SANGSTAT MEDICAL CORP
Form 424B4
October 18, 2001

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**Registration No. 333-63786**

# SANGSTAT MEDICAL CORPORATION

## 1,363,635 COMMON SHARES

This prospectus relates to 1,363,635 shares of the common stock of SangStat Medical Corporation, which the Selling Stockholders may sell from time to time.

Our common shares are traded on the Nasdaq under the symbol "SANG". On October 17, 2001, the closing sale price per share, as reported by the Nasdaq, was $22.30.

**You should consider carefully the risk factors beginning on page 4 of this prospectus before making a decision to purchase our stock.**

**Neither the SEC nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The Date of this Prospectus is October 17, 2001.

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## SUMMARY

SangStat is a biotechnology company that discovers, develops and markets therapeutic products in the transplantation, immunology and hematology/oncology areas. Since 1988, we have been dedicated to improving the outcome of organ and bone marrow transplantation through the development and marketing of products to address all phases of transplantation in the worldwide market. We are currently organized into one business segment - Pharmaceutical Products, which consists of five marketed products and three principal product candidates.

The following tables summarize our principal products and product candidates.

| **Marketed Product** | Indications/Clinical Use | Marketing |
|---|---|---|
| Thymoglobulin/ Thymoglobuline | Prevention and treatment of acute organ rejection. Rejection refers to when the recipient's body rejects the new organ. Acute rejection is a rejection episode that is treatable and reversible. Thymoglobulin is also used to treat aplastic anemia, a disease in which stem cells disappear from bone marrow, and steroid resistant graft versus host disease, a condition in which the donated organ begins to reject the recipient's body and is resistant to the use of steroids. | We (or our distributors) currently market Thymoglobulin in 56 countries, though our revenues from Thymoglobulin come primarily from Europe and North America. Thymoglobulin is approved in the U.S. only for treatment of kidney transplant acute rejection episodes. 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. We have also entered into distribution agreements with distributors in certain Asian countries. |
| Gengraf | Gengraf is normally taken daily over the lifetime of the organ recipient to prevent organ rejection. | 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. |
| Lymphoglobuline | Prevention and treatment of acute organ rejection. Lymphoglobuline is also used to treat aplastic anemia and steroid resistant graft versus host disease. | We (or our distributors) market Lymphoglobuline in over 45 countries outside the U.S. Our sales force markets it in Europe and Canada. In other countries, we sell it through our distribution agreement with Aventis or through other distributors. Aventis Pharma markets it in Japan, where a high percentage of sales occur for treatment of aplastic anemia. We have no plans to seek approval for Lymphoglobuline in the U.S. |
| Celsior | Storage solution for organs after removal from the donor and before transplantation into the recipient. | Celsior is sold throughout Europe and was launched in the U.S. in September 1999. Celsior is cleared 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. |
| SangCya Oral Solution (cyclosporine) | SangCya Oral Solution is normally taken daily over the lifetime of the organ recipient to prevent organ rejection. | We sell SangCya Oral Solution on a limited basis in Europe. SangCya Oral Solution, which is a generic version of Neoral oral solution, was withdrawn from the U.S. market in July 2000. |

| Product Candidate | Description And Potential Clinical Use |
|---|---|
| Cyclosporine Capsule | We have an exclusive license to a novel cyclosporine capsule formulation, which uses a patented technology, from TrisPharma, a small U.S. research and development company. We are conducting a small pilot study in healthy volunteers to demonstrate the new capsule's bioequivalence to Neoral cyclosporine capsules in water. We plan to file for marketing authorization in Europe in early 2002. |
| 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 currently in a multi-center, randomized, and controlled Phase II/III study for the treatment of steroid resistant graft versus host disease. We received orphan drug designation for ABX-CBL for the treatment of steroid resistant graft versus host disease in November 2000. |
| RDP58 | We are investigating the use of RDP 58 for treatment of various autoimmune disorders, particularly diseases relating to inflammation occurring in the gut which can cause diarrhea and abdominal pain. RDP58 is currently in Phase I clinical trials in the U.K. |

Prior to April 2001, we operated a second business segment - Transplantation Services, which consisted of The Transplant Pharmacy

® . The Transplant Pharmacy provided mail order distribution of drugs and transplant patient management services. We sold The Transplant Pharmacy to Chronimed Inc. in April 2001 for $1.8 million in cash. We retained the accounts receivable and inventory in this sale. As of June 30, 2001, we had approximately $1.5 million in accounts receivable, net of reserves and $103,000 in inventory that we expect to convert to cash.

We have experienced significant operating losses since incorporation in 1988. As of June 30, 2001, our accumulated deficit was $186.7 million. Our operating expenses from continuing operations have increased from approximately $50.1 million to $74.0 million to $103.2 million over the three year period ended December 31, 2000, and were approximately $44.9 million for the six months ended June 30, 2001. To date, our product revenues have been primarily derived from sales of Thymoglobulin, Lymphoglobuline, and Gengraf

. Revenues from Thymoglobulin were 60% of 2000 total revenues from pharmaceutical products, and revenues from Lymphoglobuline were 12% of 2000 total revenues from pharmaceutical products. Revenues from Gengraf were 18% of 2000 total revenues from pharmaceutical products. Novartis has 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. SangCya Oral Solution and Celsior accounted for a relatively small percentage of our revenue in 2000. 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 revenue will be adversely affected.

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. We also own a manufacturing facility in Lyon, France, where we manufacture Thymoglobulin and Lymphoglobuline. Our principal executive offices are located at 6300 Dumbarton Circle, Fremont, California 94555, and our telephone number is (510) 789-4300.

Thymoglobulin®, Thymoglobuline®, Lymphoglobuline®, Celsior® and SangCya®

are our registered trademarks. Gengraf® is a registered trademark of Abbott Laboratories, Inc. Neoral® is a registered trademark of Novartis A.G.

## RISK FACTORS

You should carefully consider the following risk factors before purchasing our common stock. 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 June 30, 2001, our accumulated deficit was $186.7 million. We have not yet had a profitable quarter. To become profitable and maintain profitability, we will have to increase revenues sufficient to cover current operating losses and expected increases in development costs as we move our pipeline products through the development process to approval.

To date, our product revenues have been primarily derived from sales of Thymoglobulin, Lymphoglobuline, and Gengraf

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

Our expectations with respect to achieving positive cash flows and financial reporting profitability are subject to much risk and uncertainty. Even if we do achieve positive cash flows or financial reporting profitability, we may not be able to maintain or increase our positive cash flows or financial reporting profitability on a quarterly or annual basis. Our ability to achieve positive cash flows and financial reporting profitability will be significantly dependent upon our success in:

- maintaining and increasing revenue from Thymoglobulin, Lymphoglobuline and Gengraf, particularly Thymoglobulin;
- successfully commercializing our product candidates, especially ABX-CBL;
- limiting our manufacturing and selling, general and administrative expenses; and
- controlling research and development expenses.

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 losses to continue in the near future as a result of a number of factors, including:

- the uncertainty in the timing and the amount of revenue we earn upon product sales;
- our achievement of research and development milestones; and

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

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

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

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

We may need to raise additional funds within the next 12 months and may not be able to secure adequate funds on terms acceptable to us.

Within the next twelve months, we may need to raise additional funds through financing and collaborative research and development arrangements with corporate partners. We may not be able to raise funds on favorable terms, if at all, and our discussions with potential collaborative partners may not result in any agreements. If adequate funds are not available, we may have to delay, scale back or eliminate one or more of our development programs or obtain funds through arrangements with collaborative partners or others where we may have to relinquish rights to certain technologies, product candidates or products that we would not otherwise relinquish. To raise funds, we may also have to sell shares of our common stock at prices below the price at which you may have purchased shares. Such sales would also cause a dilution of your percent ownership of SangStat.

Our future growth depends on sales of key products.

We expect to derive most of our future revenues from sales of Thymoglobulin, Lymphoglobuline, and Gengraf. We have limited experience selling our products in the 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 transplant 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 and Roche.

With respect to Gengraf and our generic capsules, the following factors may 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;
- our recall of SangCya Oral Solution in July 2000 from the U.S. despite continued marketing in the U.K. and Germany;
- pricing pressure from other generic competitors;
- intense competitive pressure from Novartis; and
- Novartis's litigation with Abbott.

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

Our manufacturing facility in Lyon must meet FDA standards of Good Manufacturing Practices and other regulatory guidelines. The FDA and other regulatory authorities inspect our manufacturing facility to ensure that it meets regulatory standards. We expect the FDA to inspect our Lyon facility again in October 2001 as part of its regular inspection process. If the FDA believes that we are not complying with its guidelines, it can issue a warning letter or prevent the import of Thymoglobulin into the U.S., which would reduce our revenues. In addition, Thymoglobulin and Lymphoglobuline are biological products, which are more difficult to manufacture than chemical compounds. We acquired the IMTIX division of Aventis in 1998, including certain manufacturing capabilities with respect to Thymoglobulin and Lymphoglobuline. Before the acquisition, certain batches of Thymoglobulin did not meet manufacturing specifications, resulting in a shortage of Thymoglobulin for commercial sale. We still rely on Aventis for certain important manufacturing services, including quality assurance, quality control, and lyophilization, a step in the manufacturing process which involves removing the water from the product, similar to freeze-drying. Aventis may not continue to effectively and continuously provide us these critical manufacturing services. In addition, we may 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 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 nine suppliers of rabbit serum used for the manufacturing of Thymoglobulin, but recently had a dispute with two of these suppliers. IFFA CREDO and Elevage Scientifique des Dombes, two affiliated suppliers, sued our French subsidiary, IMTIX-SangStat SAS, 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, IMTIX-SangStat recorded a charge to other expense - net of $3.3 million in the six months ended June 30, 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.

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 regulatory requirements administered by the FDA and other regulatory bodies. Failure to comply with applicable regulatory requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval, withdrawal of approvals and criminal prosecution of SangStat and our employees.

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

Except for Thymoglobulin and Lymphoglobuline, third parties manufacture all of our products and product candidates. We rely on Abbott and Gensia Sicor for the manufacture of Gengraf and SangCya Oral Solution. Fresenius Kabi France manufactures Celsior for us. There are three main risks associated with using third parties for manufacturing:

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

In addition, we may not be able to enter into commercial scale manufacturing contracts on a timely or commercially reasonable basis, or at all, for our product candidates. Abgenix, from whom we have licensed ABX-CBL, has entered into and is responsible for maintaining the manufacturing agreement 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 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, any of which would impair our competitive position either because of the delays or because of a loss of revenues. 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.

Significant movements in the 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 French franc and 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.

Two wholesalers account for a high percentage of our revenue 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, McKesson HBOC and Cardinal Health Inc. Approximately 15% and 13%, respectively, of total revenues in 2000 were derived from sales to customers who place orders through these wholesalers. We expect that we will continue to derive a substantial portion of our revenue from McKesson HBOC and Cardinal Health for the foreseeable future. Difficulties in collecting from these wholesalers could harm our financial results. No other customer accounts for more than 10% of revenues.

A change in marketing strategy and a delay in product approval have created excess 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. In addition, since our CycloTech product is only intended for use with the SangCya Oral Solution, we have discontinued the distribution of CycloTech in the U.S. Although we plan to obtain marketing approval for a cyclosporine capsule product in Europe, the inherent uncertainty of the approval process makes it very difficult to forecast a launch date for this product. We currently expect approval of a cyclosporine capsule product in the U.K. in 2002. If the approval and product launch are delayed or if we are unable to obtain approval, we may not be able to convert all the inventory into finished product and sell it before its expiration date. As a result, we could write off portions of our bulk active ingredient in the future, which could significantly reduce the gross margin reported for that future period.

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

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

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

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

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

We recalled all lots of SangCya Oral Solution from the U.S. wholesalers in July 2000 and at the same time announced its withdrawal from the U.S. market. In addition to the loss of anticipated SangCya Oral Solution revenues, the FDA

may conduct an investigation into the circumstances that led to the SangCya Oral Solution recall. Responding to an FDA investigation could be costly, time consuming, and may distract senior management from other tasks. Negative marketing may reduce sales of Gengraf or Thymoglobulin as competitors attempt to use the recall in marketing against our products and us. The FDA or other regulatory authorities may review our future drug approval applications more carefully, which may result in slower approval times. Delayed approvals would lead to a delay in revenues from these products.

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

We face an inherent business risk of exposure to product liability claims in the event that the use of our products results in adverse effects during research, clinical development or commercial use. Our product liability insurance coverage is currently limited to $25 million, which may not be adequate to cover potential liability exposures. In addition, adequate insurance coverage may not be available in the future at an acceptable cost, if at all, and a product liability claim could harm our results of operations.

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 results of operations.

Failure to convert The Transplant Pharmacy's accounts receivable and inventory to cash may result in a loss recognition.

We closed the sale of The Transplant Pharmacy, our mail order pharmacy business, on April 20, 2001. As of June 30, 2001, we had approximately $1.5 million in accounts receivable, net of reserves and $103,000 in inventory that we expect to convert to cash. If we are unable to return all of the inventory or if we have difficulties collecting accounts receivable, we may have to recognize a loss.

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

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

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

Novartis sued Abbott in August 2000 claiming that Gengraf infringes certain Novartis patents. The trial is scheduled for October 1, 2001. Novartis' 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. 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 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 would 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.

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

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

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

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

| Our Products | Competitive Products | Competitor |
|---|---|---|
| Thymoglobulin/Lymphoglobuline | Orthoclone OKT® 3 | Ortho Biotech |
| | ATGAM® | Pharmacia & Upjohn Inc. |
| | Simulect® | Novartis AG |
| | Zenapax® | F. Hoffmann La-Roche Ltd. |
| Gengraf, SangCya Oral Solution, & cyclosporine capsules | Neoral | Novartis AG |
| | Sandimmune | Novartis AG |
| | Prograf® | 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 |

We depend on collaborative relationships and any failure by our strategic partners to perform 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. 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 as well as the stock prices for competitors in our industry has historically been volatile.

The market prices for securities of pharmaceutical and biotechnology companies, including ours, are highly volatile. For example, during 2000, the price of our common stock ranged from $6.50 to $48.00 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;
· developments in patent or other proprietary rights;
· public concern as to the safety of drugs developed by us or others;
· comments made by securities analysts; and
· general market conditions.

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

Our ability to successfully commercialize our products may depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. The pricing, availability of distribution channels and reimbursement status of newly approved healthcare products is highly uncertain. 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, an increasing emphasis on managed care in the U.S. has 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 results of operations. 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. In addition, third-party payers are increasingly challenging the prices charged for medical products and services. 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 research and development activities and operations, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. As a result, we may incur significant costs to comply with environmental and health and safety regulations. Our research and development involves the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and infectious biological specimens. Although we believe that our safety procedures for handling and disposing of such

materials comply with the standards prescribed by state and federal regulations, 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, 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, will 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.

## FORWARD LOOKING STATEMENTS

This prospectus contains or incorporates 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:

- potential outcomes of our and Abbott's litigation with Novartis;
- our plans for marketing a cyclosporine capsule in Europe;
- the anticipated conversion into cash of inventory and accounts receivable following the sale of our division known as The Transplant Pharmacy;
- anticipated expenditures and timing related to FDA and foreign approval of our products;

· potential results of clinical trials; 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 are made as of the date hereof. 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 will not receive any proceeds from the sale of the shares by the selling stockholders. The selling stockholders will receive all of the proceeds of the sale of the shares. However, we will pay all reasonable costs and expenses incurred by us or the selling stockholders in connection with the registration of the shares under the Securities Act.

## SELLING STOCKHOLDERS

This prospectus relates to the sale by the selling stockholders from time to time of up to 1,363,635 shares of our common stock. However, the selling stockholders are not obligated to, and may not sell any of the shares.

The table below sets forth certain information regarding the selling stockholders as of July 31, 2001. None of the selling stockholders has held any position or office with, been employed by, or otherwise had a material relationship with SangStat or any of its predecessors or affiliates.

The table below sets forth the names of the selling stockholders, the number of shares owned, directly and beneficially, by such stockholders, the number of shares being offered by the selling stockholders and the number of shares of our common stock the selling stockholders will hold after the offering, assuming the other shares are not sold from time to time.

| Selling Stockholder | Shares Held Prior to the Offering | Percent Held prior to the Offering (1) | Shares Being Offered | Shares Remaining | Percent Held after the Offering (1) |
|---|---|---|---|---|---|
| Narragansett I, LP | 170,000 | * | 170,000 | — | — |
| Narragansett Offshore, Ltd. | 330,000 | 1.6% | 330,000 | — | — |
| Royal Bank of Canada | 330,000 | 1.6% | 330,000 | — | — |
| S.A.C. Capital Associates, LLC | 660,500 | 3.2% | 450,000 | 210,500 | 1.0% |
| Société Générale | 83,635 | * | 83,635 | — | — |
| Total: | 1,574,135 | 7.5% | 1,363,635 | 210,500 | 1.0% |

* Less than 1%.

(1) Percentages are based on 20,857,215 shares outstanding as of the July 31, 2001.

This prospectus also covers any additional shares of common stock that we may issue or be issuable by reason of any stock split, stock dividend or similar transaction involving the common stock, in order to prevent dilution.

All the selling stockholders acquired the shares being sold in this offering from us on June 20, 2001 in a private placement exempt from registration under the Securities Act of 1933 pursuant to Regulation D and/or Section 4(2) of the Securities Act. Shares not being offered by Royal Bank of Canada were acquired from us on December 29, 2000 and shares not being offered by S.A.C. Capital Associates, LLC were acquired from us on January 5, 2001 pursuant to a private placement exempt from registration under the Securities Act of 1933 pursuant to Regulation D and/or Section 4(2) of the Securities Act. We have filed a registration statement (No. 333-53720) on Form S-3 covering the resale of these shares.

## PLAN OF DISTRIBUTION

The shares may be sold or distributed from time to time by the selling stockholders. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale of the common stock covered here. The shares will be offered on the Nasdaq National Market System or in privately negotiated transactions. The selling stockholders may sell the shares registered here in one or more of the following methods:

- cross trades or block trades in which the broker or dealer so engaged will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker, dealer or underwriter as principal and resale by such broker, dealer or underwriter for its own account pursuant to this prospectus;
- "at the market" to or through market makers or into an existing market for the shares;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers, which may include long sales or short sales effected after the effective date of the registration statement of which this prospectus is a part;
- in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;
- through transactions in options, swaps or other derivatives (whether exchange-listed or otherwise); or
- any combination of the foregoing, or by any other legally available means.

The selling stockholders may also enter into option or other transactions with brokers or dealers that require the delivery by these brokers or dealers of the shares, which shares may be resold thereafter pursuant to this prospectus. In addition, a selling stockholder may pledge its shares to brokers or dealers or other financial institutions. Upon a default by a selling stockholder, the brokers, dealers or financial institutions may offer and sell the pledged shares.

In connection with the sale of shares, underwriters may receive compensation from the selling stockholders, and, if acting as agent for the purchaser of such shares, from such purchaser, in the form of discounts, concessions or commissions. Underwriters, dealers and agents that participate in the distribution of shares may be deemed to be underwriters and any discounts or commissions received by them from the selling stockholders and any profit on the resale of shares by them may be deemed to be underwriting discounts and commissions under the Securities Act. At such time that the selling stockholders elects to make an offer of shares, a prospectus supplement, if required, will be distributed that will identify any underwriters, dealers or agents and any discounts, commissions and other terms constituting compensation from such selling stockholders and any other required information.

Under agreements which may be entered into by the selling stockholders, underwriters who participate in the distribution of shares may be entitled to indemnification by the selling stockholders against certain liabilities, including liabilities under the Securities Act. We have also agreed to indemnify in certain circumstances the selling stockholders and certain control and other persons related to the foregoing person against certain liabilities, including liabilities under the Securities Act. The selling stockholders have agreed to indemnify us in certain circumstances, as well as certain related persons, against certain liabilities, including liabilities under the Securities Act.

Some of the underwriters or agents and their associates may be customers of, engage in transactions with and perform services for us in the ordinary course of business.

The selling stockholders are not obligated to, and there is no assurance that the selling stockholders will, sell any or all of the shares.

We will pay all reasonable costs and expenses incurred by us or the selling stockholders in connection with the registration of the shares under the Securities Act, including, all registration and filing fees and our legal fees and accounting fees and legal fees of one counsel selected by the selling stockholders.

We agreed with the selling stockholders to keep the registration statement effective until the shares being offered by this prospectus may be sold without registration or restriction pursuant to Rule 144(k) promulgated under the Securities Act, or, if earlier, until the distribution contemplated in this prospectus has been completed.

## VALIDITY OF SHARES

The validity of the shares has been passed upon by Carole L. Nuechterlein, our Senior Vice President and General Counsel.

## EXPERTS

The consolidated financial statements and the related consolidated financial statement schedule as of December 31, 2000 and 1999 and for each of the three years in the period ended December 31, 2000 incorporated in this prospectus by reference from our Annual Report on Form 10-K for year ended December 31, 2000 have been audited by Deloitte & Touche LLP, independent auditors, as stated in their report, which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. 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. We incorporate by reference the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended. The documents we incorporate by reference into this prospectus are:

a. Our Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended December 31, 2000;
b. Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2001 and June 30, 2001;
c. Our Current Reports on Form 8-K filed January 8, 2001, February 27, 2001, April 5, 2001, April 23, 2001, May 2, 2001, May 4, 2001, June 21, 2001, July 10, 2001, July 13, 2001, September 27, 2001 and October 9, 2001;
d. The description of our common stock contained in our registration statement on Form 8-B filed with the SEC on December 4, 1995; and
e. Our Registration Statement on Form 8-A filed with the SEC on August 25, 1995, and amended on October 9, 2001.

We will furnish to you without charge, upon your request a copy of any of the documents incorporated in this prospectus and any statement in, or incorporated in, this prospectus by reference, other than the exhibits to those documents unless those exhibits are specifically incorporated by reference. For a copy of the documents you should contact SangStat Medical Corporation, 6300 Dumbarton Circle, Fremont, CA 94555 (telephone number (510) 789-4300), Attention: Carole L. Nuechterlein, Senior Vice President and General Counsel.

## AVAILABLE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and accordingly we must file reports and other information with the Securities and Exchange Commission. All reports and other information, filed with the SEC are available to you over the Internet at the SEC's web site at http://www.sec.gov. You may read and copy any documents we file with the SEC at the SEC's Public Reference Room located at 450 Fifth Street, N.W., Washington, D.C., or at the SEC's regional offices in New York, New York and Chicago, Illinois. Please call the SEC at 1-800-SEC-0330 or visit the SEC's website for more information about the SEC's public reference facilities. You also may find information about us at our website, http://www.sangstat.com.

We have filed a registration statement on Form S-3 with the SEC under the Securities Act covering the shares offered here. This prospectus, which constitutes a part of the registration statement, does not contain all the information contained in the registration statement. Certain items are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. Statements made in this prospectus as to the content of any contract, agreement or other document are not necessarily complete. You may read the contracts, agreements and other documents attached to the registration statement for a more complete description of the agreements, contracts and other documents.

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