SANGSTAT MEDICAL CORP
Form 10-Q/A
May 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 March 31, 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 o No

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

CLASS	NUMBER OF SHARES
Common Stock	26,367,534*

* As of April 30, 2002

SangStat Medical Corporation

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SANGSTAT MEDICAL CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2002 (unaudited)	December 31, 2001 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 108,540	$ 32,822
Accounts receivable (net of allowance for doubtful accounts of $4,311 in 2002 and $4,072 in 2001)	20,698	19,872
Other receivables	2,199	480
Inventories	20,444	22,942
Prepaid expenses and other current assets	1,946	2,494
Total current assets	153,827	78,610
PROPERTY AND EQUIPMENT net	5,487	5,469
GOODWILL	578	
INTANGIBLE ASSETS (net of accumulated amortization of $3,500 in 2002 and $4,324 in 2001)	8,392	9,220
OTHER ASSETS	23,295	21,260
TOTAL	$ 191,579	$ 114,559
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 23,415	$ 22,019
Accrued liabilities	13,255	14,375
Capital lease obligations current portion	169	177
Deferred revenue current portion	3,158	3,158
Notes payable current portion	5,390	5,615
Total current liabilities	45,387	45,344
CAPITAL LEASE OBLIGATIONS	283	326
DEFERRED REVENUE	5,528	6,317
NOTES PAYABLE	20,254	30,213
STOCKHOLDERS EQUITY:		
Preferred stock, $.001 par value, 5,000 shares authorized; none outstanding		
Common stock, $.001 par value, 35,000 shares authorized; outstanding: 2002, 26,362 shares; 2001, 20,961 shares	309,722	222,521
Accumulated deficit	(186,337)	(187,015)

Accumulated other comprehensive loss		(3,258)		(3,147)
Total stockholders equity		120,127		32,359
TOTAL	$	191,579	$	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 March 31,	
	2002	**2001**
REVENUES:		
Net product sales	$ 23,355	$ 19,535
Revenue from collaborative agreements	789	790
Total revenues	24,144	20,325
COSTS AND OPERATING EXPENSES:		
Cost of product sales	10,623	8,621
Research and development	4,318	4,545
Selling, general and administrative	7,953	8,725
Amortization of intangible assets	250	348
Total costs and operating expenses	23,144	22,239
Income (loss) from continuing operations	1,000	(1,914)
OTHER INCOME (EXPENSE) NET	111	(3,795)
INCOME (LOSS) FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	1,111	(5,709)
INCOME TAX PROVISION	433	
NET INCOME (LOSS) FROM CONTINUING OPERATIONS	678	(5,709)
NET LOSS FROM OPERATIONS OF DISCONTINUED OPERATION		(763)
NET INCOME (LOSS)	$ 678	$ (6,472)
NET INCOME (LOSS) PER SHARE BASIC		
Continuing operations	$ 0.03	$ (0.29)
Discontinued operation		(0.04)
Net income (loss)	$ (0.33)	$ (0.33)
NET INCOME (LOSS) PER SHARE DILUTED		
Continuing operations	$ 0.03	$ (0.29)
Discontinued operation		(0.04)
Net income (loss)	$ 0.03	$ (0.33)
Shares Used in Per Share Computations Basic	24,032	19,414
Shares Used in Per Share Computations Diluted	24,766	19,414

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2002	**2001**
Net income (loss)	$ 678	$ (6,472)
Unrealized gains and losses on marketable securities classified as available for sale in the current period		1
Foreign currency translation adjustments	(111)	(718)
Total comprehensive income (loss)	$ 567	$ (7,189)

See notes to Condensed Consolidated Financial Statements.

SANGSTAT MEDICAL CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2002	**2001**
OPERATING ACTIVITIES:		
Net income (loss) from continuing operations	$ 678	$ (5,709)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	634	882
Non-cash interest expense	210	326
Loss on disposal of property and equipment	7	177
Changes in assets and liabilities:		
Accounts receivable	(826)	(2,437)
Other receivables	(1,719)	236
Inventories	201	1,568
Prepaid expenses and other current assets	548	(872)
Accounts payable	1,396	(2,705)
Accrued liabilities	(1,120)	3,254
Deferred revenue	(789)	(790)
Net cash used in continuing operating activities	(780)	(6,070)
Net cash used in discontinued operation		(763)
Net cash used in operating activities	(780)	(6,833)
INVESTING ACTIVITIES:		
Purchases of property and equipment	(442)	(276)
Maturities of short-term investments		358
Purchases of short-term investments		(250)
Other assets	262	2,235
Net cash (used) provided by investing activities	(180)	2,067
FINANCING ACTIVITIES:		
Sale of common stock	87,201	4,593
Notes payable borrowings	156	246
Notes payable repayments	(10,550)	(3,252)
Repayment of capital lease obligations	(51)	(164)
Net cash provided by financing activities	76,756	1,423
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(78)	(718)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	75,718	(4,061)

CASH AND CASH EQUIVALENTS, Beginning of period		32,822		19,046
CASH AND CASH EQUIVALENTS, End of period	$	108,540	$	14,985
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Cash paid during the period for interest	$	449	$	1,782

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. 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 month period ended March 31, 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 month period ended March 31, 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 March 31,	
	2002	2001
Numerator:		
Net income (loss)		
Continuing operations	$ 678	$ (5,709)
Discontinued operation		(763)
Net income (loss)	$ 678	$ (6,472)
Denominator:		
Basic:		
Weighted average number of common shares outstanding	24,032	19,414
Diluted:		
Weighted average number of common shares outstanding	24,032	19,414
Common share equivalents stock options	734	
Weighted average number of common shares and common share equivalents	24,766	19,414
Basic net income (loss) per share		
Continuing operations	$ 0.03	$ (0.29)
Discontinued operation		(0.04)
Net income (loss)	$ 0.03	$ (0.33)
Diluted net income (loss) per share		
Continuing operations	$ 0.03	$ (0.29)
Discontinued operation		(0.04)
Net income (loss)	$ 0.03	$ (0.33)

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

Accumulated other comprehensive loss consists of foreign currency translation adjustments. The balance at March 31, 2002 and December 31, 2001 was $3,258,000 and $3,147,000, respectively.

4. ***Inventories***

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

	March 31, 2002	December 31, 2001
Raw materials	$ 869	$ 2,976
Work in process	12,568	13,868
Finished goods	7,007	6,098
Total	$ 20,444	$ 22,942

In addition to these inventories, the Company has classified at March 31, 2002 and December 31, 2001 approximately $17,561,000 and $15,263,000, respectively, of raw materials inventory as other assets in the accompanying condensed consolidated balance sheet 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):

		March 31, 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	$ 1,903	$ 5,710	$ 7,613	$ 1,767	$ 5,846
Avoided royalties	14	2,514	628	1,886	2,514	584	1,930
Trademarks	10	763	267	496	763	248	515
Customer list	5	1,002	702	300	1,002	651	351
Assembled workforce	5				1,652	1,074	578
Total		$ 11,892	$ 3,500	$ 8,392	$ 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 months ended March 31, 2001, net loss for that period would have decreased by $83,000 with no effect on the reported net loss per share. 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):

		March 31, 2002		December 31, 2001
Note payable to Aventis	$	6,500	$	9,000
Discount on note payable to Aventis		(540)		(727)
Convertible note		9,802		9,779
Note payable to Abbott Laboratories		8,000		16,000
Other debt		1,882		1,776
Total		25,644		35,828
Less current portion		(5,390)		(5,615)
Long-term	$	20,254	$	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. 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 three months ended March 31, 2001. Inventory and accounts receivable-net of reserves related to TTP were $1,060,000 and $3,204,000, respectively, at March 31, 2001.

9. ***Recently Issued Accounting Pronouncements***

In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangible Assets.* SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired outside of a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives not be amortized, but will rather be tested at least annually for impairment. The Company adopted SFAS No. 142 for its fiscal year beginning January 1,

2002. The Company has evaluated existing goodwill under the transitional impairment test in SFAS No. 142 and, accordingly, has determined that no impairment was indicated. See Note 5.

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 fiscal years beginning after June 15, 2002; however early application is permitted. The Company is currently in the process of evaluating the impact of this Statement on its financial condition 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. This Statement is effective for fiscal years beginning after December 15, 2001. 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.

10. ***Litigation***

Novartis Patent Litigation With Respect to Gengraf

Novartis sued Abbott claiming that Gengraf® infringes its patents. Novartis s complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the U.S., but to date Novartis has not moved for a preliminary injunction. The trial is scheduled for July 23, 2002. Abbott informed the Company that it does not believe it infringes the Novartis patents. The Company has not been named a defendant in this lawsuit, and the Company has only limited access to information about it. 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 name the Company in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to the Company s interests. Should the Company be named in this suit, the Company may incur expenses prior to reimbursement (if any) by Abbott pursuant to its indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, Gengraf may be temporarily or permanently removed from the market, or the Company and Abbott may be required to negotiate a license on unfavorable terms.

Novartis Regulatory Litigation

U.S. Regulatory Litigation. Novartis U.S. sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia (case number 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis

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 may remain a party in the case. Novartis has filed motions related to the remaining issues in the case, and the Court has not yet ruled on Novartis s motions. 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. No date has been set for the ECJ hearing, but it is likely to be scheduled sometime in 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 capsule. Because the High Court ruled in favor of the MCA with respect to the SangCya Oral Solution marketing authorization and the Court of Appeal has referred questions of law to the ECJ, the Company believes that it is unlikely that a court would grant Novartis a preliminary injunction with respect to its cyclosporine capsule marketing authorization. If the Court of Appeals reverses the High Court s ruling following the ECJ s decisions on questions of law, either the MCA could still approve 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 June 2002.

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

Summary

Although the Company is optimistic that these disputes will ultimately be resolved in its favor, the course of litigation is inherently uncertain. With respect to Novartis s lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, the Company s revenues would be reduced. With respect to the European regulatory and trade secret lawsuits, Novartis 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 cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve the Company s MAA for its cyclosporine capsule until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004). If the Company cannot obtain approval of its cyclosporine capsule in Europe until 2004, this could have an adverse impact on the Company s future revenues and results of operations. With respect to the FDA lawsuit, Novartis 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 revenues. The litigation, if not resolved favorably to the

Company, could have a material adverse effect on the Company s business, financial condition, cash flows and operating results.

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 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, as well as those discussed elsewhere herein. These forward-looking statements are based on our current 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 commissions and royalties that are recorded in the same period as the related revenue. While we believe we can make reliable estimates for these revenue adjustments, it is possible that actual amounts realized could vary from our estimates and that the amounts of such changes could affect our operating results.

Revenue from collaborative agreements is recognized in accordance with the related contract terms. Upfront or milestone payments received under such agreements are generally recognized as revenues ratably over the life of the agreement where significant obligations for future services or 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 March 31, 2002 we classified approximately $17,561,000 of bulk cyclosporine raw materials inventory, net of reserves, 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 and were not significant for any period presented.

Income taxes

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

We have substantial deferred tax assets that relate to prior period losses, primarily in the United States. We evaluate these deferred tax assets in each tax jurisdiction by estimating the likelihood of 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 December 31, 2001, we had approximately $75 million of valuation allowances related to our net deferred tax assets.

Recently Issued Accounting Pronouncements

In June 2001, the FASB issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired outside of a business combination and the accounting for goodwill and other

intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives not be amortized, but will rather be tested at least annually for impairment. We adopted SFAS No. 142 for our fiscal year beginning January 1, 2002. Upon adoption, and pursuant to the requirements of SFAS No. 142, assembled workforce intangibles were reclassified to goodwill. We have evaluated existing goodwill under the transitional impairment test in SFAS No. 142 and, have determined that no impairment was indicated. All of our identifiable intangible assets are subject to amortization. We evaluated the useful lives of our 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 months ended March 31, 2001, net loss for that period would have decreased by $83,000 with no effect on the reported net loss per share.

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 fiscal years beginning after June 15, 2002; however early application is permitted. We are currently in the process of evaluating the impact of this Statement on our financial condition 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. This Statement is effective for fiscal years beginning after December 15, 2001. 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.

Results of Operations Three Months Ended March 31, 2002 and 2001

Revenues. Total revenues for the three months ended March 31, 2002 were $24,144,000, an increase of $3,819,000 or 19% over total revenues of $20,325,000 for the three months ended March 31, 2001. The increase was due primarily to sales of Thymoglobulin and Gengraf in the U.S., which accounted for $2,413,000 and $1,976,000 of the increase, respectively. This increase was partially offset by lower sales of other products.

Included in total revenues was revenue from collaborative agreements of $789,000 and $790,000 for the three months ended March 31, 2002 and 2001, respectively. For both periods, this revenue relates to recognition of milestone payments from Abbott Laboratories under the co-promotion agreement for Gengraf. The unamortized portion of these milestone payments is shown as deferred revenue on the Company s condensed consolidated balance sheet and will be recognized as revenue on a straight-line basis over the remaining term of the co-promotion agreement.

Cost of sales. Cost of sales was $10,623,000 for the three months ended March 31, 2002, an increase of $2,002,000 or 23% over cost of sales of $8,621,000 for the three months ended March 31, 2001. The increase in cost of sales for the three months ended March 31, 2002 was

due to the overall increase in sales and the higher relative cost of Gengraf as compared to our other products.

Research and development. Research and development expenses were $4,318,000 for the three months ended March 31, 2002, a decrease of $227,000 or 5% from research and development expenses of $4,545,000 for the three months ended March 31, 2001. The decrease in spending on research and development mainly relates to expenses for SangStat s negotiated share of development costs incurred by Abgenix for ABX-CBL that totaled approximately $1,234,000 for the three months ended March 31, 2001 as compared to approximately $685,000 for the three months ended March 31, 2002. This decrease in spending on ABX-CBL was partially offset by an increase in spending on RDP58 and the ongoing stability studies for our cyclosporine capsule.

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 months ended March 31, 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 have completed Phase I clinical trials for RDP58 and subsequently started a Phase IIa trial in October 2001. We currently expect to announce results of this trial in the second half of 2002. We are also conducting a Phase II / III study for ABX-CBL, which we expect to complete by the end of 2002. 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 by the end of 2002. The primary end-point is 180 days after enrollment. Of course, our timeline is an estimate that is 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 March 31, 2002 were $7,953,000, a decrease of $772,000 or 9% from selling, general and administrative expenses of $8,725,000 for the three months ended March 31, 2001.

The decrease in expenses for the three months ended March 31, 2002 reflects the results of SangStat s cost control efforts through the continuation of its cost-containment program, 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 March 31, 2002 was an income of $111,000, compared to an expense of $3,795,000 for the three months ended March 31, 2001. The following table shows the components of other income (expense) net.

	Three Months Ended March 31,	
	2002	**2001**
Interest expense net	$ (318)	$ (698)
Net gains/(losses) on sales of fixed assets	300	(177)
Compensation received for a termination of manufacturing agreement	375	
Reimbursement claim received from a supplier		856
Charge related to a breach of contract suit		(3,148)
Foreign exchange effects resulting from the impact of currency movements	(175)	(520)
Other, net	(71)	(108)
Other income (expense) net	$ 111	$ (3,795)

Income taxes. For the three months ended March 31, 2002, we recorded a provision of $433,000 for European income taxes compared to a zero provision for the three months ended March 31, 2001. The change in provision is attributable to the net income position of our European subsidiaries in the current period as compared to a net loss in the prior period.

Net income (loss) from continuing operations. Net income from continuing operations for the three months ended March 31, 2002 was $678,000, an increase of $6,387,000 or 112% as compared to the net loss of $5,709,000 for the three months ended March 31, 2001. The increase in net income for the three months ended March 31, 2002 was primarily due to higher product sales and lower selling, general and administration and research and development expenses, partially offset by higher cost of sales, resulting primarily from the higher product sales. In addition, the three months ended March 31, 2001 included a one-time charge of $3,148,000 related to a breach of contract suit.

Net loss from operations of discontinued operation. Net sales of transplantation services for the three months ended March 31, 2001 was $4,199,000 and the net loss from transplantation services for the three months ended March 31, 2001 was $763,000. 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 months ended March 31, 2002.

Impact of Litigation

The cyclosporine products that we sell are involved in litigation. Novartis sued our collaborator Abbott, claiming that Gengraf violates their patents. Although we are optimistic that these disputes will ultimately be resolved in our or Abbott s favor, the course of litigation is inherently uncertain. With respect to Novartis s patent infringement lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, our revenues would be reduced. With respect to the European regulatory and trade secret lawsuits, Novartis 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 an adverse impact on our business and 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 and operating results. Currently, none of these lawsuits involves significant time, resources or expense. The U.K. regulatory litigation may require additional time and expense in 2002 as we prepare for the European Court of Justice hearing.

Liquidity and Capital Resources

During the first three months of 2002 and 2001, the net cash used in continuing operating activities was approximately $780,000 and $6,070,000, respectively. The decrease in net cash used in operating activities in the first three months of fiscal 2002 was due substantially to a net income in 2002 as compared to a net loss in 2001 and increases in accounts payable and accounts receivable, partially offset by a reduction in net inventories and a decrease in accrued liabilities. The cash used in the discontinued operation approximated the net loss of the discontinued operation for the three months ended March 31, 2001. As of March 31, 2002, we had cash and cash equivalents of $108,540,000 and total assets of $191,579,000.

Net cash used in investing activities for the three months ended March 31, 2002 was $180,000 as compared to net cash provided by investing activities of $2,067,000 for the comparable quarter in 2001. The amount for the period ended March 31, 2002 is primarily the result of purchases of property and equipment, partially offset by a decrease in other assets net of raw materials inventory. The amount in 2001 is primarily the result of the maturity of short-term investments and a decrease in other assets, partially offset by purchases of property and equipment.

Net cash provided by financing activities for the three months ended March 31, 2002 was $76,756,000 as compared to $1,423,000 for the same period in 2001. In both fiscal 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. In February 2002, we repaid $8 million of a note payable to Abbott Laboratories. We intend to use

the remaining proceeds for repayment of existing debt and general corporate purposes, including in-licensing and partnering opportunities. In addition, we may use a portion of the net proceeds to acquire complementary products, product candidates or businesses. In January 2001, we completed a private placement of 421,000 shares of common stock with a group of institutional investors. The shares were issued at a discount to the closing market price on the date the agreements were signed, for aggregate proceeds of $3,999,500.

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

Euro-Currency

The Single European Currency (Euro) was introduced on January 1, 1999 with complete transition to this new currency required by January 2002. We have 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 March 31, 2002, our accumulated deficit was $186.3 million. While the quarter ended March 31, 2002 was a profitable quarter, we may recognize losses in subsequent quarters for a variety of reasons. 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. Revenues from SangCya Oral Solution were immaterial in 1999, 2000 and 2001.

Our expectations with respect to achieving positive cash flow and financial reporting profitability are subject to risk and uncertainty. While we recently had our first profitable quarter, 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;

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 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.

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; or
- product liability claims.

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

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

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

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

perception of bioequivalence;

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

pricing pressure from other generic competitors;

intense competitive pressure from Novartis; and

Novartis s litigation with the 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. If 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. IFFA CREDO and Elevage Scientifique des Dombes, two affiliated suppliers, sued our French subsidiary for breach of

contract after we reduced our orders of rabbit serum from them. As a result of a court ruling against us in this lawsuit, we 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 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 use a portion of our funds for the licensing of new products or the acquisition of 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. Moreover, 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 expect to realize quarterly profitability, we would expect that any such acquisition or licensing could have the immediate effect of causing an operating loss in future periods. Furthermore, the licensing or acquisition of new products or companies for cash could limit our financial resources, and the issuance of our stock in such a transaction could result in substantial dilution to existing stockholders.

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. In addition, since our CycloTech product is only intended for use with the SangCya Oral Solution, we have discontinued the distribution of CycloTech. 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 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 currently have product liability insurance in the amount of $25 million per claim and $25 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 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. The trial is scheduled for July 23, 2002. 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 name us in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to our interests. If Novartis names us in this suit, we may incur expenses before reimbursement, if any, by Abbott, who is obligated under our agreement to indemnify us against such suits 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 to remove Gengraf from the market before our co-promotion agreement with Abbott expires on December 31, 2004, our revenues would decrease materially.

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

Our success depends in part on our ability to obtain and enforce patent protection for our products and to preserve our trade secrets. We hold patents and pending patent applications in the U.S. and abroad. Some of our patents involve specific claims and thus do not provide broad coverage. Our patent applications or any claims of these patent applications may not be allowed, valid or enforceable. These patents or claims of these patents may not provide us with competitive advantages for our products. Our competitors may successfully challenge or circumvent our issued patents and any patents issued under our pending patent applications. Further, although we received orphan drug designation for Thymoglobulin for treatment of Myelodysplastic Syndrome, also known as pre-leukemia, we do not have patents on Thymoglobulin or Lymphoglobuline. Therefore, we are primarily dependent upon our trade secrets for these products. We have not conducted extensive patent and prior art searches with respect to our product candidates and technologies, and we do not know if third-party patents or patent applications exist or 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 involves the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and infectious biological specimens. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by 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.

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 claiming that Gengraf® infringes its patents. Novartis s complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the U.S., but to date Novartis has not moved for a preliminary injunction. The trial is scheduled for July 23, 2002. Abbott informed us that it does not believe it infringes the Novartis patents. We have not been named a defendant in this lawsuit, and we have only limited access to information about it. 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, however. Novartis may choose to name us in this suit, Abbott may not prevail, or Abbott may choose to settle on terms adverse to our interests. Should we be named in this suit, we may incur expenses prior to reimbursement (if any) by Abbott pursuant to its indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, Gengraf may be temporarily or permanently removed from the market, or we and Abbott may be required to negotiate a license on unfavorable terms.

Novartis Regulatory Litigation

U.S. Regulatory Litigation. Novartis U.S. sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia (case number 1: 99CV-00323) alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis 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. Novartis has filed motions related to the remaining issues in the case, and the Court has not yet ruled on Novartis s motions. 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. No date has been set for the ECJ hearing, but it is likely to be scheduled sometime in 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.