains subject to extensive ongoing regulatory requirements administered by the FDA and other regulatory bodies. Failure to comply with applicable regulatory requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval, withdrawal of approvals and criminal prosecution of SangStat and our employees.

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 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, 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 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.

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.

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

We have significant amounts of bulk cyclosporine active ingredient inventory that we are not using to manufacture finished product in the amount anticipated. This inventory was originally purchased for use in cyclosporine finished products to be sold in the U.S. and Europe. However, since we are now distributing Gengraf in the U.S. and we have withdrawn SangCya Oral Solution from the U.S. market, we are dependent on the European market to use this inventory. We recalled SangCya Oral Solution from the U.S. in July 2000 in response to a study in healthy volunteers that identified that SangCya is not bioequivalent to Neoral oral solution when mixed with apple juice as recommended in its labeling. We are no longer marketing this product. Although we plan to obtain marketing approval for a cyclosporine capsule product in Europe, the inherent uncertainty of the approval process makes it very difficult to forecast a launch date for this product. We currently expect to file for marketing approval of a cyclosporine capsule product in a European country by the end of 2002. If the approval and product launch are delayed, we may not be able to convert all the inventory into finished product and sell it before its expiration date. As a result, we could write off portions of our bulk active ingredient in the future, which could significantly reduce the gross margin reported for that future period. If our cyclosporine capsule product is not launched before the end of 2004, we may have to write off additional amounts for expired inventory, which would adversely impact our operating results.

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 do not anticipate filing for approval of a cyclosporine capsule product in Europe until late 2002. In addition, cost overruns and product approval delays could occur due to the following:

- unanticipated regulatory delays or demands;

unexpected adverse side effects; or

insufficient therapeutic efficacy.

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

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. 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 have 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. 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 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 are in the process of negotiating product liability insurance in the requested amount of $25 million, the same amount as we have maintained in the past, subject to the cost and availability of such insurance in the current market. We have a commitment for $10 million per claim and $10 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.

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., Italy 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 the Abbott lawsuit), and SangCya Oral Solution and our cyclosporine capsule product candidates in Europe. The course of litigation is inherently uncertain, and we may not achieve a favorable outcome. The litigation, whether or not resolved favorably to us, is likely to be expensive, lengthy and time consuming, and divert management s attention.

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

Novartis sued Abbott in August 2000 claiming that Gengraf infringes certain Novartis patents. On July 30, 2002 a jury found that Gengraf infringed one of the Novartis patents and awarded Novartis $5 million in damages. Novartis s complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the U.S. The course of litigation is inherently uncertain: Novartis may choose to sue us directly, Abbott may not prevail, Abbott may withdraw Gengraf from the market or Abbott may choose to settle on terms adverse to our interests. If Novartis sues us directly, we may incur expenses before reimbursement, if any, by Abbott, who is obligated under our agreement to indemnify us against such suits but their indemnity may not cover lost sales, if any. Should Novartis succeed in obtaining a preliminary or permanent injunction, this injunction may temporarily or permanently remove Gengraf from the market. If Abbott or we were forced or elect to remove Gengraf from the market before our co-promotion agreement with Abbott expires on December 31, 2004, our revenues would decrease significantly and our operating results would be adversely affected. However, should Gengraf be removed from the market, we estimate that the impact on earnings per share (EPS) for 2003 would be a reduction in EPS by approximately 11-15 cents. Our agreement with Abbott for Gengraf expires December 31, 2004. We may not be able to negotiate an extension or renewal of the agreement on terms favorable to us, which could substantially harm our revenue and operating results.

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

Our success depends in part on our ability to obtain and enforce patent protection for our products and to preserve our trade secrets. We hold patents and pending patent applications in the U.S. and abroad. Some of our patents involve specific claims and thus do not provide broad coverage. Our patent applications or any claims of these patent applications may not be allowed, valid or enforceable. These patents or claims of these patents may not provide us with competitive advantages for our products. Our competitors may successfully challenge or circumvent our issued patents and any patents issued under our pending patent applications. Further, although we received orphan drug designation for Thymoglobulin for treatment of Myelodysplastic Syndrome, also known as pre-leukemia, we do not have patents on Thymoglobulin or Lymphoglobuline. Therefore, we are primarily dependent upon our trade secrets for these products. We have not conducted extensive patent and prior art searches with respect to our product candidates and technologies, and we do not know if third-party patents or

patent applications exist or have been filed in the U.S., Europe or other countries. This would have an adverse effect on our ability to market our products. We do not know if claims in our patent applications would be allowed, be valid or enforceable, or that any of our products would not infringe on others patents or proprietary rights in the U.S. or abroad. We also have patent licenses from third parties whose patents and patent applications are subject to the same risks as ours.

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

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

We face substantial competition.

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. A list of our key products and product candidates, identifying principal competitive products as well as the relevant competitors, is included in the Business section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 under Competition.

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

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.

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

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

Our stock price 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 2001, the price of our common stock ranged from $7.50 to $24.87 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;

public concern as to the safety of drugs developed by us or others;

comments made by securities analysts; and

general market conditions.

Adverse economic conditions could affect our customers.

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. Terrorist attacks in New York, Washington, D.C.

and Pennsylvania in September of 2001 disrupted commerce throughout the U.S. and Europe. The continued threat of terrorism within the U.S. and Europe 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. We are unable to predict whether the threat of terrorism or the 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.

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

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

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

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

In connection with our manufacturing, research and development activities and operations, we are subject to foreign, federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. As a result, we may incur significant costs to comply with environmental and health and safety regulations. Our manufacturing, research and development involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals, infectious biological specimens and radiological materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by foreign, state and federal regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our ability to pay. Additionally, recent developments in California may make it more difficult or impossible to close facilities where radiological materials have been used. While we do not plan to close such facilities in the near future, if such restrictions are not eased, we could encounter difficulties expanding our research facilities or in establishing collaborations with third parties, and could incur expenses to retain facilities that cannot be closed.

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

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

These provisions, among other things:

limit the right of stockholders to call special meetings of stockholders;

limit the right of stockholders to present proposals, nominate directors for election or otherwise raise matters at annual meetings of stockholders without giving advance notice;

eliminate the ability of stockholders to take action by written consent;

prohibit cumulative voting in any election of directors, which may make it more difficult for a third party to gain control of our Board of Directors; and

authorize our Board of Directors to issue up to five million shares of preferred stock in one or more series and to determine the price, rights, preferences, privileges, and restrictions of those shares without any further vote or action on the part of stockholders.

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

Further, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which will prohibit us from engaging in a business combination with an

interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, even if such combination is favored by a majority of stockholders, unless the business combination is approved in a prescribed manner. The application of Section 203 also could have the effect of delaying or preventing a change of control or management.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Reference is made to part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2001. Our exposure to market risks has not changed materially since December 31, 2001.

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. On July 30, 2002 a jury found that Gengraf infringed one of the Novartis patents and awarded Novartis $5 million in damages. Abbott has requested the judge to enter a judgment in its favor, but to date, a judgment has not been entered. Novartis is expected to move for an injunction to prevent the sale of Gengraf in the U.S. Abbott informed us that it believes the jury s verdict is inconsistent and that it intends to appeal any adverse judgment. We have not been named a defendant in this lawsuit and we are not liable for the damages awarded by the jury. Under our agreement with Abbott, Abbott is obligated to indemnify us against such suits, but their indemnity may not cover lost sales, if any. The course of litigation is inherently uncertain, Novartis may choose to sue us directly, Abbott may not prevail on its motions or on appeal, Abbott may elect to withdraw Gengraf from the market or Abbott may choose to settle on terms adverse to our interests. Should we be sued by Novartis, 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 and we may be required to negotiate a license on unfavorable terms, or Gengraf may be temporarily or permanently removed from the market, which would decrease our revenues significantly and our operating results would be adversely affected. However, should Gengraf be removed from the market, we estimate that the impact on earnings per share (EPS) for 2003 would be a reduction in EPS by approximately 11-15 cents.

Novartis Regulatory Litigation

U.S. Regulatory Litigation. Novartis U.S. sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia (Case No. 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis 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. Because we permanently withdrew SangCya Oral Solution from the U.S. market in July 2000, we do not believe that this lawsuit will have any material impact on SangCya revenues but if the court declares microemulsion to be a separate dosage form, this ruling would require rescission of the AB rating for Gengraf, which would have a material impact on Gengraf revenues.

U.K. Regulatory Litigation SangCya Oral Solution. On October 18, 1999, Novartis U.K. was granted leave to seek judicial review of the decision by the Medicines Control Agency, or MCA, to approve SangCya Oral Solution (Case No. HC-1969/99). 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 is scheduled for November 7, 2002, with a ruling approximately six months thereafter. Following the ECJ ruling, the parties would go back to the Court of Appeal, which will then apply the ECJ ruling on the law to the facts of this case.

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

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

Italian Regulatory/Trade Secret Litigation. On May 5, 2000, Novartis Farma S.p.a. (Novartis Italy) served IMTIX-SangStat S.r.l., an Italian SangStat subsidiary, and IMTIX-SangStat Ltd. with a summons to the Milan Tribunal. Novartis Italy alleges that by requesting mutual recognition from the Italian Health Authorities of the SangCya Oral Solution dossier approved by the MCA, we implicitly requested that the Italian Health Authorities review the Neoral

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dossier. Novartis alleges that this request is an act of unfair competition in that (i) the Neoral data has ten year exclusivity and (ii) the data is secret and by requesting mutual recognition, we are responsible for the Health Authorities act of unfair competition following use of the Neoral dossier in reviewing the SangCya Oral Solution dossier. While the summons acknowledges that the U.K. High Court did not invalidate the SangCya Oral Solution marketing authorization, it does not acknowledge that the High Court ruled that the MCA could review the Neoral data. To the best of our knowledge, Novartis Italy has not filed suit against the Italian Health Authorities. The initial appearance of the parties before the Milan Tribunal was scheduled for January 2001. We filed our response to the complaint at that time, and the hearing has been postponed until February 2003.

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

Summary

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

IFFA CREDO and Elevage Scientifique des Dombes Breach of Contract Suit

In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes, sued our French subsidiary, IMTIX-SangStat SAS, for breach of contract. On May 2, 2001 we were notified that the Commercial Court of Lyon ruled against IMTIX-SangStat in the breach of contract suit and the court awarded the suppliers 26.5 million French Francs (approximately $3.6 million) for lost profits and reimbursement of capital expenditures. IMTIX-SangStat recorded a charge of $3,250,000 to other expense net for the year ended December 31, 2001, which, combined with reserves recorded in fiscal 2000, fully provided for the court award of

$3,600,000. On March 22, 2002, the appeals court upheld the lower court decision and assessed interest against us of approximately $204,000 which has been recorded as a charge to other income (expense) - net for the year ended December 31, 2001.

Our rabbit serum requirements are currently being met by our other suppliers.

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

We distributed our Definitive Proxy Statement, Proxy and Annual Report to Stockholders on or about April 5, 2002 to each stockholder of record as of March 18, 2002, for our Annual Meeting of Stockholders held on May 14, 2002. At our Annual Meeting, the stockholders were asked to consider four proposals.

The first proposal involved the election of directors. The nominating committee of the Board of Directors selected seven nominees, who all ran unopposed. All the nominees were then serving as our directors, except Hollings Renton, who had not previously served on our Board. The nominees of the Board, and the voting results with respect thereto, were:

Name	Votes For	Withheld
Jean-Jacques Bienaimé	23,206,316	356,841
Fredric Feldman	23,206,310	356,847
Nicholas J. Simon III	21,465,147	2,098,010
Hollings Renton	23,203,916	359,241
Richard D. Murdock	23,205,310	357,847
Andrew Perlman	23,206,316	356,841
Vincent R. Worms	23,204,516	358,641

The second proposal was an amendment to our Certificate of Incorporation to increase the number of authorized shares of our Common Stock by 5,000,000 shares, from 35,000,000 to 40,000,000. The number of shares cast for, against and abstentions were 23,060,741, 439,254, and 9,162, respectively. The affirmative vote of a majority of the shares of Common Stock outstanding as of the record date was required for approval of this proposal. The percent of shares voted in favor of this proposal was 88% of the shares of Common Stock outstanding. Therefore, proposal two was approved by the stockholders

The third proposal was a proposal to consider and approve our 2002 Stock Option Plan and the reservation of shares thereunder. The number of shares cast for, against and abstentions were 14,484,082, 6,028,869, and 44,378, respectively. The affirmative vote of a majority of the votes cast on the proposal at the Annual Meeting was required for approval of this proposal. The percent of shares voted in favor of this proposal was 71% of the shares of Common Stock outstanding. Therefore, proposal three was approved by the stockholders.

The fourth and final proposal was the ratification of our independent auditors, Deloitte & Touche LLP, for the fiscal year ending December 31, 2002. The number of shares cast for, against, and abstentions were 22,400,114, 1,159,165, and 3,878, respectively. The affirmative vote of a majority of the votes cast on the proposal at the Annual Meeting was required for approval of this proposal. The percent of shares voted in favor of this proposal was 95% of the shares of Common Stock outstanding. Therefore, proposal four was approved by the stockholders.

ITEM 5. Other Information

None

ITEM 6. Exhibits and Reports on Form 8-K

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

Exhibits	Description
3.1(1)	Certificate of Amendment of the Certificate of Incorporation, filed with the Delaware Secretary of State on June 6, 2002
3.2	Restated Certificate of Incorporation of SangStat Medical Corporation filed with the Delaware Secretary of State on July 9, 2002
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

(1) Previously filed as an Exhibit to our Form 8-K filed on June 10, 2002.

(b) We filed Current Reports on Form 8-K on May 22, 2002, June 10, 2002 and July 15, 2002.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SangStat Medical Corporation
(Registrant)

Signature	**Title**	**Date**
/s/ Stephen G. Dance Stephen G. Dance, CPA, FCA.	Senior Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	August 13, 2002