

SANGSTAT MEDICAL CORP  
Form 424B5  
February 05, 2002

Filed pursuant to Rule 424(b)(5)  
Registration Statement No. 333-76028

**PROSPECTUS SUPPLEMENT**

(To prospectus dated December 27, 2001)

**4,500,000 Shares**

**SangStat Medical Corporation**

**Common Stock**

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We are selling 4,500,000 shares of our common stock. The shares are quoted on the Nasdaq National Market under the symbol SANG. On February 4, 2002, the last sale price of the shares as reported on the Nasdaq National Market was \$17.60 per share.

**Investing in the common stock involves risks which are described in the Risk Factors section beginning on page S-5 of this prospectus supplement.**

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	<u>Per Share</u>	<u>Total</u>
Public offering price	\$17.25	\$77,625,000
Underwriting discount	\$ .99	\$ 4,455,000
Proceeds, before expenses, to SangStat Medical Corporation	\$16.26	\$73,170,000

The underwriters may also purchase up to an additional 675,000 shares at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus supplement to cover overallotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about February 8, 2002.

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**Merrill Lynch & Co.**

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**JPMorgan**

**Thomas Weisel Partners LLC**

**Wells  
Fargo  
Securities,  
LLC**

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The date of this prospectus supplement is February 4, 2002.

**TABLE OF CONTENTS**

**Prospectus Supplement**

	<b>Page</b>
<u>Prospectus Supplement Summary</u>	S-1
<u>Risk Factors</u>	S-5
<u>Special Note Regarding Forward Looking Statements</u>	S-16
<u>Use of Proceeds</u>	S-17
<u>Price Range of Common Stock and Dividend Policy</u>	S-18
<u>Capitalization</u>	S-19
<u>Dilution</u>	S-20
<u>Selected Consolidated Financial Data</u>	S-21
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	S-22
<u>Business</u>	S-32
<u>Management</u>	S-50
<u>Underwriting</u>	S-52
<u>Legal Matters</u>	S-55
<u>Experts</u>	S-55
<u>Index to Consolidated Financial Statements</u>	F-1

**Prospectus**

	<b>Page</b>
<u>About this Prospectus</u>	1
<u>Summary</u>	2
<u>Risk Factors</u>	5
<u>Forward Looking Statements</u>	14
<u>Use of Proceeds</u>	14
<u>Description of the Common Stock and Preferred Stock We May Offer</u>	15
<u>Description of the Debt Securities We May Offer</u>	17
<u>Description of the Warrants We May Offer</u>	22
<u>Plan of Distribution</u>	23
<u>Validity of Securities</u>	25
<u>Experts</u>	25
<u>Incorporation of Certain Information by Reference</u>	25
<u>Where You Can Find More Information</u>	25

**Important Notice about Information Presented in this  
Prospectus Supplement and the Accompanying Prospectus**

In this prospectus supplement and the accompanying prospectus, the terms SangStat, we, us and our refer to SangStat Medical Corporation and its wholly owned subsidiaries.

We provide information to you about the common stock in two separate documents: (a) the accompanying prospectus, which provides general information, and (b) this prospectus supplement, which describes the specific details regarding this offering. If information in this prospectus supplement is inconsistent with the prospectus, you should rely on this prospectus supplement.

You should also read and consider the information in the documents we have referred you to in Incorporation of Certain Information by Reference and Where You Can Find More Information on page 25 of the accompanying prospectus. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information, except for any information superseded by information contained directly in the prospectus or this prospectus supplement.

Except as otherwise indicated, the information in this prospectus supplement and the accompanying prospectus assumes no exercise of the underwriters overallotment option to purchase additional shares of common stock.

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You should rely only on the information incorporated by reference or provided in this prospectus supplement and the accompanying prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus supplement and the accompanying prospectus is accurate as of any date other than the date on the front of those documents.

**PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights information contained elsewhere in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. We urge you to read this entire prospectus supplement and the accompanying prospectus carefully, including the Risk Factors section and the documents identified under Incorporation of Certain Information by Reference and Where You Can Find More Information in the accompanying prospectus.*

**SangStat Medical Corporation**

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 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. Consequently, on April 20, 2001, we sold our transplantation services segment, The Transplant Pharmacy, to Chronimed.

Our primary marketed product, Thymoglobulin, a treatment for acute rejection of a kidney transplant, was launched in the U.S. in February 1999. Thymoglobulin achieved worldwide sales of \$30.6 million in 1999, \$37.9 million in 2000 and \$37.0 million in the nine months ended September 30, 2001. The success of Thymoglobulin and its potential in areas beyond solid organ transplantation has provided us with the ability to examine and develop new therapeutic opportunities outside of transplantation.

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

We currently sell the following products:

Thymoglobulin® (sold under the name Thymoglobuline® outside the U.S.);

Gengraf® cyclosporine capsule (co-promoted with Abbott Laboratories in the U.S.);

Lymphoglobuline (outside the U.S.); and

Celsior®.

Our principal products under development include:

A smaller-size cyclosporine capsule;

ABX-CBL (anti-CD147 antibody in co-development with Abgenix, Inc.); and

RDP58.

### Strategy

Our objective is to be a leader in the research, development and commercialization of high value therapeutics in the areas of immunology, hematology/oncology and auto-immune disease. Key elements of our business strategy are to:

leverage our leading transplantation franchise to continue to capture market share and expand use of our transplantation products in the market place;

expand the use of Thymoglobulin through post-marketing clinical studies and new clinical studies in areas such as hematological disorders and malignancies;

develop and expand our technology and pipeline of products in transplantation and in new therapeutic areas;

continue to invest in a biotechnology research and development infrastructure to help us develop new products and bring them to the market; and

leverage our position as an established biotechnology company with a dedicated sales force in the U.S. and Europe.

### Recent Developments

On January 22, 2002, we reported that our revenues were \$27.3 million for the fourth quarter of 2001, an increase of 48% versus the fourth quarter of 2000 and 9% versus the third quarter of 2001. We also reported at that time that our net income for the fourth quarter of 2001 was \$641,000, compared to a net loss of \$5.5 million in the fourth quarter of 2000. This resulted in net earnings per share for the fourth quarter of 2001 of \$0.03 per share, in comparison to a net loss for the fourth quarter of 2000 of \$0.30 per share. In addition, we reported that our revenues for 2001 increased to \$94.5 million, in comparison to \$63.1 million for 2000, and that our net loss was \$9.2 million, in comparison to a net loss of \$44.4 million in 2000. Our net loss per share in 2001 was \$0.46, in comparison to a net loss per share in 2000 of \$2.48. Furthermore, we reported that our cash position grew from \$25.5 million at the end of the third quarter of 2001 to \$32.8 million as of December 31, 2001.

We have experienced significant operating losses since our incorporation in 1988. As of September 30, 2001, our accumulated deficit was \$187.4 million. To date, our product revenues have been primarily derived from sales of Thymoglobulin, Gengraf and Lymphoglobuline. Revenues from Thymoglobulin, Gengraf and Lymphoglobuline were 55%, 30% and 8%, respectively, of total revenues during the nine months ended September 30, 2001. While we expect the quarter ended December 31, 2001 to be our first 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. We also are subject to litigation. Novartis sued Abbott for patent infringement with respect to Gengraf. Should Novartis succeed in obtaining a preliminary or permanent injunction, this injunction may temporarily or permanently remove Gengraf from the market.

Our principal executive offices are located at 6300 Dumbarton Circle, Fremont, California 94555, and our telephone number is (510) 789-4300. As used in this prospectus supplement, the words we, us, our and SangStat refer to SangStat Medical Corporation, a Delaware corporation, and its wholly owned subsidiaries.

Thymoglobulin<sup>®</sup>, Thymoglobuline<sup>®</sup>, Lymphoglobuline, Celsior<sup>®</sup>, SangCya<sup>®</sup> and SangStat<sup>®</sup> are our registered trademarks. Gengraf<sup>®</sup> is a registered trademark of Abbott Laboratories, Inc. Neoral<sup>®</sup> is a registered trademark of Novartis A.G.

**The Offering**

Common stock offered by SangStat Medical Corporation	4,500,000 shares
Shares outstanding after the offering	25,460,674 shares
Use of proceeds	Repayment of existing debt and general corporate purposes, including in-licensing and partnering opportunities. In addition, we may use a portion of any net proceeds to acquire complementary products, product candidates or businesses. See <b>Use of Proceeds</b> in this prospectus supplement.
Risk factors	See <b>Risk Factors</b> beginning on page S-5 for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
Nasdaq National Market symbol	SANG

The number of shares outstanding after the offering is based on shares outstanding as of December 31, 2001 and excludes:

3,487,577 shares of common stock issuable upon exercise of options and warrants outstanding as of December 31, 2001 at a weighted average exercise price of \$18.13 per share;

490,286 shares of common stock issuable upon exercise of stock options reserved for issuance as of December 31, 2001;  
and

500,773 shares of common stock issuable upon conversion of debt outstanding as of December 31, 2001.

**Summary Consolidated Financial Data**  
(in thousands, except per share data)

	Year Ended December 31,					For the Nine Months Ended September 30,	
	1996	1997	1998	1999	2000	2000	2001
(in thousands, except per share data)							
<b>Consolidated Statements of Operations Data:</b>							
Revenues:							
Net sales	\$ 2,266	\$ 2,456	\$ 10,202	\$ 42,243	\$ 60,447	\$ 42,726	\$ 64,841
Collaborative agreements		750	1,092	2,060	2,698	1,957	2,368
<b>Total revenues</b>	<b>2,266</b>	<b>3,206</b>	<b>11,294</b>	<b>44,303</b>	<b>63,145</b>	<b>44,683</b>	<b>67,209</b>
Costs and operating expenses:							
Cost of sales	2,737	2,646	5,110	18,989	39,246	30,117	29,584
Research and development	8,330	16,210	17,688	14,470	20,788	15,349	13,647
Selling, general and administrative	5,652	9,442	23,707	39,170	41,766	33,791	25,455
Acquired in-process research and development			3,218				
Amortization of intangible assets			351	1,398	1,392	1,044	1,043
<b>Total operating expenses</b>	<b>16,719</b>	<b>28,298</b>	<b>50,074</b>	<b>74,027</b>	<b>103,192</b>	<b>80,301</b>	<b>69,729</b>
Loss from continuing operations	(14,453)	(25,092)	(38,780)	(29,724)	(40,047)	(35,618)	(2,520)
Other income (expense) net	2,123	5,506	3,053	(913)	(1,602)	(1,572)	(5,795)
Loss from continuing operations before income taxes	(12,330)	(19,586)	(35,727)	(30,637)	(41,649)	(37,190)	(8,315)
Income taxes			(257)	(345)	(368)	(106)	(345)
Net loss from continuing operations	(12,330)	(19,586)	(35,984)	(30,982)	(42,017)	(37,296)	(8,660)
Net loss from discontinued operation	(444)	(1,394)	(2,480)	(2,025)	(2,342)	(1,589)	(1,144)
<b>Net loss</b>	<b>\$ (12,774)</b>	<b>\$ (20,980)</b>	<b>\$ (38,464)</b>	<b>\$ (33,007)</b>	<b>\$ (44,359)</b>	<b>\$ (38,885)</b>	<b>\$ (9,804)</b>
Net loss per share basic and diluted:							
Continuing operations	\$ (0.99)	\$ (1.27)	\$ (2.24)	\$ (1.83)	\$ (2.35)	\$ (2.09)	\$ (0.43)
Discontinued operation	(0.04)	(0.09)	(0.15)	(0.12)	(0.13)	(0.09)	(0.06)
	<b>\$ (1.03)</b>	<b>\$ (1.36)</b>	<b>\$ (2.39)</b>	<b>\$ (1.95)</b>	<b>\$ (2.48)</b>	<b>\$ (2.18)</b>	<b>\$ (0.49)</b>
Shares used in per share computations	12,405	15,376	16,080	16,888	17,910	17,857	19,973

**September 30, 2001**

	Actual	As Adjusted
<b>Consolidated Balance Sheet Data:</b>		
Cash, cash equivalents and short-term investments	\$ 25,542	\$ 82,112
Working capital	32,224	88,794
Total assets	108,519	165,089
Long-term obligations, excluding current portion	30,596	14,596
Accumulated deficit	(187,440)	(187,440)
Total stockholders' equity	31,814	104,384



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The adjusted financial data give effect to the application of the proceeds from the sale of the 4,500,000 shares offered hereby at the public offering price of \$17.25 per share, after deducting estimated underwriter discounts and commissions and offering expenses.

S-4

## RISK FACTORS

*This prospectus supplement contains forward-looking statements based on our current expectations. You should be aware that these statements are projections or estimates as to future events, and actual results may differ materially. You should carefully consider the following risk factors, in addition to the other information contained in this prospectus supplement and in any other documents to which we refer you in this prospectus supplement, before purchasing our securities. The risks and uncertainties described below are not the only ones we face.*

### **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 September 30, 2001, our accumulated deficit was \$187.4 million. While we expect the quarter ended December 31, 2001 to be our first 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 55% of total revenues in 1999, 2000 and the nine months ended September 30, 2001, respectively. Revenues from Lymphoglobuline were 19%, 12% and 8% of total revenues in 1999, 2000 and the nine months ended September 30, 2001, respectively. In addition, revenues from Gengraf were 18% and 30% of total revenues in 2000 and the nine months ended September 30, 2001, respectively. Revenues from SangCya Oral Solution were immaterial in 1999, 2000 and the first nine months of 2001.

Our expectations with respect to achieving positive cash flow and financial reporting profitability are subject to risk and uncertainty. While we recently announced 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 any securities analysts. This could cause the trading price of our common stock to decline. We therefore believe that quarter-to-quarter comparisons of our operating results may not be a good indication of our future performance, and you should not rely on them to predict our future performance or the future performance of our stock. Our operating losses have been substantial each year since inception. We also expect 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;
- 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. In particular, the realization of any of the risks described in this prospectus supplement could have a significant and adverse impact on the market price for our stock.

**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.

**Two 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 HBOC. Approximately 13% and 15%, respectively, of total revenues in 2000 were derived from sales to customers who place orders through these two wholesalers, and during the nine months ended September 30, 2001, sales to Cardinal Health Inc. and McKesson HBOC accounted for approximately 27% and 18%, respectively, of total revenues. We expect that we will continue to derive a substantial portion of our revenue from Cardinal Health Inc. and McKesson HBOC. 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. We expect the FDA to inspect our Lyon facility as part of its regular inspection process. The FDA last inspected the Lyon facility from July 31 - August 6, 2000. The FDA identified several deficiencies as a result of that inspection. We informed the FDA of our plans for addressing these issues. The FDA will review the adequacy of these actions at its next routine inspection. The FDA recently notified us that the next inspection of our Lyon facility and the Aventis manufacturing facilities would occur in March of 2002. In addition, the Canadian Bureau of Biologics has scheduled an inspection of our Lyon facility for February. 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. Before our acquisition of the IMTIX division of Aventis in 1998, certain batches of Thymoglobulin did not meet manufacturing specifications, resulting in a shortage of Thymoglobulin for commercial sale. We still rely on Aventis for certain important manufacturing services, including quality assurance, quality control, and lyophilization, a step in the manufacturing process which involves removing the water from the product, similar to freeze-drying. Aventis may not continue to effectively and continuously provide us these critical manufacturing services. In addition, we may have difficulties manufacturing Thymoglobulin or Lymphoglobuline in the future that may impair our ability to deliver products to our customers, which could reduce our revenues.

Although we 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 \$3.3 million to other expense net in the quarter ended March 31, 2001 which, combined with reserves recorded in fiscal 2000, fully provide for the court award of \$3.6 million. Although we believe the ruling was in error and have appealed the decision, we may lose this appeal.

**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 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 time-line 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 the funds from this offering or issue additional shares in connection with 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 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 was scheduled for February 20, 2002, but has been postponed and a new trial date has not yet been set. 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 this prospectus supplement 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 have 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.

S-15

**SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS**

This prospectus supplement and the accompanying prospectus contain or incorporate by reference certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act, including those identified by the words “believes,” “expects” and similar expressions. These forward-looking statements include, among others, statements regarding:

our anticipated financial results for 2002;

the timeline and potential results of preclinical development and clinical trials;

potential outcomes of our and Abbott’s litigation with Novartis;

our plans for marketing a cyclosporine capsule in Europe;

anticipated expenditures and timing related to FDA and foreign approval of our products and facilities; and

anticipated potential strategic collaborations with others.

These statements are subject to risks and uncertainties, including those set forth in the “Risk Factors” section, and actual results could differ materially from those expressed or implied in these statements. All forward-looking statements included in this prospectus supplement or the accompanying prospectus are made as of their respective dates. We assume no obligation to update any such forward-looking statement or reason why actual results might differ except as required by the Securities Exchange Act of 1934, as amended.

#### USE OF PROCEEDS

We estimate that the net proceeds from the sale of the 4,500,000 shares of common stock that we are offering will be approximately \$72.6 million, based upon a public offering price of \$17.25 per share, after deducting estimated underwriting discounts and commissions and our estimated offering expenses. If the underwriters exercise their option to purchase 675,000 additional shares in the offering, we estimate the aggregate net proceeds to us will be approximately \$83.5 million.

We anticipate that the net proceeds from this offering will be used for repayment of approximately \$16.0 million existing indebtedness to Abbott Laboratories 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, or to make strategic investments in other companies. We have not identified the amounts we plan to spend on each of these areas or the timing of such expenditures, and we will have significant discretion in the use of any net proceeds. The amounts actually expended for each purpose may vary significantly depending upon numerous factors, including the amount and timing of the proceeds from this offering and progress with our development programs. Expenditures will also depend upon the establishment of collaborative arrangements with other companies, the availability of additional financing and other factors. Investors will be relying on the judgment of our management regarding the application of the proceeds of any sale of the securities. Pending these uses, the net proceeds will be invested in interest-bearing, marketable securities. The loan made available to us by Abbott Laboratories bears an annual interest rate of 8.75 percent. As of December 31, 2001, the aggregate principal amount outstanding was \$16.0 million. The loan matures on December 31, 2004.

**PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY**

Since 1993, our common stock has traded on the Nasdaq National Market. We currently trade under the symbol SANG. The following table sets forth the high and low reported sale prices for our common stock for the periods indicated as reported on the Nasdaq National Market.

	<b>High</b>	<b>Low</b>
<b>2002</b>		
First Quarter through February 4, 2002	\$ 22.80	\$ 17.10
<b>2001</b>		
First Quarter	\$ 13.19	\$ 7.50
Second Quarter	17.00	8.88
Third Quarter	19.06	12.35
Fourth Quarter	24.87	15.88
<b>2000</b>		
First Quarter	\$ 48.00	\$ 25.88
Second Quarter	33.81	21.81
Third Quarter	29.88	12.81
Fourth Quarter	14.50	6.50

On February 4, 2002, the last reported sale price of our common stock on the Nasdaq National Market was \$17.60 per share. As of February 1, 2002, we had approximately 82 stockholders of record.

We have never declared or paid cash dividends on our common stock. We do not intend to declare or pay any cash dividends on our common stock in the foreseeable future. We plan to retain any earnings for use in the operation of our business and to fund future growth.

**CAPITALIZATION**

The following table presents our unaudited capitalization as of September 30, 2001:

on an actual  
basis; and

on an as adjusted basis to reflect the receipt and application of net proceeds of the sale of 4,500,000 shares of common stock in this offering at the public offering price of \$17.25 per share, less underwriting discounts and our estimated offering expenses.

The number of shares of common stock to be outstanding after this offering does not include:

3,487,577 shares of common stock issuable upon exercise of options and warrants outstanding as of December 31, 2001 at a weighted average exercise price of \$18.13 per share;

490,286 shares of common stock issuable upon exercise of stock options reserved for issuance as of December 31, 2001;  
and

500,773 shares of common stock issuable upon conversion of debt outstanding as of December 31, 2001.

This table should be read with Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the accompanying notes appearing elsewhere in this prospectus supplement and incorporated by reference in the accompanying prospectus.

	September 30, 2001	
	Actual	As Adjusted
	(in thousands)	
Cash, cash equivalents and short term investments	\$ 25,542	\$ 82,112
Short-term debt:		
Capital lease obligations - current portion	\$ 185	\$ 185
Notes payable - current portion	5,405	5,405
<b>Total short-term debt</b>	<b>\$ 5,590</b>	<b>\$ 5,590</b>
Long-term debt:		
Capital lease obligations	\$ 381	\$ 381
Notes payable	30,215	14,215
<b>Total long-term debt</b>	<b>30,596</b>	<b>14,596</b>
Stockholders' equity:		
Preferred stock, \$.001 par value, 5,000 shares authorized; none outstanding	\$	\$
Common stock, \$.001 par value, 35,000 shares authorized; outstanding: 2001: 20,883 shares actual; and 25,383 as adjusted	221,714	294,284
Accumulated deficit	(187,440)	(187,440)
Accumulated other comprehensive loss	(2,460)	(2,460)
<b>Total stockholders' equity</b>	<b>31,814</b>	<b>\$ 104,384</b>
<b>Total capitalization</b>	<b>\$ 68,000</b>	<b>\$ 124,570</b>



**DILUTION**

If you invest in our common stock, your interest would be diluted to the extent of the difference between the public offering price per share of our common stock and the adjusted net tangible book value per share of our common stock after this offering. Our net tangible book value per share as of September 30, 2001 is \$1.53. We calculate net tangible book value per share by dividing net tangible book value, which equals total tangible assets less total tangible liabilities, by the number of outstanding shares of our common stock.

At the public offering price of \$17.25 per share, our as adjusted net tangible book value at September 30, 2001 would have been \$4.11 per share. This represents an immediate increase in the net tangible book value per share of \$2.58 per share to existing stockholders and an immediate dilution of \$13.14 per share to new investors purchasing shares of common stock in this offering.

The following table illustrates this dilution on a per share basis:

Public offering price per share		\$ 17.25
Net tangible book value per share as of September 30, 2001	\$ 1.53	
Increase per share attributable to new investors	2.58	
	<u>          </u>	
As adjusted net tangible book value per share after this offering		<u>4.11</u>
		<u>          </u>
Dilution per share to new investors		<u>\$ 13.14</u>

To the extent that outstanding options, convertible debt or warrants are exercised, there may be further dilution to new investors.

## SELECTED CONSOLIDATED FINANCIAL DATA

You should read our selected consolidated financial data set forth below in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes thereto contained elsewhere in this prospectus supplement and incorporated by reference in the accompanying prospectus. The selected consolidated statements of operations data for the years ended December 31, 1998, 1999 and 2000 and the selected consolidated balance sheet data as of December 31, 1999 and 2000 are derived from our audited consolidated financial statements contained elsewhere in this prospectus supplement. The consolidated statements of operations data for the years ended December 31, 1996 and 1997 and the consolidated balance sheet data as of December 31, 1996, 1997 and 1998 are derived from our audited consolidated financial statements not included in this prospectus supplement or incorporated by reference in the accompanying prospectus. The consolidated statements of operations data for the nine months ended September 30, 2000 and 2001 and the consolidated balance sheet data as of September 30, 2001 are derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus supplement, and in the opinion of management include all adjustments, consisting only of normal recurring accruals, that are necessary for a fair presentation of our financial position and results of operations for these periods. The historical financial information may not be indicative of our future performance.

	Year Ended December 31,					For the Nine Months Ended September 30,	
	1996	1997	1998	1999	2000	2000	2001
(in thousands, except per share data)							
<b>Consolidated Statements of Operations Data:</b>							
Revenues:							
Net sales	\$ 2,266	\$ 2,456	\$ 10,202	\$ 42,243	\$ 60,447	\$ 42,726	\$ 64,841
Collaborative agreements		750	1,092	2,060	2,698	1,957	2,368
<b>Total revenues</b>	<b>2,266</b>	<b>3,206</b>	<b>11,294</b>	<b>44,303</b>	<b>63,145</b>	<b>44,683</b>	<b>67,209</b>
Costs and operating expenses:							
Cost of sales	2,737	2,646	5,110	18,989	39,246	30,117	29,584
Research and development	8,330	16,210	17,688	14,470	20,788	15,349	13,647
Selling, general and administrative	5,652	9,442	23,707	39,170	41,766	33,791	25,455
Acquired in-process research and development			3,218				
Amortization of intangible assets			351	1,398	1,392	1,044	1,043
<b>Total operating expenses</b>	<b>16,719</b>	<b>28,298</b>	<b>50,074</b>	<b>74,027</b>	<b>103,192</b>	<b>80,301</b>	<b>69,729</b>
Loss from continuing operations	(14,453)	(25,092)	(38,780)	(29,724)	(40,047)	(35,618)	(2,520)
Other income (expense) net	2,123	5,506	3,053	(913)	(1,602)	(1,572)	(5,795)
Loss from continuing operations before income taxes	(12,330)	(19,586)	(35,727)	(30,637)	(41,649)	(37,190)	(8,315)
Income taxes			(257)	(345)	(368)	(106)	(345)
Net loss from continuing operations	(12,330)	(19,586)	(35,984)	(30,982)	(42,017)	(37,296)	(8,660)
Net loss from discontinued operation	(444)	(1,394)	(2,480)	(2,025)	(2,342)	(1,589)	(1,144)
<b>Net loss</b>	<b>\$ (12,774)</b>	<b>\$ (20,980)</b>	<b>\$ (38,464)</b>	<b>\$ (33,007)</b>	<b>\$ (44,359)</b>	<b>\$ (38,885)</b>	<b>\$ (9,804)</b>
Net loss per share - basic and diluted							
Continuing operations	\$ (0.99)	\$ (1.27)	\$ (2.24)	\$ (1.83)	\$ (2.35)	\$ (2.09)	\$ (0.43)
Discontinued operation	(0.04)	(0.09)	(0.15)	(0.12)	(0.13)	(0.09)	(0.06)
	\$ (1.03)	\$ (1.36)	\$ (2.39)	\$ (1.95)	\$ (2.48)	\$ (2.18)	\$ (0.49)
Shares used in per share computations	12,405	15,376	16,080	16,888	17,910	17,857	19,973

December 31,

September 30,

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	1996	1997	1998	1999	2000	2001
	(in thousands)					
<b>Consolidated Balance Sheet Data:</b>						
Cash, cash equivalents and short-term investments	\$ 41,321	\$ 92,036	\$ 29,660	\$ 26,519	\$ 20,607	\$ 25,542
Working capital	40,727	93,812	46,828	63,991	39,774	32,224
Total assets	44,750	104,354	107,327	117,297	114,316	108,519
Long-term obligations, excluding current portion	1,100	1,557	16,402	49,496	44,689	37,702
Accumulated deficit	(40,826)	(61,806)	(100,270)	(133,277)	(177,636)	(187,440)
Total stockholders' equity	40,955	97,470	59,587	41,009	21,924	31,814

S-21

**MANAGEMENT'S DISCUSSION AND ANALYSIS  
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion should be read in conjunction with our consolidated financial statements, including the related notes, contained elsewhere in this prospectus supplement. The following discussion also contains forward-looking statements about our plans, objectives and future results. These forward-looking statements are based on our current expectations, and we assume no obligation to update this information. Realization of these plans and results involves risks and uncertainties, and our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those set forth under the heading "Risk Factors."*

**Overview**

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 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.

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 on a product by product basis. For the nine months ended September 30, 2001, 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 II proof-of-principle clinical trial in the U.K. 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 design of the trial included a pilot study to statistically determine the number of patients. We have completed the pilot study and have expanded the number of patients in this trial. We now expect preliminary communication of the trial results data to occur during the second quarter of 2002 with the final results available in the second quarter of 2003. 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.

On January 22, 2002, we reported that our revenues were \$27.3 million for the fourth quarter of 2001, an increase of 48% versus the fourth quarter of 2000 and 9% versus the third quarter of 2001. We also reported at that time that our net income for the fourth quarter of 2001 was \$641,000, compared to a net loss of \$5.5 million in the fourth quarter of 2000. This resulted in net earnings per share for the fourth quarter of 2001 of \$0.03 per share, in comparison to a net loss for the fourth quarter of 2000 of \$0.30 per share. In addition, we reported that our revenues for 2001 increased to \$94.5 million, in comparison to \$63.1 million for 2000, and that our net loss was \$9.2 million, in comparison to a net loss of \$44.4 million in 2000. Our net loss per share in 2001 was \$0.46, in comparison to a net loss per share in 2000 of \$2.48. Furthermore, we reported that our cash position grew from \$25.5 million at the end of the third quarter of 2001 to \$32.8 million as of December 31, 2001.

## Results of Operations

### Nine Months Ended September 30, 2001 and 2000

*Revenues.* Total revenues for the nine months ended September 30, 2001 were \$67,209,000, an increase of \$22,526,000 or 50% over net sales including product recall returns of \$44,683,000 for the nine months ended September 30, 2000. The increase for the nine months ended September 30, 2001 was due to higher sales of Gengraf, which was launched in the U.S. in May 2000, and increased sales of Thymoglobulin.

Revenues from Thymoglobulin were 55% of total revenues for the nine months ended September 30, 2001 and 62% of total revenues for the nine months ended September 30, 2000. Revenues from Lymphoglobuline were 8% of total revenues for the nine months ended September 30, 2001 and 14% of total revenues for the nine months ended September 30, 2000. Revenues from Gengraf were 30% of total revenues for the nine months ended September 30, 2001 and 13% of total revenues for the nine months ended September 30, 2000. Revenues from SangCya Oral Solution were immaterial both in the nine months ended September 30, 2001 and the nine months ended September 30, 2000.

Included in total revenues was revenue from collaborative agreements of \$2,368,000 for the nine months ended September 30, 2001, an increase of \$411,000 or 21% over revenue from collaborative agreements of \$1,957,000 for the nine months ended September 30, 2000. This revenue relates to milestone payments from Abbott Laboratories under the co-promotion agreement for cyclosporine. The unamortized portion of these milestone payments is shown as deferred revenue on our condensed consolidated balance sheet and will be recognized as revenue on a straight-line basis over the remaining term of the co-promotion agreement.

*Cost of sales.* Cost of product sales and manufacturing expenses were \$29,584,000 for the nine months ended September 30, 2001, an increase of \$11,028,000 or 59% over cost of product sales and manufacturing expenses of \$18,556,000 for the nine months ended September 30, 2000. The increase in cost of product sales and manufacturing expenses was primarily due to increased sales of pharmaceutical products combined with the higher cost of Gengraf as compared to our other products. We anticipate an increase in our total cost of product sales and manufacturing expenses in the fourth quarter of 2001 due to an increase in royalties due to Aventis on sales of Thymoglobulin, an increase in manufacturing costs at our Lyon, France, production facility resulting from a program to improve quality assurance and control, and the higher cost of sales of Gengraf, if Gengraf sales continue to increase as a percentage of total revenues. We further anticipate that this increase in costs may result in a lower gross margin in the fourth quarter of 2001 and that gross margin may remain at this lower level throughout 2002. Total cost of sales for the nine months ended September 30, 2000 included a product recall reserve of \$11,561,000 for SangCya Oral Solution that was taken in the second quarter of 2000. No such reserve has been recorded in 2001.

*Research and development.* Research and development expenses were \$13,647,000 for the nine months ended September 30, 2001, a decrease of \$1,702,000 or 11% from research and development expenses of

\$15,349,000 for the nine months ended September 30, 2000. The decrease in spending on research and development mainly relates to a license fee payment and SangStat's share of prior development costs incurred by Abgenix for ABX-CBL totaling \$3,400,000 for the nine month period ended September 30, 2000, which did not recur in 2001, and a decrease in spending on SangCya Oral Solution and related products. This decrease in spending was partially offset by an increase in spending on RDP58 and ABX-CBL during the nine month period ended September 30, 2001.

*Selling, general and administrative.* Selling, general and administrative expenses for the nine months ended September 30, 2001 were \$25,455,000, a decrease of \$8,336,000 or 25% over selling, general and administrative expenses of \$33,791,000 for the nine months ended September 30, 2000. The decrease in expenses for the nine months ended September 30, 2001 reflects the results of SangStat's cost control efforts through the continuation of its cost-containment program, including a reduction in launch and marketing expenses for Gengraf, a reduction in SangStat's share of Phase IV Gengraf study expenses, and a reduction in legal expenses associated with the Novartis lawsuit.

*Other expense net.* Other expense net for the nine months ended September 30, 2001 was \$5,795,000, compared to \$1,572,000 for the nine months ended September 30, 2000. The increase in other expense net for the nine months ended September 30, 2001 is attributable to the following:

\$3,250,000 charge related to a breach of contract suit in Europe;

\$437,000 gain on sale of marketable securities which was recognized in 2000;

\$287,000 net increase in fixed asset disposal/retirement losses; and

\$249,000 net increase in interest and other miscellaneous expenses (including the effects of the FINOVA loan termination agreement, partially offset by an \$856,000 reimbursement claim we received from a supplier).

*Income taxes.* For the nine months ended September 30, 2001, we recorded a tax provision of \$345,000 for European income taxes based upon the results of our European affiliates for the nine months of 2001. For the nine months ended September 30, 2000 we recorded a tax provision of \$106,000 based on the results of our European affiliates for the corresponding nine months of fiscal 2000.

*Net loss from continuing operations.* Net loss from continuing operations for the nine months ended September 30, 2001 was \$8,660,000, a decrease of \$28,636,000 or 77% compared to the net loss of \$37,296,000 for the nine months ended September 30, 2000. The decrease in net loss for the nine months ended September 30, 2001 was primarily due to higher product sales and lower selling, general and administration costs, partially offset by higher cost of sales and manufacturing expenses, resulting primarily from the higher product sales, and higher research and development expenses. In addition, the nine months ended September 30, 2000 included product recall expenses totaling \$11,986,000 that did not recur in 2001.

*Net loss from operations of discontinued operation.* Net loss for transplantation services for the nine months ended September 30, 2001 was \$763,000 compared to a net loss of \$1,589,000 for the nine months ended September 30, 2000. The change in net loss reflects the sale of our transplantation services business, The Transplant Pharmacy, that closed on April 20, 2001.

*Net loss from disposal of discontinued operation.* Net loss on disposal of discontinued operation of \$381,000 represents sale proceeds of \$1,800,000 less estimated expenses of \$2,181,000 incurred for the discontinued operation. These expenses primarily related to the costs associated with the closure of The Transplant Pharmacy operation including the employee severance and the estimated future lease obligations for the facilities supporting The Transplant Pharmacy.

#### **Years Ended December 31, 2000, 1999 and 1998**

*Revenues.* Total revenues for the year ended December 31, 2000 were \$63,145,000, an increase of \$18,842,000 or 43% over total revenues of \$44,303,000 for the year ended December 31, 1999. The

increase was due primarily to sales of Gengraf, which was launched in the U.S. in May 2000, and increased sales of Thymoglobulin in the U.S., which accounted for \$11,423,000 and \$10,563,000 of the increase, respectively. This increase was partially offset by lower sales outside the U.S. In particular, sales in Europe for the year ended December 31, 2000 were adversely affected by weakening currencies. Had average exchange rates remained the same as in fiscal 1999, net sales in fiscal 2000 would have been higher by \$3.1 million.

On June 29, 2000 we, in discussions with the FDA that began on June 24, 2000, concluded that a recall of SangCya Oral Solution from the U.S. market would be required. Following further discussions with the FDA as to the type of recall and mechanism for conducting it, we announced this decision on July 10, 2000. As a result, net sales for the year ended December 31, 2000 have been reduced by \$872,000 for returns of SangCya Oral Solution from customers following the product recall.

Total revenues for the year ended December 31, 1999 were \$44,303,000, an increase of \$33,009,000 or 292% over total revenues of \$11,294,000 for the year ended December 31, 1998. The increase was due primarily to sales of Thymoglobulin in the U.S. following the launch of that product in February 1999. In addition, total revenues in fiscal 1999 included a full year of sales of therapeutic products in Europe as a result of the acquisition of IMTIX, compared with only one quarter of sales in fiscal 1998.

Included in total revenues was revenue from collaborative agreements of \$2,698,000 in 2000, an increase of \$638,000 or 31% over revenue from collaborative agreements of \$2,060,000 in 1999. Revenue from such agreements in fiscal 1999 represented an increase of \$968,000 or 89% over revenue of \$1,092,000 for the year ended December 31, 1998. In 2000 and 1999, we recognized revenue of \$2,698,000 and \$1,510,000 from milestone payments from Abbott Laboratories under the co-promotion agreement for cyclosporine. The unamortized portion of these milestone payments is shown as deferred revenue on our consolidated balance sheet and will be recognized as revenue on a straight-line basis over the remaining term of the co-promotion agreement. We also recognized revenue from milestone payments of \$550,000 and \$1,036,000 in 1999 and 1998 respectively from Amgen under the collaborative distribution agreement for our cyclosporine products in certain territories outside the U.S.

Revenues from Thymoglobulin were 69% of 1999 revenues and 60% of 2000 revenues. Revenues from Lymphoglobuline were 19% of 1999 revenues and 12% of 2000 revenues. Combined revenues of these two products were 66% of 1998 revenues. In addition, revenues from Gengraf were 18% of total revenues in 2000. Revenues from SangCya Oral Solution were 16% of total revenues in 1998 and were immaterial in 1999 and 2000.

*Cost of sales.* Cost of sales was \$39,246,000 for the year ended December 31, 2000, an increase of \$20,257,000 or 107% over cost of sales of \$18,989,000 for the year ended December 31, 1999. The increase for the year ended December 31, 2000 was primarily due to the establishment of inventory reserves resulting from the U.S. recall of SangCya Oral Solution. These product recall charges, which totaled \$11,774,000, included a 100% reserve for all SangCya Oral Solution and CycloTech finished goods and components, as well as a partial reserve against our bulk cyclosporine inventories that we do not expect to use prior to lot expiration. The remainder of the increase in cost of sales for the year ended December 31, 2000 was due to the overall increase in sales and the higher cost of Gengraf compared to our other products.

Cost of sales of \$18,989,000 for the year ended December 31, 1999 represented an increase of \$13,879,000 or 272% over cost of sales of \$5,110,000 for the year ended December 31, 1998. The increase was primarily due to the increased sales of pharmaceutical products. Cost of sales in fiscal 1999 also included provisions of \$1,865,000 for short-dated SangCya Oral Solution finished goods inventory.

*Research and development.* Research and development expenses were \$20,788,000 for the year ended December 31, 2000, an increase of \$6,318,000 or 44% over research and development expenses of \$14,470,000 for the year ended December 31, 1999. The increase in spending on research and development for the year ended December 31, 2000 mainly relates to charges for a license fee and reimbursement of development costs for ABX-CBL totaling \$3.9 million, clinical trials to pursue label expansion of Thymoglobulin and continued pre-

clinical work on RDP58, a product in development that inhibits synthesis of TNF-alpha. The expenses for the year ended December 31, 2000 also included \$50,000 to cover the cost of terminating SangCya Oral Solution clinical trials following the previously discussed product recall.

Research and development expenses of \$14,470,000 for the year ended December 31, 1999 represented a decrease of \$3,218,000 or 18% over research and development expenses of \$17,688,000 for the year ended December 31, 1998. The decrease in fiscal 1999 was due primarily to a reduction in spending on clinical trials for Thymoglobulin and SangCya Oral Solution. Thymoglobulin was approved by the U.S. Food and Drug Administration (FDA) on December 31, 1998 and was launched in the U.S. in February 1999. Following its approval in the U.S. by the FDA on October 31, 1998, SangCya Oral Solution was approved by the Medicines Control Agency in the United Kingdom in February 1999 and was launched in that country in April 1999.

*Selling, general and administrative.* Selling, general and administrative expenses for the year ended December 31, 2000 were \$41,766,000, an increase of \$2,596,000 or 7% over selling, general and administrative expenses of \$39,170,000 for the year ended December 31, 1999. The increase was due primarily to the expenses of \$2,758,000 associated with the launch of Gengraf. Expenses for the year ended December 31, 2000 also included \$379,000 to cover the cost of managing the product recall of SangCya Oral Solution and terminating ongoing marketing programs. These increases in expenses were partially offset by an overall reduction in spending resulting from the cost containment measures announced in October 2000.

Selling, general and administrative expenses of \$39,170,000 for the year ended December 31, 1999 represented an increase of \$15,463,000 or 65% over selling, general and administrative expenses of \$23,707,000 for the year ended December 31, 1998. The increase in expenses in fiscal 1999 reflects the inclusion of IMTIX expenses for the whole year and an increase in expenses incurred in the U.S. This increase was due primarily to sales and marketing expenses for Thymoglobulin and SangCya Oral Solution, as well as legal expenses relating to the Novartis lawsuits.

*Acquired in-process research and development.* In connection with the acquisition of IMTIX, we recorded a charge of \$3,218,000 for purchased in-process research and development in 1998. This charge was primarily associated with the ongoing development of Anti-LFA1. During 1999, following our evaluation of the outcome of the ongoing clinical studies, we decided to discontinue the development of Anti-LFA1.

*Amortization of intangible assets.* Amortization expense for the IMTIX acquisition-related intangible assets was \$1,392,000 for the year ended December 31, 2000, a decrease of \$6,000 over amortization expense of \$1,398,000 for the year ended December 31, 1999. Amortization expense for the year ended December 31, 1998 was \$351,000 since this expense occurred only in the fourth quarter of 1998.

*Interest income.* Interest income for the year ended December 31, 2000 was \$2,016,000 compared to \$1,865,000 for the year ended December 31, 1999, and \$3,611,000 for the year ended December 31, 1998. For both fiscal 2000 and 1999, the change in interest income versus the prior year primarily reflected the change in the average cash balance available for investment.

*Interest expense.* Interest expense for the year ended December 31, 2000 was \$4,368,000 compared to \$3,034,000 for the year ended December 31, 1999 and \$404,000 for the year ended December 31, 1998. We recorded a full year of interest expense in fiscal 2000 on the notes payable to Aventis, Abbott Laboratories and the convertible note and eight months expense on the FINOVA note payable compared to 12 months for Aventis, 6 months for Abbott and 10 months for the convertible debt in fiscal 1999. The increase in fiscal 1999 over 1998 reflected interest on the note payable to Aventis and Abbott Laboratories, and the convertible note issued in March 1999.

*Other income (expense) net.* Other income (expense) net for the year ended December 31, 2000 was income of \$750,000 compared to \$256,000 for the year ended December 31, 1999 and an expense of \$154,000 for the year ended December 31, 1998. In fiscal 2000 and 1999, income was provided primarily by gains on the sale of equity securities of \$437,000 and \$223,000, respectively.



*Income taxes.* For the years ended December 31, 2000 and 1999, we recorded a provision of \$368,000 and \$345,000, respectively, for European income taxes based upon income earned by our European affiliates. For the year ended December 31, 1998, we recorded a similar provision of \$257,000 based on income earned by our European affiliates for the fourth quarter of fiscal 1998.

*Net loss from continuing operations.* Net loss from continuing operations for the year ended December 31, 2000 was \$42,017,000, an increase of \$11,035,000 or 36% compared to the net loss of \$30,982,000 for the year ended December 31, 1999. The increase in net loss for fiscal 2000 was due primarily to the product recall returns and charges of \$13,075,000 and increases in selling, general and administrative expenses, partially offset by the increase in net sales net of related cost of sales. Net loss from continuing operations for the year ended December 31, 1999 was \$30,982,000, a decrease of \$5,002,000 or 14% compared to the net loss of \$35,984,000 for the year ended December 31, 1998. The decrease in net loss was due primarily to the increase in net sales net of related cost of sales, partially offset by increases in selling, general and administrative expenses.

*Net loss from operations of discontinued operation.* Net sales of transplantation services for the year ended December 31, 2000 were \$17,502,000, an increase of \$3,637,000 or 26% over sales of \$13,865,000 for the year ended December 31, 1999. Net sales of transplantation services in fiscal 1999 represented an increase of \$5,481,000 or 65% over sales of \$8,384,000 for the year ended December 31, 1998. The increase in net sales in both fiscal 2000 and 1999 was due primarily to an increase in the number of patients serviced by The Transplant Pharmacy. Net sales for all periods consisted entirely of drug sales to transplant patients.

Net loss for transplantation services for the year ended December 31, 2000 was \$2,342,000, an increase of \$317,000 or 16% compared to the net loss of \$2,025,000 for the year ended December 31, 1999. The increase in net loss was due primarily to the increase in operating expenses, partially offset by an increase in sales of The Transplant Pharmacy. Net loss for transplantation services for the year ended December 1999 was \$2,025,000, a decrease of \$455,000 or 18% compared to the net loss of \$2,480,000 for the year ended December 31, 1998. The decrease in net loss was due primarily to the increase in sales of The Transplant Pharmacy.

#### **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 to Neoral. 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 nine months of 2001 and 2000, the net cash used in continuing operating activities was approximately \$2,914,000 and \$16,436,000, respectively. The decrease in net cash used in operating activities in

the first nine months of 2001 was due substantially to a significant reduction in net loss and a reduction in other current assets due to the reclassification of \$5,000,000 to cash and cash equivalents. This cash had previously been treated as restricted since it served as collateral for the loan with FINOVA. However, the loan was repaid in June 2001 and the cash is no longer restricted. Other factors contributing to the net cash provided by operating activities included an increase in accrued liabilities and a decrease in other receivables. Net cash used in continuing operating activities during the first nine months of 2000 was due to the net loss for the period and an increase in other current assets following the establishment of a collateral account for the FINOVA loan, partially offset by a reduction in inventories, and increases in accounts payable and accrued liabilities. The reduction in inventories was primarily due to provisions of \$11,561,000 relating to the product recall, which resulted in a corresponding increase in net loss for the period. For both periods presented, the net cash used in discontinued operation approximated the net loss of The Transplant Pharmacy. As of September 30, 2001, we had cash, cash equivalents and short-term investments of \$25,542,000 and total assets of \$108,519,000.

Net cash provided by investing activities for the nine months ended September 30, 2001 was \$5,598,000 as compared to the cash used in investing activities of \$1,701,000 for the same period in 2000. The amount for the nine months ended September 30, 2001 is primarily the result of a decrease in other assets, purchases of property and equipment and proceeds from the sale of The Transplant Pharmacy, partially offset by maturities of short-term investments. For the nine months ended September 30, 2000, cash used in investing activities was primarily due to an increase in other assets reflecting \$5,000,000 cash used as collateral for the note payable to FINOVA Capital, and the purchases of property and equipment, partially offset by maturities of short-term investments.

Net cash provided by financing activities for the nine months ended September 30, 2001 was \$7,005,000 as compared to \$20,609,000 for the same period in 2000. In both periods, cash provided by the sale of common stock was partially offset by the repayment of notes and capital lease obligations. In addition, we borrowed \$5,000,000 from FINOVA in 2000, which was repaid in June 2001. We completed two private placements in January and June 2001 for aggregate proceeds of \$18,999,485. In January 2001, we issued 421,000 shares of common stock with a group of institutional investors for aggregate proceeds of \$3,999,500 pursuant to an agreement signed in December 2000. In June 2001, we issued 1,363,635 shares of common stock with a group of institutional investors for aggregate proceeds of \$14,999,985. In both cases, the shares were issued at a discount to the closing market price on the date the agreements were signed. We intend to use the proceeds to fund working capital requirements and meet scheduled loan repayment obligations. In 2000, we issued 451,128 shares of common stock to an institutional investor in February 2000 for aggregate proceeds of \$15,000,006 and in December 2000, we issued 894,800 shares of common stock with a group of institutional investors for aggregate proceeds of \$8,500,600.

During the years ended December 31, 2000, 1999 and 1998, our net cash used in continuing operating activities was approximately \$25,610,000, \$39,885,000 and \$38,537,000 respectively. The decrease in net cash used in operating activities in fiscal 2000 was substantially due to a reduction in net inventories and increases in accounts payable and accrued liabilities, partially offset by an increase in net loss. The reduction in inventories is primarily due to provisions of \$11,774,000 relating to the SangCya Oral Solution product recall, which resulted in a corresponding increase in net loss for the year 2000. Net cash used in 2000 also included an increase in other current assets reflecting \$5,000,000 cash used as collateral for the note payable to FINOVA. In fiscal years 1999 and 1998, net cash used in operating activities was primarily due to the amount of net loss incurred, as well as an increase in inventories and a decrease in accounts payable over the prior year. In fiscal year 1999 these uses of cash were partially offset by the receipt of \$13,730,000 in milestone payments from Abbott Laboratories in connection with our co-promotion agreement with Abbott. The cash used in the discontinued operation approximated the net loss of the discontinued operation for the years ended December 31, 2000, 1999 and 1998. As of December 31, 2000, we had cash, cash equivalents and short-term investments of \$20,607,000 and total assets of \$114,316,000.

Net cash provided by investing activities totaled \$3,694,000, \$4,245,000 and \$6,489,000 during the years ended December 31, 2000, 1999 and 1998 respectively. In fiscals 2000 and 1999, cash was provided by

maturities of short-term investments, partially offset by purchases of property and equipment and short-term investments. In fiscal 1998 net cash provided by investing activities was primarily from the maturity of short-term investments, partially offset by the use of cash for the purchase of IMTIX.

Net cash provided by financing activities totaled \$27,221,000, \$39,521,000 and \$29,000 during the years ended December 31, 2000, 1999 and 1998 respectively. In both fiscal years 2000 and 1999, cash was provided by the issuance of notes payable and the sale of common stock which are described in more detail in the following paragraphs. In fiscal year 1998 net cash was provided primarily by the sale of common stock, partially offset by repayments of notes and capital lease obligations.

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

In August 2000, we entered into a global co-development, supply and license agreement with Abgenix, Inc. for ABX-CBL, an antibody developed by Abgenix. The agreement provides us with an exclusive worldwide license for the marketing and sale of ABX-CBL, an anti-CD147 monoclonal antibody for the treatment of steroid resistant graft versus host disease (GVHD). ABX-CBL is currently in a multicenter, randomized, and controlled Phase II/III study. We made an initial license fee payment of \$1,000,000 and an additional payment to Abgenix of \$1,000,000 as partial reimbursement of one-half of the development costs incurred by Abgenix between January 1, 2000 and August 8, 2000. The agreement requires us to pay a further \$900,000 as reimbursement of these development costs in two equal installments at the end of June 2001 and 2002, the first of which installments has been paid. Development costs incurred after August 8, 2000 are being shared equally, as would any potential profits from future sales of collaboration products. We share responsibility for product development, including the ongoing clinical trial. Abgenix will be responsible for manufacturing ABX-CBL. We also have the right, subject to the terms and conditions of the agreement, to commercialize other anti-CD147 antibodies developed by Abgenix. If ABX-CBL receives regulatory approval and is launched, we will be required to pay Abgenix for our share of development expenses incurred prior to January 1, 2000. The amount has not been determined, but the agreement limits our obligation to \$6,100,000. We do not have any obligation to reimburse Abgenix until the first anniversary of the launch of ABX-CBL and the timing of reimbursement varies depending on ABX-CBL's sales.

In May 1999, we received a loan of \$16 million from Abbott Laboratories. The loan bears interest at 8.75%, payable annually. The loan matures on December 31, 2004, and can be pre-paid without penalty at any time prior to maturity.

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.

## **Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk related to changes in interest rates, equity security prices and foreign currency exchange rates.

*Interest Rate Sensitivity.* We maintain a short-term investment portfolio consisting mainly of government and corporate bonds purchased with an average maturity of less than one year. These available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. If market rates were to increase immediately and uniformly by 10% from levels at December 31, 2000, the fair value of the portfolio would decline by an immaterial amount, which is consistent with the estimated effects at December 31, 1999. We generally have the ability to hold fixed income investments until maturity and therefore do not expect operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

Substantially all of our long-term obligations bear interest at fixed rates which are not subject to future increases in interest rates. The fair value of these long-term obligations, including current portion, at December 31, 2000 was \$45.2 million compared to book value of \$47.5 million (see Note 8 to Consolidated Financial Statements). The corresponding fair value at December 31, 1999 was \$49.6 million compared to book value of \$44.4 million. We therefore do not expect operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates. If our notes payable and convertible debt were subject to rate fluctuation, a hypothetical interest rate increase of 1% would have added approximately \$475,000 to our interest expense for 2000 and \$440,000 for 1999.

*Equity Price Risk.* Following the sale of our portfolio of corporate equity securities in December 1999 and January 2000 for a net gain of \$660,000, we no longer hold any such securities.

*Foreign Currency Risk.* 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. The risk due to foreign currency fluctuation 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 intend to re-assess our hedging policy from time to time as our foreign operations change. A 10% movement in the currency exchange rate would not have a material impact on our financial position or our results of operations.

All of the potential changes noted above are based on sensitivity analyses performed on our financial positions at December 31, 2000 and 1999. Actual results may differ materially.

## **Recent Accounting Pronouncements**

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

In June 2001, the FASB issued SFAS No. 141, Business Combinations and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be

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

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. We have not yet determined the impact this statement may have on our financial position or operating results.

## BUSINESS

### Overview

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 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. Consequently, on April 20, 2001, we sold our transplantation services segment, The Transplant Pharmacy, to Chronimed.

Our primary marketed product, Thymoglobulin, a treatment for acute rejection of a kidney transplant, was launched in February 1999. Thymoglobulin achieved worldwide sales of \$30.6 million in 1999, \$37.9 million in 2000 and \$37.0 million in the nine months ended September 30, 2001. The success of Thymoglobulin and its potential in areas beyond solid organ transplantation has provided us with the ability to examine and develop new therapeutic opportunities outside of transplantation.

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

We currently sell the following products:

Thymoglobulin<sup>®</sup> (sold under the name Thymoglobuline<sup>®</sup> outside the U.S.);

Gengraf<sup>®</sup> cyclosporine capsule (co-promoted with Abbott Laboratories in the U.S.);

Lymphoglobuline (outside the U.S.); and

Celsior<sup>®</sup>.

Our principal products under development include:

A smaller-size cyclosporine capsule;

ABX-CBL (anti-CD147 antibody in co-development with Abgenix, Inc.); and

RDP58.

### Background

#### *Organ Transplantation*

Organ transplantation can save or improve the lives of patients with organ failures. Transplantation involves surgically replacing the diseased or failed organ of a transplant recipient with a healthy organ from a donor. Industry sources report that each year approximately 20,000 patients in the U.S. receive donated organs, and we estimate that there are approximately twice that number of patients worldwide. While the size of the transplant population is difficult to ascertain at any given time, industry participants believe the population of organ transplant survivors to be more than 200,000 worldwide. Currently, there are approximately 260 transplant centers in the U.S.

In order to prevent rejection of implanted organs, most recipients must begin a life-long regimen of immunosuppressive therapy immediately upon receiving a donated organ. This immunosuppressive regimen usually requires daily therapy in order to prevent organ rejection and graft loss. Products that supplement immunosuppression can reduce the frequency and severity of rejection and infection episodes. These products can potentially enhance patient outcomes, while providing potential cost savings in the treatment of transplantation and its associated side effects. Our product Gengraf, an immunosuppressant, is approved in the U.S. for the prevention of kidney, liver and heart rejection.

#### *The Transplant Immune Response*

The function of the immune system is to protect the body from damage caused by invading microorganisms or other foreign matter. Differences between a donor's and a recipient's antigens can lead to the recognition of the donor's organ as foreign matter by the recipient's immune system. Specifically, the donor organ antigens are recognized by the immune system of the graft recipient as being non-self, triggering the immune system to attack and invade the graft. When the recipient's immune system attacks and invades the donated graft, rejection and loss of the graft often occur. Thymoglobulin is approved for acute kidney graft rejection in the U.S., and Thymoglobulin and Lymphoglobuline are approved for both prevention and treatment of acute graft rejection in various countries outside the U.S.

#### *The Transplant Process*

A typical transplant patient progresses through three phases:

##### *The Pre-Transplant Phase*

A transplant candidate is registered on a national computerized waiting list. A candidate usually waits months or even years for a compatible organ. Organs harvested from donors are stored in a preservation solution such as Celsior to prevent deterioration. Each organ is cross-matched with potential recipients. The organ is then shipped in the same organ preservation solution to the recipient's transplant center.

##### *The Acute Phase (Surgery and First Year Post-Transplant)*

After transplantation, the physician must prevent graft rejection for the transplant to be a success. Consequently, the success of the transplant is highly dependent on the immunosuppressive regimen that is initiated at the time of transplantation and continued daily for the rest of the patient's life. Organ recipients must be regularly monitored to measure the body's immune response and blood drug levels and to help identify acute rejection episodes. Many patients undergo one or more rejection episodes in the first year after transplant and require additional immunosuppressants.

##### *The Chronic Phase (Lifetime Post-Transplant)*

The use of immunosuppressants such as cyclosporine, initiated during the acute phase, is continued daily throughout the patient's lifetime to minimize or prevent the loss of the organ by rejection. These drugs impair the recipient's immune system in order to reduce the immune response against the graft. Even with the use of immunosuppressants, industry sources report that patients have an approximate 20% to 50% risk of losing a donated organ during the first three years following transplantation, and approximately 20% to 65% after five years. These percentages differ depending on the type of transplant. Chronic use of immunosuppressants can also lead to serious side effects, including life-threatening infections, kidney or liver toxicity and cancer.

#### *Aplastic Anemia*

Aplastic anemia, which primarily affects young people, is a disease in which the stem cells disappear from the bone marrow. Aplastic anemia has a high mortality rate and, even with treatment, quality of life is poor. A lack of stem cells in the bone marrow inhibits the production of blood cells. As a result, patients with this disease are dependent on weekly blood transfusions that require frequent visits to the physician's offices. Both Thymoglobulin and Lymphoglobuline are approved in certain countries outside of the U.S. for treatment of

aplastic anemia, and we believe that the majority of sales of Lymphoglobuline in Japan are for the treatment of aplastic anemia. Current treatments for severe aplastic anemia include immunosuppressants and, if necessary, bone marrow transplantation.

***Myelodysplastic Syndrome (MDS)***

Myelodysplastic Syndrome, or MDS, also referred to as pre-leukemia, is a rare disease in which the bone marrow functions abnormally and does not produce enough normal blood cells. The incidence of MDS is not known, but it is believed that there are approximately 10,000 to 20,000 new cases in the U.S. each year with the number increasing. Approximately 30% of patients with MDS may have their disease progress to develop into acute leukemia, a form of cancer where the patient has too many white blood cells. Weekly blood transfusions remains the principal therapy for less advanced types of MDS. Current treatments for the advanced types of the disease include chemotherapy and/or bone marrow transplantation. However, these therapies are ineffective or not available in the majority of cases.

We have orphan drug status for Thymoglobulin for the treatment of MDS and have a Phase IIb clinical study ongoing.

***Bone Marrow or Stem Cell Transplantation***

Bone marrow or stem cell transplantation is a standard therapy for many disease states, primarily cancer or pre-cancerous diseases. Stem cells, found in the peripheral blood or in the bone marrow, are given by an intravenous infusion to re-establish marrow function in a patient after ablation of the patient's bone marrow.

Immunosuppressive therapy, primarily anti-thymocyte globulin, or ATG, such as Lymphoglobuline and Thymoglobulin, chemotherapeutic agents and/or irradiation are given as part of a conditioning regimen. The goal of this regimen is threefold: to limit the patient's ability to mount an immune response to the new bone marrow or stem cells, to provide space for the new cells, and to destroy any residual cancer if the patient is being treated for a malignancy.

Some of these patients experience graft versus host disease, or GVHD. This is a condition in which the graft (i.e. the new immune system) begins to reject the host (i.e. the body). GVHD is a life-threatening complication that frequently occurs following an allogeneic bone marrow transplant. An allogeneic bone marrow transplant procedure involves transferring donor hemopoetic stem cells, the graft, from a healthy person into an immunosuppressed patient, the host. The transplant is intended to restore normal circulating blood and immune cells to a patient whose own hemopoetic and immune system has been ablated by the treatment of an underlying disease such as cancer and the conditioning regimen. Often a portion of the donor graft recognizes the host's own cells as foreign, becomes activated and attacks them, resulting in GVHD. GVHD typically involves damage to multiple organ systems, including the skin, liver and intestines. ABX-CBL is initially being developed to treat steroid-resistant GVHD.

***Crohn's Disease and Ulcerative Colitis***

Crohn's disease and ulcerative colitis are similar diseases that are often grouped together as inflammatory bowel disease. Industry sources estimate that there may be up to 1,000,000 Americans who suffer from inflammatory bowel disease. Crohn's disease is a chronic inflammatory disease of the gastrointestinal tract that usually causes diarrhea, abdominal pain, fever and rectal bleeding. Ulcerative colitis is a similar disease to Crohn's disease, but only infects the large intestine and is characterized by inflammation and ulceration of the innermost lining of the colon. Symptoms include diarrhea and sometimes abdominal pain. We are developing RDP58 for the treatment of both diseases.



**Products and Product Candidates**

The following table summarizes our principal products and product candidates.

<b>Marketed Product</b>	<b>Indications/Potential Clinical Use</b>	<b>Status</b>	<b>Marketing Rights</b>
Thymoglobulin/ Thymoglobuline	Prevention and treatment of acute graft rejection, severe aplastic anemia and steroid resistant GVHD	U.S.: Approved for treatment of acute kidney rejection episodes EU: Approved for prophylaxis and rejection in kidney, pancreas, and liver transplants; treatment of rejection crisis and acute GVHD in allogeneic bone marrow transplantation; and aplastic anemia	SangStat
Gengraf	Chronic immuosuppression (prevents organ rejection)	U.S.: Approved	SangStat and Abbott Laboratories jointly (U.S.)
Lymphoglobuline	Prevention and treatment of acute graft rejection, severe aplastic anemia and steroid resistant GVHD	Over 45 countries other than the U.S.: Approved	SangStat
Celsior	Preservation of organs prior to transplantation	U.S.: Approved only for cardiac transplantation	SangStat
<b>Product Candidate</b>	<b>Indications/Potential Clinical Use</b>	<b>Status</b>	<b>Commercialization Rights</b>
Smaller-Size Cyclosporine Capsule	Chronic immunosuppression (prevents organ rejection)	Bioequivalence study ongoing	SangStat
ABX-CBL	Treatment of steroid resistant GVHD	Phase II/III	SangStat and Abgenix
RDP58	Ulcerative colitis Crohn's disease	Phase IIb	SangStat

## Marketed Products

### *Thymoglobulin®*

Thymoglobulin is a pasteurized anti-thymocyte rabbit immunoglobulin that induces immunosuppression as a result of T-cell depletion and immune modulation. Thymoglobulin is made up of a variety of antibodies that recognize key receptors on T-cells, the cells of a transplant recipient's immune system that recognize and ultimately reject foreign objects such as transplanted organs. While the exact mechanism is unknown, researchers believe Thymoglobulin antibodies may inactivate and kill these T-cells, thus neutralizing the rejection process and allowing the transplanted organ to recover. Thymoglobulin is also used to treat aplastic anemia and steroid resistant GVHD. Thymoglobulin is approved in the U.S. only for treatment of kidney transplant acute rejection episodes.

#### *Market*

We (or our distributors) market Thymoglobulin in 56 countries, with a majority of our revenues coming from Europe and the U.S. We launched Thymoglobulin in the U.S. in February 1999. In the U.S., Thymoglobulin is currently approved for treatment of acute rejection in kidney transplant recipients. In other countries where Thymoglobulin is marketed, it generally has the following indications:

prophylaxis and rejection in kidney, pancreas, and liver transplants;

treatment of rejection crisis and acute GVHD in allogeneic bone marrow transplantation; and

aplastic anemia.

We market and sell Thymoglobulin outside Europe and North America through distributors. We have a distribution agreement with Aventis for most countries outside of Europe and North America where Thymoglobulin is marketed. We have also entered into distribution agreements with distributors in certain Asian countries and are currently re-negotiating our distribution agreement with Aventis to obtain the right to distribute directly in certain territories and extend the period covered by the agreement.

#### *Additional Clinical Studies*

##### *Induction/Prevention*

We have initiated a comparative induction study of Thymoglobulin versus Simulect, a monoclonal antibody marketed by Novartis Pharmaceuticals Inc. (Novartis) in high-risk renal transplant recipients. Our intent in this study is to generate data comparing the clinical effects of Thymoglobulin with Simulect. It is not our intent to use this trial, and the FDA has indicated that this trial will not be sufficient, to support label indication changes or expansion. This 340 patient prospective, randomized, open-label study is being conducted in over 20 transplant centers in the U.S. and Europe. Primary endpoints at 6 months will be graft survival, patient survival and incidence of acute rejection. We will also capture other important clinical data such as infections and incidence of delayed graft function. Currently, 250 patients have enrolled in the study and we expect patient enrollment to be completed by the second quarter of 2002. We expect preliminary communication of the trial results to occur during the second quarter of 2002 with the final results available in the second quarter of 2003.

##### *Hematological Disorders and Malignancies*

We have also initiated an open-label prospective, randomized, multi-center Phase IIb trial with Thymoglobulin in MDS. SangStat received orphan drug designation for Thymoglobulin for treatment of MDS in September 2000. Orphan drug designation is granted to applicants when the prevalence of the disease for which approval is sought occurs in less than 200,000 patients in the U.S. The advantages of this designation include a waiver of the user fee, possible marketing exclusivity and tax credits for development costs. These advantages are intended to encourage sponsors to develop drugs for patients with rare diseases.

The standard of care for low-risk MDS patients is weekly blood transfusions. The primary endpoint in this trial is transfusion independence at six months post therapy. This is an open-label randomized trial comparing observation (the control arm) to treatment with Thymoglobulin (3.25mg/kg for four days). Patient enrollment began in October 2000. In part because this is a rare disease, as evidenced by its orphan drug status, patient enrollment to date has been relatively slow. There are currently 25 patients enrolled in the study. We continue to expand the number of centers participating in the study with the aim of completing enrollment of 72 patients into the study by the end of 2002.

### ***Gengraf® Cyclosporine Capsules***

Cyclosporine, first approved in the U.S. in 1983, is a potent immunosuppressive agent. Cyclosporine inhibits the synthesis and release of the cytokine interleukin-2, which is essential to the body's immune response to transplanted organs. Gengraf cyclosporine capsule, a product of Abbott Laboratories, Inc., is a generic version of Neoral® capsules, which is marketed by Novartis. SangStat and Abbott co-promote and distribute Gengraf in the U.S. Gengraf is normally taken daily over the lifetime of the organ recipient to prevent organ rejection.

### ***Cyclosporine Market***

Cyclosporine is the leading immunosuppressive drug used to prevent organ and graft rejection in transplantation. Industry sources report that each year approximately 20,000 patients in the U.S. receive donated organs, and we estimate that there are approximately twice that number of patients receiving donated organs worldwide. While the size of the transplant population is difficult to ascertain at any given time, industry participants believe the population of organ transplant survivors to be more than 200,000 patients worldwide. The majority of these patients are prescribed daily doses of cyclosporine for the rest of their lives. Cyclosporine is also indicated for the treatment of rheumatoid arthritis and adult non-immunocompromised psoriasis patients. Worldwide sales of cyclosporine are greater than \$1 billion per year. The U.S. market is approximately \$500 million.

We entered into an agreement with Abbott in May 1999 for the co-promotion, distribution and research in the U.S. of Gengraf and SangCya Oral Solution. SangCya Oral Solution, which is a generic version of Neoral oral solution, was withdrawn from the U.S. market in July 2000 and is currently being sold on a limited basis only in the United Kingdom.

We launched Gengraf cyclosporine capsules in May 2000 in the U.S. through our combined SangStat/Abbott sales force. Gengraf's indications are identical to Neoral's indications and include (i) the prophylaxis of organ rejection in kidney, liver and heart allogeneic transplants; (ii) the treatment of patients with severe, active rheumatoid arthritis where the disease has not adequately responded to methotrexate; and (iii) the treatment of adult, non-immunocompromised patients with severe (i.e. extensive and/or disabling), recalcitrant, plaque psoriasis who have failed to respond to at least one systemic therapy (e.g. PUVA, retinoids or methotrexate), or in patients for whom either systemic therapies are contraindicated or cannot be tolerated.

### ***Lymphoglobuline***

Lymphoglobuline is an anti-thymocyte equine immunoglobulin that induces immunosuppression as a result of T-cell depletion and immune modulation. In certain countries outside the U.S., it is approved for the prevention and treatment of rejection episodes in kidney, heart, pancreas, or liver transplantation. In hematology, Lymphoglobuline is approved in certain countries outside the U.S. for treatment of aplastic anemia and in the treatment of steroid resistant GVHD.

### ***Market***

We (or our distributors) market Lymphoglobuline in over 45 countries outside the U.S. Our sales force markets this product in Europe and Canada. Outside these countries, we sell Lymphoglobuline through our distribution agreement with Aventis or through other distributors. Aventis markets this product in Japan, where

we believe a high percentage of sales occur for treatment of aplastic anemia. We hope to address U.S. market opportunities for Lymphoglobuline with the sale of Thymoglobulin. Therefore, we have no plans to seek approval for Lymphoglobuline in the U.S.

### ***Celsior®***

Celsior is a storage solution for organs after removal from the donor and before transplantation into the recipient. It is a sterile, nonpyrogenic, extracellular solution for hypothermic flushing and storage of hearts. Early graft loss remains a significant problem associated with cardiac transplantation and damage to the heart tissue can occur due to inadequate preservation. Effective organ preservation includes initial flushing of the heart tissue during the recovery process and cold storage while the donor heart is transported to the recipient. Celsior is the first and only flush and cold storage solution approved by the FDA for cardiac transplantation. It was designed specifically for cardiac transplantation to minimize myocardial edema, oxygen free radical-induced reperfusion injury, and diastolic stiffness.

### ***Market***

We sell Celsior throughout Europe, and we commenced marketing the product in the U.S. in September 1999. Celsior is approved for marketing in the U.S. only in connection with cardiac transplantation. Outside of Europe and North America, we sell Celsior through our distribution agreement with Aventis or through other distributors. In 1999, industry sources report that there were approximately 4,000 cardiac and lung transplants worldwide.

### **Principal Products In Development**

Consistent with our strategic changes in October of 2000, we leveraged our success with Thymoglobulin to expand our research and development initiatives to include areas outside of transplantation, including immunology, hematology/oncology and auto-immune disease. Our research and development expenses were \$17.7 million in 1998, \$14.5 million in 1999, \$20.8 million in 2000, and \$13.6 million for the nine months ended September 30, 2001. These expenses primarily relate to additional indications for marketed products and new products in development.

We currently have three principal products in development:

#### ***Cyclosporine Capsules***

We have an exclusive license to a pending patent application on a novel smaller-size cyclosporine capsule formulation from TrisPharma, a small U.S. research and development company. We expect that the capsule will be smaller than currently marketed cyclosporine capsules. We are conducting a small pilot study in healthy volunteers to demonstrate the new capsule's bioequivalence to Neoral cyclosporine capsules in water. The other filing requirements include a larger bioequivalence trial and stability testing. If the results of the bioequivalence trial and stability testing are positive, we presently expect to file for marketing approval in a major European country in late 2002. We have withdrawn our Marketing Authorization Application in the U.K. for our cyclosporine capsule product known as Sang-2000 in favor of this newer formulation. We intend to follow the European Community Mutual Recognition Procedure for obtaining regulatory approval in multiple Member States.

#### ***ABX-CBL***

In August 2000, we entered into a global co-development, supply and license agreement for ABX-CBL with Abgenix under which we obtained an exclusive worldwide license for the marketing and sale of ABX-CBL. ABX-CBL is an anti-CD147 monoclonal antibody for the treatment of steroid resistant GVHD. The CD147 antigen is selectively expressed on activated immune cells including T cells, B cells and natural killer cells. In allogeneic blood and marrow transplantation (BMT), these activated immune cells attack a host's own cells as

foreign, resulting in GVHD, where the transplanted cells are attempting to reject the recipient. GVHD often leads to damage to multiple organ systems, including the skin, liver and intestines. First line therapy is high dose corticosteroids, which have a success rate of approximately 50%. Steroid resistant GVHD has a high mortality rate. We believe ABX-CBL has the ability to destroy activated immune cells without affecting the rest of the immune system.

ABX-CBL is currently in a multi-center, randomized, and controlled Phase II/III study. The study is designed to demonstrate statistically significant efficacy of a single dose level of ABX-CBL in comparison to a control group of patients. Many patients that undergo an allogeneic bone marrow transplant develop steroid resistant GVHD for which there is currently no standard approved therapy available. However, many physicians prescribe a treatment regimen using the polyclonal equine antibody, ATGAM. In this study, patients are randomized to receive Atgam (30mg/kg QOD for 6 doses) in the control group versus patients who received ABX-CBL (0.1mg/kg/d for 14 days followed by 12 infusions over the next 6 weeks) in the treatment arm. Our primary endpoint of this study is patient survival at 180 days. As of January 15, 2002, we have enrolled 77 out of 92 patients planned for this study and presently expect to complete the study by the end of 2002.

We received orphan drug designation for ABX-CBL for the treatment of steroid resistant GVHD in November 2000.

### ***RDP58***

RDP58 is a novel inhibitor of TNF-alpha synthesis currently in Phase II clinical trials in the U.K. This is our first product candidate from our own research and development efforts to enter such a clinical trial. RDP58 was designed using our drug design approach, in collaboration with Synt:em, that integrates advanced biology, biophysics chemistry and information technology in a coordinated effort to design and develop potential therapeutic products. We are investigating the use of RDP58 for treatment of various auto-immune disorders. Ulcerative colitis and Crohn's disease are the two auto-immune disorders being examined in the current Phase II study.

### ***Overview***

Cytokines are protein messengers that coordinate the functions of immune cells and certain other cells and tissues. TNF-alpha is a cytokine that, when released in excess, can trigger activation of immune responses and inflammation. Continuous excessive TNF-alpha release can cascade into a variety of auto-immune diseases including inflammatory bowel disease, rheumatoid arthritis and psoriasis. There are currently a number of therapeutic products that target inhibition of TNF-alpha release. TNF inhibitors, including Remicade and Enbrel, have been approved for treatment since 1998 and 1999, respectively. They are considered the standard of care in the treatment of a variety of auto-immune diseases including Crohn's disease and rheumatoid arthritis. These therapeutic agents are being examined as a treatment for a number of other auto-immune diseases, including psoriasis, psoriatic arthritis and ankylosing spondylitis.

Animal models, including studies in primates, suggest that RDP58 could decrease levels of TNF-alpha, reduce inflammation, and improve clinical outcomes. Currently marketed TNF-alpha inhibitors work by binding to TNF-alpha after synthesis and excretion by the cell, thus neutralizing TNF-alpha in the blood before it can participate in the inflammatory response. In contrast, we believe RDP58 prevents the translation of TNF-alpha RNA, thereby preventing the synthesis of TNF-alpha protein within the cell. We believe that RDP58 could be a more efficient inhibitor of TNF-alpha as it prevents the synthesis of the protein as opposed to current therapy which attempts to inhibit the effects of its expression post-synthesis.

RDP58 is currently being tested in an oral formulation consisting of D-isomer amino acids. This form of the peptide is resistant to break-down during the digestive process, which is important for any oral therapeutic agent. Current TNF-alpha inhibitors are only available in non-oral form, either through a subcutaneous injection or through intravenous administration.

### *Clinical Studies*

We filed for Clinical Trial Exemption (CTX) with the U.K. Medicines Control Agency (the U.K. equivalent to the U.S. FDA) for RDP58 in September 2001 after successful completion of a Phase I normal volunteer dose escalation safety study. In the Phase I study, three groups of nine healthy volunteers participated in a dose escalation study using 3 doses for a total of 28 days. Oral RDP58 was found to be safe and well tolerated. The CTX allowed us to initiate Phase II proof-of-principle clinical trials in the fourth quarter of 2001. The Phase II trials are prospective, randomized, blinded trials in patients with mild-to-moderate ulcerative colitis or Crohn's disease. We expect to complete patient enrollment and announce the results of these studies in the second half of 2002. Pending the results of these studies, a clinical development and regulatory pathway will be defined and implemented.

### *Other Preclinical Developments*

RDP58 is the subject of four additional development programs: neurology, non-IBD gastro-intestinal disorders, dermatology and pulmonary.

*Neurology.* RDP58 has been studied in the experimental auto-immune encephalomyelitis model of multiple sclerosis in rodents. The model is the standard of preclinical investigation for new therapeutic agents in the treatment of multiple sclerosis. The model requires animals to be injected with myelin basic protein on day 0, thus developing a predictable paralysis of the tail and hind limbs that begins on day 10 (after injection), peaks on day 12-13 and is completely resolved by day 18-20. The paralysis is used to simulate the mechanism of action found in multiple sclerosis. RDP58, when given as a single dose via intra-thecal injection, diminishes the paralysis in a dose dependent manner in this acute model (using doses of 15ug, 45ug and 150ug). At the highest dose, the paralysis appears to be completely eliminated. The timing of the treatment also has an impact on the disease progression. RDP58 can be given as a single dose on day 4, day 7 or day 10 after inoculation with myelin basic protein.

The currently approved standard of care for the treatment of multiple sclerosis is beta-interferon. Beta-interferon as a treatment regimen is most efficacious when commenced at the earliest point in the disease's progression, usually immediately after diagnosis and before any symptoms of the disease present themselves. Furthermore, beta interferon has been shown to be increasingly ineffective as the disease progresses and has shown little efficacy in minimizing or halting symptoms, such as paralysis after they present themselves in a patient. We believe that RDP58 presents a unique opportunity in multiple sclerosis as our preclinical models demonstrate that disease progression may be halted after the presentation of symptoms.

*Non-IBD Gastro-intestinal disorders.* Chemotherapy-induced diarrhea and diarrhea related to HIV are two significant gastro-intestinal disorders that affect thousands of people each year. CPT-11 is the most active drug against colon adenocarcinoma, a form of colon cancer. Diarrhea is the most common side effect that limits the amount of CPT-11 that patients can tolerate. Prevention of diarrhea will allow increases in the dosage of CPT-11, potentially increasing their response to this treatment. RDP58 has been shown to significantly decrease the incidence of diarrhea and mortality in a murine model of CPT-11 toxicity. In this model, 93% of mice given 200mg/kg of CPT-11 developed diarrhea and had a 63% mortality rate. In the study, of the mice that were given RDP58 in their drinking water starting three days before treatment with CPT-11, only 33% developed diarrhea and 93% of the animals survived. These preliminary experiments are being followed by studies to prove that RDP58 does not increase the rate of tumor growth and that RDP58 allows an increase in the maximally tolerated dose of CPT-11.

HIV-related diarrhea is a malabsorption syndrome that results in nutrient loss and poor drug absorption. This translates into increased weight loss and viral tiers in patients who suffer from HIV-related colitis. Researchers at the University of California at Davis, with the support of scientists at SangStat, were awarded a National Institute of Health grant to study the impact of RDP58 on the gastro-intestinal complications of HIV in the HIV primate model. In this study, RDP58 was found to increase the CD4+ lymphocyte population of the GI mucosa. We expect to explore this finding in a pilot clinical trial.

*Dermatology.* TNF-alpha appears to play an important role in psoriasis and possibly in atopic dermatitis. RDP58 has been fashioned into a topical gel that will be used to determine efficacy in these two dermatologic diseases. Animal toxicology studies are underway. We expect to begin patient studies after completion of the toxicology studies.

*Pulmonary.* RDP58 is a powder formulation that may be used as an aerosol to provide inhalation therapy for asthma, chronic obstructive pulmonary disease, sarcoidosis and other pulmonary diseases. Preliminary animal experiments have been performed to demonstrate the feasibility of this approach. We are pursuing partners to continue development in this therapeutic arena.

### **Sales and Marketing**

In the U.S., we market products through our direct sales force. As of December 31, 2001, we had 21 account managers, supervised by three regional sales directors, who call on or sell primarily to the approximately 260 transplant centers in the U.S. A number of the account managers have backgrounds in transplantation, either from selling other transplant products or with clinical backgrounds as nurses or as transplant coordinators in transplant centers. We also have two national account directors who call on group purchasing organizations and managed care groups.

Sales to Cardinal Health Inc. and McKesson HBOC accounted for 27% and 18%, respectively, of total revenues for the nine months ended September 30, 2001. Sales to Cardinal Health Inc. and McKesson HBOC accounted for 13% and 15%, respectively, of total revenues in 2000. Sales to McKesson HBOC accounted for approximately 11% of our total revenues in 1999.

We have approximately 32 sales and marketing people throughout the major European markets.

### **Strategic Relationships**

We evaluate on an ongoing basis potential collaborative relationships with corporate and other partners where such relationships may complement and expand SangStat's research, development, sales and marketing capabilities.

### **Abbott Laboratories**

In May 1999, we signed a multi-year co-promotion, distribution and research agreement with Abbott for SangCya Oral Solution (which was withdrawn from the U.S. market in July 2000) and Gengraf in the U.S. We are the exclusive distributor for Gengraf in the U.S. and share marketing, promotional and development expenses as well as the profits from the co-promotion of the product with Abbott. The agreement ends December 31, 2004 unless both companies agree to extend it. Pursuant to this agreement, Abbott made an equity investment of \$14 million during 1999 in exchange for approximately 894,000 shares of common stock, representing a premium to fair market value at that time aggregating to \$1.3 million. In addition, Abbott made a series of up-front and milestone payments totaling \$20.8 million, including \$1.9 million received in January 2000 and \$5.0 million received in May 2000, and a long-term loan of \$16 million to us received during 1999. In January 2000, we made a milestone payment of \$4.0 million to Abbott under the terms of the agreement. No further milestone payments are required from either company. All up-front and milestone payments received, net of milestone payments made, and the premium received on the sale of common stock to Abbott are recorded as deferred revenue and recognized ratably over the term of the agreement as revenue from collaborative agreements. In May 2000, Abbott and we launched Gengraf, the cyclosporine capsule developed by Abbott. In connection with the equity investment, Abbott and we entered into a Right of First Refusal Agreement and a Registration Rights Agreement, and amended and restated our existing Supply Agreement.

***Abgenix***

In August 2000, we entered into a global co-development, supply and license agreement with Abgenix, Inc., for ABX-CBL, an antibody developed by Abgenix. Under the agreement, we have an exclusive worldwide license for the marketing and sale of ABX-CBL. ABX-CBL is an anti-CD147 monoclonal antibody for the treatment of steroid resistant GVHD and is currently in a multicenter, randomized, and controlled Phase II/III study. Development costs will be shared equally, as would any potential profits from the sales of collaboration products. We share responsibility for product development with Abgenix, including the ongoing Phase II/III clinical trial. We will market any potential products and Abgenix will be responsible for manufacturing ABX-CBL. We also have the right, subject to the terms and conditions of the agreement, to commercialize other anti-CD147 antibodies developed by Abgenix.

Under the terms of the agreement, we made an initial license fee payment of \$1 million to Abgenix. Two additional milestone payments of \$1 million are due to Abgenix under the terms of the agreement contingent on achievement of certain milestones. The license fee payment and the milestone payments, if any are paid to Abgenix, will be non-refundable and non-creditable against any future obligations under this agreement.

If ABX-CBL receives regulatory approval and is launched, we will be required to pay Abgenix for our share of development expenses incurred prior to January 1, 2000. The amount has not been determined, but the agreement limits our obligation to \$6,100,000. We do not have any obligation to reimburse Abgenix until the first anniversary of the launch of ABX-CBL and the timing of reimbursement varies depending on ABX-CBL's sales. We also must reimburse Abgenix for one-half of the development costs incurred for ABX-CBL from January 1, 2000 to August 8, 2000, with our share being approximately \$1.9 million. We have paid Abgenix \$1.4 million as of September 30, 2001 and the remaining \$0.5 million is payable by the end of June 2002. The license fee and the initial reimbursement of development expenses are recorded as research and development expenses.

***Aventis***

We entered into a Distribution Agreement with Aventis in May 1999 that expires March 31, 2002. Aventis is our exclusive distributor for Thymoglobulin and Lymphoglobuline for most countries outside of North America, Europe and Japan (where Thymoglobuline and Lymphoglobuline are distributed by Aventis). The contract has minimum purchase requirements. If Aventis does not meet these minimums, the agreement becomes non-exclusive, which means we can sell to another distributor in the same country. Aventis sells these products either through its local subsidiary or through a distributor that often distributes other Aventis products. We renegotiated this agreement in 2001 and have contracted directly with distributors in Asia where Aventis has no direct presence (e.g. Israel and certain Asian countries). We are also in negotiations to extend the current contract directly with Aventis subsidiaries in the countries where Aventis does have a direct presence and with current Aventis distributors in certain other countries (e.g. Middle East, Africa and Russia).

Aventis also performs certain steps in the manufacturing process of Thymoglobulin and Lymphoglobuline. In addition, pursuant to the purchase of IMTIX on September 30, 1998, we pay Aventis royalties on Thymoglobulin and Lymphoglobuline contingent upon the sales of these products. In 1999 and 2000, royalty payments on Lymphoglobuline to Aventis totaled approximately \$646,000 and \$622,000 respectively. For the nine months ended September 30, 2001, royalty payments on Lymphoglobuline and Thymoglobulin totaled approximately \$557,000. We expect these royalty payments to increase in future years since we began paying royalties on Thymoglobulin during the third quarter of 2001. The royalty payments on Thymoglobulin increased on the third anniversary of the purchase of IMTIX (October 1, 2001) and will decrease again three years thereafter.

***Synt:em***

In July 2001, we entered into a three year research collaboration agreement for the discovery of next generation RDP58 molecules with Synt:em, a French biopharmaceutical company. The aim of this collaboration is to design novel RDP58-like compounds for the inhibition of inflammation in new in vivo applications using



Synt:em s proprietary rational design technology, Acti:mapThe agreement builds on earlier development efforts between SangStat and Synt:em with Allotrap peptides which led to the original discovery of RDP58. Under the terms of the collaboration SangStat performs in vitro and in vivo testing of peptides and novel rationally designed peptides while Synt:em uses its Acti:map technology to perform the rational design work.

### Competition

The drug industry is very competitive. The drugs we market compete with existing and new drugs being created by pharmaceutical, biopharmaceutical, and 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 for us. Many of the competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing the desired therapeutic effect than products we are developing or marketing and may be more effective and less costly. In addition, many of our competitors have significantly greater experience than we do in conducting clinical trials of pharmaceutical products and obtaining regulatory approvals of such products. This could cause our competitors to succeed in commercializing products more rapidly than we can. The principal factors upon which our products compete are:

- product utility,
- therapeutic benefits,
- ease of use,
- pricing, and
- effective marketing.

We believe we compete favorably with respect to all of these factors.

Competitive products with respect to our material products include the following:

Our Products	Competitive Products	Competitor
Thymoglobulin/ Lymphoglobuline	Orthoclone OKT <sup>®</sup> 3	Ortho Biotech
	ATGAM <sup>®</sup>	Pharmacia
	Simulect <sup>®</sup>	Novartis AG
	Zenapax <sup>®</sup>	Roche
Gengraf & cyclosporine capsules	Neoral	Novartis AG
	Sandimmune	Novartis AG
	Prograf <sup>®</sup>	Fujisawa Pharmaceutical Co. Ltd.
	Rapamune	American Home Products (AHP)
	Generic cyclosporine capsule	Eon Labs
	Generic cyclosporine capsule	Sidmak

Competitive products with respect to our product candidates include the following:

Our Product Candidates	Competitive Products	Competitor
ABX-CBL	MEDI-507	Medimmune/BioTransplant
	Nuvion(HuM291)	Protein Design Labs
RDP58	Enbrel®	Immunex AHP
	Remicade®	Johnson & Johnson

Gengraf and our cyclosporine capsule in development are generic and compete against the branded cyclosporine products as well as other generic cyclosporine products that have been or may be approved. These products also compete against Prograf, marketed by Fujisawa Pharmaceutical Co. Ltd, which was approved by the FDA to be taken instead of cyclosporine. Roche's Cellcept® is indicated as a conjunctive therapy, to be taken with cyclosporine rather than instead of cyclosporine. As noted above, Thymoglobulin competes with OKT3, ATGAM, Simulect, and Zenapax. In the U.S., Thymoglobulin has been successful in establishing a market share against these products, which were all previously on the market. In Europe, Novartis and Roche have just started selling Simulect and Zenapax, respectively, and we believe that the launch of these two products may impact sales of Thymoglobulin and Lymphoglobuline in Europe.

ABX-CBL is expected to compete against two products that are also in clinical trials for the treatment of GVHD: Medimmune/BioTransplant's MEDI-507 and Protein Design Labs' Nuvion. In addition, other products are used for the prevention of GVHD and would therefore eliminate the need to use ABX-CBL for treatment.

RDP58 is an inhibitor of TNF-alpha synthesis. TNF-alpha is a cytokine released in excess in various autoimmune disorders. For that reason, many companies are pursuing development of a TNF-alpha inhibitor and we believe there could be substantial competition in this area. In addition, Immunex/AHP's Enbrel and Johnson & Johnson's Remicade are both TNF-alpha inhibitors that are currently approved for rheumatoid arthritis and Crohn's disease, respectively.

#### Patents and Proprietary Technology

We have twenty-seven issued patents and nine pending patent applications in the U.S. and are pursuing corresponding patent applications in other countries with respect to the products we are selling, the products we have in development and our research areas. We aggressively seek patent protection on our inventions and our policy is to enforce our intellectual property rights. We have no issued patents covering Thymoglobulin and Lymphoglobuline, and rely on our manufacturing know-how to protect these products. We have issued patents covering Celsior. With respect to our cyclosporine capsules, we have in-licensed a pending formulation patent application. The cyclosporine compound is no longer patent-protected and there are several generics on the market in the U.S. We are pursuing patent protection for RDP58 and we believe that an issued patent may give us a competitive advantage.

Our patents expire on various dates beginning in the year 2008 and ending in the year 2017.

In addition, as discussed above, we have also licensed in certain patents and patent technology. We have an exclusive, worldwide license from Stanford University for certain issued patents and pending patent applications in the HLA and peptide area. We have licensed from Abgenix certain patents and patent applications that relate to ABX-CBL. We have licensed additional patents relating to cyclosporine from the University of North Carolina and Tris Pharma. Except for the University of North Carolina, with respect to which we prosecute certain patents and patent applications, the licensor for each of these licenses is primarily responsible for prosecution of these patents and patent applications.

Patent applications in the U.S. are maintained in secrecy until patents issue. Since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we were the first to discover compositions covered by our pending patent applications or the first to file patent applications on such compositions. Our pending patent applications may not result in issued patents, our issued patents may not afford protection against a competitor and our products may infringe on other patents.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements with our employees and consultants.

We have registered or applied for registration of the names of all of our marketed products and plan to register the names of our products under development once a name has been selected for the product candidate.

### **Manufacturing**

Manufacturing pharmaceutical products is a highly regulated process. The FDA and other regulatory agencies require that manufacturing be done in accordance with current Good Manufacturing Practices, or GMP. Additionally, products can only be manufactured in facilities approved by the applicable regulatory authorities.

When we acquired IMTIX in 1998, we also acquired the manufacturing unit in Lyon, France that manufactured Thymoglobulin and Lymphoglobuline. Currently Aventis also performs certain steps in the manufacturing process of Thymoglobulin and Lymphoglobuline under contract to us. We perform the remaining manufacturing steps ourselves in manufacturing facilities that we lease from Aventis. These agreements with Aventis expire on dates ranging from 2008 to 2013. In 1999, partially in response to a letter from the FDA, we improved certain manufacturing processes at the Lyon facility and have continued to improve these manufacturing processes in 2000 and 2001, including moving part of our operations to a new manufacturing building in the same location. We expect the FDA to inspect our Lyon facility as part of its regular inspection process. The FDA recently notified us that the next inspection of our Lyon and the Aventis manufacturing facilities would occur in March. In addition, the Canadian Bureau of Biologics has scheduled an inspection of our Lyon facility for February. We believe that our facility currently complies with GMP. However, we likely would be unable to quickly and efficiently replace our manufacturing capacity if we were unable to manufacture Thymoglobulin or Lymphoglobuline as a result of subsequent FDA or other regulatory inspections or otherwise, or if one of our manufacturers were unable to manufacture one of our other products for us.

We have no other manufacturing facility and the Lyon facility could not be used for products other than biologics. Therefore, we rely on third parties to manufacture our other products, both those that we sell and those in development. We depend on such third parties to perform their obligations in compliance with all regulatory requirements and on a timely basis. If any of our contract manufacturers fail to perform, such failure may delay our clinical development or submission of products for regulatory approval or result in product shortages with respect to our marketed products.

Abgenix is responsible for the manufacturing of ABX-CBL. If the supplier they have chosen is unwilling or unable to perform, it may delay our clinical development or submission of products for regulatory approval, or result in product shortages with respect to our marketed products.

With respect to raw materials, we have agreements for commercial scale production of cyclosporine bulk material with Gensia Sicor and Abbott. Our Gensia Sicor agreement runs until October 31, 2013 and has an automatic five-year term renewal unless one party gives notice. Our Abbott agreement terminates December 31, 2004 and is automatically renewed until one party gives notice. Bulk cyclosporine is difficult to manufacture since it must be extracted from whole cells and carefully purified. We have an obligation to purchase a certain percentage of our future bulk cyclosporine requirements from Gensia Sicor and a minimum fixed amount from Abbott, subject to certain conditions being met. We believe we have sufficient quantities of bulk cyclosporine to meet our current needs. We believe we also have sufficient quantities of raw materials for our other products and product candidates.

### **Warehousing and Distribution**

We use a logistics provider to store and distribute our products from one central warehousing location in Memphis, Tennessee. When our logistics provider receives a purchase order through electronic data input, phone, mail or facsimile, it sends the order to the warehouse for shipment, usually within 24 hours, to the customer placing the order. The logistics provider is also responsible for invoicing and collections.

## Government Regulation

Our research and development activities, preclinical studies and clinical trials, and ultimately the manufacturing, marketing and labeling of our products, are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries ( Regulatory Agencies ). The U.S. Federal Food, Drug, and Cosmetic Act (the Act ) and the regulations promulgated thereunder and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising, promotion, import and export of our products and product candidates. Preclinical study and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would harm our ability to commercialize any product candidates we develop and our ability to receive product revenues. If regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed.

Our products in clinical trials during 2002 may include Thymoglobulin for expanded labeling, ABX-CBL, RDP58, and bioequivalence studies for our cyclosporine capsule product.

Our clinical trials may not be completed successfully or within any specified time period. Either the FDA or we may suspend clinical trials at any time, if either of us concludes that clinical subjects are being exposed to an unacceptable health risk, or for other reasons. The conduct of clinical trials is complex and difficult, especially in Phase III. The design or the performance of the Phase III clinical trial protocols may not be successful.

The results of preclinical studies and clinical trials are submitted in an application to seek FDA approval to market the drug or biological product for a specified use. The testing and approval process requires substantial time and effort, and there can be no assurance that any approval will be granted for any product or that approval will be granted according to any schedule. The FDA may refuse to approve an application if it believes that applicable regulatory criteria are not satisfied. The FDA may also require additional testing for safety and efficacy of the drug. Moreover, if regulatory approval of a drug product is granted, the approval will be limited to specific indications. Our product candidates may not receive regulatory approvals for marketing, or if approved, that approval may not be for the indications that we requested.

Other Regulatory Agencies follow similar procedures to those required by the FDA and require that the safety and efficacy of our pharmaceutical product candidates be supported through adequate and well-controlled clinical trials. If the results of our pivotal clinical trials submitted in application for approval do not establish the safety and efficacy of our product candidate to the satisfaction of any Regulatory Agency, we will not receive the approvals necessary to market our product candidate in that country.

In the European Union, or EU, the registration process for products can be done through a decentralized procedure. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more Member States, certify that the dossier is identical to that on which the first approval was based or explain any differences and certify that identical dossiers are being submitted to all Member States from which recognition is sought. Within 90 days of receiving the application and assessment report, each Member State must decide whether to recognize the approval. The procedure encourages Member States to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. If such disputes cannot be resolved within the 90-day period provided for review, the application will be subject to a binding arbitration procedure.

Following approval, Regulatory Agencies continue to regulate our approved and marketed products. We must report adverse drug events associated with our products to Regulatory Agencies. In addition, Regulatory Agencies also inspect on a regular basis the equipment and facilities used to manufacture our products. A Regulatory Agency may suspend the manufacturing facilities (and order a recall of our products manufactured in that facility) if the Regulatory Agency believes that the product has not been manufactured in compliance with regulations. Further, the labeling, advertising, and promotion of our products must adhere to strict guidelines

from Regulatory Agencies. 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.

## **Litigation**

### ***Novartis Patent Litigation With Respect to Gengraf***

Novartis sued Abbott claiming that Gengraf<sup>®</sup> infringes its patents. Novartis' complaint includes a plea for injunctive relief to prevent the sale of Gengraf in the U.S., but to date Novartis has not moved for a preliminary injunction. The trial date was scheduled for February 20, 2002, but has been postponed and a new trial date has not yet been set. 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' 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' 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 early 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' cyclosporine capsule. An agreement was reached between the parties in which Novartis agreed to stay the judicial review until the earlier of (i) the decision on the judicial review of

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

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

*Italian Regulatory/Trade Secret Litigation.* On May 5, 2000, Novartis Farma S.p.A. (Novartis Italy) served IMTIX-SangStat S.r.l., an Italian SangStat subsidiary, and IMTIX-SangStat Ltd. with a summons to the Milan Tribunal. Novartis Italy alleges that by requesting mutual recognition from the Italian Health Authorities of the SangCya Oral Solution dossier approved by the MCA, we implicitly requested that the Italian Health Authorities review the Neoral dossier. Novartis alleges that this request is an act of unfair competition in that (i) the Neoral data has ten year exclusivity and (ii) the data is secret and by requesting mutual recognition, we are responsible for the Health Authorities act of unfair competition following use of the Neoral dossier in reviewing the SangCya Oral Solution dossier. While the summons acknowledges that the U.K. High Court did not invalidate the SangCya Oral Solution marketing authorization, it does not acknowledge that the High Court ruled that the MCA could review the Neoral data. To the best of our knowledge, Novartis Italy has not filed suit against the Italian Health Authorities. The initial appearance of the parties before the Milan Tribunal was scheduled for January 2001. We filed our response to the complaint at that time, and the hearing has been postponed until June 2002.

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

### **Summary**

Although we are optimistic that these disputes will ultimately be resolved in our favor, the course of litigation is inherently uncertain. With respect to Novartis' lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, our revenues would be reduced. With respect to the European regulatory and trade secret lawsuits, Novartis' requested relief, if granted, could have a negative economic impact on us depending on how the MCA would proceed with our Marketing Authorization Application (MAA) for our capsule product. The MCA could approve our MAA for cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve our MAA for our cyclosporine capsule until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004). If we cannot obtain approval of our cyclosporine capsule in Europe until 2004, this could have an adverse impact on our future revenues and results of operations. With respect to the FDA lawsuit, Novartis' requested relief would mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating to Neoral. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not

automatically substitute Gengraf for Neoral capsules and this would harm revenues. The litigation, if not resolved favorably to us, could have a material adverse effect on our 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 our French subsidiary, IMTIX-SangStat SAS, for breach of contract. On May 2, 2001 we were notified that the Commercial Court of Lyon ruled against IMTIX-SangStat in the breach of contract suit and the court awarded the suppliers 26.5 million French Francs (approximately \$3.6 million) for lost profits and reimbursement of capital expenditures. IMTIX-SangStat recorded a charge of \$3,250,000 to other expense net for the nine months ended September 30, 2001, which, combined with reserves recorded in fiscal 2000, fully provide for the court award. We believe that the ruling was in error and have appealed the decision. The hearing for the appeal was heard on November 8, 2001 and a decision is expected during the first quarter of 2002.

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

**Employees**

As of December 31, 2001, we employed 263 people worldwide, of which 101 are in the U.S. and Canada and 162 are in Europe, which includes approximately 65 employees in our manufacturing facility in Lyon, France. Most of our employees in the Lyon, France, facility are represented by labor unions. We believe that we maintain good relations with our employees.

## MANAGEMENT

Our executive officers and directors and their ages at December 31, 2001 are as follows:

Name	Age	Position
Jean-Jacques Bienaimé	48	President, Chief Executive Officer, Chairman of the Board of Directors
Steve Aselage	50	Senior Vice President, North American Sales and Marketing
Roland Buelow, Ph.D.	43	Senior Vice President, Research and Development
Stephen G. Dance	50	Senior Vice President, Finance
Ralph E. Levy	53	Senior Vice President, Operations
Raymond J. Tesi, M.D.	46	Senior Vice President, Clinical Development and Medical Affairs
Robert C. Floch, Ph.D.	53	General Manager of IMTIX-SangStat
Fredric J. Feldman, Ph.D.	61	Director
Richard D. Murdock	54	Director
Andrew J. Perlman, M.D., Ph.D.	54	Director
Nicholas J. Simon III	53	Director
Vincent R. Worms	49	Director

Jean-Jacques Bienaimé has been our President and Chief Operating Officer since June 1998 and became Chief Executive Officer on February 1, 1999. He was elected to the Board of Directors in March 1999. Mr. Bienaimé became Chairman of the Board of Directors in October 2000. From September 1992 to May 1998 Mr. Bienaimé was with Rhone Poulenc Rorer, Inc., a pharmaceutical company, rising to the position of Senior Vice President, Corporate Marketing and Business Development. He is currently a member of the board of Fox Chase Cancer Center and Aerogen Inc. Mr. Bienaimé received his degree in economics from Ecole Supérieure de Commerce de Paris in France and an M.B.A. from the Wharton School, University of Pennsylvania.

Steve Aselage joined us in February 1999 and currently is our Senior Vice President, North American Sales and Marketing. From 1995 to January 1999, Mr. Aselage was the Director of Sales and Marketing at Advanced Tissue Sciences, a tissue engineering company. Mr. Aselage received a B.S. in biology from the University of Notre Dame.

Roland Buelow, Ph.D. joined us in 1993 and currently is our Senior Vice President of Research and Development. Dr. Buelow received a Ph.D. in Biology from the Max-Planck Institute for Biology in Tuebingen, Germany. Dr. Buelow visited the University of Texas as a Fulbright scholar and spent two years at Stanford Medical School.

Stephen G. Dance has been our Senior Vice President, Finance since April 1999. From July 1998 to April 1999, Mr. Dance was Director of Financial Accounting, Planning and Reporting at Plantronics, Inc., a telecommunications company. From 1983 to July 1998, Mr. Dance held various positions with Syntex Corporation, a pharmaceutical company, which was acquired by Roche Holding Ltd., also a pharmaceutical company, in 1994, serving most recently as Controller, Syntex Laboratories, Inc. Mr. Dance holds a B.A. in French from Leeds University in England, is a Certified Public Accountant in the State of California and a fellow of the Institute of Chartered Accountants in England and Wales.

Ralph E. Levy joined us in 1990 and currently is our Senior Vice President, Operations. Mr. Levy received a B.S. in chemistry from the City College of New York and an M.S. in chemistry from Seton Hall University.

Raymond J. Tesi, M.D. joined us in May 1997 and currently is our Senior Vice President, Clinical Development and Medical Affairs. From 1994 until 1997, Dr. Tesi was an associate professor of surgery and director of the extra-renal transplantation program at Tulane Medical School in New Orleans, Louisiana. He was a transplantation surgical fellow at the Ohio State University Hospital. Dr. Tesi received an M.D. from the Washington University School of Medicine in St. Louis, Missouri.



Robert C. Floch, Ph.D. has been the General Manager of our IMTIX-SangStat subsidiary since we acquired IMTIX in September 1998. In addition, Dr. Floch has been General Manager at SangStat Atlantique, our previous operating subsidiary in France, since 1992. Dr. Floch received a doctor of pharmacy degree and a Ph.D. in medical chemistry from the University of Nantes.

Fredric J. Feldman, Ph.D. has been a director since March 1992. He has been the President of FJF Associates, a consultant to health care venture capital and emerging companies, since February 1992. From September 1995 to June 1996 he was the Chief Executive Officer of Biex, Inc. a women's healthcare company. Dr. Feldman returned to his position as Chief Executive Officer of Biex from 1999 to 2000. He is also a director of Biex, Inc., OrthoLogic Corporation, and Ostex International, Inc. Dr. Feldman received his Ph.D. in Analytical Chemistry from the University of Maryland and his B.S. in Chemistry from Brooklyn College of City University of New York.

Richard D. Murdock has been a director since October 1993. From December 1998 until February 2001, Mr. Murdock was the President and Chief Executive Officer and a director of Kyphon, Inc., an orthopedic medical device company. From September 1991 to October 1998, Mr. Murdock served as the Chief Executive Officer and a director of CellPro, Incorporated, a public biotechnology company. Mr. Murdock received his B.S. in Zoology from the University of California at Berkeley.

Andrew J. Perlman, M.D., Ph.D. has been a director since December 1992. Dr. Perlman has been the Executive Vice President at Tularik, Inc., a public biotechnology company, since September 1999. From November 1997 to September 1999, Dr. Perlman served as Tularik's Vice President, Medical Research and Corporate Development. From January 1993 to November 1997, Dr. Perlman served as Tularik's Vice President of Medical Research. Dr. Perlman received his M.D. and his Ph.D. in Physiology from New York University.

Nicholas J. Simon III has been a director since July 2001. Mr. Simon joined Genentech, Inc. in December 1989 and from 1994 to April 2000 served as Vice President of Business and Corporate Development. In April 2000, Mr. Simon resigned from Genentech and founded Collabra Pharma, Inc. (formerly iO Pharmaceuticals) where he has been the Chief Executive Officer and a director since that time. Mr. Simon is also Chairman of the Board of Deltagen, Inc., a public company, and serves on the board of directors of several private companies. Mr. Simon holds an M.B.A. from Loyola College.

Vincent R. Worms has been a director since October 1991. Mr. Worms has been a General Partner of Partech International, a venture capital management fund, since 1982. Mr. Worms is presently a director of Informatica. He received his engineering degree from Ecole Polytechnique in Paris, and his M.S. degree from the Massachusetts Institute of Technology.

## UNDERWRITING

We intend to offer the shares of common stock through the underwriters named below. Subject to the terms and conditions described in a purchase agreement among us and the underwriters, we have agreed to sell to the underwriters, and the underwriters severally have agreed to purchase from us, the number of shares listed opposite their names below.

Underwriter	Number of Shares
Merrill Lynch, Pierce, Fenner & Smith Incorporated	1,710,000
J.P. Morgan Securities Inc.	1,710,000
Thomas Weisel Partners LLC	855,000
Wells Fargo Securities, LLC	225,000
Total	4,500,000

The underwriters have agreed to purchase all of the shares sold under the purchase agreement if any of these shares are purchased. If an underwriter defaults, the purchase agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the purchase agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as, and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the purchase agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### Commissions and Discounts

The representative has advised us that the underwriters propose initially to offer the shares to the public at the initial public offering price on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$.59 per share. The underwriters may allow, and the dealers may reallocate, a discount not in excess of \$.10 per share to other dealers. After the initial public offering, the public offering price, concession and discount may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their overallotment option.

	Per Share	Without Option	With Option
Public offering price	\$ 17.25	\$ 77,625,000	\$ 89,268,750
Underwriting discount	\$ .99	\$ 4,455,000	\$ 5,123,250
Proceeds, before expenses, to SangStat	\$ 16.26	\$ 73,170,000	\$ 84,145,500

The expenses of the offering, not including the underwriting discount, are estimated at \$600,000 and are payable by us.

### Overallotment Option

We have granted an option to the underwriters to purchase up to 675,000 additional shares at the public offering price less the underwriting discount. The underwriters may exercise this option for 30 days from the date of this prospectus supplement solely to cover any overallotments. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the purchase agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

### **No Sale of Similar Securities**

We, our directors and our executive officers have agreed, with exceptions, not to sell or transfer any common stock for 90 days after the date of this prospectus supplement without first obtaining the written consent of Merrill Lynch. Specifically, we and these other individuals have agreed not to directly or indirectly:

offer, pledge, sell or contract to sell any common stock;

sell any option or contract to purchase any common stock;

purchase any option or contract to sell any common stock;

grant any option, right or warrant for the sale of any common stock;

lend or otherwise dispose of or transfer any common stock;

request or demand that we file a registration statement related to the common stock; or

enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lockup provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

### **Nasdaq National Market**

Our shares of common stock are traded on the Nasdaq National Market under the symbol SANG.

### **Price Stabilization And Short Position**

Until the distribution of the shares is completed, SEC rules may limit the underwriters and selling group members from bidding for or purchasing our common stock. However, the representative may engage in transactions that stabilize the price of our common stock, such as bids or purchases that peg, fix or maintain that price.

If the underwriters create a short position in the common stock in connection with the offering, i.e., if they sell more shares than are listed on the cover page of this prospectus, the representative may reduce that short position by purchasing shares in the open market. The representative may also elect to reduce any short position by exercising all or part of the over-allotment option described above. Purchases of the common stock to stabilize its price or to reduce a short position may cause the price of the common stock to be higher than it might be in the absence of such purchases.

Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters makes any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

### **Passive Market Making**

In connection with this offering, underwriters and selling group members may engage in passive market making transactions in the common stock on the Nasdaq National Market in accordance with Rule 103 of Regulation M under the Exchange Act during a period before the commencement of offers or sales of common stock and extending through completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered

below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

**Electronic Distribution**

Merrill Lynch will be facilitating Internet distribution for this offering to certain of its internet subscription customers. Merrill Lynch intends to allocate a limited number of shares for sale to its online brokerage customers. An electronic prospectus is available on the Web site maintained by Merrill Lynch. Other than the prospectus in electronic format, the information on the Merrill Lynch Web site relating to this offering is not a part of this prospectus supplement.

**Other Relationships**

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us and our subsidiaries. They have received customary fees and commissions for these previous transactions.

S-54

#### **LEGAL MATTERS**

Certain legal matters relating to the shares of common stock offered hereby will be passed upon for SangStat Medical Corporation by Skadden, Arps, Slate, Meagher & Flom LLP, Palo Alto, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins, Costa Mesa, California.

#### **EXPERTS**

The consolidated financial statements of SangStat Medical Corporation as of December 31, 2000 and 1999 and for each of the three years in the period ended December 31, 2000 and the related consolidated financial statement schedule included in this prospectus supplement and incorporated by reference in the accompanying prospectus have been audited by Deloitte & Touche LLP, independent auditors, as stated in their report which is included in this prospectus supplement and incorporated by reference in the accompanying prospectus.

These consolidated financial statements and the related consolidated financial statement schedule have been so included in the prospectus supplement and incorporated by reference in the accompanying prospectus in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

S-55

**SANGSTAT MEDICAL CORPORATION**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<u>Page</u>
<u>Independent Auditors Report</u>	F-2
Annual Consolidated Financial Statements:	
<u>Consolidated Balance Sheets for the years ended December 31, 2000 and 1999</u>	F-3
<u>Consolidated Statements of Operations for the years ended December 31, 2000, 1999 and 1998</u>	F-4
<u>Consolidated Statements of Comprehensive Loss for the years ended December 31, 2000, 1999, and 1998</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2000, 1999 and 1998</u>	F-5
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2000, 1999 and 1998</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
Consolidated Financial Statement Schedules:	
<u>Schedule II Valuation and Qualifying Accounts for the years ended December 31, 2000, 1999 and 1998</u>	F-28
Interim Unaudited Condensed Consolidated Financial Statements:	
<u>Condensed Consolidated Balance Sheets at September 30, 2001 (unaudited) and December 31, 2000</u>	F-29
<u>Condensed Consolidated Statements of Operations for the nine months ended September 30, 2001 and 2000 (unaudited)</u>	F-30
<u>Condensed Consolidated Statements of Comprehensive Loss for the nine months ended September 30, 2001 and 2000 (unaudited)</u>	F-30
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2001 and 2000 (unaudited)</u>	F-31
<u>Notes to Condensed Consolidated Financial Statements</u>	F-32

**INDEPENDENT AUDITORS REPORT**

To the Board of Directors and Stockholders  
of SangStat Medical Corporation:

We have audited the accompanying consolidated balance sheets of SangStat Medical Corporation and subsidiaries (collectively, the Company ) as of December 31, 2000 and 1999, and the related consolidated statements of operations, comprehensive loss, stockholders equity and cash flows for each of the three years in the period ended December 31, 2000. Our audits also included the consolidated financial statement schedule listed in the Index to Consolidated Financial Statements on page F-1. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such consolidated financial statement schedule referenced above, when considered in relation to the basic consolidated financial statements as a whole, presents fairly, in all material respects, the information set forth therein.

DELOITTE & TOUCHE LLP

San Jose, California  
February 13, 2001 (March 13, 2001 as to Note 15)

## SANGSTAT MEDICAL CORPORATION

## CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2000	1999
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 19,046	\$ 16,862
Short-term investments	1,561	9,657
Accounts receivable (net of allowance for doubtful accounts of \$3,128 in 2000 and \$1,469 in 1999)	17,569	12,782
Other receivables	2,333	2,906
Inventories	40,056	46,270
Prepaid expenses and other current assets	6,912	2,306
	<u>87,477</u>	<u>90,783</u>
Total current assets	87,477	90,783
PROPERTY AND EQUIPMENT net	6,539	5,574
INTANGIBLE ASSETS (net of accumulated amortization of \$3,141 in 2000 and \$1,749 in 1999)	11,142	12,534
OTHER ASSETS	9,158	8,406
	<u>114,316</u>	<u>117,297</u>
TOTAL	\$ 114,316	\$ 117,297
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
CURRENT LIABILITIES:		
Accounts payable	\$ 17,553	\$ 11,851
Accrued liabilities	13,938	5,511
Capital lease obligations current portion	257	700
Deferred revenue current portion	3,158	4,426
Notes payable current portion	12,797	4,304
	<u>47,703</u>	<u>26,792</u>
Total current liabilities	47,703	26,792
CAPITAL LEASE OBLIGATIONS	535	125
DEFERRED REVENUE	9,475	9,304
NOTES PAYABLE	34,679	40,067
COMMITMENTS AND CONTINGENCIES (Notes 9 and 18)		
STOCKHOLDERS EQUITY:		
Preferred stock, \$.001 par value 5,000 shares authorized; none outstanding		
Common stock, \$.001 par value, 35,000 shares authorized; outstanding: 2000, 18,942 shares; 1999, 17,354 shares	201,766	174,990
Accumulated deficit	(177,636)	(133,277)
Accumulated other comprehensive loss	(2,206)	(704)
	<u>21,924</u>	<u>41,009</u>
Total stockholders equity	21,924	41,009
TOTAL	\$ 114,316	\$ 117,297



*See notes to consolidated financial statements.*

F-3

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

(in thousands, except per share data)

	Year Ended December 31,		
	2000	1999	1998
<b>REVENUES:</b>			
Net sales	\$ 61,319	\$ 42,243	\$ 10,202
Product recall returns	(872)		
Revenue from collaborative agreements (Note 9)	2,698	2,060	1,092
<b>Total revenues</b>	<b>63,145</b>	<b>44,303</b>	<b>11,294</b>
<b>COSTS AND OPERATING EXPENSES:</b>			
Cost of sales:			
Cost of product sales and manufacturing expenses	27,472	18,989	5,110
Product recall charges	11,774		
Research and development (includes product recall expenses of \$50 for the year ended December 31, 2000)	20,788	14,470	17,688
Selling, general and administrative (includes product recall expenses of \$379 for the year ended December 31, 2000)	41,766	39,170	23,707
Acquired in-process research and development			3,218
Amortization of intangible assets	1,392	1,398	351
<b>Total costs and operating expenses</b>	<b>103,192</b>	<b>74,027</b>	<b>50,074</b>
Loss from continuing operations	(40,047)	(29,724)	(38,780)
<b>OTHER INCOME (EXPENSE), NET:</b>			
Interest income	2,016	1,865	3,611
Interest expense	(4,368)	(3,034)	(404)
Other income (expense), net	750	256	(154)
Other income (expense), net	(1,602)	(913)	3,053
<b>LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES</b>	<b>(41,649)</b>	<b>(30,637)</b>	<b>(35,727)</b>
<b>INCOME TAX PROVISION</b>	<b>(368)</b>	<b>(345)</b>	<b>(257)</b>
<b>NET LOSS FROM CONTINUING OPERATIONS</b>	<b>(42,017)</b>	<b>(30,982)</b>	<b>(35,984)</b>
<b>NET LOSS FROM OPERATIONS OF DISCONTINUED OPERATION</b>	<b>(2,342)</b>	<b>(2,025)</b>	<b>(2,480)</b>
<b>NET LOSS</b>	<b>\$ (44,359)</b>	<b>\$ (33,007)</b>	<b>\$ (38,464)</b>
<b>NET LOSS PER SHARE basic and diluted (Note 1)</b>			
Continuing operations	\$ (2.35)	\$ (1.83)	\$ (2.24)
Discontinued operation	(0.13)	(0.12)	(0.15)
	\$ (2.48)	\$ (1.95)	\$ (2.39)
<b>WEIGHTED AVERAGE COMMON SHARES</b>	<b>17,910</b>	<b>16,888</b>	<b>16,080</b>

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	Year Ended December 31,		
	2000	1999	1998
Net loss	\$ (44,359)	\$ (33,007)	\$ (38,464)
Reversal of unrealized gain on marketable securities sold during the period	(644)		
Unrealized gains and (losses) on marketable securities classified as available for sale in the current period	40	1,078	(494)
Foreign currency translation adjustments	(898)	(1,388)	89
<b>Total comprehensive loss</b>	<b>\$ (45,861)</b>	<b>\$ (33,317)</b>	<b>\$ (38,869)</b>

*See notes to consolidated financial statements.*

F-4

## SANGSTAT MEDICAL CORPORATION

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands, except share data)

	Common Stock		Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount			
<b>Balances, January 1, 1998</b>	16,009,531	\$ 159,265	\$ (61,806)	\$ 11	\$ 97,470
Exercise of stock options	205,320	869			869
Stock option compensation expense		117			117
Accumulated translation adjustment				89	89
Unrealized loss on investments				(494)	(494)
Net loss			(38,464)		(38,464)
<b>Balances, December 31, 1998</b>	16,214,851	160,251	(100,270)	(394)	59,587
Issuance of common stock	893,996	12,661			12,661
Exercise of stock options	244,927	1,859			1,859
Issuance of stock for services		160			160
Stock option compensation expense		59			59
Accumulated translation adjustment				(1,388)	(1,388)
Unrealized gain on investments				1,078	1,078
Net loss			(33,007)		(33,007)
<b>Balances, December 31, 1999</b>	17,353,774	174,990	(133,277)	(704)	41,009
Issuance of common stock	1,345,928	23,401			23,401
Exercise of stock options	242,644	2,631			2,631
Warrant issued in connection with financing		744			744
Accumulated translation adjustment				(898)	(898)
Reversal of unrealized gain on marketable securities sold during the period, net				(604)	(604)
Net loss			(44,359)		(44,359)
<b>Balances, December 31, 2000</b>	18,942,346	\$ 201,766	\$ (177,636)	\$ (2,206)	\$ 21,924

*See notes to consolidated financial statements.*

**SANGSTAT MEDICAL CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

Year Ended December 31,

	2000	1999	1998			
<b>OPERATING ACTIVITIES:</b>						
Net loss from continuing operations	\$ (42,017)	\$ (30,982)	\$ (35,984)			
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization	3,780	2,921	1,873			
Non-cash interest expense	1,365	1,476				
Acquired in-process research and development			3,218			
Loss on disposal of property and equipment	836	167				
Stock compensation expense		219	117			
Deferred income taxes	130	88	257			
Changes in assets and liabilities:						
Accounts receivable	(4,787)	(1,819)	(4,163)			
Other receivables	573	(465)	(656)			
Inventories	6,214	(12,895)	(18,980)			
Prepaid expenses	(4,606%)	(82,425)	-100.0%			
License fees	-	-%	224,500	25.4%	(224,500)	-100.0%
Hosting fees	-	-%	119,716	13.5%	(119,716)	-100.0%
Other revenue	83,150	22.8%	79,389	9.0%	3,761	4.7%
<b>Total revenues</b>	<b>364,898</b>	<b>100.0%</b>	<b>884,586</b>	<b>100.0%</b>	<b>(519,688)</b>	<b>-58.7%</b>
<b>COST OF REVENUES</b>	<b>599,420</b>	<b>164.3%</b>	<b>1,046,400</b>	<b>118.3%</b>	<b>(446,980)</b>	<b>-42.7%</b>
<b>GROSS LOSS</b>	<b>(234,522)</b>	<b>-64.3%</b>	<b>(161,814)</b>	<b>-18.3%</b>	<b>(72,708)</b>	<b>-44.9%</b>
<b>OPERATING EXPENSES:</b>						
General and administrative	880,605	241.3%	1,469,892	166.2%	(589,287)	-40.1%
Sales and marketing	414,808	113.7%	513,408	58.0%	(98,600)	-19.2%
Research and development	356,104	97.6%	50,080	5.7%	306,024	611.1%
Loss on disposal of assets, net	3,471	.9%	398,962	45.1%	(395,491)	-99.1%
<b>Total operating expenses</b>	<b>1,654,988</b>	<b>453.5%</b>	<b>2,432,342</b>	<b>275.0%</b>	<b>(777,354)</b>	<b>-32.0%</b>
<b>LOSS FROM OPERATIONS</b>	<b>(1,889,510)</b>	<b>-517.8%</b>	<b>(2,594,156)</b>	<b>-293.3%</b>	<b>704,646</b>	<b>27.2%</b>

<b>OTHER INCOME</b>						
<b>(EXPENSE):</b>						
Interest expense, net	(953,703)	-261.4%	(687,909)	-77.8%	(265,794)	38.6%
Gain (loss) on legal settlements, net	177,019	48.5%	556,517	62.9%	(379,498)	-68.2%
Change in market value of settlement related financial instruments	(295,000)	-80.8%	-	-%	(295,000)	-100.0%
Total other expense	(1,071,684)	-293.7%	(131,392)	-14.9%	(940,292)	-715.6%
<b>NET LOSS</b>	<b>\$ (2,961,194)</b>	<b>-811.5%</b>	<b>\$ (2,725,548)</b>	<b>-308.2%</b>	<b>\$ (235,646)</b>	<b>-8.7%</b>

Revenues. Total revenues for the nine months ended September 30, 2011 were \$364,898 compared to \$884,586 for the same period in 2010, representing a decrease of \$519,688, or 58.7%. Our overall decrease in revenues was driven by substantial declines in subscription, professional service, license and hosting fees. During the period, we focused time and efforts to market and promote our newly released SmartOn™ Mobile product. Select items are discussed in detail below.

Subscription Fees – Subscription fees for the nine months ended September 30, 2011 were \$281,748 compared to \$378,556 for the same period in 2010, representing a decrease of \$96,808, or 26%. This decline is primarily attributable to the ongoing migration of one direct-selling organization customer to its own technology solution coupled with a decrease in demand for new subscription relationships during the first, second and third quarters of 2011.

Professional Service Fees - Professional service fees for the nine months ended September 30, 2011 were \$0 compared to \$82,425 for the same period in 2010 representing a decrease of \$82,425, or 100%. This decrease is primarily due to a significant decline in web consulting services provided to customers and no new sales of professional services as we focused time and efforts to market and promote our newly released SmartOn™ Mobile product during the first, second and third quarters of 2011.

License Fees - License fees for the nine months ended September 30, 2011 were \$0 compared to \$224,500 for the same period in 2010, representing a decrease of \$224,500, or 100%. There was no license fee revenue recognized in the first, second and third quarters of 2011 due to the cancellation of a term license that commenced in December 2009 and no new sales.

Hosting Fees – Hosting fees for the nine months ended September 30, 2011 were \$0 as compared to \$119,716 for the same period in 2010, representing a decrease of \$119,716 or 100%. This decrease is caused by lack of customer traffic for clients and the loss of clients that required hosting services.

Other Revenue - Other revenue for the nine months ended September 30, 2011 totaled \$83,150 compared to \$79,389 for the same period in 2010. This revenue is generated from non-core activities. Other revenue is generated by the billings of merchant processing fees to our customers on behalf of their member transactions. We expect these revenue streams to continue as we continue to service our subscription based customers.

#### Cost of Revenues

Cost of revenues for the nine months ended September 30, 2011 was \$599,420 compared to \$1,046,400 for the same period in 2010, representing a decrease of \$446,980, or 43%. This decrease was primarily the result of the decrease of development personnel previously involved with the development and servicing of the major customer that left the Company during 2010.

#### Operating Expenses

Operating expenses for the nine months ended September 30, 2011 were \$1,654,988 compared to \$2,432,342 for the same period in 2010 representing a decrease of \$777,354, or 32%. This decrease is the direct result of our concerted efforts to reduce operating expenses by improving efficiencies and eliminating unnecessary costs. Select items are discussed in detail below.

General and Administrative - General and administrative expenses for the nine months ended September 30, 2011 were \$880,605 compared to \$1,469,892 for the same period in 2010, representing a decrease of \$589,287, or 40%. This decrease is primarily attributable to reductions in: bad debt expense of \$407,000 because we chose not to continue to do services for and invoice customers who were unable to pay; \$148,000 of legal expense because we have been able to settle the outstanding litigation that we were involved with since 2007; \$44,000 in audit and professional fees due to a reduction of additional services required and increased efficiencies in our finance and accounting function; and a \$25,000 decrease in insurance expense due to change in coverage. These decreases were offset by the recognition of an additional \$7,000 in compensation expense associated with the grant of stock options to current employees; and \$8,000 of additional expense for the granting of restricted stock to Board Member Shlomo Elia during the nine-month period ended September 30, 2011.

Sales and Marketing - Sales and marketing expenses for the nine months ended September 30, 2011 were \$414,808 compared to \$513,408 for the same period in 2010, representing a decrease of \$98,600, or 19%. The decrease is primarily attributable to \$118,000 decrease in outsourced public relations, marketing consulting and advertising costs and the reduction of external recruiting costs of \$17,000 offset by \$37,000 of additional wages and associated benefit costs.

Research and Development - Research and development expenses for the nine months ended September 30, 2011 were \$356,104 compared to \$50,080 for the same period in 2010, representing an increase of \$306,024, or 611%. This increase is primarily attributable to an emphasis on research and continued product development during the first and second quarters of 2011.

Loss on disposal of assets – Loss on disposal of assets for the nine months ended September 30, 2011 was \$3,471 compared to a loss of \$398,962 for the same period in 2010, representing a decrease of \$395,491 or 99%. This decrease is due to the fact that we wrote off the previously capitalized software development costs for OneBiz® during the third quarter of 2010 since the product value could not be justified and we incurred a minor loss in 2011 related to the disposal of office equipment.

#### Other Income (Expense)

Other income (expense) for the nine months ended September 30, 2011 and 2010 comprise the following:

	Nine Months Ended		Change	
	September 30, 2011	September 30, 2010	Dollars	Percent
Interest expense, net	\$ (953,703)	\$ (687,909)	\$ (265,794)	-38.6%
Gain (loss) on legal settlements, net	177,019	556,517	(379,498)	-68.2%
Change in market value of settlement related financial instruments	(295,000)	-	(295,000)	-100.0%
Total other (expense) income	\$ (1,071,684)	\$ (131,392)	\$ (940,292)	-715.6%



Interest Expense, Net – We incurred net interest expense of \$953,703 for the nine months ended September 30, 2011 compared to net interest expense of \$687,909 for the same period in 2010, representing an increase of \$265,794, or 40%. Interest expense increased as a result of increased borrowings during the nine-month period.

Gain on Legal Settlements, Net – Net gain on legal settlements decreased 68% to \$177,019 for the nine months ended September 30, 2011 from \$556,517 for the same period in 2010. This net decrease was primarily attributable to the fact that the District Court approval of the Class Action settlement of 1,475,000 shares was finalized on July 1, 2011 and the per share valuation for the accrued liability was higher than the per share market price on the date of District Court approval. Prior to the shares being accounted for as a Financial Instrument, their prior accounting treatment required us to revalue the shares on the date of the approval of the Class Action lawsuit settlement.

Change in market value of settlement related financial instruments – The shares to settle to the Class Action lawsuit have not been issued. Therefore, according to U.S. GAAP, the liability for the Class Action lawsuit settlement is currently accounted for as a Financial Instrument which was initially valued at \$1,622,500 at the date of the District Court's approval and is now recorded at \$1,917,500 due to an increase in the per share price of our common stock at September 30, 2011.

#### Provision for Income Taxes

We have not recorded a provision for income tax expense because we have been generating net losses. Furthermore, we have not recorded an income tax benefit for the third quarter of 2011 primarily due to continued substantial uncertainty based on objective evidence regarding our ability to realize our deferred tax assets, thereby warranting a full valuation allowance in our financial statements. We have approximately \$54,000,000 in net operating loss carryforwards, which may be utilized to offset future taxable income.

Utilization of our net operating loss carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss carryforwards before utilization. The net operating loss carryforward amount will expire between 2011 and 2029.

#### Liquidity and Capital Resources

##### Overview

As of September 30, 2011, our principal sources of liquidity were cash and cash equivalents totaling \$351,766 and current accounts receivable of \$970, net of allowance for doubtful accounts, as compared to \$1,110,209 of cash and cash equivalents and \$8,931 in accounts receivable as of December 31, 2010. As of September 30, 2011, we had drawn \$5,000,000 on the \$6,500,000 IDB Credit Facility, leaving \$1,500,000 available under the credit facility for our operations. Deferred revenue at September 30, 2011 was \$26,000 as compared to \$23,000 at December 31, 2010.

As of November 7, 2011, our principal sources of liquidity were cash and cash equivalents totaling approximately \$608,112 and accounts receivable of approximately \$915. In addition, we continued to have \$1,500,000 available under the IDB Bank Credit Facility. As of November 7, 2011, we also have a commitment from our convertible secured subordinated noteholders to purchase up to an additional \$5.425 million in Notes upon approval and call by our Board of Directors.

Cash Flow from Operations. Cash used in operations for the nine months ended September 30, 2011 totaled \$3,620,707, up from \$2,801,610 for the same period in 2010. This increase of \$819,097 is primarily due to the

payment required to fund the Nouri settlement and the class action lawsuit during 2011.

Cash Flow from Investing Activities. Cash used in investing activities for the nine months ended September 30, 2011 totaled \$10,052, up from \$7,009 for the same period in 2010. This increase is primarily due to the fact that we acquired more computer equipment in the first nine months of 2011 compared to the same period in 2010.

Cash Flow from Financing Activities. Cash provided by financing activities for the nine months ended September 30, 2011 totaled \$3,001,314, up from \$2,745,509 for the same period in 2010. This increase of \$255,805 is primarily due to cash raised in 2011 from debt borrowings to fund operations.

The net cash for the nine months of 2011 from our financing activities was generated through debt financing, as described below.

## Debt Financing

As of September 30, 2011, we had notes payable totaling \$19,539,350. The detail of these notes is as follows:

Note Description	As of September 30, 2011	As of December 31, 2010	Maturity	Rate Prime, not less than 4.0 %
IDB credit facility	\$ 5,000,000	\$ 4,000,000	May 2012	5.4%
Insurance premium note	33,983	21,778	July 2011	8.0-18.0%
Various capital leases	170,367	185,255	Various	8.0%
Convertible notes	14,375,000	12,500,000	November 2013	
Totals	19,579,350	16,707,033		
Less current portion of debt	5,050,053	40,564		
Long-term portion of debt	\$ 14,529,297	\$ 16,666,469		

## Line of Credit

On December 6, 2010, we entered into (i) a \$6,500,000 Promissory Note or “the “IDB Note”, as borrower, and (ii) a Letter Agreement for a \$6,500,000 Term Loan Facility (the “Letter Agreement”), each with Israel Discount Bank of New York (“IDB”) as lender.

Under the IDB Note and Letter Agreement, IDB will make available to the Company one or more term loan advances in the maximum aggregate principal amount of \$6,500,000 or the “IDB Credit Facility”. The IDB Credit Facility is secured by two irrevocable standby letters of credit issued by UBS Switzerland in favor of IDB in the aggregate amount of \$6,500,000 or the “SBLC”, each issued with Atlas Capital S.A. or “Atlas” as account party. Atlas and the Company anticipate finalizing in the near future the terms of the Company’s reimbursement of Atlas for any future drawdowns on the SBLC. Any advances drawn on the IDB Credit Facility must be repaid on the earlier of (a) May 31, 2012 or (b) 180 days prior to the expiration date of the SBLC. Interest on each advance under the IDB Credit Facility accrues, at the Company’s election, at LIBOR plus 300 basis points or IDB’s prime rate plus 100 basis points, provided that the annual rate of interest for each advance shall never be less than four percent. Interest accrued on each advance is due quarterly and payable in arrears on the last day of each February, May, August and November commencing on the last day of February 2011.

## Convertible Notes

We have issued convertible subordinated notes, as amended, or the Notes, under the Convertible Secured Subordinated Note Purchase Agreement, dated November 14, 2007 or, as amended, the Note Purchase Agreement, between the Company and the convertible noteholders, under which we are entitled to elect to sell to the convertible noteholder, and the convertible noteholders are obligated to buy Notes.

Sales of Notes to the convertible noteholders are subject to certain conditions, including the absence of events or conditions that could reasonably be expected to have a material adverse effect on the ability of the Company to perform its obligations under the Note Purchase Agreement.

As of September 30, 2011, we had \$14.375 million aggregate principal amount of Notes due November 14, 2013 outstanding, after a \$200,000 reduction of such current outstanding debt on account of a sale-leaseback of our equipment with the noteholders in 2009. The Notes have been sold as follows:

As of September 30, 2011					
Note Buyer	Date of Purchase	Amount of Convertible Note	Interest Rate	Due Date	
Atlas Capital	Various	\$ 11,925,000	8%	11/14/2013	
Blueline Fund	November 14, 2007	500,000	8%	11/14/2013	
Crystal Management	Various	750,000	8%	11/14/2013	
HSBC Private Bank (Suisse), SA	November 21, 2008	250,000	8%	11/14/2013	
UBP, Union Bancaire Privee	Various	900,000	8%	11/14/2013	
William Furr	November 14, 2007	250,000	8%	11/14/2013	
Less – lease conversion	September 4, 2009	(200,000)			
Total Convertible Notes		\$ 14,375,000			

During a Board of Directors Meeting, held on June 15, 2011, the Board unanimously approved a resolution to increase the total aggregate principal amount of Notes for sale to new convertible noteholders or existing noteholders from \$15.3 million to \$20.3 million. The terms of sale, maturity and interest rate remain consistent with the Notes already sold. We may now sell up to \$20.3 million aggregate principal amount of Notes to new convertible noteholders or existing noteholders with an outside maturity date of November 14, 2013. In addition, the maturity date definition for each of the Notes is the date upon which the note is due and payable, which is the earlier of (1) November 14, 2013, (2) a change of control, or (3) if an event of default occurs, the date upon which noteholders accelerate the indebtedness evidenced by the Notes. The conversion price for each outstanding Note and any additional Notes sold in the future is the same and set at the lowest applicable conversion price for all the Notes, determined according to the formula described in Note 6 in the Company's 2010 Annual Report on Form 10-K for the year ended December 31, 2010.

On October 11, 2011 and November 7, 2011, the Company sold individual Notes to Atlas in the principal amount of \$300,000 each due November 14, 2013, upon substantially the same terms and conditions as the previously issued Notes.

#### Going Concern

Our independent registered public accountants for the fiscal year ended December 31, 2010 have issued an explanatory paragraph in their report included in our Annual Report on Form 10-K for the year ended December 31, 2010 in which they express substantial doubt as to our ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts or classification of liabilities that might be necessary should we be unable to continue as a going concern. Our continuation as a going concern depends on our ability to generate sufficient cash flows to meet our obligations on a timely basis, to obtain additional financing that is currently required, and ultimately to attain profitable operations and positive cash flows. There can be no assurance that our efforts to raise capital or increase revenue will be successful. If our efforts are unsuccessful, we may have to cease operations and liquidate our business.

#### Legal Proceeding Development

Please refer to Part I, Item 3 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and Notes 1, 3 and 5 to our financial statements contained elsewhere in this Quarterly Report on Form 10-Q for a further description of material legal proceedings.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

N/A

## ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our interim Chief Executive Officer has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, or Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our Interim Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective at the reasonable assurance level.

We routinely review our internal control over financial reporting and from time to time make changes intended to enhance the effectiveness of our internal control over financial reporting.

We will continue to evaluate the effectiveness of our disclosure controls and procedures and internal control over financial reporting on an ongoing basis and will take action as appropriate. There has been no change to our internal control over financial reporting, as such, term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the three months ended September 30, 2011 that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

## ITEM 1. LEGAL PROCEEDINGS

On July 1, 2011, the District Court issued a Final Judgment and Order of Partial Dismissal with Prejudice in the Class Action lawsuit. Please refer to Note 5 to our financial statements contained in this Quarterly Report on Form 10-Q for a further description of the Class Action.

## ITEM 6. EXHIBITS

Exhibit No.	Description
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<u>31.1</u> *	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a)
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<u>31.2</u> *	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a)
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<u>32.1</u> **	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350
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<u>32.2</u> **	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350
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101.1\*\* The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in XBRL (extensible Business Reporting Language): (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Cash Flows and (iv) related notes to these financial statements, tagged as blocks of text.\*\*

\* = Filed herewith.

\*\* = Furnished herewith

SIGNATURES

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

Smart Online, Inc.

/s/ Dror Zoreff

Dror Zoreff

Date: November 14, 2011

Principal Executive Officer, Interim CEO and  
President

/s/ Thaddeus J. Shalek

Thaddeus J. Shalek

Date: November 14, 2011

Chief Financial Officer



EXHIBIT INDEX

Exhibit Description  
No.

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32.1\*\* Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350

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