# SANGUI BIOTECH INTERNATIONAL INC

Form 10KSB September 28, 2001

> UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED June 30, 2001 FORM 10-KSB Annual REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 Sangui BioTech International, Inc. (Exact name of registrant as specified in its charter) Colorado \_\_\_\_\_\_ (State or other jurisdiction of incorporation) 84-1330732 0-29233 \_\_\_\_\_\_ \_\_\_\_\_ (Commission File Number) (IRS Employer Identification No.) 1508 Brookhollow Drive, Suite 354, Santa Ana, CA 92705 \_\_\_\_\_\_ (Address of principal executive offices) (Zip Code) (714) 429-7807 -----Registrant's telephone number, including area code: Securities to be registered under Section 12(b) of the Act: Name of each exchange on which Title of each class to be so registered each class is to be registered None N/A

Securities to be registered under Section 12(g) of the Act:

Common Stock, no par value

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(Title of class)

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

Yes [X] No [ ]

Check whether there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B in this Form, and will not be contained, to the best of Registrant's incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

Yes [ ] No [X]

The issuer's revenue for the fiscal year ended June 30, 2001 was \$567,007.

The market value of the voting stock held by non-affiliates of the issuer as of September 25, 2001 was approximately \$10,354,613.

The number of shares of the common stock outstanding as of September 25, 2001 was 40,514,363.

Documents incorporated by reference: None.

Part III of this Form 10 KSB is incorporated by reference to the Registrant's definitive proxy statement, which is expected to be filed within 120 days of the end of the Registrant's fiscal year ended June 30, 2001.

FORWARD LOOKING STATEMENT

This Annual Report contains forward-looking statements concerning, among other things, the Company's prospects affecting our potential and our business strategies.

These forward looking statements involve risks and uncertainties. Actual results may differ materially from those predicted by the forward-looking statements because of various factors and possible events, including those discussed under "Risk Factors". Because these forward looking statements involve risks and uncertainties, actual results may differ significantly from those predicted in these forward looking statements. These statements may be accompanied by words such as "believe," "estimate," "project," "expect," "anticipate," or "predict" that conveys the uncertainty of future events or outcomes. These statements are based on assumptions that the Company believes are reasonable; however, many factors could cause the Company's actual results in the future to differ materially from the forward-looking statements made herein and in any other documents or oral presentations made by, or on behalf of, the Company. Important factors which could cause actual results to differ materially from those in forward-looking statements include, among others, the

ability to obtain additional financing, which is not assured; rapid technological developments and changes; problems in developments of the Company's products; price and product competition by competitors; general economic conditions; and factors discussed in the Company's SEC filings.

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PART 1

ITEM 1. DESCRIPTION OF BUSINESS

HISTORY

Sangui BioTech, Inc. ("SBT") was incorporated in Delaware on August 2, 1996, and began operations in October 1996. In August 1997, Citadel acquired one hundred percent (100%) of the outstanding common shares of SBT, and as a result, SBT became a wholly-owned subsidiary of Citadel. Thereafter, Citadel Investment System Inc, a publicly held company, changed its name to Sangui BioTech International, Inc. Sangui BioTech International Inc. is referred in this report as the Company or SGBI. The Company's business operations are conducted through four subsidiaries: SBT, SanguiBioTech AG ("Sangui AG"), GlukoMediTech AG ("Gluko AG"), and Sangui Biotech Singapore Pte Ltd. ("Sangui Singapore").

SBT is principally engaged in the development and manufacturing of immunodiagnostic kits, which are sold by SBT in niche markets in the United States and Europe. SBT is located in Santa Ana, California. The California laboratory facility, approximately 3,360 square feet, is devoted to immunodiagnostic research, development, manufacturing, and marketing, as well as the Company's administrative functions.

Sangui AG was established and organized under the laws of Germany in Mainz, Germany, on November 25, 1995. Sangui AG is in the business of developing hemoglobin-based artificial oxygen carriers as blood volume substitutes and blood additive and products thereof. The officers of Sangui AG are Professor Wolfgang Barnikol, M.D., Ph.D., Sieglinde Borchert, Ph.D., Harald Poetzschke, M.D. and Detlev Freiherr von Linsingen, attorney. The members of Sangui AG's supervisory board are Professor Joachim Lutz, M.D., Dora Malek, attorney, Oswald Burkhard, M.D., Ph.D., Cornelius Grau, businessman, Professor Dietrich Gronemeyer, M.D. and Doris Barnikol, Ph.D.

Gluko AG was established and organized under the laws of Germany in Mainz, Germany, on July 15, 1996. Gluko AG is developing a long-term implantable glucose sensor, by-products thereof, and sensors. The officers of Gluko AG are Professor Wolfgang Barnikol, M.D., Ph.D., Sieglinde Borchert, Ph.D., Kai Zirk, engineer, and Detlev Freiherr von Linsingen, attorney-at-law. The members of Gluko AG's supervisory board are Professor Dietrich Gronemeyer, M.D., Dora Malek, attorney-at-law, Oswald Burkhard, M.D., Ph.D., Cornelius Grau, business man, Professor Joachim Lutz, M.D. and Doris Barnikol, Ph.D.

Since April 1998, the facilities of Sangui AG and Gluko AG, about 800 square meters, are located on the premises of the Forschungs- und Entwickungszentrum of the University of Witten/Herdecke, Witten, Germany.

Sangui Singapore was incorporated in Singapore on May 15, 1999. Sangui Singapore is the Asia regional office for the Company and is expected to be engaged in the business of carrying out research and development projects as well as animal experiments in conjunction with the German subsidiaries. The premises of the company, about 350 square meters, are located in the Science Park II, Gemini Building, Singapore.

On March 30, 2000, the Company acquired all the outstanding common stock of Felnam Investments, Inc. ("Felnam"). The transaction was funded through the issuance of 100,000 shares of the Company's stock valued at \$0 per share due to the Company treating the transaction as a recapitalization of the Company. In conjunction with the transaction, the Company incurred approximately \$ 180,000 of transaction costs which were charged to operations.

To date, neither SGBI nor any of its subsidiaries has had profitable operations. The Company has never been profitable and, through June 30, 2001, the Company's accumulated deficit exceeded \$11.6 million. The Company expects to continue to incur substantial and increasing losses over at least the next several years as it expands its research and development efforts, testing activities and

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manufacturing operations. All of the Company's potential products are in development except for the immunodiagnostic test kits. The Company will need to obtain substantial additional capital to fulfill its business plan.

BUSINESS OF THE COMPANY

The Company's mission is the development of novel proprietary products.

The special focus of Sangui AG is on developing oxygen carriers capable of human organ support in cases of acute and chronic lack of oxygen or blood loss due to surgery, accident, arterial occlusion, anemia or other causes. The Company seeks to develop and commercialize such artificial oxygen carriers with blood volume substitute/blood additive technologies by reproducibly synthesizing polymers of defined molecular sizes. The Company also develops oxygen carriers for external application in the medical and cosmetic fields in the form of jellies and emulsions for the regeneration of the skin.

The second important project pertains to Gluko AG's long term implantable glucose sensor for day and night monitoring of a patient's glucose level. The project is designed to obviate the need for persistent blood sampling and to provide required information on a continuous basis, which could minimize the harmful effects of peaks and troughs in the patient's blood sugar level.

SBT has completed the development of nine in vitro diagnostics kits. Five products have been cleared for marketing by the United States Food and Drug Administration ("FDA"). The other four kits were sold overseas with Certificate of Exportability from the FDA. In December, 2000, the Company's only competitor in the CDT business, Axis/Shields, a Norwegian Company purchased by Shields Diagnostics of United Kingdoms, filed a lawsuit against the Company for alleged infringement on a U.S. patent held by Axis Biochemical ASA. The Company has reached a settlement with Axis/Shields and agreed to discontinue the sales of the Company's CDT product, trade-marked ChronAlco ID CDT test kit. Sales related to this test kit totalled \$312,000 and \$279,000 for the years ended June 30, 2001 and 2000, respectively. The Company has since re-designed its CDT product, called ChronAlco ID II CDT test kit, to resolve the patent conflict. The Company has since sold the new version of CDT kit, i.e. ChronAlco ID II CDT test kit, to its distributors and customers. There is no significant loss or gain of the Company's CDT business.

# ARTIFICIAL OXYGEN CARRIER

There are several products in development that are polymers of natural hemoglobins with oxygen carrying abilities similar to native hemoglobin:

The Company seeks to develop and commercialize proprietary artificial blood volume substitute/artificial oxygen carrier technologies by synthesizing reproducible polymers of defined molecular sizes. The experiments completed in the Company's laboratories demonstrated that it is possible to polymerize hemoglobins isolated from pigs resulting in huge soluble molecules, the so-called hyperpolymers. In August 2000 the Company finalized its work on the pharmaceutical formulation of the oxygen carrier for laboratory scale. In February 2001 a pilot production in a laboratory scale has been carried out in the Company's clean room. At present the Company is working on the upscale process.

Blood Volume Substitute

The need for blood volume substitutes is growing because of: (i) reduced willingness of the population to give blood; and (ii) contamination of donors with HIV and hepatitis viruses. The worldwide market for stored blood is estimated to total about US \$ 5 billion per year.

Invasive surgery, resulting from such causes as transplantation or accidents, can result in substantial loss of blood. In such circumstances, blood volume has to be substituted to avoid shock. Blood substitution must be done with an isoncotic solution that has the same colloid-osmotic pressure as blood

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plasma. Such blood volume substitutes are called "plasma expanders". These expanders use macromolecules like polysaccharides or gelatin to generate the oncotic pressure.

Blood additive

In cases where the native blood oxygen carrier system does not deliver enough oxygen to tissues of the heart, brain, extremities, kidneys and other organs or to cancer tumors, a critical clinical situation arises requiring another oxygen carrier strategy. In these cases, the patients do not have a blood volume deficiency, but suffer from an oxygen deficiency. To compensate for this oxygen deficiency, an artificial oxygen carrier must be introduced into the circulatory system and this additive must have no influence on the oncotic pressure, i.e., it must have a negligible oncotic pressure as compared to normal, which is about 30hPa. Sangui AG has polymerized various hyperpolymers in small quantities, as described above with characteristics such as sufficiently low viscosity and a negligible oncotic pressure at the desired concentration and desired hematocrit concentration.

Small animal exchange experiments with artificial oxygen carriers carried out by the Company have demonstrated that these carriers are very effective in oxygen transport already in small concentrations within the blood plasma and that they show a synergistic effect with native transport systems. Also it was possible to synthesize hyperpolymeric oxygen carriers which exhibit almost no immunogenicity in mice sensitized to hemoglobin. Experiments conducted in alert rats with a magnetometric method appear to demonstrate that the hyperpolymer hemoglobins irritate the reticulo-endothelial system of the liver far less than emulsions of fluorocarbon or encapsulated hemoglobins solutions.

The management of Sangui AG believes that the additive feature of the oxygen carrier under development, could potentially address a market possibly equal to or larger than that of blood volume substitutes. It has been reported that the oxygenation of solid tumors makes them more sensitive to radio and

chemo therapy. Management believes that its blood additive technologies, for which there are no known competitive products, could be very attractive in the medical field. Therefore, the development of an artificial oxygen carrier has become the primary focus of the management of SGBI. However, such a market projection for plasma expanders and additives, as therapeutics for oxygen deficiency disorders, cannot be ascertained, since such products are not available in the marketplace.

If oxygen carriers can be used successfully in the cancer field, this could be expected to speed the approval process for the use of blood volume substitutes based on similar technologies. However, there can be no assurances that these applications will be approved by the various government regulatory agencies, including but not limited to the FDA in the United States and the similar agencies in Germany and other Western European countries.

It should be noted that this specialized or niche application, if successfully developed, would have a market potential substantially smaller than the overall market of artificial blood volume substitute or the therapeutic market (with oxygen carrier as an additive or therapeutic agent) for more widespread oxygen deficiency disorders such as myocardial infarction and stroke.

Sangui AG has received a grant from the government of the German state of Northrhine-Westphalia in an amount of more than US \$2,000,000 which covers 40% of the estimated costs of the research and pre-clinical development of the Company's polymer hemoglobin based artificial oxygen carrier. Sangui AG has received installments of approximately 1,880,000 German Marks (approximately US\$818,000) from the grant to reimburse 40% of its research and development expenses and related capital expenditures in the period from April 1998 through June 2001.

Oxygen carriers for regeneration of the skin
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The healthy skin is supplied with oxygen, both through the supply from inside and also through diffusion from outside, in which connection with the proportion of the supply of the exterior cell layers of the upper skin, the so-called Stratum germinativum, located directly beneath the Stratum corneum, is normally around 50 percent. Lack of oxygen of the skin will cause degenerative alterations of various extent, ranging from surface damage to open wounds. The cause for the lack of oxygen may be the normal aging process, but also burns or radiation. Impairment of the blood flow, for example caused by diabetes mellitus, can also lead to insufficient oxygen supply and resulting skin damage.

The new preparations under development by Sangui AG have been designed to contribute to supporting the regeneration of the skin in the case of lack of oxygen. In addition to the therapy, these preparations are also intended for purposes of prevention, among others for the improved oxygen supply of the skin in the course of a radiation therapy, or in the case of an acne treatment.

The basic idea of the mode of effectiveness consists of the mechanism of the facilitated oxygen diffusion. The oxygen carriers are intended to increase the diffuse flow of oxygen from outside, when having been worked into the exterior cell layers.

GLUCOSE SENSOR AND TECHNICAL BETA-CELL

Over 5% of the inhabitants of the industrialized countries suffer from diabetes. About one tenth of these patients are afflicted with diabetes mellitus. Type 1, which means they are dependent for life on the parenteral  $\frac{1}{2}$ 

application of insulin. In addition, about 10 % of the Type II diabetics also get insulin dependent during the course of their illness.

Diabetes Type I patients suffer from the irreversible destruction of the so called beta cells of the pancreas (absolute insulin deficiency); the beta cells normally produce the hormone, insulin.

Diabetes Type II patients suffer from a relative insulin deficiency; the insulin receptors are insensitive to the hormone.

The central problem of the diabetic is to properly and constantly measure the blood glucose level, ideally 24 hours a day, and thereby to know how to adjust, quantitatively, the glucose level in the tissues by administering insulin, for example, in order to stabilize the blood sugar level at its normal value of 1 g/L. Only a rough adjustment may be achieved during waking hours when the patient is able to sample a drop of blood from the fingertips periodically, and to determine the level of glucose with the aid of dipsticks.

Nevertheless, the permanent sampling of blood and the need to inject insulin deteriorate the quality of life. An enormous danger for the diabetic patient arises when he is asleep, i.e. one third of his life time, when he is neither able to sample the glucose level in his blood system, nor to adjust it, if necessary.

Furthermore, as shown by measurements using a short time (only 3 days) glucose monitoring system based on the enzymatic detection of glucose, (even in patients who seem to be well adjusted) dramatic changes of the blood sugar occur during night and day.

Infectious diseases and vegetative disorders are also reasons for uncontrollable disturbances and variations of the glucose level, even during waking hours. Those are very dangerous for the patient as it is explained below:

A glucose level which remains too low over long periods of time results in damage to organs with high metabolism, such as the brain. Brain cells which die cannot be replaced. If a glucose level remains too high, the typical long term sequelae of Type I diabetes occur, such as peripheral circulatory deficiencies resulting in the need for amputation of extremities and detachment of the retina resulting in blindness.

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Accordingly, it should be of substantial advantage to be able to constantly and automatically monitor the blood sugar level of the patient. To do so, the glucose monitor must stay at or in the patient for a long period of time making the procedure cost effective and efficacious. Problems ofinfection, comfort, and the risk of detachment should all favor a permanently implantable sensor.

The device being developed by the Company communicates via radio signals with a control panel/modem outside the body and supplies the patient with the necessary information. In combination with a dosage pump for insulin (internal or external) an artificial beta-cell for insulin dependent diabetics could be realized. Until now, an implantable glucose sensor has been the missing link in the development of a beta cell for the automatic dispensation of insulin.

German insurance companies have estimated the possible savings for a patient with Type I diabetes to range from between approximately \$6,000 to \$8,000 per annum. Based on a unit price of about \$7,000, the market potential

for the developed countries could amount to several billion dollars per year.

The following experimental results were obtained in furtherance of the Company's objective of developing an implantable glucose sensor on the basis of physical measurement systems:

- \* polarimetric, infrared and refraktometric measurements of glucose concentrations in the physiological range resulted in electronic signals, sufficiently high for further processing
- $^{\star}$   $\,$  glucose is responsible for at least 95% of the optical rotation of ultrafiltered blood plasma
- $^{\star}$   $\,$  the  $\,$  concentration of glucose in ultrafiltrated tissue fluid equals that of blood
- $^{\star}$  the level of glucose in an implanted ultrafiltrating hollow fiber did not drift, in the sense of decreasing, over a period of three weeks
- $^{\star}$   $\,$  the adjusting time of the glucose level in the hollow fiber is about ten minutes and is also stable over a period of three weeks

Gluko AG presented a first model of a long-term implantable glucose sensor at the Duesseldorf MEDICA Show in November 1998. The Company demonstrated an improved model comprised of a miniaturized optical system (which includes a light source, diodes, light detectors and an integrated sensor electronics which has not been finally miniaturized yet) at the Duesseldorf MEDICA Show in November 1999. In August 2000, the Company stated a further development of its concept for the long term implantable glucose sensor which offers the Company an additional possibility to also develop an "insertable" sensor for the initial clinical adjustment of diabetics. In contrast to an implanted sensor this is completely under the skin and has no connection at all through the skin to the outside, an inserted sensor is "pierced" through the skin. In contrast to the implantable sensor, the functional capacity does not depend on a complete miniaturizing of the electronic system. Gluko's engineers have advanced the construction of the sensor in such a way that in future all moveable mechanic parts can be completely dispensed. Since the final mechanically moveable sensor component a micro pump with a relatively high energy demand - has been omitted, the sensor might become safer in operation. The change might have a positive effect on the sensor's energy supply.

In September 1999, Gluko AG received a grant from the German state of Northrhine-Westphalia in the amount of approximately \$2,000,000 for the long term implantable glucose sensor. The grant will cover 40% of the budget project cost from December 1998 to November 2001. Gluko AG has already received installments of approximately 800,000 German Marks (approximately \$365,000) from the grant to reimburse 40% of its relevant expenses in the period from December 1998 through June 2001. The grant requires the Company's economic ability to cover 60% of the project costs on its own. An additional condition of the grant is that if the product is developed before 2003, it must be produced in the German state of Northrhine-Westphalia.

#### BY PRODUCTS

The knowledge gained during developing the glucose sensor, has resulted in the development of two by-products based on the measuring systems of the glucose sensor:

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 $^{\star}$  a high precision analytical micro system for monitoring and controlling of (bio)chemical processes in biotechnology, chemistry and Pharma industry and  $^{\star}$  a polarimeter/spectrometer designed for laboratory work

During his work at the University in Mainz, Germany, one area of Professor Barnikol's research focused on respiration processes. From this research work Gluko AG's projects in the field of anesthesia, intensive care and sleep diagnostics are derived. The product line comprises monitoring devices as:

- \* a sensor tube
- \* a sensor connector for new borns
- \* a nose sensor
- \* a main stream respiratory oxygen sensor

Further by products of the Gluko AG are:

- \* an oxygen sensor device for the skin (skin-oxy-meter)
- \* an equipment for small animal (rats and also mice) experiments
- \* a respiratory microvalve
- \* a micro respiratory flow sensor

#### IMMUNODIAGNOSTIC TEST KITS

The Company has developed a number of immunodiagnostic products including the niche Carbohydrate-Deficient Transferrin (CDT) test kit. The Company plans to attempt to increase the sales of its products by (1) introducing its products to additional distributors covering geographic markets, which the Company currently has no coverage, and (2) offering the products to established distributors and larger companies who have established distribution and worldwide marketing network at significant discounts.

SBT has completed the research and development of certain health care products which are intended to be produced, promoted, marketed, and used world-wide. SBT's products consist of: (i) a CDT- test kit, which is used to detect chronic alcohol abuse; (ii) a urinary micro-albumin test, which is a diagnostic test to detect small amounts of proteinuria in diabetes mellitus; (iii) two different kits for the measurement of Parathyroid Hormone, which is a diagnostics adjunct to the differential diagnosis of hyper- and hypo-parathyroidism.; (iv) ACTH (Adrenocorticotropic Hormone), a niche endocrine test for adrenal cortex function; (v) Calcitonin, another endocrine test for a rare disease; (vi)Erythropoietin (EPO), a test for certain types of anemia; and (vii) TSH (Thyroid Stimulating Hormone or Thyrotropin), a common and popular thyroid function test, but faced with over forty (40) competitors' products on the same test.

All the products are based on the microplate format, except for the Parathyroid Hormone (PTH) IRMA and TSH IRMA. This microplate or microtiter platform was chosen, because microplate readers are quite common in the clinical and hospital medical laboratory setting. All the test kits, except TSH, are targeted at the niche laboratory market. Nonetheless, due to the aging or maturation of the in vitro diagnostics industry, unprecedented fierce competition coupled with healthcare cost containment has resulted in the appearance of the previous niche tests on the menu of proprietary instrumentation made by billion dollar well-capitalized companies owned by the world-class pharmaceutical companies. At present, the only product, which truly can be considered "niche" is the CDT.

\* CDT (Carbohydrate Deficient Transferrin). Has been reported as the most reliable test for identification of chronic alcohol abuse. The worldwide market potential is estimated at between US \$1.5 million to US \$2 million per annum. The market potential has been reduced, due to the discontinuation of reimbursement in Germany. This test uses microplate format Turbidimetric Immunoassay with

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prepackaged chromatography columns. The SBT CDT test kit, trademarked as ChronAlco I.D. in Germany, has been found to be superior to the product made by the only other manufacturer (competitor) by two leading German scientists. However, the Company's only CDT competitor, Axis/Shields has changed its product such that the Axis/Shields new product is quite similar to the Company's. The Company has no patent or patent application for its CDT assay. About 55% of the product sales realized by the Company were derived from this product for the fiscal year ended June 30, 2001.

- \* Intact-PTH on the ELISA Microplate format (2nd Generation). This product has been cleared under the 510(k) regulations by the FDA in late December 1997. It has one distinct advantage over the two other ELISA microplate PTH kits on the market. It is faster and easier, with performance characteristics similar or superior to the competitors. Nonetheless, the sales increase has been gradual. The management believes that the lack of significant sales is mostly likely due to the current market trend of complete turn-key (hands off or complete) automation in the laboratory business, dominated by divisions of large pharmaceutical companies.
- \* Intact-PTH IRMA (ImmunoRadioMetricAssay). The radioactive version will compete mainly based on price. The worldwide market potential for all the PTH kits, with over 12 competitors, is estimated at US \$ 50 million per annum, dominated by large companies with proprietary fully automated instrumentation.
- \* Microalbumin quantitative test via TIA. Highly sensitive determination of small quantities of albumin in urine. Early detection of microalbuminuria can prevent subsequent irreversible renal impairment in patients with Diabetics Mellitus. The worldwide market potential is estimated at US\$5 million per annum. However, the Company has derived negligible sales for the last three years (since the completion of product development on this product) due to market dominance of large companies, such as Roche/ Boehringer Mannheim and Beckman Instruments, Inc.
- $^{\star}$  ACTH (Adrenocorticotropic Hormone) ELISA. This product is the only 2nd Generation ELISA Kit in the market. This test is intended for the assessment of adrenal cortex function such as Addison Disease and the differential diagnosis of Cushing Syndrome. The estimated market potential size is US \$ 5 million per annum.
- $^{\star}$  Calcitonin ELISA. This product is the only ELISA in the market. This is another calcium metabolism test. The test volume has been increasing in Europe and the US. The estimated market potential size is US \$ 1 million per annum.
- \* Erythropoietin (EPO) ELISA. Quantitation of serum erythropoietin concentration serves as a diagnostic adjunct in determining the cause of anemia or erythrocytosis (an increase of red blood cell mass). Also, Amgen, Inc. manufacturers the drug Erythropoietin, trade-name Epogen. Hence, it is believed that there is a small market for drug monitoring as well. However, there are several competitors including at least one competitor with fully automated system.
- \* TSH IRMA. TSH (Thyrotropin) is a very useful, if not the most important, screening test for thyroid function assessment. However, there are at least forty kits in the market-place, so this product is not a niche product. The Company's kit is based on the ImmunoRadioMetricAssay and was originally developed specifically for sale to a small German distributor, who had overestimated its ability to sell significant quantities in Germany.

The majority of the sales and repeat orders are from Germany and the United States.

To date, the Company's efforts to sell its products to emerging markets such as the mainland China, Hong Kong and Taiwan have been unsuccessful and the sales to date have been very limited. At present, the Company intends to comply with the regulations published by the Notified Bodies of the CE (European Community) for in vitro diagnostic kits. The Company plans to implement the requirements in compliance with the CE Mark regulations before the deadline in 2003.

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DEVELOPMENT PROCESS

#### ARTIFICIAL OXYGEN CARRIER

In December 1997 the Company decided that porcine hemoglobin should be used as basic material for its artificial oxygen carriers. In March 1999 the Company came to the fundamental decision as to which hemoglobin hyperpolymer will go into preclinical investigation and that glutaraldehyde will be taken as cross linker and pyridoxalphosphate as effector. The fine adjustment of the formula of the artificial oxygen carriers — optimized for laboratory scale — was finalized in Summer 2000. This fine adjustment comprises different conditions like concentrations of glutaraldehyde and pyridoxalphoshate, incubation times, and temperature.

In laboratory scale the manufacturing is set out as follows: First, pure porcine blood must be obtained from slaughterhouses. The blood must not be contaminated with endotoxins released by bacteria or other contaminating material. Therefore, it must be guaranteed that the pigs, of which the blood is taken, were neither ill nor had received medicine. The state of health of the pigs has to be contractually fixed with the pig breeders. In order to determine and prove the purity of the source material as well as that of intermediate and final products, an analytic department has been set up.

After release of the hemoglobin molecules from erythrocytes, about fifteen molecules are cross-linked to a hyperpolymer molecule by a chemical reaction using glutaraldehyde as a cross-linker. This hemoglobin hyperpolymer is the artificial oxygen carrier. An advantage of the hyperpolymer structure is that it prevents the oxygen carrier from secreting via the kidneys which would have harmful effects on the patients.

Pyridoxalphosphate is used as an effector by which the oxygen binding properties of the hemoglobin hyperpolymer molecules, for instance the functional oxygen transport capacity, are adjusted properly. During all preparation steps defined conditions have to be chosen and maintained carefully (e.g. temperature, pH of the solutions). After preparation of the oxygen carrying hyperpolymers, they are separated into a high molecular fraction and a low molecular fraction to obtain the blood additive and the blood volume substitute, respectively.

At this point in time, the Company is developing the upscaling process for preparation of a large amount of oxygen carrier for preclinical and clinical trials. According to regulatory requirements, all drugs have to pass through preclinical and clinical trials before approval (e.g. FDA approval: Federal drug administration) and launching to the market. In preclinical trials, experiments using animal models and tissue culture models have to be carried out to evaluate the efficacy and safety of the developed drug. Phase I of the clinical trials, so called "human pharmacology" comprises the application of the drug in healthy volunteers. Phase II is called "therapeutic explanatory" and comprises trials with a small number of ill patients. Phase III is called "therapeutic confirmation" and comprises trials with a larger number of ill patients.

Management of the Company believes that the European and FDA approval process will take at least several years.

IMPLANTABLE GLUCOSE-SENSOR AND TECHNICAL BETA-CELL

The glucose sensor under development by Gluko AG is based on physical methods for the determination of the diabetic's glucose level. Three physical measurement systems have been developed for the glucose detection system: a polarimetric, an infrared system, and a refractometric system. These systems have to be proved to be specific for in vitro determination of glucose levels in the physiological range of 50 to 500 milligram glucose per decilitre. At present, it is not settled which one of the systems will be used in the first generation of the sensor. Gluko AG endeavors to install

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two independent measuring systems in its sensor to increase the specificity and accuracy of the glucose determination.

The sensor will be implanted into the subcutaneous fat tissue in the stomach area near the belly button. The Company endeavors to develop a glucose sensor that might be implanted for a period of three to five years. To protect the detection system inside the measuring chamber from large compounds of the interstitial fluid, especially from proteins, and to increase the specificity of the system, an exchange membrane will be part of the sensor.

During the day, it is planned to send the measuring signal telemetrically to a glucose watch which the diabetic patient will carry at his wrist. During the night, the telemetric signal will be sent to a receiver which will monitor the glucose level and warn the patient of hypoglycemia and hyperglycemia acoustically.

The latest further development in the sensor construction provides the additional possibility of developing also an "insertable" sensor for the initial clinical adjustment of diabetics. In contrast to an implanted sensor that is completely under the skin and has no connection at all through the skin to the outside, an inserted sensor is so to speak "pierced" through the skin and it has a connection to the outside. The insertable sensor of the Company is being designed to allow a continuous glucose determination over several days and to exhibit the same measuring principles and almost the identical design as the implantable sensor. In contrast to the implantable sensor, the functional capacity does not depend on a complete miniaturizing of the electronic system. The analyzing unit will be outside of the human body and connected by cable with the insertable sensor.

The construction of the glucose sensor has been changed so that all moveable mechanical parts can be completely dispensed in an effort to increase the safety of the sensor and to have a positive effect on the sensors' energy supply.

According to regulatory requirements, all medical devices have to pass through clinical trials before approval (e.g. FDA approval; Federal drug administration) and launching to the market. Unlike the Company's oxygen carriers that are classified under pharmaceutical products, glucose sensors are classified as medical devices and have a different approval process. The clinical trials for the glucose sensor do not have different phases and entails doing studies immediately with diabetic patients.

Management of the Company believes that European and FDA approval process will take at least several years for the implantable glucose sensor.

#### PATENTS AND PROPRIETARY RIGHTS

The Company has the policy of seeking patents covering its research and development and all modifications and improvements thereto. The German subsidiaries Sangui AG and Gluko AG have been granted 15 patents belonging to 14 patent families. Furthermore, the subsidiaries have applied for 37 patents belonging to 23 patent families.

# MARKETING AND DISTRIBUTION

Other than the immunodiagnostic products, the Company has not yet manufactured its products in commercial quantities.

SBT markets its immunodiagnostic products through a distributor in a particular country. The products are targeted at the smaller laboratories in Western Europe and the United States, who may have insufficient test volume to justify the installation of "turn-key" fully automated proprietary

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instrumentation by the large competitors. It also includes end users like independent clinical, hospital or physician operated laboratories.

The Company sells its CDT kits mainly through one German distributor, selling directly to one customer in the US, and one distributor covering Switzerland and Austria. In December, 2000, the Company's only competitor in the CDT business, Axis/Shields, a Norwegian Company purchased by Shields Diagnostics of United Kingdoms, filed a lawsuit against the Company for alleged infringement on a U.S. patent held by Axis Biochemical ASA. The Company has reached a settlement with Axis/Shields and agreed to discontinue the sales of the Company's CDT product, trade-marked ChronAlco ID CDT test kit. The Company has since re-designed its CDT product, called ChronAlco ID II CDT test kit, to resolve the patent conflict. The Company has since sold the new version of CDT kit, i.e. ChronAlco ID II CDT test kit, to its distributors and customers. There is no significant loss or gain of the Company's CDT business.

The Company has limited experience in sales and marketing of products. In general, the distributor is required to commit to a minimum sales volume in order to maintain an exclusive position in a given territory. It is not uncommon to provide a 30 to 50 % discount or even more from the product transfer price. The distributor typically uses the margin to pay for the shipping costs, its overhead, sales staff and keep the balance as profit. To date, the Company's has made exclusive distribution agreements in the certain sales territories, i.e. Austria, Italy and Turkey.

Two customers accounted for approximately 54% of sales for the year ended June 30, 2001. Four customers accounted to approximately 70% of sales for the year ended June 30, 2000.

To raise its profile, the Company regularly participates in various medical and health related product exhibitions and trade fairs, for instance the latest Medica 2000 held in Duesseldorf.

#### GOVERNMENT REGULATION

SGBI and its subsidiaries are, and will continue to be, subject to governmental regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, and other similar laws of general application, as to all of which SGBI believes it and its

subsidiaries are in material compliance.

Because of the nature of the operations of SGBI and its subsidiaries and the use of hazardous substances and their ongoing research and development and manufacturing activities, SGBI and its subsidiaries are subject to stringent federal, state and local laws, rules, regulations and policies governing the use, generation, manufacturing, storage, air emission, effluent discharge, handling and disposal of certain materials and wastes. Although it is believed that SGBI and its subsidiaries are in material compliance with all applicable governmental and environmental laws, rules, regulations and policies, there can be no assurance that the business, financial conditions, and results of operations of SGBI and its subsidiaries will not be materially adversely affected by current or future environmental laws, rules, regulations and policies, or by liability occurring because of any past or future releases or discharges of materials that could be hazardous.

Additionally, the clinical testing, manufacture, promotion and sale of a significant majority of the products and technologies of the subsidiaries, and to a much less extent to SGBI, if those products and technologies are to be offered and sold in the United States, are subject to extensive regulation by numerous governmental authorities in the United States, principally the FDA, and corresponding state regulatory agencies. Additionally, to the extent those products and technologies are to be offered and sold in markets other than the United States, the clinical testing, manufacture, promotion and sale of those products and technologies will be subject to similar regulation by corresponding foreign regulatory agencies. In general, the regulatory framework for biological health care products is more rigorous than for non-biological health care products. Generally, biological health care products must be shown to be safe, pure, potent and effective. There are numerous state and federal statutes and regulations that govern or influence the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising, distribution and promotion of biological health care products. Non-compliance with applicable requirements can result in, among other things, fines, injunctions, seizures of products, total or partial suspension of product

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marketing, failure of the government to grant pre-market approval, withdrawal of marketing approvals, product recall and criminal prosecution.

COMPETITION

IMMUNODIAGNOSTIC KITS

Intact-PTH IRMA

TYPE OF IMMUNODIAGNOSTIC KIT MAJOR COMPETITORS

Intact-PTH on the ELISA Microplate format Abbott Laboratories

Bayer

Hoffman La-Roche

DPC

Nichols Institute Diagnostics

DSL (Diagnostic Systems

Laboratories)

Bio Rad DiaSorin

Diasor

Nichols IncStar

DSL

ACTH ELISA Bayers

DPC

Nichols Institute

DSL CIS DiaSorin

Euro Diagnostics

Calcitonin ELISA Nichols Institute Diagnostics

DPC

Mitsubishi DiaSorin DSL

CDT Axis Biochemical,
ASA (Axis/Shields)

Hoffman-La-Roche (Distributor of one older Version of Axis kit)

Erythropoietin ELISA R&D Laboratories

Nichols Institute

DLS DPC

Microalbumin quantitative test via TIA BMC/ Hitachi

Beckman DPC

The market for the products and technologies of the Company is highly competitive, and SBT expects competition to increase. SBT will compete with many other health care research product suppliers, most of which will be larger than SBT.

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Some of the competitors of SBT offer a broad range of equipment, supplies, products and technology, including many of the products and technologies contemplated to be offered by SBT. To the extent that customers exhibit loyalty to the supplier that first supplies them with a particular product or technology, the competitors of SBT may have an advantage over SBT with respect to products and technologies first developed by such competitors. Additionally, many of the competitors of SBT have, and will continue to have, greater research and development, marketing, financial and other resources than SBT and, therefore, represent and will continue to represent significant competition in the anticipated markets of SBT. As a result of their size and the breadth of their product offerings, certain of these companies have been and will be able to establish managed accounts by which, through a combination of direct computer links and volume discounts, they seek to gain a disproportionate share of orders for health care products and technologies from prospective customers. Such managed accounts present significant competitive barriers for SBT. It is anticipated that SBT will benefit from their participation in selected markets which, as they expand, may attract the attention of the competitors of SBT. There can be no assurance that the Company will be able to compete successfully in these markets.

The competition in the US \$20 billion diagnostic business is fierce, mainly dominated by the large pharmaceutical and larger established biotechnology companies such as Abbott Laboratories, Hoffman La Roche etc.

For its CDT kits, the Company's only competitor is Axis Biochemicals, ASA, in Oslo, Norway which has entered into European and distributorship arrangements with Bio Rad Laboratories, Inc. and Roche Diagnostics, a division of Hoffman-La-Roche. Large competitors with complete automation with proprietary

instrumentation have offered packaged reagent rental programs to potential customers, for which the use of instrument is not paid by the customers except for some small commitment to purchase the products. These large companies dominate essentially over 80% of the endocrine assay markets in the developed countries such as the United States, Western Europe and Japan with their proprietary fully automated instruments. SBT can only attempt to increase the sales for its endocrine products to small laboratories through its distributors and seek to enter emerging markets in Latin America, Asia and Eastern Europe, where the need for endocrine has been traditionally minimal, due to the prevalent poverty and in some cases over-population.

#### BLOOD VOLUME SUBSTITUTE

In the business of blood volume substitute, there are at least six large companies that have obtained substantial capitalization either through equity funding or through acquisition by large corporations, such as Baxter International acquiring Somatogen. Other future competitors are Hemosol Inc. in Canada, Northfield, Alliance Pharmaceutical and Biopure Corporation.

Nearly all these companies have already made strategic marketing alliances with large companies with established marketing and distribution channels, such as Johnson and Johnson, Eli Lilly and Company, and Pharmacia/Upjohn. Most of these companies have already proceeded Clinical Trial Phase III with the FDA. Biopure Corporation has received approval in South Africa to treat acute anemia in surgery patients. To be competitive, the Company is attempting to develop well-characterized and differentiated products in unique formulations which could capture some of the market as a new generation of oxygen carrier/additives to address the markets of artificial blood volume substitutes as well as the potential new market of therapeutics for oxygen deficiencies.

#### BLOOD ADDITIVE

In the business of blood additive, Sangui AG is not aware of any existing or potential competitors.

## GLUCOSE SENSOR

The Company is not aware of any glucose sensing implants currently available. In the last few years different approaches have been chosen by companies to reduce the pain caused by the finger pricks necessary for the determination of the blood glucose. Cygnus Inc., Redwood City, California, USA, for example, has been developing a device which collects interstitial fluid at the diabetic's wrist by use of electrical energy.

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Cygnus applied for FDA approval. and is currently engaged in further testing of the device. On devices close to an implantable glucose sensor, MiniMed Inc. of Sylmar, CA has submitted to FDA a Notification on a Continuous Glucose Sensor For Diabetes in December, 1997. MiniMed Inc. announced its intention to produce and market this product. It expects to utilize the sensor for a series of products, the first two of which will be a physician diagnostic device and an alarm product to warn people with diabetes of dangerously low glucose levels. However, the reagents for the MiniMed's sensor are stable for only three days. By contrast to the objective of an implantable long term glucose sensor by Gluko AG, the MiniMed's sensor does not solve the problem in the long term.

Gluko AG is aware of three other companies also developing implantable glucose sensors. Medical Research Group, LLC, MRG, a privately-held company has been developing a glucose sensor and is planning to connect this sensor with an insulin pump developed by MiniMed. The sensor under

development by Synthetic Blood International, Kettering, Ohio, USA is based on an enzymatic glucose determination. Animas, Corp., Frazer, Pennsylvania, USA has been developing an implantable glucose sensor based on infrared spectroscopy.

#### RISK FACTORS

An investment in SGBI involves significant risks associated with economic, business, market and financial factors and developments which may have adverse impacts on the Company's future performance, including significant risks not normally associated with investing in equity securities of United States companies including the following:

# LIMITED OPERATING HISTORY OF THE COMPANY; LOSSES ARE EXPECTED TO CONTINUE

The Company is a relatively new entity with a limited operating history upon which a significant evaluation of the Company's prospects can be made. The prospects of SGBI must be considered keeping in mind the risks, expenses, and difficulties frequently encountered in the establishment of a new business in an ever changing industry and the research, development, manufacture, distribution, and commercialization of esoteric medical technology, procedures, and products and related technologies. There can be no assurance that unanticipated technical or other problems will not occur which would result in material delays in product commercialization or that the efforts of SGBI will result in successful product commercialization. SGBI has been operating at a loss and expects its costs to increase as its development efforts and testing activities accelerate. It is currently unknown when profitable operations might be achieved.

#### DEPENDENCE ON KEY PERSONNEL

The future success of the Company will depend on the service of its key scientific personnel in its pharmaceutical, chemistry and biochemistry departments and, when appropriate, computer hardware and software engineering, electrical and mechanical engineering and management personnel and, additionally, its ability to identify, hire and retain additional qualified personnel. There is intense competition for qualified personnel in the areas of the activities of SGBI and there can be no assurance that SGBI will be able to attract and retain personnel necessary for the development of the business of SGBI. Because of the intense competition, there can be no assurance that SGBI will be successful in adding technical personnel if needed to satisfy its staffing requirements. Failure to attract and retain key personnel could have a material adverse effect on SGBI.

SGBI and its subsidiaries are dependent on the efforts and abilities of their senior management. The loss of various members from management could have a material adverse effect on the business and prospects of SGBI. In particular, SGBI will depend on the service of Professor Wolfgang Barnikol because he is instrumental in his expertise in the development of the oxygen carrier and glucose sensor products. There can be no assurance that upon the departure of key personnel from the service of SGBI or its subsidiaries that suitable replacement personnel will be available.

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#### FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FUNDING

Although the Company's cash position is strong, substantial funds will be required to effect the Company's development plans. The Company will require additional cash for: (i) payment of increased operating expenses; (ii) payment of development expenses; and (iii) further implementation of

those business strategies. Such additional capital may be raised by additional public or private financing, as well as borrowings and other resources. To the extent that additional capital is received by SGBI by the sale of equity or equity-related securities, the issuance of such securities will result in dilution to the Company's shareholders. There can be no assurance that additional funding will be available on favorable terms, if at all. SGBI may also seek arrangements with collaborative partners in order to gain additional funding, marketing assistance or other contributions. However, such arrangements may require SGBI to relinquish rights or reduce its interests in certain of its the technologies or product candidates. The inability of the Company to access the capital markets or obtain acceptable financing could have a material adverse effect on the results of operations and financial condition of the Company. Moreover, if funds are not available from any sources, the Company may not be able to continue to operate.

#### LICENSES AND CONSENTS

The utilization or other exploitation of the products and services developed by SGBI or its subsidiaries may require SGBI or its subsidiaries to obtain licenses or consents from the producers or other holders of copyrights or other similar rights relating to the products and technologies of SGBI or its subsidiaries. In the event SGBI or its subsidiaries are unable, if so required, to obtain any necessary license or consent on terms which the management of SGBI or its subsidiaries consider to be reasonable, SGBI or its subsidiaries may be required to cease developing, utilizing, or exploiting products or technologies affected by those copyrights or similar rights. In the event SGBI or its subsidiaries is challenged by the holders of such copyrights or other similar rights, there can be no assurance that SGBI or its subsidiaries will have the financial or other resources to defend any resulting legal action, which could be significant.

#### TECHNOLOGICAL FACTORS

The market for the products and technology developed by SGBI is characterized by rapidly changing technology which could result in product obsolescence or short product life cycles. Similarly, the industry is characterized by continuous development and introduction of new products and technology to replace outdated products and technology. Accordingly, the ability of SGBI to compete will be dependent upon the ability of SGBI to provide new and innovative products and technology. There can be no assurance that competitors will not develop technologies or products that render the proposed products and technology of SGBI obsolete or less marketable. SGBI will be required to adapt to technological changes in the industry and develop products and technology to satisfy evolving industry or customer requirements, any of which could require the expenditure of significant funds and resources, and SGBI does not have a source or commitment for any such funds and resources. Development efforts relating to the technological aspects of the various products and technologies to be developed by SGBI are not substantially completed. Accordingly, SGBI will continue to refine and improve those products and technologies. Continued refinement and improvement efforts remain subject to the risks inherent in new product development, including unanticipated technical or other problems which could result in material delays in product commercialization or significantly increased costs. In addition, there can be no assurance that those products and technologies will prove to be sufficiently reliable or durable in wide spread commercial application. The products or technologies sought to be developed by SGBI will be the result of significant efforts which may result in errors that become apparent subsequent to widespread commercial utilization. In such event, SGBI would be required to modify such products or technologies and continue with additional research and development, which could delay the plans of SGBI and cause SGBI to incur additional cost.

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EARLY STAGE OF PRODUCT DEVELOPMENT; LACK OF COMMERCIAL PRODUCTS; NO ASSURANCE OF SUCCESSFUL PRODUCT DEVELOPMENT

Although the Company is currently marketing immunodiagnotic kits, its primary efforts are devoted on the development of proprietary products involving artificial oxygen carriers and glucose sensors.

The potential products of SGBI will require additional pre-clinical and clinical development, regulatory approval and additional investment prior to commercialization, either by SGBI independently or by others through collaborative arrangements. Potential products that appear to be promising at early stages of development may be ineffective or be shown to cause harmful side effects during pre-clinical testing or clinical trials, fail to receive necessary regulatory approvals, be difficult to manufacture, be uneconomical to produce, fail to achieve market acceptance or be precluded from commercialization by proprietary rights of others. There can be no assurance that any potential products will be successfully developed, prove to be safe and efficacious in clinical trials, satisfy applicable regulatory standards, be capable of being produced in commercial quantities at acceptable costs or achieve commercial acceptance.

All products and technologies under development by SGBI will require significant commitment of personnel and financial resources. Several products will require extensive evaluation and pre-marketing clearance by the FDA and comparable agencies in other countries prior to commercial sale. SGBI regularly re-evaluates its product development efforts. On the basis of these re-evaluations, SGBI may abandon development efforts for particular products. No assurance can be given that any product or technology under development will result in the successful introduction of any new product. The failure to introduce new products into the market on a timely basis could have a material adverse effect on the business, financial conditions or results of operation of SGBI.

The technologies of SGBI have not yet been tested in humans and there can be no assurance that human testing of potential products based on such technologies will be permitted by regulatory authorities or, even if human testing is permitted, that products based on such technologies will be shown to be safe or efficacious. Potential products based on the technologies of SGBI are at an early stage of testing and there can be no assurance that such products will be shown to be safe or effective.

#### MARKET ACCEPTANCE

There can be no assurance that the products and technologies of SGBI will achieve a significant degree of market acceptance, and that acceptance, if achieved, will be sustained for any significant period or that product life cycles will be sufficient (or substitute products developed) to permit SGBI to achieve or sustain market acceptance which could have a material adverse effect on the business, financial condition, and results of operations of SGBI.

## GOVERNMENT REGULATION; NO ASSURANCE OF PRODUCT APPROVAL

The clinical testing, manufacture, promotion, and sale of biotechnology and pharmaceutical products are subject to extensive regulation by numerous governmental authorities in the United States, principally the FDA, and corresponding state and foreign regulatory agencies prior to the introduction of those products. Management of SGBI believes that many of the potential products of SGBI will be regulated by the FDA under current regulations of the FDA. Other federal and state statutes and regulations may govern or influence the

testing, manufacture, safety, effectiveness, labeling, storage, record-keeping, approval, advertising, distribution and promotion of certain products developed by SGBI. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, seizure of products, suspensions of regulatory approvals, product recalls, operating restrictions, re-labeling costs, delays in sales, cessation of manufacture of products, the imposition of civil or criminal sanctions, total or partial suspension of product marketing, failure of the government to grant pre-market approval, withdrawal of marketing approvals and criminal prosecution.

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The FDA's requirements include lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. In particular, human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval requirements by the FDA and agencies in Germany, Singapore and other countries. Although the time required for completing such testing and obtaining such approvals is uncertain, satisfaction of these requirements typically takes a number of years and varies substantially based on the type, complexity and novelty of each product. Neither SGBI nor its subsidiaries can accurately predict when product applications or submissions for FDA or other regulatory review may be submitted. Management of the Company has no experience in obtaining regulatory clearance on these types of products. The lengthy process of obtaining regulatory approval and ensuring compliance with applicable law requires the expenditure of substantial resources. Any delays or failure by SGBI or its subsidiaries to obtain regulatory approval and ensure compliance with appropriate standards could adversely affect the commercialization of such products, the ability of SGBI to earn product or royalty revenue, and its results of operations, liquidity and capital resources.

Pre-clinical testing is generally conducted in laboratory animals to evaluate the potential safety and effectiveness of a drug. The results of these studies are submitted to the FDA, which must be approved before clinical trials can begin. Typically, clinical evaluation involves a time consuming and costly three-phase process. In Phase I, clinical trials are conducted with a small number of subjects to determine the early safety profile, the pattern of drug distribution and metabolism. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, large-scale, multi-center, comparative trials are conducted with patients afflicted with a target disease in order to provide enough data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical trials and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based upon the data which have been accumulated to that point and its assessment of the risk/benefit ratio to the patient.

Clinical trials and the marketing and manufacturing of products are subject to the rigorous testing and approval processes of the FDA and foreign regulatory authorities. The process of obtaining FDA and other required regulatory approvals is lengthy and expensive. There can be no assurance that SGBI will be able to obtain the necessary approvals to conduct clinical trials for the manufacturing and marketing of products, that all necessary clearances will be granted to SGBI or their licensors for future products on a timely basis, or at all, or that FDA review or other actions will not involve delays adversely affecting the marketing and sale of the products or SGBI. In addition, the testing and approval process with respect to certain new products which SGBI may seek to introduce is likely to take a substantial number of years and involve the expenditure of substantial resources. There can be no assurance that pharmaceutical products currently in development will be cleared for marketing by the FDA. Failure to obtain any necessary approvals or failure to comply with

applicable regulatory requirements could have a material adverse effect on the business, financial condition or results of operations of SGBI. Further, future government regulation could prevent or delay regulatory approval of the products of SGBI.

There can be no assurance as to the length of the clinical trial period or the number of patients the FDA will require to be enrolled in the clinical trials in order to establish the safety and effectiveness of the products of SGBI. SGBI may encounter significant delays or excessive costs in their efforts to secure necessary approvals, and regulatory requirements are evolving and uncertain. Future United States or foreign legislative or administrative acts could also prevent or delay regulatory approval of the products of SGBI. If commercial regulatory approvals are obtained, they may include significant limitations on the indicated uses for which a product may be marketed. In addition, a marketed product is subject to continual FDA review. Later discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product, or even the removal of the product from the market, as well as possible civil or criminal sanctions. Failure of SGBI to obtain marketing approval for any of their products under development on a timely basis, or FDA withdrawal of marketing approval once obtained, could have a material adverse effect on the business, financial condition and results of operations of SGBI.

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Any party that manufactures therapeutic or pharmaceutical products is required to adhere to applicable standards for manufacturing practices and to engage in extensive record keeping and reporting. Any manufacturing facilities of SGBI are subject to periodic inspection by state and federal agencies, including the FDA and comparable agencies in foreign countries.

The effect of governmental regulation may be to delay the marketing of new products for a considerable period of time, to impose costly requirements on the activities of SGBI or to provide a competitive advantage to other companies that compete with SGBI. There can be no assurance that FDA or other regulatory approval for any products developed by SGBI will be granted on a timely basis, if at all or, if granted, that compliance with regulatory standards will be maintained. Adverse clinical results by SGBI could have a negative impact on the regulatory process and timing. A delay in obtaining, or failure to obtain, regulatory approvals could preclude or adversely affect the marketing of products and the liquidity and capital resources of SGBI. The extent of potentially adverse governmental regulation that might result from future legislation or administrative action cannot be predicted.

SGBI will be subject to regulatory authorities in Germany, Singapore, and other countries governing clinical trials and product sales. Even if FDA approval is obtained, approval of a product by the comparable regulatory authorities of other countries must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from country to country and the time required may be longer or shorter than that required for FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the health authorities of any other country. There can be no assurance that any foreign regulatory agency will approve any product submitted for review by SGBI.

SGBI is subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with its research work. The extent and character of governmental regulation that might result

from future legislation or administrative action cannot be accurately predicted.

INTENSE COMPETITION

Competition in the biotechnology and pharmaceutical industries is intense and is expected to increase. SGBI and its subsidiaries compete directly with the research departments of biotechnology and pharmaceutical companies, chemical companies and, possibly, joint collaborations between chemical companies and research and academic institutions. Management of SGBI is aware that other companies and businesses have developed and are in the process of developing technologies and products which may be competitive with the products and technologies developed and offered by SGBI. The biotechnology and pharmaceutical industries continue to undergo rapid change. There can be no assurance that competitors have not or will not succeed in developing technologies and products that are more effective than any which have been or are being developed by SGBI or which would render the technology and products of SGBI obsolete. Many of the competitors of SGBI have substantially greater experience, financial and technical resources and production, marketing and development capabilities than SGBI. Accordingly, certain of those competitors may succeed in obtaining regulatory approval for products more rapidly or effectively than SGBI.

#### UNCERTAINTIES ASSOCIATED WITH PATENTS AND PROPRIETARY RIGHTS

The success of SGBI and its subsidiaries may depend in part on their ability to obtain patents for their technologies and products, if any, resulting from the application of such technologies, to defend patents once obtained and to maintain trade secrets, both in the United States and in foreign countries.

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The success of SGBI will also depend upon avoiding the infringement of patents issued to competitors. There can be no assurance that SGBI will be able to obtain patent protection for products based upon the technology of SGBI. Moreover, there can be no assurance that any patents issued to SGBI or its subsidiaries will not be challenged, invalidated or circumvented or that the rights granted there under will provide competitive advantages to SGBI. Litigation, which could result in substantial cost to SGBI, may be necessary to enforce the patent and license rights of SGBI or to determine the scope and validity of its and others' proprietary rights.

Due to the length of time and expense associated with bringing new products through development and the length of time required for the governmental approval process, the biotechnology and pharmaceutical industries have traditionally placed considerable importance on obtaining and maintaining patent and trade secret protection for significant new technologies, products and processes. The enforceability of patents issued to biotechnology and pharmaceutical firms can be highly uncertain. Federal court decisions establishing legal standards for determining the validity and scope of patents in the field are in transition. In addition, there can be no assurance that patents will be issued or, if issued, any such patents will afford SGBI protection from infringing patents granted to others.

A number of biotechnology and pharmaceutical companies, and research and academic institutions, have developed technologies, filed patent applications or received patents on various technologies that may be related to the business of Sangui and its Subsidiaries. Some of these technologies, applications or patents may conflict with the technologies of SGBI. Such conflicts could also limit the scope of the patents, if any, that SGBI or its subsidiaries may be able to obtain or result in the denial of the patent applications of SGBI.

In December, 2000, the Company's only competitor in the CDT business,

Axis/Shields, a Norwegian Company purchased by Shields Diagnostics of United Kingdoms, filed a lawsuit against the Company for alleged patent infringement. The Company reached a settlement with Axis/Shields and agreed to discontinue the sales of the Company's CDT product, trade-marked ChronAlco ID CDT test kit. The Company has since re-designed its CDT product, called ChronAlco ID II CDT test kit, to resolve the patent conflict. The Company has since sold the new version of CDT kit, i.e. ChronAlco ID II CDT test kit to its distributors and customers. There has been no significant loss or gain of the Company's CDT business. The Company believes its new ChronAlco ID II CDT test does not infringe the patent and patent application held by Axis/Shields. Nonetheless, there can be no assurance that the Company will prevail if a lawsuit is brought by Axis/Shields.

Many of the competitors of SGBI have, or are affiliated with companies having, substantially greater resources than SGBI, and such competitors may be able to sustain the costs of complex patent litigation to a greater degree and for longer periods of time than SGBI. Uncertainties resulting from the initiation and continuation of any patent or related litigation could have a material adverse effect on the ability of SGBI to compete in the marketplace pending resolution of the disputed matters. Moreover, an adverse outcome could subject SGBI to significant liabilities to third parties and require SGBI to license disputed rights from third parties or cease using the technology. In the event that third parties have or obtain rights to intellectual property or technology used or needed by SGBI, there can be no assurance that any licenses would be available to SGBI or would be available on terms reasonably acceptable to SGBI.

SGBI may rely on certain proprietary technologies, trade secrets, and know-how that are not patentable. Although SGBI has taken steps to protect their unpatented trade secrets and technology, in part through the use of confidentiality agreements with their employees, consultants and certain of its contractors, there can be no assurance that: (i) these agreements will not be breached; (ii) SGBI would have adequate remedies for any breach; or (iii) the proprietary trade secrets and know-how of SGBI will not otherwise become known or be independently developed or discovered by competitors.

RISK OF PRODUCT LIABILITY; POTENTIAL UNAVAILABILITY OF INSURANCE

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The business of SGBI will expose it to potential product liability risks that are inherent in the testing, manufacturing and marketing of human pharmaceutical and therapeutic products. SGBI does not currently have product liability insurance, and there can be no assurance that SGBI will be able to obtain or maintain such insurance on acceptable terms or, if obtained, that such insurance will be adequate to cover potential product liability claims or that a loss of insurance coverage or the assertion of a product liability claim or claims would not materially adversely affect the business, financial condition and results of operations of SGBI. SGBI faces an inherent business risk of exposure to product liability and other claims in the event that the development or use of its technology or 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 possess regulatory approval for commercial sale. There can be no assurance that SGBI will avoids significant product liability exposure. While SGBI has taken, and will continue to take, what it believes are appropriate precautions, there can be no assurance that it will avoid significant liability exposure. An inability to obtain product liability insurance at acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of products developed by SGBI. A product liability claim could have a material adverse effect on the business, financial condition and results of

operations of SGBI.

UNCERTAINTIES RELATING TO PRICING AND THIRD-PARTY REIMBURSEMENT

The operating results of SGBI may depend in part on the availability of adequate reimbursement for the products of SGBI from third-party payers, such as government entities, private health insurers and managed care organizations. Third-party payers are increasingly 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 product for only a portion of the purchase price of the product. In the case of the products of SGBI, 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 physicians. There can be no assurance that reimbursement, if available, will be adequate. Moreover, certain of the products of SGBI may not be of the type generally eligible for third-party reimbursement. If adequate reimbursement levels are not provided by government entities or other third-party payers for the products of SGBI, the business, financial condition and results of operations of SGBI would be materially adversely affected. A number of legislative and regulatory proposals aimed at changing the nation's health care system have been proposed in recent years. While SGBI cannot predict whether any such proposals will be adopted, or the effect that any such proposal may have on its business, such proposals, if enacted, could have a material adverse effect on the business, financial condition or results of operations of SGBI.

#### RISK OF PRODUCT RECALL; PRODUCT RETURNS

Product recalls may be issued at the discretion of SGBI, the FDA or other government agencies having regulatory authority for product sales and may occur due to disputed labeling claims, manufacturing issues, quality defects or other reasons. No assurance can be given that product recalls will not occur in the future. Any product recall could materially adversely affect the business, financial condition or results of operations of SGBI. There can be no assurance that future recalls or returns would not have a material adverse effect upon the business, financial condition and results of operations of SGBI.

# RISKS OF INTERNATIONAL SALES AND OPERATIONS

SGBI's results of operations are subject to fluctuations in the value of the German Deutschmark against the U.S. Dollar due to SGBI's German subsidiaries. Although management of SGBI will monitor exposure to currency fluctuations, there can be no assurance that exchange rate fluctuations will not have a material adverse effect on the results of operations or financial condition of SGBI. In the future, SGBI could be required to sell its products in other currencies, which would make the management of currency fluctuations more difficult and expose SGBI to greater risks in this regard.

The products of SGBI will be subject to numerous foreign government standards and regulations that are continually being amended. Although SGBI will endeavor to satisfy foreign technical and regulatory standards, there can

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be no assurance that the products of SGBI will comply with foreign government standards and regulations, or changes thereto, or that it will be cost effective for SGBI to redesign its products to comply with such standards or regulations. The inability of SGBI to design or redesign products to comply with foreign standards could have a material adverse effect on SGBI's business, financial condition and results of operations.

LACK OF COMMERCIAL MANUFACTURING AND MARKETING EXPERIENCE

SGBI has not yet manufactured its products, other than its nine in vitro immunodiagnostic products, in commercial quantities. Its subsidiaries will be engaged in manufacturing pharmaceutical products which will be subject to much more stringent regulatory requirements, as compared to the in vitro diagnostic products. No assurance can be given that its subsidiaries, on a timely basis, will be able to make the transition from manufacturing clinical trial quantities to commercial production quantities successfully or be able to arrange for contract manufacturing. SGBI and its subsidiaries have no experience in the sales, marketing and distribution of products. There can be no assurance that SGBI will be able to establish sales, marketing and distribution capabilities or make arrangements with collaborators, licensees or others to perform such activities or that such efforts will be successful.

The manufacture of the products of SGBI involves a number of steps and requires compliance with stringent quality control specifications imposed by SGBI and by the FDA. Moreover, SGBI's products can only be manufactured in a facility that has undergone a satisfactory inspection by the FDA. For these reasons, SGBI would not be able to quickly replace its manufacturing capacity if it were unable to use its manufacturing facilities as a result of a fire, natural disaster (including an earthquake), equipment failure or other difficulty, or if such facilities are deemed not in compliance with the FDA's GMP requirements and the non-compliance could not be rapidly rectified. The inability or reduced capacity of SGBI to manufacture their products would have a material adverse effect on SGBI's business and results of operations.

SGBI may enter into arrangements with contract manufacturing companies to expand its production capacities in order to satisfy requirements for its products, or to attempt to improve manufacturing efficiency. If SGBI chooses to contract for manufacturing services and encounters delays or difficulties in establishing relationships with manufacturers to produce, package and distribute its finished products, clinical trials, market introduction and subsequent sales of such products would be adversely affected. Further, contract manufacturers must also operate in compliance with the FDA's GMP requirements; failure to do so could result in, among other things, the disruption of product supplies.

#### HAZARDOUS MATERIALS AND ENVIRONMENTAL MATTERS

The research and development processes of SGBI involves the controlled storage, use and disposal of hazardous materials and radioactive compounds. SGBI is subject to federal, state and local laws and regulations governing the use, generation, manufacturing, storage, handling, and disposal of such materials and certain waste products. Although SGBI does not currently manufacture commercial quantities of its product candidates, it produces limited quantities of such products for its clinical trials and SGBI intends to manufacture commercial quantities of its products. Although SGBI believes that its safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, SGBI could be held liable for any damages that result, and any such liability could exceed the resources of SGBI. There can be no assurance that SGBI will not be required to incur significant costs to comply with current or future environmental laws and regulations nor that the operations, business or assets of SGBI will not be materially or adversely affected by current or future environmental laws or regulations.

#### DEPENDENCE ON MAJOR CUSTOMERS

The Company has a relatively small customer base. Two customers accounted for approximately 51% of accounts receivable as of June 30, 2001 and

approximately 54% of sales for the year ended June 30, 2001. Four customers accounted for approximately 70% of sales for the year ended June 30, 2000, respectively. Although the Company is currently the supplier of certain immunodiagnostic kits to these customers, there is no assurance that the Company will continue to be the supplier or the supplier of choice. In the event that the Company loses the business from any of its major customers, this would have a significant negative impact on the Company's sales.

#### HUMAN RESOURCES

The Company considers its relations with its employees to be favorable. As of June 30, 2001 the Company and its subsidiaries have 31 fulltime employees of which 24 were involved in research and development and 7 were responsible for administrative matters. The Company had consulting arrangements with 5 individuals as of that date.

# ITEM 2. Properties

The Company's US laboratory facility consists of approximately 3,360 square feet located in Santa Ana, California. Rent expense for the fiscal year ended June 30, 2001 was approximately \$53,000.

The German subsidiaries, approximately 800 square meters, are based in the Forschungs- und Entwicklungszentrum of the University Witten/Herdecke, Germany. Rent expense for the fiscal year was approximately \$65,000.

The Singaporean subsidiary, approximately 350 square meters, is based in the Science Park II, Gemini Building. Rent expense for the fiscal year was approximately \$74,000.

# ITEM 3. Legal Proceedings

On July 26, 2001, the Company commenced a lawsuit in the United States District Court for the District of Colorado against Helmut Kappes, a director of the Company. In the lawsuit, the Company alleges that Mr. Kappes is engaged in conduct related to the Company's affairs that is fraudulent, dishonest and a gross abuse of his authority or discretion as a director and that his removal from the Company's Board of Directors would be in the best interest of the Company. Among other things, the Company alleges that Mr. Kappes caused the Company to enter into a contract with Axel Kleinkorres without adequate disclosure of Mr. Kappes's conflicts of interest and that the remuneration paid to Mr. Kleinkorres was excessive. The Company also alleges that Mr. Kappes is engaged in an improper exchange offer campaign involving the Company's shares. The Court issued a Temporary Restraining Order suspending Mr. Kappes from the Board of Directors of the Company and restraining Mr. Kappes from pursuing the exchange offer. The Temporary Restraining Order has expired. The Company has filed a Motion for Preliminary Injunction which is pending.

The Company seeks the removal of Mr. Kappes from the Company's Board of Directors, an injunction against Mr. Kappes and his affiliates from exchanging the Company's shares for shares of an entity in which Mr. Kappes has a financial interest, compensatory damages in an amount to be determined and costs of the action. Mr. Kappes has not yet filed an Answer to the Complaint by the Company in the lawsuit.

ITEM 4.

Submission of matters to a vote of security holders

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Not applicable

PART II

ITEM 5. MARKET FOR SGBI'S SECURITIES

 $\operatorname{SGBI's}$  common stock is presently traded on the OTC Bulletin Board operated by  $\operatorname{Nasdaq}$  under the  $\operatorname{symbol}$   $\operatorname{SGBI}$ .

The following table sets forth the high and low closing prices for shares of SGBI common stock for the calendar periods noted, as reported by the National Daily Quotation Service and the Over-The-Counter Bulletin Board. Quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

YEAR	PERIOD	CLOSING HIGH	PRICES LOW
2001	First quarter	\$1.45	\$0.94
	Second quarter	\$0.93	\$0.48
2000	First quarter	\$5.00	\$2.00
	Second quarter	\$3.31	\$2.06
	Third quarter	\$2.72	\$1.75
	Fourth quarter	\$2.38	\$1.11
1999	Third quarter	\$4.19	\$2.00
	Fourth quarter	\$3.63	\$1.50

In addition to freely tradeable shares, SGBI has numerous shares of common stock outstanding which could be sold pursuant to Rule 144. In general, under Rule 144, subject to the satisfaction of certain other conditions, a person, including one of our affiliates, who has beneficially owned restricted shares of common stock for at least one year is entitled to sell, in certain brokerage transactions, within any three-month period, a number of shares that does not exceed the greater of 1% of the total number of outstanding shares of the same class, or the average weekly trading volume during the four calendar weeks immediately preceding the sale. A person who presently is not and who has not been an affiliate for at least three months immediately preceding the sale and who has beneficially owned the shares of common stock for at least two years is entitled to sell such shares under Rule 144 without regard to any of the volume limitations described above.

At August 21, 2001, the number of record holders of the Company's common stock was 2,090. The Company did not pay any cash dividends during the past two fiscal years and does not contemplate paying dividends in the foreseeable future.

RECENT SALES OF UNREGISTERED SECURITIES

During the fiscal year ended June 30, 2001, the Company did not sell

unregistered shares of its Common Stock.

ITEM 6.

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

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The following discussion contains forward-looking statements that are subject to business and economic risks and uncertainties, and the Company's actual results could differ materially from these forward looking statement. The following discussion regarding the financial statements of the Company should be read in conjunction with the financial statements and notes thereto.

FISCAL 2001 COMPARED TO FISCAL 2000

RESULTS OF OPERATIONS

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SALES. Sales increased 32% to approximately \$567,000 in 2001 from approximately \$429,000 in 2000. This increase of \$138,000 is attributed to an increase in sales of the Company's immunodiagnostic kits.

COST OF SALES. Cost of sales increased 40% to approximately \$395,000 in 2001 from approximately \$283,000 in 2000. This increase of \$112,000 is related to costs associated with the increase in sales of the Company's immunodiagnostic kits. The Company's gross margin decreased to 30% in 2001 from 34% in 2000 primarily due to additional costs incurred in 2001 for quality control purposes.

GENERAL AND ADMINISTRATIVE. General and administrative expenses, exclusive of amortization of prepaid consulting fees of approximately \$444,000, decreased 48% to approximately \$670,000 in 2001 from approximately \$1,283,000 in 2000. In 2000, general and administrative expenses included one time professional and consulting fees of approximately \$180,000 related to the acquisition of Felnam Investments, Inc. and \$470,000 of other non-recurring professional and consulting fees. This decrease in non-recurring charges of approximately \$650,000, combined with an increase of approximately \$37,000 in other general and administrative expenses, results in a net decrease of \$613,000 in 2001.

COMPENSATION EXPENSE RELATED TO STOCK OPTIONS. Compensation expense related to stock options was \$1,000,000 in 2001, which represents the amortization of the fair value of stock options previously issued to the chairman of the Company. There was no compensation expense related to stock options in 2000.

AMORTIZATION OF PREPAID CONSULTING FEES. Amortization of prepaid consulting fees decreased 72% to \$444,000 in 2001 from \$1,572,500 in 2000. The decrease of \$1,128,500\$ results from an extension of the corresponding consulting agreement for an additional 24 months effective July 2000.

Sangui AG

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RESEARCH AND DEVELOPMENT. Research and development expenses increased 449% to approximately \$785,000 in 2001 from approximately \$143,000 in 2000, due to increased research and development activities.

GENERAL AND ADMINISTRATIVE. General and administrative expenses increased 78% to approximately \$562,000 in 2001 from approximately \$315,000 in 2000. This increase of \$247,000 is attributed to increases in staffing and operating expenses.

Gluko AG

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RESEARCH AND DEVELOPMENT. Research and development expenses increased 295% to approximately \$162,000 in 2001 from approximately \$41,000 in 2000, due to increased research and development activities.

GENERAL AND ADMINISTRATIVE. General and administrative expenses increased 65% to approximately \$162,000 in 2001 from approximately \$98,000 in 2000. This increase of \$64,000 is attributed to increases in staffing and operating expenses.

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Sangui Singapore

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GENERAL AND ADIMISTRATIVE. General and administrative expenses were approximately \$183,000 in 2001. There were insignificant amounts of general and administrative expenses in 2000. This increase is attributed to full time operations beginning during the most recent fiscal year.

SGBI

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NET LOSS. The Company's net loss was approximately \$3,628,000, or approximately nine cents per common share, in 2001, compared to approximately \$3,120,000, or nine cents per common share, in 2000. This increase in net loss is a result primarily of increased research and development expenses and an increase in compensation expense related to stock options, offset by a decrease in amortization of prepaid consulting fees.

LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2001 the Company had cash and liquid marketable securities of approximately \$5.8 million. The Company believes that its available cash will be sufficient to satisfy its requirements for at least the fiscal year ending June 30, 2002. Moreover, the Company is able to collect about \$2.3 million of its funds granted by the German state of Northrhine-Westfalia. However, the Company will need substantial additional funding to fulfill its business plan and the Company intends to explore financing sources for its future development activities during the current year. No assurance can be given that these efforts will be successful.

ITEM 7. FINANCIAL STATEMENTS

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Independent Auditors' Report

Consolidated Balance Sheet

Consolidated Statements of Operations and Comprehensive Income (Loss)

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to the Consolidated Financial Statements

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SANGUI BIOTECH INTERNATIONAL, INC.

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED JUNE 30, 2001

WITH

INDEPENDENT AUDITORS' REPORT THEREON

#### INDEPENDENT AUDITORS' REPORT

To the Stockholders of Sangui Biotech International, Inc.

We have audited the accompanying consolidated balance sheet of Sangui Biotech International, Inc. (the "Company") as of June 30, 2001, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements 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 consolidated 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, based on our audits, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Sangui BioTech International, Inc. at June 30, 2001, and the results of their operations and their cash flows for each of the years in the two-year period then ended, in conformity with accounting principles generally accepted in the United States of America.

CORBIN & WERTZ

Irvine, California, U.S.A. August 16, 2001

# SANGUI BIOTECH INTERNATIONAL, INC. CONSOLIDATED BALANCE SHEET

# ASSETS

	JUNE 30,					
	2001					
Current assets Cash and cash equivalents	\$ 2,354,584 3,463,509 128,928 70,021 362,736 					
Property and equipment-net	514,188					
Total assets	36,867  \$ 6,930,833 					
LIABILITIES & STOCKHOLDERS' EQUITY						
Accounts payable and accrued expenses	\$ 288,617					
Stockholders' equity Preferred stock, no par value; 5,000,000 shares authorized; no shares issued and outstanding Common stock: no par value; 50,000,000 shares authorized, 40,514,363 shares issued and outstanding	- 18,305,881					
Additional paid-in capital	1,000,000 (661,169) (356,370) (11,646,126)					
Total stockholders' equity	6,642,216  \$ 6,930,833 					

See independent auditors' report and accompanying notes to consolidated financial statements

# SANGUI BIOTECH INTERNATIONAL, INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

# YEAR ENDED JUNE 30, 2001 2000 567,007 \$ 429,400 395,282 282,611 171,725 146,789 Operating expenses 946,959 183,878 1,577,315 1,696,458 Research and development. . . . . . . . . . . . . . Compensation expense related to stock options . 1,000,000 -151**,**317 147,191 151,317 443,831 1,572,500 Depreciation and amortization . . . . . . . . Amortization of prepaid consulting fees . . . . 4,115,296 3,604,153 \_\_\_\_\_ (3,943,571) (3,457,364) Other income Interest income, net of interest expense of 276,824 138,861 38,886 118,067 - 80,557 approximately \$7,000 and \$16,000, respectively. 80,557 Gain on marketable securities . . . . . . . . 315,710 337,485 (3,627,861) (3,119,879) Other comprehensive (loss) Foreign currency translation adjustments. . . . (310,272) (47,746) Unrealized gain on marketable securities 64,716 (3,873,417) \$ (3,167,625) Comprehensive loss. . . . . . . . . . . . . . . \$ \_\_\_\_\_\_ Net loss available to common shareholder per common share

Basic and diluted weighted average		
number of common shares outstanding	40,514,363	32,879,796

See independent auditors' report and accompanying notes to consolidated financial statements

# SANGUI BIOTECH INTERNATIONAL, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED JUNE 30, 2001 AND 2000

	Preferred Stock		Common Sto	
	 Shares	 Amount	Shares	
Balance at July 1, 1999	505,000 \$	5,050	31,867,878	
Issuance of common stock for cash at \$1.15 per share	-	_	466,485	
Issuance of common stock for cash at \$0.964 (including 80,000 shares issued for finders fees)	-	-	8,080,000	
Issuance of common stock for the recapitalization of Felnam Investments	-	-	100,000	
Receipt of stock subscriptions	-	-	-	
Amortization of prepaid consulting fees	-	-	_	
Currency translation adjustments	-	-	_	
Net loss		_	-	
Balance at June 30, 2000	505,000	5,050	40,514,363	
Receipt of stock subscriptions	_	-	_	
Write-off of stock subscriptions	_	_	_	
Cancellation of preferred stock	(505,000)	(5,050)	_	
Compensation expense related to stock options	_	-	-	
Amortization of prepaid consulting fees	-	_	_	
Currency translation adjustments	-	_	_	
Unrealized gain on marketable securities and cash equivalents	-	_	_	
Net loss	_	-	_	

Balance at June 30, 2001	-	\$ -	40,514,363 \$
	Stock Subscriptions	Prepaid Consulting Fees	Accumulated Other Comprehensi Income (Los
Balance at July 1, 1999	\$ (341,072)	\$ (2,677,500)	\$ (63,
Issuance of common stock for cash at \$1.15 per share	-	-	
Issuance of common stock for cash at \$0.964 (including 80,000 shares issued for finders fees)	(429,708)	-	
Issuance of common stock for the recapitalization of Felnam Investments	-	-	
Receipt of stock subscriptions	224,413	-	
Amortization of prepaid consulting fees	-	1,572,500	
Currency translation adjustments	-	-	(47,
Net loss		-	
Balance at June 30, 2000	(546 <b>,</b> 367)	(1,105,000)	(110,
Receipt of stock subscriptions	321,367	-	
Write-off of stock subscriptions	225,000	-	
Cancellation of preferred stock	-	-	
Compensation expense related to stock options	_	-	
Amortization of prepaid consulting fees	_	443,831	
Currency translation adjustments	_	-	(310,
Unrealized gain on marketable securities and cash equivalents	-	-	64,
Net loss	-	-	
Balance at June 30, 2001	\$ - 	\$ (661,169)	\$ (356 <b>,</b>

See independent auditors' report and accompanying notes to consolidated financial statements

# SANGUI BIOTECH INTERNATIONAL, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

	YEAR ENDED JUI	NE
	2001	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	\$ (3,627,861)	\$ (
Compensation expense related to stock options	1,000,000	
Depreciation and amortization	147,191	
Amortization of prepaid consulting fees	443 <b>,</b> 831	
dain on marketable securities		
Changes in operating asset and liabilities:		
Accounts receivable	(73,210)	
Grant receivable	176,844 9,669	
Prepaid expenses and other assets	(147,226)	
Accounts payable and accrued expenses	58,412	
Net cash used in operating activities	(2,012,350)	(
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(4,394,972)	
Purchase of property and equipment		
Proceeds from sale of marketable securities	996,179	
Cash grants received for property and equipment	-	
Net cash (used in) provided by investing activities	(3,633,419)	
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of common stock	_	
Collection of stock subscription receivable	321,367	
	201 267	
Net cash provided by financing activities	321,367	
Effect of exchange rate changes on cash	(310,272)	
Net (decrease) increase in cash and cash equivalents	(5,634,674)	
Cash and cash equivalents, beginning of period	7,989,258	
Cash and cash equivalents, ending of period		\$ ==

					==
Income taxes			 	\$ 800	==
	-		 	\$ 7,309	\$
Cash paid during		l for:			

See accompanying notes to accompanying consolidated financial statements for more information on non-cash investing and financing activities during the years ended June 30, 2001 and 2000.

See independent auditors' report and accompanying notes to consolidated financial statements

SANGUI BIO TECH INTERNATIONAL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEAR ENDED JUNE 30, 2001

NOTE 1 - ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Business

Supplemental disclosures:

Sangui BioTech International, Inc., incorporated in Colorado in 1995, and its subsidiaries (collectively, the "Company") are engaged in the research, development, manufacture, and sales of medical products.

The Company's wholly owned subsidiary Sangui Bio Tech, Inc. ("SBT") incorporated in Delaware in 1996, is located in Santa Ana, California. SBT manufactures in vitro immunodiagnostic blood test kits that are primary sold in the United States and Europe. , The Company has three subsidiaries located outside the United States , SanguiBioTech AG ("Sangui AG"), GlukoMediTech, AG ("Gluko AG"), and Sangui BioTech PTE Ltd. ("Sangui Singapore").

Sangui AG, incorporated in Mainz, Germany in 1995, is engaged in the development of artificial oxygen carriers (blood substitute and additives). Gluko AG, incorporated in Mainz, Germany in 1996, is engaged in the development of glucose implant sensors.

Sangui Singapore, incorporated in Singapore in 1999, is a regional office for the Company and its subsidiaries and is carrying out research and development projects in conjunction with Sangui AG and Gluko AG.

Risks and Uncertainties

The Company's line of in vitro immunodiagnostic products, as well as the future pharmaceutical (artificial oxygen carriers or blood substitute and additives) and in vivo biosensors (glucose implant sensor) being developed by its German subsidiaries, are deemed as medical devices or biologics, and as such are governed by the Federal Food and Drug and Cosmetics Act and by the regulations of state agencies and various foreign government agencies. Currently, most of the Company's immunodiagnostic tests for use with humans have been cleared by the above regulatory agencies. There can be no assurance that the Company will maintain the regulatory approvals required to market its products elsewhere. The pharmaceutical and biosensor products, under development in Germany, will be subject to more stringent regulatory

requirements, because they are in vivo products for humans. The Company and its subsidiaries have no experience in obtaining regulatory clearance on these types of products. Therefore, the Company will be subject to the risks of delays in obtaining or failing to obtain regulatory clearance.

The Company's revenues from product sales derived from its immunodiagnostic blood test kits are small. However, management believes its current cash and liquid marketable securities totaling approximately \$5.8 million at June 30, 2001, are sufficient to fund the Company's operations and working capital requirements at least through June 30, 2002.

### Consolidation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and include the accounts of the Company and its wholly owned domestic and foreign subsidiaries. All significant intercompany accounts and transactions have been eliminated. Certain amounts in 2000 and have been reclassified to conform to the current year's presentation.

## Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United Sates of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates made by management are, among others, provisions for losses on accounts receivable, realizability of long-lived assets, and estimates for deferred income tax valuation allowance. Actual results could differ from those estimates.

## Financial Instruments

The Company has adopted Statement of Financial Accounting Standards ("SFAS") No. 107 "Disclosures About Fair Value of Financial Instruments." SFAS No. 107 requires disclosure of fair value information about financial instruments when it is practicable to estimate that value. The carrying amount of the Company's cash, accounts receivable, accounts payable and accrued expenses approximate their estimated fair values due to the short-term nature of these financial statements. Marketable securities are stated at fair value based upon quoted market prices and are classified as available-for-sale securities.

### Derivative and hedging activities

In June 1998, the Financial Accounting Standards Board ("FASB") issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," which establishes standards for accounting of derivative instruments including certain derivative instruments embedded in other contracts, and hedging activities. Management has completed its evaluation of the various issues related to SFAS No. 133 for the year ended June 30, 2001, and the Company has no derivative instruments or hedging activities, as defined by SFAS No. 133. Therefore, the adoption of SFAS No. 133 had no impact on the Company's consolidated financial position or operations.

Concentration of Risk

Two customers accounted for 51% of accounts receivable as of June 30, 2001 and approximately 54% of sales for the year ended June 30, 2001. Four customers accounted for 70% of sales for the year ended June 30, 2000. The loss of any of these customers in the future would significantly affect the Company's operating results (see Note 10).

Foreign Currency Translation

Assets and liabilities of the Company's German and Singapore operations are translated into U.S. dollars at period-end exchange rates. Net exchange gains or losses resulting from such translation are excluded from net earnings but are included in comprehensive income and accumulated in a separate component of stockholders' equity. Income and expense are translated at weighted average exchange rates for the period. During fiscal 2001 and 2000, the Company had foreign exchange transaction gains included in other income of approximately \$33,600 and \$100,000, respectively.

Cash and Cash Equivalents

The Company maintains its cash in uninsured accounts and not in bank depository accounts insured by the Federal Deposit Insurance Corporation (FDIC). The Company has not experienced any losses in these uninsured accounts. Cash and cash equivalents include time deposits for which the Company has no requirements for compensating balances and mutual funds of money markets. As of June 30, 2001, the Company's mutual funds had a fair market value of \$629,319 with a cost of \$595,077 resulting in an unrealized gain of \$34,242, and the Company's time deposits had a currency translation gain of \$38,865. The Company recorded the entire amount of \$73,107 as unrealized gain under other comprehensive income in the statement of stockholders' equity. The Company also maintains bank accounts in Germany.

Marketable Securities

Marketable securities are classified as available-for-sale, as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Unrealized gains and losses are excluded from earnings and are reported as a separate component of other comprehensive loss in shareholders' equity. Realized gains and losses are included in income and are determined based on the specific identification of the securities bought and sold (see Note 3).

Inventories

Inventories, which consist primarily of finished immunodiagnostic products and related materials, are stated at the lower of cost or market with cost determined on a first-in, first-out (FIFO) basis. The Company regularly monitors inventory for excess or obsolete items and makes any valuation corrections when such adjustments are needed.

Property and Equipment

Property and equipment are recorded at cost and are depreciated or amortized

using the straight-line method over the expected useful lives, which range from three to five years. Depreciation expense for the years ended June 30, 2001 and 2000 was \$137,750 and \$131,440, respectively. Expenditures for normal maintenance and repairs are charged to income, and significant improvements are capitalized. The cost and related accumulated depreciation of assets are removed from the accounts upon retirement or other disposition; any resulting gain or loss is reflected in the statement of operations.

### Patents

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Patents are recorded at cost and are depreciated using the straight-line method over their estimated useful lives, which range from three to eleven years. Amortization expense for the years ended June 30, 2001 and 2000 was \$9,441 and \$19,877, respectively.

### Impairment of Long-Lived Assets

The Company accounts for the impairment and disposition of long-lived assets in accordance with SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to Be Disposed Of" which requires that long-lived assets and certain identifiable intangibles to be held and used by an entity be reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. The Company reviews its intangible and other long-lived assets for events or changes in circumstances which indicate that their carrying value may not be recoverable. As of June 30, 2001, management of the Company believes that no impairment has been indicated. There can be no assurances, however, that market conditions will not change or demand for the Company's products will continue which could result in impairment on long-lived assets in the future.

## Revenue Recognition

Revenues from product sales are recognized at the time of shipment.

In December 1999, the Securities and Exchange Commission released Staff Accounting Bulletin No. 101, "Revenue Recognition in the Financial Statements" ("SAB No. 101"), which provides guidance on the recognition, presentation and disclosure of revenue in the financial statements and which was effective October 1, 2000. The adoption of SAB No. 101 did not have a material impact on the Company's financial statements.

# Research and Development

Research and development are charged to operations as they are incurred. Legal fees and other direct costs incurred in obtaining and protecting patents are expensed as incurred.

### Grants

The Company receives grants from the German government which are used to fund research and development activities and the acquisition of equipment (see note 10). Revenue from grants for the reimbursement of research and development expenses are offset against research and development expenses when the related expenses are incurred. Grants related to the acquisition of tangible property are recorded as a reduction of the properties' historical cost.

Income Taxes

The Company accounts for deferred income taxes using the liability method in accordance with SFAS No. 109, "Accounting for Income Taxes." Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is provided for significant deferred tax assets when it is more likely than not that such assets will not be recovered.

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation issued to employees using the intrinsic value based method as prescribed by Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees" ("APB 25"). Under the intrinsic value based method, compensation is the excess, if any, of the fair value of the stock at the grant date or other measurement date over the amount an employee must pay to acquire the stock. Compensation, if any, is recognized over the applicable service period, which is usually the vesting period. The FASB has issued SFAS No. 123 "Accounting for Stock-Based Compensation." This standard, if fully adopted, changes the method of accounting for all stock-based compensation to the fair value based method. For stock options and warrants, fair value is determined using an option pricing model that takes into account the stock price at the grant date, the exercise price, the expected life of the option or warrant and the annual rate of quarterly dividends. Compensation expense, if any, is recognized over the applicable service period, which is usually the vesting period.

The adoption of the accounting methodology of SFAS No. 123 for employees is optional and the Company has elected to continue accounting for stock-based compensation issued to employees using APB 25; however, pro forma disclosures, as if the Company adopted the cost recognition requirements under SFAS No. 123, are required to be presented (see Note 6).

In March 2000, the FASB issued Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions involving Stock Compensation, an interpretation of APB 25." FIN 44 clarifies the application of APB 25 for (a) the definition of employee for purposes of applying APB 25, (b) the criteria for determining whether a plan qualifies as a noncompensatory plan, (c) the accounting consequence for various modifications to the terms of a previously fixed stock option or award, and (d) the accounting for an exchange of stock compensation awards in a business combination. The adoption of the provisions of FIN 44 did not have a material effect on the financial statements.

Basic and Diluted Earnings (Loss) Per Common Share

The Company computes net loss per common share using SFAS No. 128 "Earnings Per Share." Basic earnings (loss) per common share is computed based on the weighted average number of shares outstanding for the period. Diluted earnings (loss) per share is computed by dividing net income (loss) by the weighted average shares outstanding assuming all dilutive potential common shares were issued. Basic and diluted loss per share are the same as the effect of stock options on loss per share are anti-dilutive and thus not included in the diluted loss per share calculation (see Note 8).

Comprehensive Income

The Company adopted SFAS No. 130 "Reporting Comprehensive Income." SFAS No. 130 establishes standards for reporting and display of comprehensive income and its components in a full set of general-purpose financial statements. Total comprehensive income represents the net change in stockholders' equity during a period from sources other than transactions with stockholders and as such, includes net earnings. For the Company, the components of other comprehensive income are the changes in the cumulative foreign currency translation adjustments and unrealized gains (losses) on marketable securities and cash equivalents and are recorded as components of stockholders' equity.

Segments of an Enterprise and Related Information

The Company adopted SFAS No. 131 "Disclosures about Segments of an Enterprise and Related Information." SFAS No. 131 establishes standards for the way public companies report information about segments of their business in their annual financial statements and requires them to report selected segment information in their quarterly reports issued to shareholders. It also requires entity-wide disclosures about the products and services an entity provides, the material countries in which it holds assets and reports revenues and its major customers (see Note 11).

## New Accounting Pronouncements

In July 2001, the FASB issued SFAS No. 141, "Business Combinations", which is effective for business combinations initiated after June 30, 2001. SFAS No. 141 eliminates the pooling of interest method of accounting for business combinations and requires that all business combinations occurring on or after July 1, 2001 are accounted for under the purchase method. The Company does not expect SFAS No. 141 to have a material impact on its financial statements.

In July 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets", which is effective for fiscal years beginning after December 15, 2001. Early adoption is permitted for entities with fiscal years beginning after March 15, 2001, provided that the first interim financial statements have not been previously issued. SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets should be accounted for in the financial statements upon their acquisition and after they have been initially recognized in the financial statements. SFAS No. 142 requires that goodwill and intangible assets that have indefinite useful lives not be amortized but rather be tested at least annually for impairment, and intangible assets that have finite useful lives be amortized over their useful lives. SFAS No. 142 provides specific guidance for testing goodwill and intangible assets that will not be amortized for impairment. In addition, SFAS No. 142 expands the disclosure requirements about goodwill and other intangible assets in the years subsequent to their acquisition. Impairment losses for goodwill and indefinite-life intangible assets that arise due to the initial application of SFAS No. 142 are to be reported as resulting from a change in accounting principle. However, goodwill and intangible assets acquired after June 30, 2001 will be subject immediately to the provisions of SFAS No. 142. The Company does not expect SFAS No. 142 to have a material effect on its financial statements.

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 and is effective for fiscal years beginning after June 15, 2002. The Company does not expect SFAS No. 143 to have a material impact on its financial statements.

## NOTE 2 - BUSINESS ACQUISITIONS

On March 30, 2000, the Company acquired all the outstanding common stock of Felnam Investments, Inc. ("Felnam"). The transaction was funded through the issuance of 100,000 shares of the Company's stock valued at \$0 due to the Company treating the transaction as a recapitalization of the Company. In conjunction with the transaction, the Company incurred approximately \$180,000 of

transaction costs, which are charged to operations. The net assets and results of operations of Felnam were not material to the Company's consolidated financial statements. Accordingly, pro forma financial information was not disclosed.

### NOTE 3 - AVAILABLE FOR SALE SECURITIES

Available for sale securities consist of the following at June 30, 2001:

	Cost	Fair Market Value		Unrealized Loss	
Corporate bonds due within one year	\$3,471,900	\$	3,463,509	\$	(8,391)

During fiscal 2000, the Company sold remaining shares from a previous investment with a book value of zero for \$80,557 which is included in gain on sale of securities in the accompanying statement of operations.

### NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following at June 30, 2001:

Leasehold improvements	\$ 139 <b>,</b> 268
Technical and laboratory equipment	990,061
Office equipment	31,170
	1,160,499
Less accumulated depreciation and amortization	(646,311)
	\$ 514,188
	======

### NOTE 5 - PATENTS

Patents consist of the following at June 30, 2001:

Patents \$ 79,934

Less accumulated amortization (43,067)

\$ 36,867

NOTE 6 - STOCKHOLDERS' EQUITY

Common Stock

The Company is authorized to issue 50,000,000 shares of no par value common stock. The holders of the Company's common stock are entitled to one vote for each share held of record on all matters to be voted on by those stockholders.

On September 15, 1998, the Company entered into an exchange agreement with Euro-American GmbH to sell 1,062,394 shares of its common stock at \$0.50 per share, or \$531,197. Payment was in the form of a promissory note bearing interest at 9% with monthly payments of \$24,267, maturing September 1, 2000. Principal payments of \$116,655 and \$224,413 were received on the note during the years ended June 30, 2001 and 2000, respectively. At June 30, 2001, the note is paid in full.

During the fiscal year ended June 30, 2000, the Company issued 466,485 shares of common stock to Euro-American GmbH for \$536,458 of which \$50,000 was received during the fiscal year ended June 30, 1999.

In 1999, the Company issued 2,600,000 shares of its common stock to a consultant in exchange for a public relations/promotions contract covering the period January 1999 to December 2002, as amended in August 2000. The fair value of the services, \$3,145,000, is being amortized ratably over the contract period. For the years ended June 30, 2001 and 2000, the Company recognized \$444,000 and \$1,572,500 of amortization expense, respectively. The unamortized balance of the prepaid asset at June 30, 2001 was \$661,169 which the Company has offset against stockholders' equity in the accompanying financial statements.

During 2000, the Company entered into a subscription with Euro-America GmbH valued at \$7,712,000, of which the Company received \$7,487,000. The balance, \$225,000, was recorded as stock subscription receivable as of June 30, 2000. On June 30, 2001, the Company's Board of Directors authorized - because of the deficiency in collection - the writing off of the \$225,000 of stock subscription receivable which the Company has recorded as a reduction of common stock in the accompanying statement of stockholders' equity.

Preferred Stock

The Company is authorized to issue 5,000,000 shares of non-voting no par value preferred stock. The Board of Directors has not designated any liquidation value or dividend rates. During the year ended June 30, 2001, the Company cancelled all 505,000 shares of its preferred stock that had been issued.

Stock Options

From time to time, the Company may issue stock options pursuant to various agreements and other contemporary agreements.

In November 1999, pursuant to an agreement with its chairman, the Company issued the chairman options to purchase 3,000,000 shares of common stock at an exercise price of \$0.01 valued at \$10,845,000 (under APB 25). The options can be exercised at the time the Company completes the development of the artificial oxygen carrier or the implantable sensor and receives regulatory approval from either Germany, the United States or Singapore, which the Company is amortizing to compensation expense over the remaining estimated vesting period of the options since the Company is in the process of developing the artificial oxygen carrier and implantable sensor. The options are exercisable through June 30, 2009. As a result, the Company recognized compensation expense of \$1,000,000 in fiscal 2001 related to the vesting of the options.

Option activity for the years indicated below is as follows:

	Options	Weighted
		Average Price
Outstanding, June 30, 1999	_	_
Granted	3,000,000	\$0.01
Exercised	_	_
Cancelled/Forfeited	_	_
Outstanding, June 30, 2000 and 2001	3,000,000	\$0.01
	=======	========
Exercisable, June 30,2001	_	_
	=======	
Weighted average fair value of options		
granted in 1999		\$3.62
		==========

3,000,000 of the options outstanding at June 30, 2001 have an exercise price of \$0.01 per share and a weighted average remaining contractual life of 8 years; none of these options are exercisable at June 30, 2001.

SFAS 123 Pro Forma Information

The Company has adopted the disclosure-only provisions of SFAS No. 123. Pro forma information regarding net income (loss) is required by SFAS No. 123, and has been determined as if the Company had accounted for its employee's stock options under the fair value method of SFAS No. 123. The fair value for these options was estimated at the date of grant using the Black Scholes option pricing model with the following assumptions for the year ended June 30, 2000: risk free interest rate of 6.0%; expected dividend yield of 0% (for all years); volatility factor of 62.5%; and an expected term of three years.

For purpose of pro forma disclosures, the estimated fair value of the options is amortized to expense over the option vesting period. Adjustments are made for options forfeited prior to vesting. The effect on compensation expense and net loss had compensation cost for the Company's stock option issuances been determined based on fair value on the date of grant consistent with the provisions of SFAS No. 123 is as follows for the years ended June 30:

2001 2000

Net loss

As reported. . \$(3,627,861) \$(3,119,879) Pro forma. . \$(3,627,861) \$(3,119,879)

Net loss per share:

As reported. . \$ (0.09) \$ (0.09) Pro forma. . \$ (0.09) \$ (0.09)

### NOTE 7 - INCOME TAX PROVISION

\_\_\_\_\_

There is no income tax expense recorded for the years ended June 30, 2001 and 2000, due to the Company's net losses.

Income tax expense for the years ended June 30, 2001 and 2000 differed from the amounts computed by applying the U.S. federal income tax rate of 34 percent for the following reasons:

	2001	2000
Income tax expense (benefit) at U.S. federal statutory rates .	\$(1,233,000)	\$(1,010,000)
Net operating losses not benefited	1,233,800	1,011,600
State and local income taxes, net of federal income tax effect	(800)	(1,600)
	\$ -	\$ -

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets at June 30, 2001 are presented below:

Deferred tax assets:

Net operating loss carryforwards \$ 1,638,000 Less valuation allowance. . . . (1,638,000) Net deferred tax assets. . . . \$ -

As of June 30, 2000, the Company had net operating loss carryforwards of approximately \$3,858,000 \$3,506,000, and \$3,795,000 available to offset future taxable Federal, state, and foreign income, respectively. The federal and state carryforward amounts expire in varying amounts between 2001 and 2011. The foreign net operating loss carryforwards do not have an expiration period.

## NOTE 8 - BASIC AND DILUTED LOSS PER COMMON SHARE

The following is a reconciliation of the numerators and denominators of the basic and diluted loss per common share computations:

Numerator for basic and diluted loss earnings per common share net loss \$(3,627,861) \$(3,119,8)

Denominator for basic and diluted earnings per

	========	=======
Basic and diluted loss per common stock	\$ (0.09)	\$ (0.
	========	=======

#### NOTE 9 - RELATED PARTY TRANSACTIONS

As described in Note 6, the Company wrote-off \$225,000 of stock subscription receivable due from Euro-American GmbH.

## NOTE 10 - COMMITMENTS AND CONTINGENCIES

### Operating Leases

The Company leases its office and laboratory facilities in the United States, Germany, and Singapore under three operating leases which expire through December 2003, respectively.

Future minimum lease payments under these leases at June 30, 2001 are:

June 30,	
2002 2003 2004	\$271,000 251,000 45,000
	567 <b>,</b> 000

Rent expense for the years ended June 30, 2001 and 2000 was approximately \$210,000 and \$120,000, respectively.

### Grants

In November 1998, the German state of Northrhine-Westphalia granted Sangui AG German Marks (DM) 3,574,575 for the research and development of the Company's artificial oxygen carrier. The grant originally covered the period

from April 1998 to March 2001 but was extended to June 2002. In September 1999, Northrhine-Westphalia granted the Company's subsidiary, Gluko AG, DM 4,340,764 for the research and development of the Company's long-term implantable glucose sensor. The grant originally covered the period from December 1998 to November 2001, including retroactive months, but was extended to June 2002.

The grants covers 40% of eligible research and development costs and capital expenditures and are subject to the Company's ability to cover the remaining 60% of the costs. An additional condition of the grant is that the product was originally to be developed and subsequently produced in the German state of Northrhine-Westphalia if developed by 2003.

Based on research and development expenditures and capital expenditures through June 30, 2000, the Company had qualified for \$817,560, of the grants. There

were no research and development expenditures and capital expenditures in fiscal 2001which qualified for grants. Approximately \$736,000 related to research and development expenditures has been recorded as a reduction of research and development expenses and \$81,490 related to capital expenditures was recorded as a reduction to the historical costs of property and equipment, as of June 30, 2000. As of June 30, 2001, all of the grants the Company had qualified for so far have been received.

Legal proceedings

On December 20, 2000, Axis/Shields ASA, a Norway Corporation (Axis), filed a lawsuit in the United States District Court in the Southern California District, alleging that the manufacture or sale by Sangui USA of its Carbohydrate-Deficient Transferring ("CDT") test kit, which is used to detect chronic alcohol abuse, constituted an infringement of patent rights owned by Axis. On March 26, 2001, the Company settled the lawsuit with Axis in which the Company agreed to pay Axis \$50,000 in damages which is recorded in general and administrative expenses in the accompanying consolidated statement of operations. In addition, the Company agreed to cease the manufacture and sale of the ChronAlco CDT test kit by June 26, 2001. Sales related to this test kit totalled \$312,000 and \$279,000 for the years ended June 30, 2001 and 2000, respectively. Sangui USA redesigned and introduced a new kit in May 2001.

On July 26, 2001, the Company commenced a lawsuit in the United States District Court for the District of Colorado against a director of the Company. In the lawsuit, the Company alleges that the director is engaged in conduct related to the Company's affairs that is fraudulent, dishonest and a gross abuse of his authority or discretion as a director and that his removal from the Company's Board of Directors would be in the best interest of the Company. Among other things, the Company alleges that the director caused the Company to enter into a contract without adequate disclosure of the director's conflicts of interest and that the remuneration paid in conjunction with this contract was excessive. The Company also alleges that the director is engaged in an improper exchange offer campaign involving the Company's shares. The Court issued a Temporary Restraining Order suspending the director from the Board of Directors of the Company and restraining the director from pursuing the exchange offer. The Temporary Restraining Order has expired. The Company has filed a Motion for Preliminary Injunction which is pending.

The Company seeks the removal of the director from the Company's Board of Directors, an injunction against the director and his affiliates from exchanging the Company's shares for shares of an entity in which the director has a financial interest, compensatory damages in an amount to be determined and costs of the action. The director has not yet filed an Answer to the Complaint by the Company in the lawsuit.

NOTE 11 - BUSINESS SEGMENTS

The Company Reports it business segments based on geographic regions, which are As follows for the years ended June 30:

2001 2000

Net sales:		
Sangui USA	\$ 567,007 - - -	\$ 429,400 - - -
	\$ 567,007 ======	\$ 429,400
Net loss:		
Sangui USA	\$1,895,170 1,102,167 447,456 183,068  \$3,627,861	\$2,397,120 548,587 156,460 17,712  \$3,119,879
Depreciation and amortization		
Sangui USA	\$ 14,570 98,031 34,590	\$ 42,264 91,242 17,811
	\$ 147,191 =======	\$ 151,317
Identifiable assets		
Sangui USA	\$1,288,538 2,491,604 2,828,593 322,098  \$6,930,833	

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON AN ACCOUNTING AND FINANCIAL DISCLOSURE

None

ITEM 13 EXHIBITS AND REPORTS ON FORM 8-K

(a) Index to Exhibits

Exhibit No.

2.1 (1) Exchange Agreement between MRC Legal Services LLC and SanguiBioTech International, Inc., dated of March 31, 2000 (1)

- 3.1 (1) Articles of Incorporation of the Company (1)
- 3.2 (1) Bylaws of the Company(1)
- 3.3 Articles of Association of GlukoMeditech Aktiengesellschaft (2)
- 3.4 Articles of Association of SanguiBiotech Aktiengesellschaft (2)
- 3.5 Memorandum and Articles of Association of Sangui Biotech Singapore Pte. Ltd. (3)
- 4.1 Stock Option Agreement between Professor Wolfgang Barnikol and Sangui Biotech International, Inc. dated October 12, 2000 (2)
- 10.1 Office Lease between Brookhollow Office Park and Sangui Biotech International, Inc. dated September 4, 1996 and as amended 2000 (3)
- 10.2 Fee Agreement between GlukoMeditech AG and Dr. Seiglinde Borchert dated June 15, 1998 (2)
- 10.3 Fee Agreement between SanguiBiotech AG and Dr. Seiglinde Borchert dated June 15, 1998 (2)
- 10.4 Service Contract between GlukoMeditech AG and Dr. Wolfgang Barnikol dated June 30, 1998 (2)
- 10.5 Service Contract between SanguiBiotech AG and Dr. Wolfgang Barnikol dated June 30, 1998 (2)
- 10.6 Service Agreement between Axel Kleinkorres Promotionsagentur and Sangui Biotech International, Inc. dated April 26, 1999 (2)
- 10.7 Amendment to Service Agreement between Axel Kleinkorres Promotionsagentur and Sangui Biotech International, Inc. dated August 18, 2000 (2)
- 10.8 Appropriation Notice from North-Rhine-Westphalia to GlukoMediTech AG dated November 30, 1998 (2)
- 10.9 Appropriation Notice from North-Rhine-Westphalia SanguiBiotech AG dated November 30, 1998 (2)
- 10.10 Lease Contract for Business Rooms between Research and Development Centre, Witten, Germany and GlukoMeditech AG dated June 6, 2000 (2)
- 10.11 Additional Agreement to Lease Contract between Research and Development Centre, Witten, Germany and GlukoMeditech AG dated June 7, 2000 (2)
- 10.12 Additional Agreement to Lease Contract between Research and Development Centre, Witten, Germany and SanguiBiotech AG dated June 7, 2000 (2)
- 10.13 Assignment of Patents and Royalty Agreement with Dr. Wolfgang Barnikol (3)
- 10.14 Prolongation Letter for SanguiBiotech AG Grants
- 21.1 Subsidiaries of the Company (2)

(2) Filed as an Exhibit to the original Report on Form 10-KSB filed on

<sup>(1)</sup> Filed as an Exhibit to the Report on Form 8-K filed on or about April 4, 2000 and incorporated herein by reference.

October 13, 2000.

- (3) Filed as an Exhibit to the amended Report on Form 10-KSB filed on November 20, 2000.
- (b) Reports on Form 8-K

None

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report on Form 10-KSB to be signed on its behalf by the undersigned hereunto duly authorized.

SANGUI BIOTECH INTERNATIONAL, INC.

/s/ Wolfgang Barnikol

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Wolfgang Barnikol President and Director

Date: September, 28, 2001

In accordance with the Exchange Act, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ Wolfgang Barnikol Professor Wolfgang Barnikol, M.D., Ph.D.	President and Chief Executive Officer	9/28/01
/s/ Sieglinde Borchert Sieglinde Borchert, Ph.D.	Chief Operating Officer	9/28/01
/s/ Harald Potzschke. Harald Potzschke, M.D.	Chief Scientific Officer	9/28/01
/s/ Detlev Baron Von Linsingen Detlev Baron Von Linsingen	Chief Financial Officer	9/28/01
/s/ Patrick Onishi Patrick Onishi	Corporate Secretary	9/27/01
/s/ Oswald Burkhard Oswald Burkhard, M.D., Ph.D	Director	9/27/01
/s/ Dora Malek Dora Malek, attorney	Director	9/27/01

/s/ Joachim Lutz

Professor Joachim Lutz, M.D. Director 9/27/01

[unsigned]

Helmut Kappes Director