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BIOSPECIFICS TECHNOLOGIES CORP

Form 10KSB

November 22, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-KSB

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 0-19879

BIOSPECIFICS TECHNOLOGIES CORP.

(Name of small business issuer in its charter)

Delaware

11-3054851

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification No.)

35 Wilbur Street, Lynbrook, New York

11563

(Address of principal executive offices)

(Zip Code)

Issuer's telephone number, including area code: (516) 593-7000

Securities registered pursuant to Section 12(b) of the Act: None Securities
registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$.001

Check whether the Issuer (1) filed all reports required to be filed by
Section 13 or 15(d) of the Exchange Act 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 ☐ No ☒

Check if there is no disclosure of delinquent filers in response to
Item 405 of Regulation S-B contained in this form and no disclosure will be
contained, to the best of Registrant's knowledge, in definitive proxy or
information statements incorporated by reference in Part III of this Form 10-KSB
or any amendment to this Form 10-KSB. ☐

Issuer's revenues for its most recent fiscal year were approximately
\$3,240,000. The aggregate market value of common voting stock held by
non-affiliates of the Issuer was \$5,264,510 computed by reference to the last

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sale price at which the stock was sold on November 1, 2004 as reported by the OTC Pink Sheets. As of November 1, 2004, 5,326,341 shares of common stock were outstanding.

PART I

ITEM 1. BUSINESS OF BIOSPECIFICS

The entire discussion in this report, as well as any other management discussion of the Company's goals and expectations, contains Forward-Looking statements that are subject to certain risks and uncertainties that could cause actual results to differ materially from those projected. The words believe, expect, intend, anticipate, variations of such words and similar expressions identify Forward-Looking statements, but their absence does not mean that the statement is not Forward-Looking. These statements are not guaranties of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Item 1 Business of BioSpecifics, including without limitation, Risk Factors, and Item 6 Management's Discussion and Analysis, as well as those discussed in any documents incorporated by reference herein. Readers are cautioned not to place undue reliance on these Forward-Looking statements, which speak only as of the date of this report. BioSpecifics undertakes no obligation to update any Forward-Looking statement to reflect new information, events or circumstances after the date of this report or to reflect the occurrence of unanticipated events. When used in this annual report, the terms BioSpecifics, Company, we, our, ours and us refer to BioSpecifics Technologies Corp. and its consolidated subsidiaries.

OVERVIEW

Biospecifics Technologies Corp., was incorporated in Delaware in 1990. Since that time the Company and its subsidiaries have not entered into bankruptcy, receivership, or any similar proceedings, and have not had any material reclassifications, merger, consolidation or purchase or sale of a significant amount of assets not in the ordinary course of business. We have been engaged in the business of manufacturing and licensing for sale a fermentation derived enzyme named Collagenase ABC (the "enzyme" or the "product"), approved by the U.S. Food and Drug Administration ("FDA") for debriding chronic dermal ulcers and severely burned areas. This product is by prescription only in the United States and is applied topically. We are also developing additional products derived from this enzyme for potential use as pharmaceuticals. On June 3, 2004 we signed a development and licensing agreement with Auxilium Pharmaceuticals, Inc ("the Auxilium Agreement") that covers all potential uses of the enzyme in an injectable form other than for wound healing (see subsequent events for more detail).

We derive most of our net sales of the product, (historically, approximately 90%) and all royalty revenues, from one customer in the United States, Abbott Laboratories and its subsidiaries ("Abbott") who, pursuant to an exclusive licensing agreement (the "Agreement"), compounds the product into Collagenase Santyl(R) Ointment ("Santyl(R)" or "ointment"), a topical prescription drug used to treat dermal ulcers and burns. The royalty revenues from Abbott were earned on North American sales of Santyl(R) to distributors by Smith & Nephew, Inc. ("S&N") through December 31, 2003. On June 30, 2003 a sub-license agreement under which S&N marketed Santyl(R) ointment terminated. Effective January 1, 2004, the Ross Products Division of Abbott Laboratories Inc. assumed United States marketing responsibility for Collagenase Santyl(R) Ointment. During 2003, the Abbott Agreement automatically renewed for an additional 10-year period, to August 2013. Collagenase Santyl(R) Ointment is sold primarily to long-term care

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centers.

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In June 2004, we entered into a development and license agreement with Auxilium Pharmaceuticals, Inc. ("the Auxilium Agreement"). Under the agreement, we have granted Auxilium the rights to develop products containing our enzyme ("AA4500") for the treatment of Peyronie's and Dupuytren's disease. We have granted Auxilium the exclusive world-wide license to any products developed under the agreement other than dermal formulations labeled for topical administration. We also granted Auxilium the option to develop and license the technology for use in other indications other than dermal formulations labeled for topical administration. The agreement extends, on a country-by-country and product-by-product basis, for the longer of the patent life, the expiration of any regulatory exclusivity period or 12 years. Auxilium may terminate the agreement with 90 days written notice. Auxilium is obligated to pay all clinical and regulatory development costs on an on-going basis, to purchase commercial inventory from us and to pay royalties based on product sales. In addition, Auxilium is obligated to make milestone payments for contract initiation, receipt of technical data, manufacturing process development, the one-year anniversary date, filing of regulatory applications and receipt of regulatory approval.

In June 2004, we received an up-front payment under the agreement totalling \$2,500,000. In August 2004, we received an additional \$2,500,000 for delivery of all in-process research and development material product data relating to Dupuytren's and Peyronie's disease. We may also receive up to \$10,500,000 of contingent milestone payments under this agreement if all existing conditions are met. Additional milestone obligations may be due if Auxilium exercises an option to develop and license our enzyme for additional medical indications.

Prior to the signing of the Auxilium Agreement, we funded operations by (1) modification of the terms of two loans, principally, by deferring a balloon payment of \$364,000 due in November 2003 to November 2004; and deferring the payment of \$100,000 principal due on a promissory note from March 2004 to March 2005; (2) receiving a \$250,000 advance of royalties from Abbott Laboratories, our major customer, in January 2004 and a \$500,000 royalty advance at the end of March 2004, both of which are to be repaid from royalties to be earned from distribution of Santyl(R) Ointment during 2004 (of which \$94,000 and \$130,000 were repaid from royalties earned during the respective quarters ended March 31, 2004 and June 30, 2004); (3) our chairman's deferred salary of \$100,000 during the three months ended June 2003 has been applied against the chairman note receivable in March 2004 and (4) deferring or making partial payments to creditors. Due to manufacturing problems encountered in 2003, we will be able to supply Abbott with only limited quantities of our enzyme throughout 2004 and will continue to incur significant operating losses exclusive of the income received from the Auxilium Agreement. As a result of payments received under the Auxilium Agreement, we generated positive cash flow during both the second and third quarters of 2004.

In March 2003 we changed our fiscal year end from January 31 to December 31. Our first fiscal year using this new basis is the twelve months ending December 31, 2003 similarly in this report we compare the twelve months ended December 31, 2003 ("calendar year 2003") to the twelve months ended January 31, 2003 ("fiscal year 2003").

The year ended January 31, 2003 is not materially different to the eleven month period, therefore the eleven months ended December 31, 2002 is not presented.. The eleven months period ended December 31, 2003 is also presented.

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THE COMPANY'S PRODUCT AND MARKETS

Collagenase ABC

Our principal drug product, Collagenase ABC, is an enzyme that digests collagen, the body's principal connective tissue. The drug is approved by the FDA for topical enzymatic debridement of dermal ulcers (wounds), such as pressure ulcers (also known as "bed sores") and second and third degree burns.

In general, necrotic (i.e., dead or devitalized) tissue must be debrided (removed) from a dermal ulcer either surgically, by enzyme, or by autolysis (the much slower natural process) before proper healing can take place. Necrotic tissue is largely collagen and is anchored to dermal ulcers by strands of collagen. The unique ability of collagenase to digest collagen in necrotic tissue and thereby effect the debridement of a wound is an important part of the healing process associated with dermal ulcers and helps provide a healthy base for the growth of new tissue. Collagenase ABC does not attack collagen in healthy tissue or in newly formed granulation tissue.

Manufacture, Sale and Distribution of Collagenase ABC

Our collagenase ABC enzyme powder is the active pharmaceutical ingredient of a topical ointment, known as Collagenase Santyl(R) Ointment (Santyl(R)) in the United States. We do not directly market the product to end-users. We manufacture and supply the product in powder form, primarily to Abbott, and to a lesser extent, pharmaceutical companies in Brazil and India, which compound the product into ointment that is then marketed to end-users.

In 1999, as a result of inspectional observations made by the FDA, on Form 483, of deficiencies in our compliance with FDA good manufacturing practices and policies ("GMP") regulations at our Lynbrook and Curacao facilities, and at Abbott Laboratories, (hereinafter referred to as "our Subcontractor"), the FDA advised us in a letter (the "FDA letter") that it would revoke our license to manufacture the enzyme and ointment unless we could immediately provide satisfactory assurance to the FDA (including submitting a comprehensive plan of corrective action) addressing the FDA's observations and demonstrate compliance with the applicable GMP regulations. We submitted such a plan in 1999.

Pursuant to this plan, we voluntarily suspended manufacture of the product in March 2000 to allow for major renovations at our manufacturing facilities in Curacao and Lynbrook. Beginning March 2000, we supplied Abbott with the product from inventory built up in anticipation of the upgrade. This built up inventory was depleted in July 2002.

The FDA notified us on July 28, 2003 that our request to supplement our biologics license for collagenase ABC was approved ("FDA approval"). The supplement included major renovations to the manufacturing facility, utility systems, and process equipment at our Curacao facility. The FDA notification acknowledged our written commitments to provide additional information regarding ongoing studies and when to submit this information to our biologics license for review. As a result of the FDA approval, enzyme product manufactured at the Curacao facility is now being distributed to Abbott. Regardless of this FDA approval, the FDA letter will remain in effect until we demonstrate compliance with the applicable federal standards and regulations, which we understand to be two "satisfactory annual GMP inspections" of our Lynbrook and Curacao manufacturing facilities. We believe that we have made progress in complying

with the applicable federal standards and regulations, although there can be no assurances as to when the FDA letter will be rescinded, if at all. During the quarter ended June 30, 2004, the FDA completed an inspection of our Lynbrook facility. We are hopeful that after the next FDA inspection is completed at our Lynbrook facility, we will be eligible to have the FDA letter rescinded. In May 2004, the FDA inspected the facility of our Subcontractor. To the best of our knowledge, the FDA has not commented on the inspection, nor is the FDA obligated to do so. The FDA has not conducted an inspection of our Curacao facility since July 2002.

Prior to the FDA approval, the renovated Curacao facility went into limited production of quarantine inventory during the fiscal year ended January 31, 2002. However, FDA approval was required before Santyl(R) could be made from inventory manufactured at the renovated Curacao facility. With FDA approval, deliveries of finished inventory of the product manufactured at the renovated Curacao facility were subsequently resumed. There have been no studies made to determine how substantial the impact of prior manufacturing delays have been on the market for Santyl(R) Ointment.

Abbott Agreement and Sublicense

In March 2001, Abbott Laboratories acquired Knoll Pharmaceutical Company ("KPC", collectively, "Abbott"), our original licensee for product applications relating to the treatment of skin ulcers and burns. Since 1972, we have sold Collagenase ABC, our only commercial product to date, principally in the United States through exclusive license agreements with Abbott, under which we supply Abbott with the product, monitor the production of Santyl(R) by Abbott, and collect a royalty on the distribution of Santyl(R) (the "Abbott Agreement" or the "Agreement"). KPC marketed the ointment under its registered trademark, Collagenase Santyl(R), in the United States from 1972 to January 2000, and in Canada from 1994 to January 2000. Commencing February 2000, S&N began marketing Collagenase Santyl(R) under a sublicensing agreement made with KPC, which Abbott assumed. The January 2000 sub-license agreement under which S&N marketed Santyl(R) ointment terminated on June 30, 2003 but S&N agreed to continue to market Collagenase Santyl(R) through the end of 2003. The Ross Products Division of Abbott Laboratories Inc. assumed United States marketing responsibility for Collagenase Santyl(R) Ointment effective January 1, 2004. During calendar 2003, the Abbott Agreement automatically renewed for an additional 10-year period, to August 2013.

It is our belief that we will be able continue providing Abbott with quantities of the enzyme they require on a going forward basis. The Abbott Agreement provides that Abbott is our exclusive licensee to market Collagenase Santyl(R) ("Santyl(R)") in the United States and Canada so long as Abbott uses its best efforts to increase sales. Abbott pays us for the product, at a price that is subject to annual adjustment based upon increases in our actual manufacturing costs, not to exceed increases in the consumer price index for certain items. Abbott also pays us a royalty based upon net Santyl(R) sales. Royalties for the calendar year ended December 31, 2003 and the fiscal year ended January 31, 2003 were approximately \$1,684,000 and \$2,141,000, respectively. As part of the Abbott Agreement, KPC and its U.S. affiliates, and its successor Abbott, (i) agreed not to seek, or become a party to, any license or other agreement for the production or purchase of collagenase powder or collagenase ointment from any source other than us, (ii) will make no efforts to achieve registration with the FDA for collagenase powder manufactured by parties other than us, and (iii) will not collaborate with any third party attempting to achieve a registration.

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Abbott accounted for approximately \$3,093,000 and \$3,196,000 of our product sales and royalties for the calendar year 2003 and fiscal year 2003, respectively. These amounts were approximately 95% and 78% of our revenues during the calendar year 2003 and fiscal year 2003, respectively. At December 31, 2003, we had approximately \$1.6 million of firm booked orders with Abbott for the product. We will not be able to fulfill all these orders in a timely manner due to the time required to manufacture our product. Both parties have agreed on a manufacturing and delivery timetable for future deliveries of product and manufacture of Santyl(R).

Our product is approved in two other countries, Brazil and India, and sold to commercial customers in those countries, who compound the product into ointment. During the calendar year ended December 31, 2003 and the fiscal year ended January 31, 2003, sales to the customer in Brazil represented approximately 0% and 19% of total revenues, respectively, and sales to the customer in India represented approximately 5% and 3% of total revenues, respectively. We have a license agreement with the customer in India. There is no license and supply agreement with the customer in Brazil, and we will only make limited deliveries of the product to either our Brazilian or Indian customers at least through 2004, as we are currently devoting all of our manufacturing to Abbott's requirements. The product and purified collagenase are also sold for non-sponsored research purposes.

Other Agreements for the Distribution of Collagenase ABC

In 1994, we entered into a 10-year license and supply agreement with a Swiss pharmaceutical company to market an ointment containing the product in two European countries and several Middle Eastern countries. In June 1994, we entered into a multi-year license with an Italian pharmaceutical company that had agreed to market an ointment containing the product in Italy subject to the receipt of requisite Italian governmental approval. The Company is no longer pursuing these agreements as the enzyme has not received approval in any of these countries.

In 1996, we entered into an agreement to license the product for sale as an ointment in Germany to the German subsidiary of an international pharmaceutical company. The agreement called for an initial payment on signing and further payments if, and when, the German health authority grants marketing approval of Collagenase ABC ointment. During fiscal 1997, we recognized \$20,000 in license fees and deferred revenue of \$45,000 from this agreement. We submitted collagenase ointment to the German health authority for marketing approval in 1997, whose final decision remains pending.

Proposed Products and Uses

We expect that a substantial portion of our business activities in the future will be the research and development ("R&D"), followed by manufacturing and licensing, of various proposed injectable Collagenase ABC products and their uses. It is anticipated that the terms of the Auxilium Agreement will provide us with sufficient funds to continue such research and development and provide us with the necessary funding to set up a manufacturing facility for the injectable.

Injectable Collagenase ABC

We have developed a proprietary process to further purify Collagenase ABC. We have investigated using this purified form of collagenase as an injectable to

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remove collagen that interferes with normal bodily functioning or is unsightly.

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We, our affiliates, and individual investigators are clinically testing in the United States injectable collagenase for treatment of Dupuytren's disease, Peyronie's disease, frozen shoulder, and lipolysis. See "Investigational New Drug Applications ("IND's") for Injectable Collagenase ABC". We produced purified collagenase for injection at our facility in Lynbrook, N.Y. that has been, and will be, used in U.S. clinical trials. Effective with the signing of the agreement with Auxilium, Auxilium will be responsible for completion of any Phase 2 and Phase 3 clinical studies for all potential uses they elect to pursue. We will still be responsible for all Phase 1 clinical studies. We sell small amounts of purified collagenase for non-human research in the United States and other countries.

Investigational New Drug Applications ("INDs") for Injectable Collagenase ABC

We, our affiliates, or individual investigators have filed INDs with the FDA, and are in the clinical testing process, for additional products using injectable Collagenase ABC. The INDs permit testing our drug candidates on humans. None of these products have completed testing.

Dupuytren's Disease

Dupuytren's disease is a deforming condition of the hand in which one or more fingers, commonly the ring and little fingers, contract toward the palm, often resulting in functional disability. We were granted a United States patent for the use of our collagenase enzyme to treat this condition in July 2000. The use of collagenase for the treatment of Dupuytren's disease has received "orphan drug" designation from the FDA. Orphan drug designation is based on the provisions of the Orphan Drug Act. The designation is given to products used to treat a specified rare disease or condition defined as affecting fewer than 200,000 people in the United States. Orphan drug designation imparts certain benefits including a seven year period of exclusivity after approval for marketing, the ability to apply for clinical research grant funds, tax credits for costs of clinical trials performed in the U.S., assistance from FDA in protocol development, and possible waivers from "user fees" charged by the FDA after drug approval. A dose response study was successfully completed at Stanford University and at State University at Stony Brook Hospital and Medical Center ("Stony Brook"). The results were submitted to the FDA in support of concluding Phase 2. An end of Phase 2 meeting was held in August 2001 with the FDA to discuss how to proceed with Phase 3 studies. The investigators at Stony Brook received a grant from the FDA in September 2002 to conduct Phase 3 clinical trials to determine safety and efficacy of collagenase for this use. The clinical trials on Dupuytren's disease are summarized in an article in the September 2002 issue of the Journal of Hand Surgery. As part of the agreement with Auxilium, Auxilium is responsible for all Phase 3 clinical trials, along with the related expenses.

Peyronie's Disease

We are seeking to develop a product for the treatment of Peyronie's disease, a condition in which collagen plaques form on the shaft of the penis and interfere with erection and sexual intercourse. Initial tests on approximately 200 men have shown favorable results in dissolving the plaques by injecting purified collagenase directly into such plaques. We cannot assure you that this treatment

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will be proven effective. We were awarded a patent for this use in March 2000 and received "orphan drug" designation from the FDA in March 1996. A study to optimize this treatment was completed at Devine-Tidewater Urology, Norfolk, Virginia, the largest United States center for the study and treatment of

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Peyronie's disease. In August 1999, the trial's investigator reported on 22 patients who were treated in an open label trial. The investigator reported encouraging results. A new clinical trial was initiated in January 2004 and the study is continuing. As part of the agreement with Auxilium, Auxilium is responsible for all further clinical trials with the related expenses.

Frozen Shoulder

Frozen shoulder is a clinical syndrome of pain and severely decreased motion in the shoulder joint. This syndrome afflicts up to 2 million patients annually. A double blind randomized placebo controlled dose response study is being conducted at Stony Brook using collagenase injection for treatment of adhesive capsulitis, better known as "frozen shoulder. Positive clinical results were presented at the March 2004 meeting of the Orthopaedic Research Society in San Francisco.

Lipolysis

Lipomas are benign fatty tumors that occur as bulges under the skin. A clinical investigation is currently being performed with collagenase injection in the treatment of skin lipomas. . The concept of using collagenase for removal of fat is discussed in a European Patent Application issued June 2002.

OTHER PROPOSED PRODUCTS AND USES

Treatment of Burns

Collagenase Santyl(R) has received FDA approval for the treatment of burns. A number of studies have been conducted, which compared the efficacy of Collagenase Santyl(R) to standard treatment (silver sulfadiazine), for deep second degree burns. The results of these studies have been favorable showing faster cleaning and healing, as well as economic benefits. We are considering the development of other dosage forms for the treatment of burns.

Collagenase for Wound Healing

In vitro studies conducted at Tufts University Medical School showed that collagenase treatment of skin cells significantly enhances cell migration and growth after injury. Clinical and laboratory investigations further profiling the potential role of collagenase and its pharmacological activity in wound healing are being pursued. We have been assigned two patents awarded to Tufts University relating to this discovery. Pre-clinical experiments have been conducted. Additionally, clinical experiments to confirm the observations made at Tufts are being planned.

Glaucoma and Treatment of Other Eye Disorders

We collaborated with Bausch & Lomb in a clinical investigation to confirm

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previous studies on the use of our collagenase to treat glaucoma. The collagenase treatment reduced IOP (intraocular pressure) in open angle glaucoma patients for at least three months post treatment with no vision-threatening complications. The results of the clinical investigation were published in May 2002 in the Archives of Ophthalmology.

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PRODUCT LIABILITY

The sale of the product, as well as the development of any additional products of ours, exposes us to potential product liability claims, both directly from patients using the product or potential products, as well as from our agreement to indemnify certain distributors of the products for claims made against such distributors. We have limited product liability insurance for the use of Collagenase Santyl(R) and clinical experiments in the United States for its additional product candidates. To date, no product liability claims have been made against us.

COMPETITION

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, are engaged in activities similar to ours. Many of our competitors have substantially greater financial and other resources, larger research and development staffs, and significantly greater experience in regulatory approval procedures. We do not have comparable resources, and do not intend to compete with, major pharmaceutical companies in drug marketing, except in possible niche marketing, for one or more of the products, if feasible.

Our debriding ointment product, Collagenase Santyl(R), competes primarily with other available enzymatic debridement products in the United States. Those currently available are manufactured or marketed by Healthpoint Ltd. and the Dow B. Hickam division of Marion Labs. Since January 2004, S&N has been marketing a non-collagenase enzymatic debriding ointment in the United States. A potential debridement agent was known to be under development by Genzyme Tissue Repair Division, and other large drug companies may also have debridement products under development. Debriding products also compete with surgical debridement and mechanical debridement using hydrotherapy. We believe enzymatic debridement is superior to surgical and mechanical debridement, because those procedures are painful, labor intensive, and remove viable tissue along with necrotic tissue. In December 1994, the Federal Agency for Health Care Policy and Research ("AHCPR") issued Clinical Practice Guideline Number 15 entitled "Treatment of Pressure Ulcers". Collagenase is the only product suggested for enzymatic treatment of pressure ulcers by the guideline. Unlike the other available enzymatic debriding products, ours is collagen specific. Approximately 75% of skin is collagen, making this enzyme particularly appropriate for the debridement of necrotic tissue.

In Europe, Knoll AG ("KAG") markets an ointment substantially similar to our Collagenase Santyl(R) Ointment under the trade name "Irurol(R)". In January 2000, Smith & Nephew plc acquired worldwide marketing rights to Irurol(R) excluding the United States and Canada, as that ointment is not FDA approved for sale in the United States or Canada. KAG, which, as part of the global pharmaceutical business of BASF, was acquired by Abbott in March 2001.

Colleges, universities, governmental agencies and other public and private research organizations continue to conduct research, and are becoming more active in, seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed, some of which may be

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directly competitive with our products. We expect competition to intensify as technological advances occur in the development of pharmaceutical products of biologic origin.

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MARKETING

We do not have our own sales staff and instead rely on licensees who have recognition and acceptance in the marketplace. During the quarter ended December 31, 2003, we decided to liquidate our German subsidiary, Biospecifics Pharma GmbH, which was established in November 1995. Its purpose was to identify additional licensees, assist us in achieving the clinical and scientific data necessary to obtain product approvals in the EU, and assist licensees in registration of products, which objectives were not realized. See "Employees".

We may decide to directly market certain products under development, particularly if the market is well defined, the number of specialists who address the targeted indication is small, and we have the financial resources at that time to engage in those activities.

RESEARCH AND DEVELOPMENT

Since inception (1957 and 1976 for the New York and Curacao subsidiaries, respectively), we have expended over \$27.2 million in research on collagenase and other products. We incurred approximately \$885,000 and \$1,069,000 in research and development activities during calendar year 2003 and fiscal year 2003, respectively.

GOVERNMENT REGULATION

Regulation in the United States

All pharmaceutical manufacturers in the U.S. are subject to extensive regulation by the federal government, principally the FDA, and, to a lesser extent, by state governments. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other federal statutes and regulations govern or influence the testing, approval, manufacture, safety, labeling, storage, record keeping, advertising, promotion, sale and distribution of products. Non-compliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of the government to enter into supply contracts or to approve new drug applications, and criminal prosecution. The FDA also has the authority to revoke drug approvals previously granted.

Our products in development will require regulatory clearance prior to commercialization. The nature and extent of regulation may differ with respect to different products. In order to test, produce, and market certain therapeutic products in the United States, mandatory procedures and safety standards, approval processes, and manufacturing and marketing practices, established by the FDA, must be satisfied. Obtaining FDA approval has historically been a costly and time-consuming process.

We are also licensed by, registered with, and subject to, regulation and periodic inspection by the New York State Department of Health and the New York State Board of Pharmacy, pursuant to federal and state legislation relating to drugs and narcotics.

In 1999, as a result of inspectional observations made by the FDA, on Form 483, of deficiencies in our compliance with FDA good manufacturing practices and

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policies ("GMP") regulations at our Lynbrook and Curacao facilities, and at Abbott Laboratories, (hereinafter referred to as "our Subcontractor"), the FDA advised us in a letter (the "FDA letter") that it would revoke our license to manufacture the enzyme and ointment unless we could immediately provide satisfactory assurance to the FDA (including submitting a comprehensive plan of corrective action) addressing the FDA's observations and demonstrate compliance with the applicable GMP regulations. We submitted such a plan in 1999.

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Pursuant to this plan, we voluntarily suspended manufacture of the product in March 2000 to allow for major renovations at our manufacturing facilities in Curacao and Lynbrook. Beginning March 2000, we supplied Abbott with the product from inventory built up in anticipation of the upgrade. This built up inventory was depleted in July 2002

The FDA notified us on July 28, 2003 that our request to supplement our biologics license for collagenase ABC was approved ("FDA approval"). The supplement included major renovations to the manufacturing facility, utility systems, and process equipment at our Curacao facility. The FDA notification acknowledged our written commitments to provide additional information regarding ongoing studies and when to submit this information to our biologics license for review. As a result of the FDA approval, enzyme product manufactured at the Curacao facility is now being distributed to Abbott. Regardless of this FDA approval, the FDA letter will remain in effect until we demonstrate compliance with the applicable federal standards and regulations, which we understand to be two "satisfactory annual GMP inspections" of our Lynbrook and Curacao manufacturing facilities. We believe that we have made progress in complying with the applicable federal standards and regulations, although there can be no assurances as to when the FDA letter will be rescinded, if at all. During the quarter ended June 30, 2004, the FDA completed an inspection of our Lynbrook facility. We are hopeful that after the next FDA inspection is completed at our Lynbrook facility, we will be eligible to have the FDA letter rescinded. In May 2004, the FDA inspected the facility of our Subcontractor. To the best of our knowledge, the FDA has not commented on the inspection, nor is the FDA obligated to do so. The FDA has yet to conduct an inspection of our Curacao facility.

Foreign Regulation of Pharmaceutical Products

The marketing of pharmaceutical products outside the United States is subject to the regulatory requirements of the country in which the product is marketed. These requirements may vary widely from country to country. Approval in foreign countries is required regardless of whether FDA approval has been obtained in the United States. Nevertheless, the time required to obtain such approval may be longer or shorter than required to obtain FDA approval, and there can be no guarantees that such approvals will be granted.

Our subsidiary in Curacao has produced the pharmaceutical substance "Collagenase ABC (Sterile)" for incorporation into ointment. As this product is not a pharmaceutical end product, it need not be officially registered with the Bureau of Pharmaceutical Affairs of the Netherlands Antilles (the "Pharmaceutical Bureau"). However, the plant in which the product has been produced and the production process are subject to inspection by the Pharmaceutical Bureau under the laws and regulations of the Netherlands Antilles. Production was suspended during the upgrade, as discussed above in "Regulation in the United States". Production restarted during the third quarter of 2003.

PATENT AND TRADEMARK PROTECTION

Patents

We are the assignee or licensee of nine U.S. and one European patent. We are not able to ascertain whether these patents will provide any value. We are the assignee of additional U.S. patent rights that have expired as well as certain

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foreign patent rights corresponding to certain of the foregoing patents. We have other patents under application. There can be no assurances when, if ever, such patents will be issued, or that such patents, if issued, will be of any value to us.

Trademarks

We have registered the name Salutyl(R) for our collagenase ointment in a number of countries other than the United States. Trademarks for other countries are protected for varying periods of time. We use the trademarked name "Cordase" for the injectable collagenase being developed for the treatment of Dupuytren's disease.

EMPLOYEES

We have 39 full-time employees, of which 23 are located at the Lynbrook facility and 16 are at the Curacao facility. There are also 5 part-time employees in Lynbrook and 1 in Curacao. None of these employees are represented by a union. We consider our relationship with our employees to be good.

We have entered into confidentiality agreements with most of our employees. Pursuant to such agreements, each employee in Lynbrook agrees to keep all of our proprietary and other information secret and confidential and to return all property to us upon termination. These employees further agree not to divulge any trade secrets during their respective terms of employment and thereafter without our prior written consent and further to assign to us all inventions, discoveries, and improvements which they make during the term of employment, within one year thereafter, or utilizing any of our trade secrets. The agreement executed by Curacao employees provides that they will not divulge any data connected with the production process in Curacao. There can be no assurance that any particular court would enforce any, or all, of the terms of any such agreements.

We have ceased operations in Germany and are in the process of liquidating our subsidiary in Germany, Bio Pharma, which was managed by Rainer Friedel, MD., and Ph.D. Dr. Friedel was a member of our board of directors until his resignation on April 30, 2004.

RISK FACTORS RELATED TO OUR BUSINESS

Substantial debt levels

In November 2001, ABC-Curacao borrowed a non-amortizing loan of \$455,000 at 6.5% interest due in November 2003 from Korpodeko, a Netherlands Antilles agency. In connection with this loan, ABC-Curacao agreed to pledge as collateral substantially all of the assets owned by ABC-Curacao, including the upgraded facility's manufacturing assets with a book value of approximately \$4.7 million at December 31, 2003. BioSpecificals has also guaranteed the Korpodeko loan. In September 2003, Korpodeko agreed to modify the terms of the loan. Korpodeko permitted us to repay 20%, or \$91,000 of the loan principal, which we did in

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December 2003, and pay the remaining principal, or \$364,000 in November 2004. In return, we agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004.

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On March 11, 2003, we borrowed \$100,000 from an unaffiliated individual lender, evidenced by a one-year promissory note, bearing interest of 8% per annum. We also granted to the lender warrants to purchase up to 10,000 common shares of BioSpecifics at \$1.18, the closing price on that day, until March 11, 2008. The cost associated with these warrants, based on Black-Scholes methodology, is \$5,000 and was recorded as interest expense during the calendar year ended December 31, 2003. Our chairman has personally guaranteed this loan. On March 8, 2004, the lender agreed to extend the promissory note for one year, or until March 11, 2005.

On June 19, 2003, the Company entered into a financing transaction with Bio Partners LP, a private investor group, pursuant to which the Company sold to Bio Partners in a private placement (i) a \$1.575 million convertible note, (the "Note") issued at face value, and (ii) 295,312 shares of Company common stock, issued at par value, or \$.001 per share. The net proceeds to the Company were approximately \$890,000, after the payment of expenses and repayment of \$500,000 previously advanced to the Company by a principal of Bio Partners.

The Note matures on June 19, 2005 and bears interest at a rate of 12% per annum with an effective interest rate of 36%. Interest-only payments under the Note are payable monthly in arrears and the entire principal amount is payable at maturity. At the time the agreement was made, up to \$1,141,875 aggregate principal amount of the Note is convertible into the Company's common stock at any time, at a conversion price of \$2.50 per share, subject to customary adjustments. The Note also contains restrictions on the Company's ability to incur debt as long as the Note is outstanding. The Note is secured by a pledge of substantially all of the assets of the Company and the Company's New York subsidiary, Advance Biofactures Corporation ("ABC"). In addition, ABC has guaranteed the obligations of the Company under the Note and our chairman, Edwin H. Wegman, has personally guaranteed 50% of the obligations of the Company under the Note. The loan discount of \$281,000 and loan costs of \$258,000 on the Note are being amortized over two years, the expected life of the Note.

Reliance on a Single Product for Revenues

Collagenase ABC enzyme is our sole source of revenues from the sale of product. Commencing with the second quarter of 2004, we began receiving payments under the terms of the Auxilium Agreement.

Uncertainty of Government Regulatory Requirements and Future Manufacture of the Enzyme

The manufacture and marketing of Collagenase ABC enzyme is subject to regulation in the United States by the federal government, principally the FDA. As previously discussed, we stopped manufacturing the enzyme and began upgrading the Curacao facility in March 2000. In May 2001 we completed the upgrade and went back into limited manufacturing. In April 2002 we filed with the FDA a "Prior Approval Supplement" ("PAS") for the Curacao facility upgrade. In July 2002, the FDA completed a Pre-Approval Inspection of this facility. At the conclusion of the inspection, the FDA inspectors provided us with a list of observations on FDA Form 483 and in August 2002, FDA issued a "Complete Response" letter with respect to the Pre-Approval Inspection. We responded to

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the FDA letter in November 2002 with a plan that is aimed at addressing issues raised in the "Complete Response" letter.

The FDA notified us on July 28, 2003 that our request to supplement our biologics license for collagenase ABC was approved ("FDA approval"). The supplement included major renovations to the manufacturing facility, utility systems, and process equipment at our Curacao facility. The FDA notification acknowledged our written commitments to provide additional information regarding ongoing studies and when to submit this information to our biologics license for

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review. As a result of the FDA approval, enzyme product manufactured at the Curacao facility is now being distributed to Abbott. Regardless of this FDA approval, the FDA letter will remain in effect until we demonstrate compliance with the applicable federal standards and regulations, which we understand to be two "satisfactory annual GMP inspections" of our Lynbrook and Curacao manufacturing facilities. We believe that we have made progress in complying with the applicable federal standards and regulations, although there can be no assurances as to when the FDA letter will be rescinded, if at all. During the quarter ended June 30, 2004, the FDA completed an inspection of our Lynbrook facility. We are hopeful that after the next FDA inspection is completed at our Lynbrook facility, we will be eligible to have the FDA letter rescinded. In May 2004, the FDA inspected the facility of our subcontractor. The FDA has not conducted an inspection of our Curacao facility since July 2002.

Dependence on Abbott Laboratories

We derive most of our net sales and all of our royalty revenue from the topical ointment business, through an exclusive license agreement, which expires in August 2013, with a pharmaceutical company in the United States, Abbott Laboratories, which in March 2001 acquired Knoll Pharmaceutical Company ("KPC", collectively, "Abbott"), the Company's original licensee. Revenues are derived from two sources: i.) sales of Collagenase ABC enzyme in powder form (the "product" or the "enzyme") to Abbott and to a lesser extent foreign pharmaceutical companies, and ii.) royalties paid by Abbott on its U.S. sales of Collagenase Santyl(R) Ointment, which contains the product, to distributors.

Delisting of Common Stock from The Nasdaq Stock Market

In December 2003, Nasdaq had informed us that we were not in compliance with the independent directors and audit committee composition requirements. Nasdaq changed our symbol from "BSTC" to BSTCC" because of this noncompliance but allowed us 90 days to comply with this requirement. In late February 2004, we added Michael Schamroth to our board of directors, on a temporary basis, subject to vote at the next shareholders meeting, and informed Nasdaq of this appointment. By doing so, we satisfied the minimum requirement of three independent directors. However, when we informed Nasdaq of the director appointment, we also informed it that at December 31, 2003 we were no longer in compliance with the \$2.5 million minimum stockholders' equity requirement. On March 3, 2004 Nasdaq invited us to make a written submission with respect to the minimum stockholders' equity deficiency, which we submitted on March 10, 2004.

On March 22, 2004 the Nasdaq Listings Qualifications Panel (the "Panel") informed us in writing of its determination to delist our common stock from The NASDAQ SmallCap Market effective with the open of business on March 24, 2004. The Nasdaq notice stated that the Panel's determination was based on our failure to satisfy the \$2.5 million shareholders' equity requirement as of December 31,

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2003. Our common stock was immediately eligible for quotation on the OTC Bulletin Board effective with the open of business on March 24, 2004. The OTC Bulletin Board symbol assigned to us is BSTC. No application was required to be filed for inclusion on the OTC Bulletin Board.

Our Common Stock traded on The NASDAQ SmallCap Market tier of the Nasdaq Stock Market ("Nasdaq") under the symbol "BSTCC" until March 23, 2004. On March 24, 2004, our common stock began trading on the OTC Bulletin Board under the symbol BSTC. Effective May 2004, our stock was moved from the OTC Bulletin Board to the

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Pink Sheets due to our failure to file our financial reports on a timely basis with the SEC.

SUBSEQUENT EVENTS

In June 2004, we entered into a development and license agreement with Auxilium Pharmaceuticals, Inc. ("the Auxilium Agreement"). Under the agreement, we have granted Auxilium the rights to develop products containing our enzyme ("AA4500") for the treatment of Peyronie's and Dupuytren's disease. We have granted Auxilium the exclusive world-wide license to any products developed under the agreement other than dermal formulations labeled for topical administration. We also granted Auxilium the option to develop and license the technology for use in other indications other than dermal formulations labeled for topical administration. The agreement extends, on a country-by-country and product-by-product basis, for the longer of the patent life, the expiration of any regulatory exclusivity period or 12 years. Auxilium may terminate the agreement with 90 days written notice. Auxilium is obligated to pay all clinical and regulatory development costs on an on-going basis, to purchase commercial inventory from us and to pay royalties based on product sales. In addition, Auxilium is obligated to make milestone payments for contract initiation, receipt of technical data, manufacturing process development, the one-year anniversary date, filing of regulatory applications and receipt of regulatory approval.

In June 2004, we received an up-front payment under the agreement totalling \$2,500,000. In August 2004, we received an additional \$2,500,000 for delivery of all in-process research and development material product data relating to Dupuytren's and Peyronie's disease. We may also receive up to \$10,500,000 of contingent milestone payments under this agreement if all existing conditions are met. Additional milestone obligations may be due if Auxilium exercises an option to develop and license our enzyme for additional medical indications.

On March 8, 2004, the holder of a one-year promissory note, bearing interest of 8% per annum which was due March 11, 2004 extended the note for one year.

In March 2004, our chairman's deferred salary of \$100,000 has been applied against the chairman note receivable.

On March 22, 2004 the Nasdaq Listings Qualifications Panel (the "Panel") informed us in writing of its determination to delist our common stock from The NASDAQ SmallCap Market effective with the open of business on March 24, 2004. The Nasdaq notice stated that the Panel's determination was based on our failure to satisfy the \$2.5 million shareholders' equity requirement as of December 31, 2003. Our common stock was immediately eligible for quotation on the OTC Bulletin Board effective with the open of business on March 24, 2004. The OTC Bulletin Board symbol assigned to us is BSTC. No application was required to be filed for inclusion on the OTC Bulletin Board.

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Our Common Stock traded on The NASDAQ SmallCap Market tier of the Nasdaq Stock Market ("Nasdaq") under the symbol "BSTCC" until March 23, 2004. On March 24, 2004, our common stock began trading on the OTC Bulletin Board under the symbol BSTC. Effective May 2004, our stock was moved from the OTC Bulletin Board to the Pink Sheets due to our failure to file our financial reports on a timely basis with the SEC.

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We have ceased operations in Germany and are in the process of liquidating our subsidiary in Germany, Bio Pharma, which was managed by Rainer Friedel, MD., and Ph.D. Dr. Friedel was a member of our board of directors until his resignation on April 30, 2004.

Michael Schamroth became an interim director as of February 24, 2004 and was elected by the Board of Directors in a special meeting. His term will expire at the next annual meeting where he can stand for re-election to the Board.

ITEM 2. DESCRIPTION OF PROPERTY.

We lease two facilities, one in Lynbrook, New York and one in Curacao, Netherlands Antilles. The New York facility, also our administrative headquarters, contains 3,500 square feet of office space and 11,500 square feet of laboratory, production, and storage facilities. We lease this facility from the Wilbur Street Corporation ("WSC"), which is owned by The S.J. Wegman Company, the principal stockholder of the Company and an affiliate of Edwin H. Wegman, President of the Company. On January 30, 1998, WSC and the Company entered into a triple net lease agreement, which provides for an annual rent starting at \$125,000, which can increase annually by the amount of annual increase in the Consumer Price Index for the greater New York metropolitan region. The lease term is 7 years, expiring January 31, 2005. During each of the fiscal years ended December 31, 2003 and January 31, 2003, we paid rent and real estate taxes of \$125,000 (approximately \$8.33 per square foot) relating to this lease agreement. We believe that the terms of this lease are reasonable and the rent charged is no greater than that which would be charged by an unaffiliated landlord for comparable facilities, based on appraisals of the property.

We also lease a building in Brievengat, Curacao, Netherlands Antilles from an unrelated company wholly owned by the Insular Territory of Curacao. This building is our principal manufacturing facility, and is licensed by the FDA to produce Collagenase ABC. The facility has approximately 15,750 square feet of usable space. The lease, which was originally entered into with the Insular Territory of Curacao on January 1, 1977, is automatically renewable upon the same terms every five years, unless either party gives notice of termination three months prior to the expiration of the five-year period. The lessor is entitled to revalue the rent for each successive five-year period, and the lease has been automatically renewed through March 1, 2006. The current rent is approximately \$37,000 per year.

ITEM 3. LEGAL PROCEEDINGS.

None

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None to date. The next annual meeting will include a vote to elect interim board of director member Michael Schamroth as a full director of the Company

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PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

In December 2003, Nasdaq had informed us that we were not in compliance with the independent directors and audit committee composition requirements. Nasdaq changed our symbol from "BSTC" to BSTCC" because of this noncompliance but allowed us 90 days to comply with this requirement. In late February 2004, Michael Schamroth was added to our board of directors in a special meeting, on a interim basis, subject to vote at the next shareholders meeting, and informed Nasdaq of this appointment. By doing so, we satisfied the minimum requirement of three independent directors. However, when we informed Nasdaq of the director appointment, we also informed it that at December 31, 2003 we were no longer in compliance with the \$2.5 million minimum stockholders' equity requirement. On March 3, 2004 Nasdaq invited us to make a written submission with respect to the minimum stockholders' equity deficiency, which we submitted on March 10, 2004.

As described above, on March 24, 2004, our common stock began trading on the OTC Bulletin Board under the symbol BSTC. Effective May 2004, our stock was moved from the OTC Bulletin Board to the Pink Sheets due to our failure to file our financial reports on a timely basis with the SEC.

As we currently meet the NASDAQ independent audit committee guidelines and expect to meet the \$2.5 million shareholders equity requirement, we anticipate reapplying to the Nasdaq SmallCap Market upon filing all of our overdue financial reports. However, there can be no assurance that we will be successful in reapplying to the Nasdaq SmallCap Market.

On November 1, 2004, the closing price for our Common Stock was \$2.00. The table below sets forth the high and low sale prices for our Common Stock for the period February 1, 2002 through December 31, 2003, as reported by Nasdaq.

QUARTER ENDED	HIGH	LOW
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December 31, 2003	\$1.99	\$1.05
September 30, 2003	\$2.00	\$0.79
June 30, 2003	\$1.59	\$0.60
March 31, 2003	\$2.15	\$1.06
January 31, 2003	\$3.96	\$0.66
October 31, 2002	\$1.95	\$0.60
July 31, 2002	\$2.34	\$1.13
April 30, 2002	\$2.45	\$1.56

On July 14, 2004, there were 113 stockholders of record of our Common Stock

It is our current policy to retain earnings to finance the growth and development of our business and not pay dividends. Any payment of cash dividends in the future will depend upon our financial condition, capital requirements and earnings as well as such other factors as the Board of Directors may deem relevant. Our Board of Directors authorized two buyback programs for the repurchase of a total of 600,000 shares of common stock. Through July 1999, a total of 361,380 shares were repurchased at an average price of \$5.29 per share. We have not repurchased shares since that time and have suspended the buyback for the foreseeable future.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS

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Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995

Information provided by us or statements contained in this report or made by our employees, if not historical, are forward looking information, which involve uncertainties and risks.

We caution readers that important factors may affect our actual results and could cause such results to differ materially from forward-looking statements made by us or on our behalf. Such factors include, but are not limited to, changing market conditions, the impact of competitive products and pricing, the timely development and approval by the Food and Drug Administration ("FDA") and foreign health authorities of potential products, market acceptance of our potential products, and other risks detailed herein and in other filings we make with the Securities and Exchange Commission. Additionally there can be no assurance that our agreement with Auxilium will provide us with new products in the future. Further, any forward looking statement or statements speak only as of the date on which such statements were made, and we undertake no obligation to update any forward looking statement or statements to reflect events or circumstances after the date on which such statement or statements were made.

Summary

We are a biopharmaceutical company focusing on wound healing and tissue remodeling. We manufacture Collagenase ABC enzyme, (the "enzyme") which is the active ingredient in the prescription drug Collagenase Santyl(R) Ointment sold by Abbott Laboratories in the United States and indicated for debriding chronic dermal ulcers and second and third degree burns. As previously mentioned, in June 2004, we signed a development and license agreement with Auxilium Pharmaceuticals to develop an injectable form of our enzyme (AA4500) for treating Dupuytren's disease, Peyronie's disease, frozen shoulder, lipomas, and other conditions, except for dermal formulations labeled for topical administration. We have initiated Phase 3 clinical trials for Dupuytren's disease. A clinical trial for Peyronie's disease began in January 2004. A Phase 2 trial for frozen shoulder is ongoing. Effective with the signing of the Auxilium Agreement, they are now responsible for certain of these clinical trials, including the trials already commenced for Dupuytren's and Peyronie's disease.

We derive most of our sales revenues, (historically, approximately 90%) and all of our royalty revenues, from one customer in the United States, Abbott Laboratories ("Abbott") who, pursuant to an exclusive licensing agreement (the "Agreement"), compounds the product into Collagenase Santyl(R) Ointment ("Santyl(R)" or "ointment"), a topical prescription drug used to treat dermal ulcers and burns. The royalty revenues from Abbott were earned on North American sales of Santyl(R) to distributors by Smith & Nephew, Inc. ("S&N") through December 31, 2003. The January 2000 sub-license agreement under which S&N marketed Santyl(R) ointment terminated on June 30, 2003 but it was agreed they would continue to market through the end of 2003. The Ross Products Division of Abbott Laboratories Inc. assumed United States marketing responsibility for Collagenase Santyl(R) Ointment effective January 1, 2004. During 2003, the Abbott Agreement automatically renewed for an additional 10-year period, to August 2013. Collagenase Santyl(R) Ointment is sold primarily to long-term care centers, where it is believed that Abbott's Ross Products Division has built a strong market position and reputation.

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The preparation of the financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts in the financial statements and the accompanying notes. Actual results could differ from those estimates. We believe the following accounting policies are the most critical to us.

RESEARCH AND DEVELOPMENT

Research and development expenses ("R&D") include internal costs, such as salaries and benefits, costs of materials, and facility costs. R&D also consists of third party costs, such as medical professional fees, contract manufacturing costs for material used in clinical trials, and costs associated with clinical study R&D arrangements. We fund R&D at medical research institutions under agreements that are generally cancelable. All of these costs are charged to R&D as incurred, which may be measured by percentage of completion, contract milestones, patient enrollment, or the passage of time.

At the initiation of clinical study R&D contracts, we make an estimate of the duration and expected completion date of the contract, which may require a change due to accelerations, delays or other adjustments to the contract period or work performed. Changes in these estimates could have a significant effect on the amount of R&D costs that we realize in a specific period.

Accounting for the Impairment or Disposal of Long-Lived Assets.

SFAS No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets" requires judgments regarding future operating or disposition plans for marginally performing assets. The application of both of these policies has affected the amount and timing of charges to operating results that have been significant in recent years. We evaluate our long-lived assets for impairment on an annual basis, or whenever events and circumstances indicate that the carrying amount may not be recoverable, including our business judgment of when to close underperforming operations. These impairment evaluations require an estimation of fair value based on recent negotiations to sell certain assets. Should the carrying amount not be deemed to be recoverable, we write the assets down to their fair value. For the year ended December 31, 2003, we did not take any impairment charges.

RESULTS OF OPERATIONS

In March 2003 we changed our fiscal year end from January 31 to December 31. Our first fiscal year using this new basis is the twelve months ending December 31, 2003. In this report we compare the twelve months ended December 31, 2003 ("calendar year 2003") to the twelve months ended January 31, 2003 ("fiscal year 2003"), because it is not practical to recast the prior comparative periods ended December 31, 2002. The eleven months period ended December 31, 2003 is also presented.

Net sales include the sales of Collagenase ABC enzyme recognized at the time it is shipped to customers, primarily Abbott. Net sales also include fees we charge Abbott for testing Collagenase Santyl(R) Ointment it contract manufactures with the enzyme.

As a result of the FDA approval, we may now distribute to Abbott enzyme manufactured at our renovated Curacao facility. In September 2003, we delivered the first available enzyme manufactured at the renovated Curacao facility to Abbott.

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Net sales recorded for fiscal 2003 were from delivery of stockpiled enzyme inventory to Abbott. We depleted that stockpiled enzyme inventory during fiscal 2003. During calendar 2003, we sold limited amounts of enzyme produced at the renovated facility in Curacao to an international customer. International sales have historically represented approximately 10% of total revenues; however, we expect minimal sales to international customers at least through 2004.

Net sales were \$1,555,625 and \$1,938,706 for the calendar year 2003 and fiscal year 2003, respectively, a decrease in calendar 2003 of \$383,081 or 20% from fiscal 2003. Enzyme shipments to Abbott in calendar 2003 were from enzyme manufactured at the renovated Curacao facility. Enzyme shipments to Abbott in fiscal 2003 were from enzyme that had been stockpiled prior to the renovation, which began in March 2000. We delivered less enzyme during calendar 2003 because we did not achieve our 2002 and 2003 enzyme manufacturing and inventory level goals due to delays caused by manufacturing and personnel issues associated with the renovated plant. We believe we have solved most of the manufacturing and personnel issues and have achieved increases in manufacturing in 2004. However, due to these problems encountered in calendar 2003, we will be able to supply Abbott with only limited quantities of our enzyme throughout 2004 and will continue to incur significant operating losses, exclusive of the revenue received from the Auxilium Agreement.

Royalties earned on Collagenase Santyl(R) Ointment sales by S&N were \$1,683,915 and \$2,140,534 for the calendar year 2003 and fiscal year 2003, respectively, representing a decrease in calendar 2003 of \$456,619 or 21%. Santyl(R) sales during calendar 2003 were significantly lower than fiscal 2003 levels because of lack of sufficient enzyme available to manufacture Santyl(R). As previously described, Abbott's inventory of Santyl(R) ointment, which it has supplied to S&N for distribution and on which we earn royalties, was depleted by the end of July 2003, and only replenished in November 2003, with the first delivery of enzyme we made in September 2003. There was no distribution of Santyl during the three months August through October 2003; therefore, no royalties were earned during that period. We expect Santyl(R) sales to continue to be negatively impacted in 2004, because we did not achieve our 2003 enzyme manufacturing and inventory level goals. We are on target to meet our production objectives in 2004.

The sub-license agreement under which Smith & Nephew marketed Santyl(R) ointment terminated on June 30, 2003 but they continued to market it through the end of 2003. The Ross Products Division of Abbott Laboratories Inc. assumed United States marketing responsibility for Collagenase Santyl(R) Ointment effective January 1, 2004.

Cost of sales was \$2,843,921 and \$3,205,235, respectively, during calendar year 2003 and fiscal year 2003, a decrease in calendar 2003 of \$361,314 or 11%. We had a negative gross profit margin in both calendar year 2003 and fiscal year 2003 due to delays and manufacturing and personnel issues associated with the renovated plant.

General and administrative expenses ("G&A") were \$2,615,007 and \$3,045,319 respectively, during calendar year 2003 and fiscal year 2003, a decrease in calendar 2003 of \$430,312, or 14%. During fiscal 2003, our production and regulatory personnel spent a significant portion of their time preparing for the FDA inspection of the Curacao facility, which took place in July 2002, the cost of which was allocated to G&A in fiscal 2003.

Research and development expenses ("R&D") were \$884,685 and \$1,069,045 respectively, during calendar year 2003 and fiscal year 2003, a decrease in calendar 2003 of \$184,360 or 17%. Development efforts have been curtailed in our

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attempt to conserve cash.

Other expense, net was \$184,940 and \$23,094 respectively, during calendar year 2003 and fiscal year 2003, an increase in other expense, net of \$161,846. The increase is due to interest expense on the 12% Senior Secured Convertible Note borrowed in June 2003 and the March 2003 promissory note, and amortization of the 12% Note's discount. The interest and discount amortization on these debt instruments approximated \$180,000 during calendar 2003. Interest expense in both periods also includes interest on the two-year, 6.5% non-amortizing loan from Korpodeko, a Curacao development corporation established to develop industry on the island of Curacao. In September 2003, Korpodeko agreed to modify the terms of the loan, by permitting us to repay 20%, or \$91,000 of the loan principal in November 2003, and pay the remaining principal, or \$364,000 in November 2004. In return, the Company agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004. In December 2003, we repaid the \$91,000 of loan principal.

The (expense) benefit for income taxes was (\$13,000) and \$260,464 respectively during calendar year 2003 and fiscal year 2003. The net benefit in fiscal 2003 relates to US federal and state refunds of approximately \$425,000 due by carrying back most of the fiscal 2003 net operating loss to tax payments made in prior taxable fiscal years, net of write-off of deferred tax assets. Due to a change in the US tax law, we can only carryback net operating losses 2 years. We recorded no income tax benefit for calendar 2003 because of uncertainties with respect to the timing of future utilization of net operating loss benefit. Also, the difference between the United States Federal statutory tax rate of 34% and the effective tax rate in fiscal 2003 is due to the tax effect of foreign sourced losses for which no benefit can be taken. Since 1976, our Curacao subsidiary has had a 2% profit tax rate granted to it by the Curacao government (the "2% tax holiday"). In November 2000, the Curacao government retroactively extended the 2% tax holiday for another 15 years

We have ceased operations in Germany and are in the process of liquidating our subsidiary in Germany, Bio Pharma, which was managed by Rainer Friedel, MD., and Ph.D.

LIQUIDITY, CAPITAL RESOURCES AND CHANGES IN FINANCIAL CONDITION

Our primary source of working capital is from operations, which includes sales of product, testing fees, royalties, periodic license fees, and borrowings. At December 31, 2003, we had a working capital deficit of approximately \$824,000. The principal use of cash during the year ended December 31, 2003 was approximately \$1.6 million for operating activities. Sources of cash included approximately \$481,000 of repayments by our chairman of his notes, an increase of \$100,000 in short term debt, and proceeds from a \$1,575,000 two year senior secured convertible note bearing 12% interest, described below.

As previously mentioned, under the terms of the Auxilium Agreement we received, in June 2004 and August 2004, payments totalling \$5,000,000. We may also receive \$10,500,000 of contingent milestone payments under this agreement if all existing conditions are met. Additional milestone obligations may be due if Auxilium exercises an option to develop and license our enzyme for additional medical indications.

Prior to the signing of the Auxilium Agreement, we funded operations by (1) modification of the terms of two loans, principally, by deferring a balloon payment of \$364,000 due in November 2003 to November 2004; and deferring the payment of \$100,000 principal due on a promissory note from March 2004 to March 2005; (2) receiving a \$250,000 advance of royalties from Abbott Laboratories,

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our major customer, in January 2004 and a \$500,000 royalty advance at the end of March 2004, both of which are to be repaid from royalties to be earned from distribution of Santyl(R) Ointment during 2004 (of which \$94,000 and \$130,000 were repaid from royalties earned during the respective quarters ended March 31, 2004 and June 30, 2004); (3) our chairman's deferred salary of \$100,000 during the three months ended June 2003 has been applied against the chairman note receivable in March 2004, and (4) deferring or making partial payments to creditors. Due to manufacturing problems encountered in 2003, we will be able to supply Abbott with only limited quantities of our enzyme throughout 2004 and will continue to incur significant operating losses exclusive of the income received from the Auxilium agreement. As a result of payments due under the Auxilium Agreement, we generated positive cash flow during the second quarter of 2004.

On June 19, 2003, the Company entered into a financing transaction with Bio Partners LP, a private investor group, pursuant to which the Company sold to Bio Partners in a private placement (i) a \$1.575 million convertible note, (the "Note") issued at face value, and (ii) 295,312 shares of Company common stock, issued at par value, or \$.001 per share. The net proceeds to the Company were approximately \$890,000, after the payment of expenses and repayment of \$500,000 previously advanced to the Company by a principal of Bio Partners.

The Note matures on June 19, 2005 and bears interest at a rate of 12% per annum with an effective interest rate of 36%. Interest-only payments under the Note are payable monthly in arrears and the entire principal amount is payable at maturity. At the time the agreement was made, up to \$1,141,875 aggregate principal amount of the Note is convertible into the Company's common stock, at a conversion price of \$2.50 per share, subject to customary adjustments. The Note also contains restrictions on the Company's ability to incur debt as long as the Note is outstanding. The Note is secured by a pledge of substantially all of the assets of the Company and the Company's New York subsidiary, Advance Biofactures Corporation ("ABC"). In addition, ABC has guaranteed the obligations of the Company under the Note and our chairman, Edwin H. Wegman, has personally guaranteed 50% of the obligations of the Company under the Note. The loan discount of \$281,000 and loan costs of \$258,000 on the Note are being amortized over two years, the expected life of the Note.

In November 2001, ABC-Curacao borrowed a non-amortizing loan of \$455,000 at 6.5% interest due in November 2003 from Korpodeko. In connection with this loan, ABC-Curacao agreed to pledge as collateral substantially all of the assets owned by ABC-Curacao, including the upgraded facility's manufacturing assets with a book value of approximately \$4.7 million at December 31, 2003. BioSpecifics has also guaranteed the Korpodeko loan. In September 2003, Korpodeko agreed to modify the terms of the loan. Korpodeko permitted us to repay 20%, or \$91,000 of the loan principal, which it did in December 2003, and pay the remaining principal, or \$364,000 in November 2004. In return, we agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004. On the consolidated balance sheet as of December 31, 2003, short-term liabilities include the remaining \$364,000 due November 2004. Long-term obligations at December 31, 2003 include operating leases of approximately \$159,000 annually through December 2004.

On March 22, 2004 the Nasdaq Listings Qualifications Panel (the "Panel") informed us in writing of its determination to delist our common stock from The NASDAQ SmallCap Market effective with the open of business on March 24, 2004. The Nasdaq notice stated that the Panel's determination was based on our failure to satisfy the \$2.5 million shareholders' equity requirement as of December 31, 2003. Our common stock was immediately eligible for quotation on the OTC Bulletin Board effective with the open of business on March 24, 2004. The OTC

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Bulletin Board symbol assigned to us is BSTC. No application was required to be filed for inclusion on the OTC Bulletin Board. BioSpecifics had the right to request that the Nasdaq Listing and Hearing Review Council (the "Listing Council") review this decision. The request for review had to be made in writing and received within 15 days from the date of the Nasdaq decision. We did not request the Nasdaq Listing Council to review the delisting decision. The Listing Council had the option, on its own motion, to determine to review any Panel decision within 45 calendar days after issuance of the written decision, or until May 6, 2004. If the Listing Council had determined to review this decision, it could have affirmed, modified, reversed, dismissed or remanded the decision of the Panel. We would have been notified in the event the Listing Council determined that this matter would have been called for review. No such review was requested by us nor did the Listing Council opt to review the Panel decision.

Our Common Stock traded on The NASDAQ SmallCap Market tier of the Nasdaq Stock Market ("Nasdaq") under the symbol "BSTCC" until March 23, 2004. On March 24, 2004, our common stock began trading on the OTC Bulletin Board under the symbol BSTC. Effective May 2004, our stock was moved from the OTC Bulletin Board to the Pink Sheets due to our failure to file our financial reports on a timely basis with the SEC.

As we currently meet the NASDAQ independent audit committee guidelines and expect to meet the \$2.5 million shareholders equity requirement, we anticipate reapplying to the Nasdaq SmallCap Market upon our filing of all overdue financial reports. However, there can be no assurance that we will be successful in reapplying to the Nasdaq SmallCap Market.

ITEM 7. FINANCIAL STATEMENTS

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Consolidated Statements of Cash Flows for Calendar Year ended December 31, 2003 and Fiscal Year ended January 31, 2003, and eleven months ended December 31, 2003	F-5
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ITEM 8. CHANGES IN, AND DISAGREEMENTS WITH ACCOUNTANTS, ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 8A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls

Disclosure controls are controls and other procedures that are designed to

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ensure that information that we are required to disclose in the reports we file pursuant to the Securities Exchange Act of 1934 is recorded, processed, summarized and reported. We have evaluated the effectiveness of such controls.

Limitation on the Effectiveness of Controls

Our management does not expect that our disclosure controls or our internal controls over financial reporting will prevent all error and fraud. A control system, no matter how well conceived and operated can provide only reasonable, but not absolute assurance that the objectives of a control system are met. Further, any control system reflects limitations on resources and the benefits of a control system must be considered relative to its costs. These limitations also include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of a control. A design of a control system is also based upon certain assumptions about potential future conditions over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Conclusions

There were no changes in our internal controls that occurred during the quarter covered by this report that have materially affected, or are reasonably likely to materially affect our internal controls.

ITEM 8B. OTHER INFORMATION

NONE

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS, COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT.

The Board of Directors is divided into three classes, each of which serves for a term of three years, with only one class of directors being elected in each year. The term of office of the first class of directors, presently consisting of Thomas L. Wegman and Dr. Paul A. Gitman will expire at the Annual Meeting in 2006, the term of office of the second class of directors, presently consisting of Henry Morgan and Michael Schamroth will expire on the date of the Annual Meeting in 2004, and the third class of directors, consisting of Edwin H. Wegman will expire on the date of the Annual Meeting in 2005. Dr Friedel resigned as a Director and the Managing Director of Biospecifics Pharma GmbH on April 30, 2004. We do not anticipate replacing Dr. Friedel on the Board. In each case, barring death, resignation or removal, each director serves from the date of his election until the end of his term and until his successor is elected and qualified.

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The directors have the positions with the Company and principal occupations set forth in the table below.

NAME	AGE AT MAY 15, 2004	POSITION WITH THE COMPANY AND PRINCIPAL OCCUPATION	DIRECTOR
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Edwin H. Wegman	84	Chairman of the Board and President	1990
Thomas L. Wegman	49	Director, Executive Vice President	1994
Dr. Paul A. Gitman	63	Director; Director, Quality and Resource Management, Long Island Jewish Medical Center	1990
Henry Morgan	83	Director; Senior partner of the law firm Morgan, Melhuish, Monaghan, Arvidson, Abrutyn & Lisowski	1990
Michael Schamroth	64	Director, owner of M. Schamroth & Sons	2004

Edwin H. Wegman has had the principal occupation and positions with the Company set forth in the table above for the past five years, and has held similar positions with the Company's subsidiaries, Advance Biofactures Corporation ("ABC-New York") and Advance Biofactures of Curacao ("ABC-Curacao"), for the past five years.

Thomas L. Wegman was Secretary and Treasurer of the Company from inception to July 1997, at which time he assumed his current position. In addition, he has held, for the past five years, similar positions with the Company's subsidiaries, ABC-New York and ABC-Curacao.

Dr. Gitman is Medical Director at Long Island Jewish Medical Center since January 1, 1995 and prior thereto was an independent physician engaged in the practice of internal medicine with Spellman Mykoff & Gitman, MD, P.C.

Henry Morgan has had the principal occupation set forth in the table above for the past five years. For personal reasons, Mr. Morgan resigned from the board on May 16, 2003 and rejoined the board on July 10, 2003.

Michael Schamroth became an interim director as of February 24, 2004. Mr. Schamroth's appointment to the Board will be ratified at the Company's next stockholders' meeting, which should take place near the end of 2004. Mr. Schamroth, who runs a fourth generation family owned business, has in excess of twenty years of experience as a Board Member of a major Long Island based health system. His many roles have included Chairman of the Board, Chairman of the Compensation Board and Member of the Finance Committee.

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To the Company's knowledge, based solely on its review of the copies of Forms 4 and 5 furnished to it, the Company believes that all Section 16(a) reporting requirements were complied with during the fiscal year ended December 31, 2003.

EXECUTIVE OFFICERS

In addition to the executive officers named above, the Company employed Albert Horcher as its Secretary, Treasurer, and Principal Financial and Chief Accounting Officer. Mr. Horcher, 44, is a certified public accountant and served in these positions from July 1997 to April 2004, when he resigned from the Company. From February 1991 to July 1997, he served as the Company's Controller and Principal Financial and Chief Accounting Officer. In addition, he held for the past five years similar positions with the Company's subsidiaries, ABC-New York and ABC-Curacao. Executive officers are elected annually by the Board of Directors and serve at the discretion of the Board.

BOARD MEETINGS AND COMMITTEES

During the last fiscal year that ended December 31, 2003, the Board of Directors met 5 times. All incumbent directors, with the exception of Mr. Schamroth who

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joined the board in 2004, attended at least 80% of board meetings.

Audit Committee. The Board has an Audit Committee consisting of Dr. Paul A. Gitman, and Henry Morgan. The function of the Audit Committee is to recommend selection of the Company's independent accountants, review with the independent accountants the results of their audits, review with the independent accountants and management the Company's financial reporting and operating controls and the scope of audits, review all budgets of the Company and its subsidiaries and make recommendations concerning the Company's financial reporting, accounting practices and policies and financial, accounting and operating controls and safeguards and review matters relating to the relationship between the Company and its auditors. The audit committee met 4 times during the fiscal year ended December 31, 2003

Stock Option Committee. The stock option committee consists of Dr. Paul A Gitman and Henry Morgan. The function of the Stock Option Committee is to administer the Company's 1993 Stock Option Plan (the "1993 Plan") which expired July 2004, the Company's 1997 Stock Option Plan (the "1997 Plan"), and the Company's 2001 Stock Option Plan (the "2001 Plan"). The stock option committee did not meet during the last fiscal year.

Executive Committee. The executive committee consists of Edwin H. Wegman and Thomas L. Wegman. The function of the Executive Committee is, except for certain matters reserved to the full Board, to exercise all of the powers of the Board in the management of the business of the Company during intervals between Board meetings, if necessary. The executive committee held numerous meetings during the last fiscal year.

The Board does not have nominating or compensation committees.

Family Relationships

Edwin Wegman, our Chief Executive Officer, is the father of Thomas Wegman, who is our Executive Vice President.

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Involvement in Certain Legal Proceedings

None of our directors, executive officers, promoters or control persons has been involved in any of the following events during the past five years:

1. any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; 2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); 3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, or any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; or 4. being found by a court of competent jurisdiction (in a civil action), the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Audit Committee Financial Expert

Our Board of Directors has determined that it does not have a member of its audit committee that qualifies as an "audit committee financial expert" as

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defined in Item 401(e) of Regulation S-B, and is "independent" as the term is used in Item 7(d)(3)(iv) of Schedule 14A under the Securities Exchange Act of 1934, as amended.

We believe that retaining an independent director who would qualify as an "audit committee financial expert" would be overly costly and burdensome and is not warranted in our current circumstances.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's officers, directors and persons who beneficially own more than ten percent of the Common Stock to file reports of ownership and changes in ownership with the Securities and Exchange Commission. These reporting persons also are required to furnish the Company with copies of all Section 16(a) forms they file.

Code of Ethics

Our company's board of directors does not currently have a Code of Business Conduct and Ethics but will be adopting one during the current calendar year that will apply to, among other persons, members of our Board of Directors, our company's officers including our president (being our principal officer) and our company's chief financial officer (being our principal financial and accounting officer), contractors, consultants and advisors. As adopted, our Code of Business Conduct and Ethics will set forth written standards that are designed to deter wrongdoing and to promote:

1. honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
2. full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with, or submit to, the Securities and Exchange Commission and in other public communications made by us;

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3. compliance with applicable governmental laws, rules and regulations;
4. the prompt internal reporting of violations of the Code of Business Conduct and Ethics to an appropriate person or persons identified in the Code of Business Conduct and Ethics; and 5. accountability for adherence to the Code of Business Conduct and Ethics.

ITEM 10. - EXECUTIVE COMPENSATION

The following table sets forth information concerning compensation for services rendered in all capacities awarded to, or earned by, certain of the Company's executive officers for the fiscal years indicated. There are no other officers who earned an aggregate salary and bonus in excess of \$100,000 during the fiscal year ended December 31, 2003. These executive officers also serve in the same capacities in ABC-New York, and ABC-Curacao, except for Dr. Friedel.

SUMMARY COMPENSATION TABLE

	Annual Compensation (no other compensation applicable)	Long-Term Compensation (no restricted stock grants were issued)
--	--	---

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Edwin H. Wegman President	12/31/03	297,402 (1)	-
	1/31/03	405,169	39,000
	1/31/02	405,169	100,000

Thomas L. Wegman Executive Vice President	12/31/03	193,147	-
	1/31/03	205,895	45,000
	1/31/02	205,895	50,000

Rainer Friedel Managing Director	12/31/03	192,500	-
	1/31/03	192,500	20,000
	1/31/02	192,500	50,000

Albert Horcher Secretary and Treasurer	12/31/03	118,469	-
	1/31/03	120,692	20,000
	1/31/02	120,692	20,000

(1) Mr. Edwin H. Wegman's salary for the three months ended June 30, 2003 for approximately \$100,000 was deferred and subsequently, in March 2004, applied to, the chairman note receivable with the Company.

DIRECTOR COMPENSATION

The Company has no specific policy for compensating directors. In past fiscal years, directors, who were not employees, were compensated for meetings attended in person at the Company's headquarters, at a rate of \$1,500 per meeting. They were also granted stock options. However, during the year ended December 31, 2003, none of the incumbent directors, and none of the former directors, were paid for any meetings attended in person, and no accruals were made.

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ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

To the Company's knowledge, the table that follows sets forth the beneficial ownership of shares of Common Stock as of July 14, 2004 of (i) those persons or groups known to the Company to beneficially own more than 5% of the Common Stock, (ii) each director and nominee of the Company, (iii) each executive officer whose compensation exceeded \$100,000 (each, a "named executive officer") in the calendar year ended December 31, 2003 (calendar 2003"), and (iv) all directors and executive officers of the Company as a group. The information is determined in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), based on information furnished by the persons listed or contained in filings made by them with the Securities and Exchange Commission. Unless indicated below, the stockholders listed possess sole voting and investment power with respect to their shares and the business address of each stockholder is c/o BioSpecifics Technologies Corp., 35 Wilbur St., Lynbrook, New York 11563.

NAME AND ADDRESS OF BENEFICIAL OWNER	NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED	PERCENT OF CLASS
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Edwin H. Wegman (1) (5)	2,235,192	39.4%
Thomas L. Wegman (2) (5)	240,544	4.2
Paul A. Gitman, MD. (3) (5)	72,925	1.3
Henry Morgan (5)	35,425	*
Michael Schamroth (4) (5)	110,000	1.9
Bio Partners LP (5)	295,312	5.5
Directors and executive officers as a group (5 persons)	2,694,086	46.8%

(*) Less than 1%.

(1) Includes 1,843,327 shares of Common Stock owned by The S.J. Wegman Company, a partnership of which Edwin H. Wegman is the sole general partner. Includes 120,000 shares beneficially owned by The Isabel H. Wegman Rev. Trust. The sole trustee of this trust is the estate of Mr. Wegman's brother. Includes options to purchase 66,750 shares of Common Stock that are currently exercisable. Does not include options to purchase 79,250 shares of Common Stock that are not currently exercisable. Edwin H. Wegman is the father of Thomas L. Wegman.

(2) Includes 7,300 shares of Common Stock held by Thomas L. Wegman's wife and child. Includes options to purchase 205,800 shares of Common Stock that are currently exercisable. Thomas L. Wegman is a son of Edwin H. Wegman.

(3) Includes 16,500 shares of Common Stock held by Dr. Gitman's wife and children. Includes options to purchase 35,425 shares of Common Stock that are currently exercisable. Dr. Gitman's business address is c/o Long Island Jewish Medical Center, 270-05 76th Ave., New Hyde Park, New York 11040.

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(4) Includes 100,000 shares owned by M. Schamroth & Sons and options to purchase 10,000 shares of Common Stock, which are currently exercisable.

(5) Listed address is 35 Wilbur Street, Lynbrook, New York 11563

Equity Compensation Plan Information

We maintain three equity compensation plans, the 1993 stock option plan (which expired July 2004), the 1997 stock option plan and the 2001 stock option plan.

In July 1994, the Company's stockholders approved a stock option plan (the "1993 plan") for eligible key employees, directors, independent agents, and consultants who make a significant contribution toward the Company's success and development and to attract and retain qualified employees. Under the 1993 plan, qualified incentive stock options and non-qualified stock options may be granted to purchase up to an aggregate of 200,000 shares of the Company's common stock, subject to certain anti-dilution provisions. The exercise price per share of common stock may not be less than 100% (110% for qualified incentive stock options granted to stockholders owning at least 10% of common shares) of the fair market value of the Company's common stock on the date of grant. In general, the options vest and become exercisable in four equal annual installments following the date of grant, although the Board of Directors, at its discretion, may provide for different vesting schedules, and expire ten years (five years for qualified incentive stock options granted to stockholders owning at least 10% of common shares) after such date. In accordance with terms

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of the 1993 plan, no option shall be granted under the plan subsequent to ten years after its effective date, or July 2004.

In July 1997, the Company's stockholders approved a stock option plan (the "1997 plan") with terms identical to the 1993 plan. The 1997 plan authorizes the granting of awards of up to an aggregate of 500,000 shares of the Company's common stock, subject to certain anti-dilution provisions.

In August 2001, the Company's stockholders approved a stock option plan (the "2001 plan"), with terms similar to the 1997 plan. The 2001 plan authorized the granting of awards of up to an aggregate of 750,000 shares of the Company's common stock, subject to certain anti-dilution provisions. On December 16, 2003, stockholders approved an amendment to the 2001 stock option plan which increased the number of shares authorized for grant from 750,000 shares to 1,750,000 shares, an increase of 1,000,000 shares. A total of 1,750,000 shares of common stock are now authorized for issuance under the amended 2001 plan.

The following table sets forth information regarding securities authorized for issuance under our equity compensation plans as of December 31, 2003.

	Number of securities to be issued upon exercise of outstanding options	Weighted average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	1,350,625	\$1.77	1,018,625

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EXECUTIVE STOCK OPTION GRANT TABLE

Executive	Total Options Issued	Number Exercisable	Exercisable and unexercised
Edwin Wegman	139,000	66,750	13,250
Thomas Wegman	205,800	205,800	115,000
Paul Gitman, M.D.	35,425	35,425	15,425
Henry Morgan	35,425	30,000	10,000

There were no grants of options to the executives of the Company during the fiscal year ended December 31, 2003 and no officer or director exercised any option during the year ended December 31, 2003.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The S.J. Wegman Company owns Wilbur Street Corporation ("WSC"), which has leased to ABC-New York a building serving as a manufacturing facility and headquarters

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in Lynbrook, New York for over 30 years. The building also serves as the Company's administrative headquarters. Edwin H. Wegman, the Company's Chairman of the Board and President, is the President of WSC and the sole general partner of The S.J. Wegman Company, a limited partnership. In January 1998, WSC and the Company entered into a triple net lease agreement that provides for an annual rent starting at \$125,000, which can increase annually by the amount of annual increase in the Consumer Price Index for the greater New York metropolitan region. The lease term is 7 years, expiring January 31, 2005. The Company believes that the terms of this lease are reasonable and the rent charged is no greater than that which would be charged by an unaffiliated landlord for comparable facilities, based on appraisals of the property

The Company has two outstanding loans to the Company's chairman. One loan, whose principal balance at December 31, 2003 is \$494,302 is a demand promissory note, bears interest at 9% per annum, and is collateralized by approximately 1,800,000 shares of the Company's stock. Another loan, whose principal balance at December 31, 2003 is \$56,820 is a demand promissory note, bears interest at 9% per annum, and is uncollateralized. The Company also has two loans with Wilbur St. Corporation ("WSC"), an affiliate of the chairman. One loan is a non-amortizing mortgage from WSC in the amount of \$82,606 and bears interest at 9% per annum; the other is for advances to WSC in the amount of \$15,647. For financial statement purposes, all these loans, which aggregate \$649,375 of principal, are classified as components of stockholders' equity in the balance sheet and appear as "Notes due from chairman and other related party". During calendar 2003, the Chairman repaid net principal of \$375,935 on these loans. There is no assurance that the Company will be able to collect on these notes. Interest income accrued for these loans but not recognized for financial statement purposes aggregated approximately \$42,000 and \$101,000 for the calendar year 2003 and fiscal 2003, respectively.

ABC-New York has notes payable to a former director of the Company and to a partner of the S.J. Wegman Company, an affiliate, amounting to \$15,010 at December 31, 2003. The notes, which bear interest at 9% per annum, are payable on demand.

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ITEM 13. EXHIBITS, LISTS AND REPORTS ON FORM 8-K.

(A) EXHIBITS FILED

- | | |
|-------------|---|
| Exhibit 3.1 | Certificate of Amendment of Certificate of Incorporation of Registrant, as amended. (Previously filed with Registrant's Registration Statement on Form S-18 "Registration Statement" and incorporated herein by reference.) |
| Exhibit 3.2 | Registrant's by-laws as amended. (Previously filed as Exhibit 3.2 and 3.2(a) to Registrant's Registration Statement and incorporated herein by reference.) |
| Exhibit 3.3 | Registrant's by-laws as amended [Note: section 1.15 deleted in its entirety]* |
| Exhibit 4.1 | Copy of Promissory Note executed by Edwin H. Wegman in favor of Advance Biofactures Corporation. (Previously filed as Exhibit 28.1 to Registrant's Registration Statement and incorporated herein by reference.) |
| Exhibit 4.2 | Copy of Promissory Note executed by Advance Biofactures Corporation in favor of Sherman C. Vogel and |

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Clarification of Loan executed by Advance Biofactures Corporation and Sherman C. Vogel, and. (Previously filed as Exhibit 28.2 to Registrant's Registration Statement and incorporated herein by reference.)

- Exhibit 4.3 Copy of Promissory Note executed by Advance Biofactures Corporation in favor of Myron E. Wegman. (Previously filed as Exhibit 28.3 to Registrant's Registration Statement and incorporated herein by reference.)
- Exhibit 10.1 Form of 1991 Stock Option Plan of the Registrant. (Previously filed as Exhibit 10.1 to Registrant's Registration Statement and incorporated herein by reference.)
- Exhibit 10.2 Form of 1993 Stock Option Plan of Registrant. (Previously filed on the Registrant's Form S-8 Registration No. 33-95116 dated July 28, 1995 and incorporated herein by reference.)
- Exhibit 10.3 Copy of Agreement between Advance Biofactures Corporation and Knoll Pharmaceutical Company, without exhibits. (Previously filed as exhibit 10.3 to Registrant's 10-KSB for the year ended January 31, 1995 and incorporated herein by reference.)
- Exhibit 10.4 Copy of Lease between Advance Biofactures Corporation and the Wilbur Street Corporation. (Previously filed as exhibit 10.4 to Registrant's 10-KSB for the year ended January 31, 1998 and incorporated herein by reference.)
- Exhibit 10.5 Copy of Lease between the Curacao Industrial and International Trade Development Company (Curinde) N.V. and Advance Biofactures Corporation of Curacao, N.V. (English translation). (Previously filed as Exhibit 10.5 to Registrant's Registration Statement and incorporated herein by reference.)
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- Exhibit 10.6 Copy of Agreement between Bio-Specifics N.V. (a wholly-owned subsidiary of Advance Biofactures of Curacao, N.V.) and Sheldon R. Pinnell, MD. (Previously filed as Exhibit 10.17 to Registrant's Registration Statement and incorporated herein by reference.)
- Exhibit 10.7 Copy of Employment Agreement with Dr. Rainer Friedel (English summary attached). (Previously filed as exhibit 10.18 to Registrant's 10-KSB for the year ended January 31, 1996 and incorporated herein by reference.)
- Exhibit 10.8 Copy of Collagenase ABC license agreement between Advance Biofactures of Curacao, N.V. and a Swiss company, without exhibits. (Previously filed as exhibit 29.2 to Registrant's 10-KSB for the year ended January 31, 1995 and incorporated herein by reference.)
- Exhibit 10.9 Form of 1997 Stock Option Plan of Registrant. (Previously filed on the Registrant's Form S-8 Registration No. 333-36485 dated September 26, 1997 and

incorporated herein by reference.)

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Exhibit 24 Development and Licensing Agreement dated June 3, 2004
 between BioSpecifics Technologies Corp. and Auxilium
 Pharmaceuticals, Inc.

Exhibit 31.1 Certification pursuant to Section 302 of the
 Sarbanes-Oxley Act of 2002*

Exhibit 32.1 Certification pursuant to Section 906 of the
 Sarbanes-Oxley Act of 2002*

* Filed herewith

(B) REPORTS ON FORM 8-K

Form 8-K dated March 22, 2004
Form 8-K dated June 10, 2004
Form 8-K dated June 10, 2004

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ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our principal accountants for each of the past two years has been BDO Seidman, LLP.

Audit Fees

The aggregate audit fees billed for each of the last two fiscal years for professional services rendered by our principal accountants for the audit of our annual financial statements included in our report on form 10-KSB and review of our quarterly financial statements included in our Reports on Form 10-QSB were \$80,000 and \$86,000 in the year ended December 31, 2003 and January 31, 2003, respectively.

Audit Related Fees

For the fiscal years ended December 31, 2003 and January 31, 2003, there were no aggregate fees billed for assurance and related services by BDO Seidman, LLP relating to the performance of the audit of our financial statements, which are not reported under the caption "Audit Fees" above.

Tax Fees

The aggregate fees billed in each of the last two fiscal years for professional services rendered by our principal accountants for tax compliance, tax advice and tax planning were \$26,000 and \$38,500 in fiscal years ended December 31, 2003 and January 31, 2003, respectively. These services included, in each fiscal year reported, preparation of our corporate income tax returns, tax planning advice related to our tax returns and tax advice relating to contemplated corporate transactions.

All Other Fees

Other than the fees described above, we have not incurred any fees for any services rendered by our principal accounting firm.

Pre-approval Policies and Procedures

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It is our policy that, before we engage our principal accountants for any audit or non-audit services, the engagement is approved by our audit committee. Our audit committee has delegated to Henry Morgan, its Audit Committee Chairman, and an independent director, the authority to grant such pre-approval during periods when the audit committee is not in session and a meeting cannot be readily convened. A decision by Mr. Morgan to pre-approve an audit or non-audit service must be presented to the full audit committee at its next scheduled meeting. All fees paid to, and or billed by, our principal accountants were approved in accordance with the policy described above beginning May 6, 2003.

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SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIOSPECIFICS TECHNOLOGIES CORP.
(Registrant)

Date: November 2, 2004

By: /s/ Edwin H. Wegman

Edwin H. Wegman, Chairman and President

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

/s/ Edwin H. Wegman

Edwin H. Wegman

Chairman of the Board, President and
Director (Principal Executive Officer),
and Interim Principal Accounting Officer

November

/s/ Thomas L. Wegman

Thomas L. Wegman

Executive Vice President and Director

November

/s/ Paul A. Gitman,

M.D. Paul A. Gitman, M.D.

Director

November

/s/ Michael Schamroth

Michael Schamroth

Director

November

/s/ Henry Morgan

Henry Morgan

Director

November

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders of
BioSpecifics Technologies Corp.

We have audited the accompanying consolidated balance sheet of BioSpecifics Technologies Corp. and subsidiaries as of December 31, 2003, and the related consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows for the years ended December 31, 2003 and January 31, 2003, and the eleven months ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BioSpecifics Technologies Corp. and Subsidiaries as of December 31, 2003 and the results of its operations and its cash flows for the years ended December 31, 2003 and January 31, 2003, and the eleven months ended December 31, 2003, in conformity with U.S. generally accepted accounting principles.

/s/ BDO Seidman, LLP

Melville, New York

March 22, 2004, except for Note 15, as to

Which the date is June 3, 2004

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BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES

Consolidated Balance Sheet

	December 31, 2003

Assets	
Current assets:	
Cash and cash equivalents	\$ 268,998
Marketable securities	3,026
Accounts receivable, net	306,786
Inventories, net	880,452
Prepaid expenses and other current assets	47,151

Total current assets	1,506,413
Other assets - loan costs	203,457
Property, plant and equipment, net	3,845,102

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5,554,972
=====

Liabilities and Stockholders' Equity

Current liabilities:	
Accounts payable and accrued expenses	\$ 1,806,850
Notes payable to related parties	15,010
Deferred revenue	45,000
Short-term debt - Korpodeko	364,000
Short-term debt - promissory note	100,000

Total current liabilities	2,330,860
Minority interest in subsidiaries	89,728
Senior secured convertible 12% note, net of discount .	1,364,591
Commitments and contingencies	
Stockholders' equity:	
Series A Preferred stock, \$.50 par value, 700,000 shares authorized; none outstanding	--
Common stock, \$.001 par value; 10,000,000 shares authorized; 5,249,528 shares issued	5,249
Additional paid-in capital	4,144,207
Retained earnings	180,949
Treasury stock, 361,380 shares at cost	(1,911,237)
Notes receivable from chairman and other related party	(649,375)

Total stockholders' equity	1,769,793

	\$ 5,554,972
	=====

See accompanying notes to consolidated financial statements.

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BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES

Consolidated Statements of Operations

	Year ended December 31, 2003	January 31, 2003
	-----	-----
Revenues:		
Net sales	\$ 1,555,625	\$ 1,938,706
Royalties	1,683,915	2,140,534
	-----	-----
	3,239,540	4,079,240
Costs and expenses:		
Cost of sales	2,843,921	3,205,235
General and administrative	2,615,007	3,045,319
Research and development	884,685	1,069,045

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	6,343,613	7,319,599
Loss from operations	(3,104,073)	(3,240,359)
Other income (expense):		
Investment income	22,794	23,462
Interest expense	(207,734)	(46,556)
	(184,940)	(23,094)
Loss before benefit (expense) for income taxes and minority interest	(3,289,013)	(3,263,453)
Income tax benefit (expense)	(13,000)	260,464
Loss before minority interest	(3,302,013)	(3,002,989)
Minority interest in loss of subsidiaries	77,413	78,220
Net loss	(\$3,224,600)	(\$2,924,769)
Basic and diluted net loss per share	(\$ 0.68)	(\$ 0.64)
Weighted-average common shares outstanding	4,734,867	4,564,336

See accompanying notes to consolidated financial statements

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BioSpecifics Technologies Corp
Consolidated Statements of Stockholders' Equity

	Common Stock			Preferred Stock	
	Shares	Amount	APIC	Shares	Amount
Balances - 31 Jan 2002	4,912,216	\$ 4,912	\$ 3,800,104	0	
Foreign currency translation	--	--	--	--	--
Consultant option grants	--	--	7,600	--	--
Options exercised	27,000	27	26,973	--	--
Proceeds from Chairman	--	--	--	--	--
Net (loss)	--	--	--	--	--
Balances - 31 Jan 2003	4,939,216	4,939	3,834,677	0	
Less: Jan 2003 activity	na	na	na	na	na
Balances - 31 Dec 2002	4,939,216	4,939	3,834,677	0	
Foreign currency translation	--	--	--	--	--
Consultant option grants - IS	15,000	15	14,985	--	--
BioPartners loan/discount	295,312	295	280,546	--	--
Geller warrants, Garut options	--	--	14,000	--	--
Proceeds from Chairman	--	--	--	--	--
Net (loss)	--	--	--	--	--
Balances - 31 Dec 2003	5,249,528	\$ 5,249	\$ 4,144,208	0	

[RESTUBBED-

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	Treas stock	Due from Chairman	Currency Transl	Stkholder Eq Total	
	-----	-----	-----	-----	
Balances - 31 Jan 2002	(\$1,911,237)	(\$1,116,378)	\$ 15,811	\$ 6,894,227	(
	=====	=====	=====	=====	
Foreign currency translation	--	--	(6,823)	(6,823)	
Consultant option grants	--	--	--	7,600	
Options exercised	--	--	--	27,000	
Proceeds from Chairman	--	91,069	--	91,069	
Net (loss)	--	--	--	(2,924,769)	
	-----	-----	-----	-----	
Balances - 31 Jan 2003	(1,911,237)	(1,025,309)	8,988	4,088,304	
	=====	=====	=====	=====	
Less: Jan 2003 activity	na	(105,000)	na	124,303	
Balances - 31 Dec 2002	(1,911,237)	(1,130,309)	8,988	4,212,607	
Foreign currency translation	--	--	(8,988)	(8,988)	
Consultant option grants - IS	--	--	--	15,000	
BioPartners loan/discount	--	--	--	280,841	
Geller warrants, Garut options	--	--	--	14,000	
Proceeds from Chairman	--	480,934	--	480,934	
Net (loss)	--	--	--	(3,224,600)	
	-----	-----	-----	-----	
Balances - 31 Dec 2003	(\$1,911,237)	(\$ 649,375)	\$ 0	\$ 1,769,794	(
	=====	=====	=====	=====	

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BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	Twelve months ended		
	December 31, 2003	January 31, 2003	ende
	-----	-----	-----
Cash flows from operating activities:			
Net loss	(\$3,224,600)	(\$2,924,769)	(\$2,
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation and amortization	699,129	636,657	
Options and warrants issued for services	14,000	7,600	
Issuance of stock for services	15,000	--	
Amortization of loan discount	70,137	--	
Minority interest in loss of subsidiaries	(77,413)	(78,220)	
Deferred taxes	--	164,536	
Changes in operating assets and liabilities:			
Accounts receivable	562,024	1,616,574	
Inventories	(231,572)	105,258	(
Prepaid expenses and other current assets	(13,003)	(21,270)	
Accounts payable and accrued expenses	150,302	192,110	
Income taxes	417,000	(425,000)	
	-----	-----	-----
Net cash used in operating activities	(1,618,996)	(726,524)	(1,

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Cash flows from investing activities:			
Net paydown of notes receivable from chairman	480,934	91,069	
Expenditures for property, plant and equipment	(16,189)	(52,268)	
	-----	-----	-----
Net cash provided by investing activities	464,745	38,801	
	-----	-----	-----
Cash flows from financing activities:			
Interest accrued on notes payable to related parties	500	500	
Exercise of stock options	--	27,000	
Increase in short-term debt	100,000	--	
Decrease in short-term debt	(91,000)	--	
Proceeds from senior secured convertible debt	1,575,000	--	1,
Proceeds from issuance of common stock	295	--	
Deferred loan costs, net	(203,457)	--	(
	-----	-----	-----
Net cash provided by financing activities	1,381,338	27,500	1,
	-----	-----	-----
Effect of exchange rates on cash and equivalents	(8,988)	(6,823)	
Increase (decrease) in cash and cash equivalents	218,099	(667,046)	
Cash and cash equivalents at beginning of year	50,899	693,215	
	-----	-----	-----
Cash and cash equivalents at end of year	\$ 268,998	\$ 26,169	\$
	=====	=====	=====
Supplemental disclosures of cash flow information:			
Cash paid during the year for:			
Interest	157,599	46,555	
	=====	=====	=====
Income taxes	0	14,050	
	=====	=====	=====

See accompanying notes to consolidated financial statements

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BIOSPECIFICS TECHNOLOGIES CORP.
AND SUBSIDIARIES

Notes to Consolidated Financial Statements
December 31, 2003 and January 31, 2003

Organization and Description of Business

BioSpecifics Technologies Corp. ("the Company") was incorporated under the laws of the State of Delaware in 1990. The Company produces a fermentation-derived enzyme named Collagenase ABC (the "product" or "enzyme") that is licensed by the U.S. Food and Drug Administration (the "FDA"). The Company operates production facilities in Lynbrook, New York (the "Lynbrook Plant or Facility") and in Curacao, Netherlands Antilles (the "Curacao Plant or Facility"). The Company is also researching and developing additional products derived from this enzyme for potential use as pharmaceuticals.

Historically, the Company's revenues have been from one customer in the United States, Abbott Laboratories ("Abbott") who, pursuant to an exclusive licensing agreement (the "Abbott Agreement", or the "Agreement"), compounds the product into Collagenase Santyl(R) Ointment ("Santyl(R)" or "Ointment"), a prescription drug used to treat a variety of skin wounds (the "topical ointment business"). The Company also earns royalties on the sale of Santyl(R) to distributors by

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Abbott.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its majority-owned subsidiaries, Advance Biofactures Corp. ("ABC - New York") and Advance Biofactures of Curacao N.V. ("ABC - Curacao") and its wholly owned subsidiary, Biospecifics Pharma GmbH ("Bio Pharma") of Germany. All significant intercompany transactions and balances have been eliminated in consolidation. We have ceased operations in Germany and are in the process of liquidating Bio Pharma of Germany.

Change in Fiscal Year

In March 2003 we changed our fiscal year end from January 31 to December 31. Our first fiscal year using this new basis is the twelve months ending December 31, 2003 similarly in this report we compare the twelve months ended December 31, 2003 ("calendar year 2003") to the twelve months ended January 31, 2003 ("fiscal year 2003"). The year ended January 31, 2003 is not materially different to the eleven month period therefore the eleven months ended December 31, 2002 is not presented.. The eleven months period ended December 31, 2003 is also presented.

As a result of the signing of the Auxilium Agreement in June 2004, the Company now has sufficient liquidity to fund its operations (See Note 15).

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Cash and Cash Equivalents

For purposes of the statement of cash flows, the Company considers all temporary investments and time deposits with original maturities of three months or less to be cash equivalents.

Marketable Securities

Marketable securities principally consist of investments in common and preferred stocks. These investments are classified as trading securities and are adjusted to market value at the end of each accounting period. Unrealized holding gains and losses on trading securities are included in investment and other income in the accompanying consolidated statements of operations.

Inventories

Inventories are stated at the lower of cost (determined on a first-in, first-out basis) or market.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation. Machinery and equipment, furniture and fixtures, and autos are depreciated on the straight-line basis over their estimated useful lives of 5 to 10 years. Leasehold improvements are being amortized over the lesser of their estimated useful lives or the life of the lease which is approximately 8 to 10 years.

Impairment of Long-Lived Assets

The Company evaluates the net realizable value of its property and equipment and other assets in accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS

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144"), relying on a number of factors including operating results, business plans, economic projections and anticipated future cash flows. SFAS 144 requires recognition of impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets or the business to which such intangible assets relate. The Company recorded no impairment charges for the year ended December 31, 2003 and January 31, 2003.

Income Taxes

The Company uses the liability method of accounting for income taxes, as set forth in Statement of Financial Accounting Standards ("SFAS") No. 109 "Accounting for Income Taxes". Under this method, deferred income taxes, when required, are provided on the basis of the difference between the financial reporting and income tax bases of assets and liabilities at the statutory rates enacted for future periods.

Cumulative Translation Adjustment

The assets and liabilities of ABC Curacao are denominated in U.S. dollars. ABC-Curacao conducts local transactions in local currency, which is translated using average exchange rates for the period. The local currency in Curacao is pegged to the US dollar; therefore gains and losses resulting from translation are minimal and not included in stockholders' equity as accumulated other comprehensive income or loss.

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Gains and losses resulting from translation of the Euro, the functional currency of Bio Pharma GmbH had been included in stockholders' equity as accumulated other comprehensive income (loss).

Revenue Recognition

Net sales include the sales of Collagenase ABC enzyme that are recognized at the time the product is shipped to customers. Net sales also include nominal fees the Company charges Abbott for testing Santyl(R) Ointment products manufactured by Abbott. Net sales from testing are recognized when Santyl(R) is released by the FDA for distribution. The Company also earns royalties on Santyl(R) sales in the United States pursuant to its licensing agreement with Abbott. Royalties are recognized during the period in which the Ointment is delivered to distributors in the United States, as reported to the Company by Abbott. The royalty revenues from Abbott for both periods presented were earned on North American sales of Santyl(R) to distributors by Smith & Nephew, Inc. ("S&N") through December 31, 2003.

From time to time, the Company enters into licensing agreements with pharmaceutical companies regarding the sale of the Company's approved product and potential products. License fees and milestone payments for potential products are recognized when earned and the item is delivered under the guidance of EITF No. 00-21 "Revenue Arrangements with Multiple Deliverables". The Company did not recognize any license fee revenue during the periods ended December 31, 2003 and January 31, 2003.

Research and Development

The Company conducts various research and development activities for the approved product and for potential products. Research and development costs are charged to expense when incurred. These costs amounted to \$ 884,685 and \$1,069,045 in the calendar 2003 and fiscal 2003, respectively.

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Net Loss Per Share

Net loss per share is presented under SFAS No. 128 "Earnings per Share". In accordance with SFAS No. 128, basic and diluted net loss per share has been calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period.

Diluted net loss per share reflects the potential dilution that would occur if common stock equivalents were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company. Potentially dilutive securities have been excluded from the computation for the years ended December 31, 2003 and January 31, 2003, as their effect is antidilutive. For the years ended December 31, 2003 and January 31, 2003, potential dilutive securities representing 1,350,625 and 1,358,325 options outstanding are not included as their effect would be antidilutive. Furthermore, for the year ended December 31, 2003 the Company also has 456,750 shares that would be issued assuming \$1,141,875 aggregate principal amount of the convertible Note were converted into the Company's common stock at a conversion price of \$2.50 per share, subject to customary adjustments. These potentially dilutive securities are not included since their effect would be anti-dilutive because of the net loss incurred.

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Stock Based Compensation

The Company has three stock-based employee compensation plans in effect which are described more fully in Note 10. The Company accounts for all transactions under which employees receive shares of stock or other equity instruments in the Company based on the price of its stock in accordance with the provisions of Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees." No stock-based employee compensation cost for stock options is reflected in net loss, as all options granted under the plan had an exercise price equal to the market value of the underlying common stock on the date of grant. The Company recorded an expense of \$14,000 and \$7,600 during calendar 2003 and fiscal 2003, respectively, for options granted to consultants. The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 "Accounting for Stock-Based Compensation".

Year ended	December 31, 2003	January 31, 2003	Eleven Months Ended December 31, 2002
Net loss as reported	(\$3,224,600)	(\$2,924,769)	(\$2,995,000)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net effect of minority interest	(221,361)	(280,297)	(196,000)
Proforma net loss	(3,445,961)	(3,205,066)	(3,191,000)
Basic and diluted net loss per share:			
As reported	(\$0.68)	(\$0.64)	(\$0.64)

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Proforma SFAS 123	\$ (0.73)	\$ (0.70)	(\$0
-------------------	-----------	-----------	------

The fair value for each option granted was estimated at the date of grant using the Black-Scholes option-pricing model, one of the allowable valuation methods under SFAS 123, with the following assumptions:

Year Ended	December 31, 2003	January 31, 2003	Eleven Months Ended December 31, 2002
Average risk free interest rates	4.75%	4.50%	4.75%
Average expected life (in years)	5.00	5.00	5.00
Volatility	82%	82%	82%

The weighted-average fair value of the options granted during the calendar year 2003 and fiscal year 2003 was estimated to be \$0.95 and \$0.69, respectively, for options granted at market value.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions in determining the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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Fair Value of Financial Instruments

The carrying amounts reported in the balance sheet for cash, accounts payable, and accrued expenses approximate fair value based on the short-term maturity of these instruments. It is impractical to determine the fair value of notes receivable due from the chairman and other related party.

Concentration of Credit Risk

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents and trade accounts receivable. The Company places its cash and cash equivalents with high quality credit institutions. At times, such investments may be in excess of the FDIC or SIPC insurance limit. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risks. Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of trade accounts receivable, as the Company does not require collateral or other securities to support customer receivables. (see Note 9.)

Recently Issued Accounting Pronouncements

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FIN No. 46 "Consolidation of Variable Interest Entities" was effective immediately upon its issuance during fiscal 2003 for all enterprises with interests in variable interest entities created after January 31, 2003. In December 2003, FASB issued FIN No. 46 (R) that changes the effective dates for the recording of interests in variable interest entities created before February 1, 2003 beginning with the first interim reporting period ending after March 15, 2004. If an entity is determined to be a variable interest entity, it must be consolidated by the enterprise that absorbs the majority of the entity's expected losses if they occur, or receives a majority of the entity's expected residual returns if they occur, or both. Where it is reasonably possible that the enterprise will consolidate or disclose information about a variable interest entity, the enterprise must disclose the nature, purpose, size and activity of the variable interest entity and the enterprise's maximum exposure to loss as a result of its involvement with the variable interest entity in all financial statements issued after January 31, 2003.

A determination has been made that although the lessor of its operating facility is a variable interest entity, the Company is not the primary beneficiary. Under FIN 46 the lessor will not be consolidated in the Company's consolidated balance sheet. The adoption of this interpretation in 2004 is not expected to have an effect on the Company's financial statements.

3. Marketable Securities

Marketable securities at December 31, 2003 consist of common and preferred stock, with a cost basis of \$245,713 unrealized holding losses of \$242,687, and fair market value of \$3,026. Fair values are based upon quoted market prices.

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4. Inventories, net

Inventories, net at December 31, 2003 consist of:

Raw materials	\$ 65,166
Work-in-process	815,286

	\$880,452
	=====

5. Property, Plant and Equipment, net

Property, plant and equipment at December 31, 2003 consist of:

Machinery and equipment	\$2,379,795
Furniture and fixtures	371,917
Leasehold improvements	4,079,120

	6,830,832
Less accumulated depreciation and amortization	(2,985,730)

	\$3,845,102
	=====

Depreciation and amortization expense amounted to \$699,129 and \$636,657 for calendar 2003 and fiscal year 2003, respectively.

6. Accounts Payable and Accrued Expenses

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Accounts payable and accrued expenses at December 31, 2003 consist of the following:

Trade accounts payable and accrued expenses	\$ 984,509
Accrued legal and other professional fees	542,036
Accrued payroll and related costs	280,305

	\$1,806,850
	=====

7. Income Taxes

The (expense) benefit for income taxes consist of the following:

Year ended	December 31, 2003	January 31, 2003
	-----	-----
Current:		
Federal	\$ (13,000)	\$ 425,000
State	--	--
	\$ (13,000)	\$ 425,000
	-----	-----
Deferred:		
Federal	--	(148,783)
State	--	(15,753)
	--	(164,536)
	-----	-----
Total	\$ (13,000)	\$ 260,464
	-----	-----

The effective income tax rate of the Company differs from the federal statutory tax rate of 34% in calendar 2003 and fiscal 2003 as a result of the effect of the following items:

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Year ended	December 31, 2003	January 31, 2003
	-----	-----
Computed tax benefit at statutory rate	\$ 1,118,264	\$ 1,109,574
Tax effect of foreign sourced loss	(506,511)	(307,645)
State income taxes, net of federal tax benefit	--	(10,397)
Non-deductible expenses	(4,116)	(4,143)
Orphan drug and other tax credits	--	20,000
Increase in valuation allowance	(620,637)	(546,925)
	-----	-----
	\$ (13,000)	\$ 260,464
	=====	=====

The components of the Company's deferred tax assets, pursuant to SFAS No. 109, are summarized as follows:

Year ended	December 31, 2003	January 31, 2003
	-----	-----
Tax Credit Carryforwards	1,033,693	\$ 1,037,182
Inventory	34,226	172,776
Accrued expenses	61,918	144,638
Depreciation and amortization	49,351	77,917
Capital loss carryforward	66,412	66,412
Net operating loss carryforward	873,962	--

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Net deferred tax assets before	-----	-----
valuation allowance	2,119,562	1,498,925
Valuation allowance	(2,119,562)	(1,498,925)
	-----	-----
Net deferred tax asset	\$ --	\$ --
	=====	=====

SFAS No. 109 requires a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. The Company increased the valuation allowance by \$620,637 during the year ended December 31, 2003. The net deferred tax asset has been fully reserved due to the uncertainty of the Company's ability to generate taxable income under the more likely than not criteria of FAS 109.

The Company had domestic losses before taxes of \$1,784,230 and \$2,234,994 for the years ended December 31, 2003 and January 31, 2003, respectively. The Company had foreign losses before taxes of \$1,447,370 and \$950,239 for the years ended December 31, 2003 and January 31, 2003, respectively. The Company has permanently reinvested the accumulated earnings of its foreign subsidiaries, mostly in the form of plant, property and equipment, and therefore will not repatriate the net balance of such earnings (approximately \$.9 million as of December 31, 2003) to the United States.

In November 2000, the Curacao government extended the 2% profit tax holiday enjoyed by AB-Curacao for an additional 15 years. The statutory rate is 30%.

At December 31, 2003, the Company has net operating loss carryforwards of approximately \$2.1 million and \$4.0 million for Federal and State income tax purposes, respectively. These will expire at various dates from 2022 and 2023. As December 31, 2003, the Company has approximately \$1,000,000 in tax credits which expire at various dates from 2018 through 2023.

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8. Credit Facilities

The Company, through its subsidiary ABC-Curacao, has a two-year, non-amortizing loan of \$455,000 at 6.5% interest from Korpodeko, a Curacao development corporation established to develop industry on the island of Curacao. The entire principal was due November 2003. In September 2003, Korpodeko agreed to modify the terms of the loan. Korpodeko permitted the Company to repay 20%, or \$91,000 of the loan principal in December 2003, and pay the remaining principal, or \$364,000 in November 2004. In return, the Company agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004. On the consolidated balance sheet as of December 31, 2003, short-term liabilities include the remaining \$364,000 due November 2004. Substantially all of the Company's fixed assets located in Curacao, with a book value of \$3.2 million at December 31, 2003, are pledged as collateral for these obligations. The Company has also guaranteed the Korpodeko loan.

In March 2003, the Company borrowed \$100,000 from an individual lender, evidenced by a one-year promissory note, bearing interest of 8% per annum, which was due March 11, 2004. In March 2004, the holder of the note extended the note for one year. The Company granted to the lender warrants to purchase up to 10,000 common shares of the Company at \$1.18, the closing price on that day, until March 11, 2008. The fair value of these warrants, based on Black-Scholes methodology, is \$5,000 and was recorded as interest expense during the calendar year 2003. The Company's chairman has personally guaranteed the promissory note.

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On June 19, 2003, the Company entered into a financing transaction with Bio Partners LP, a private investor group, pursuant to which the Company sold to Bio Partners in a private placement (1) a \$1.575 million convertible note (the "Note"), issued at face value, and (2) 295,312 shares (the "Shares") of Company common stock, issued at par value, or \$.001 per share. The net proceeds to us were approximately \$890,000, after the payment of expenses and repayment of \$500,000 previously advanced to us by a principal of Bio Partners. The Note matures on June 19, 2005 and bears interest at a rate of 12% per annum with an effective interest rate of 36%. Interest-only payments under the Note are payable monthly in arrears and the entire principal amount is payable at maturity. Up to \$1,141,875 aggregate principal amount of the Note is convertible into the Company's common stock at any time, at a conversion price of \$2.50 per share, subject to customary adjustments. The Note also contains restrictions on the Company's ability to incur debt as long as the Note is outstanding. The Note is secured by a pledge of substantially all of the assets of BioSpecifics and its New York subsidiary, Advance Biofactures Corporation ("ABC"). In addition, ABC has guaranteed the obligations of the Company under the Note and the chairman has personally guaranteed 50% of the obligations under the Note. The loan discount of \$281,000 (representing the fair value of the shares issued) and loan costs of \$258,000 on the Note are being be amortized over the expected life of the Note.

9. Major Customer and Royalty and License Agreements

The Company's primary royalty and license agreements are for its FDA approved product, Collagenase ABC. The Company derives most of its net sales of the product and all of its royalty revenues from one customer in the United States, Abbott Laboratories ("Abbott") who, pursuant to an exclusive licensing agreement (the "Agreement"), compounds the product into Collagenase Santyl(R) Ointment ("Santyl(R)" or "ointment"), a prescription drug used to treat dermal ulcers and burns.

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Abbott accounted for approximately \$2,906,000 and \$3,196,000 of our product sales and royalties for the calendar year 2003 and fiscal year 2003, respectively. These amounts were approximately 90% and 78% of our revenues during the calendar year 2003 and fiscal year 2003, respectively. At December 31, 2003, we had firm booked orders with Abbott for the product. We will not be able to fulfill all these orders in a timely manner due to the time required to manufacture our product. Abbott and the Company have agreed on a manufacturing and delivery timetable for future deliveries of product and manufacture of Santyl(R).

The royalty revenues from Abbott were earned on North American sales of Santyl(R) to distributors by Smith & Nephew, Inc. ("S&N") through December 31, 2003. The January 2000 sub-license agreement under which S&N marketed Santyl(R) ointment terminated on June 30, 2003 but it was agreed they would continue to market through the end of 2003. The Ross Products Division of Abbott Laboratories Inc. assumed United States marketing responsibility for Collagenase Santyl(R) Ointment effective January 1, 2004. During 2003, the Abbott Agreement automatically renewed for an additional 10-year period, to August 2013. The minimum annual royalty is \$60,000 per year. Royalties from Abbott were \$1,683,915 and \$2,140,534 in calendar year 2003 and fiscal year 2003, respectively.

In fiscal 1997, the Company entered into an agreement to license Collagenase ABC for sale in Germany to the German subsidiary of an international pharmaceutical company. The agreement calls for an initial payment on signing and further payments if and when the German health authority grants marketing approval of Collagenase ABC ointment. Accordingly, deferred revenue at December 31, 2003 is

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\$45,000 from this agreement. The deferred revenue is refundable if approval in Germany is not obtained.

10. Stockholders' Equity

Stock Option Plans

In July 1994, the Company's stockholders approved a stock option plan (the "1993 plan", which expired July 2004) for eligible key employees, directors, independent agents, and consultants who make a significant contribution toward the Company's success and development and to attract and retain qualified employees. Under the 1993 plan, qualified incentive stock options and non-qualified stock options may be granted to purchase up to an aggregate of 200,000 shares of the Company's common stock, subject to certain anti-dilution provisions. The exercise price per share of common stock may not be less than 100% (110% for qualified incentive stock options granted to stockholders owning at least 10% of common shares) of the fair market value of the Company's common stock on the date of grant. In general, the options vest and become exercisable in four equal annual installments following the date of grant, although the Board of Directors, at its discretion, may provide for different vesting schedules, and expire ten years (five years for qualified incentive stock options granted to stockholders owning at least 10% of common shares) after such date. In accordance with terms of the 1993 plan, no option shall be granted under the plan subsequent to ten years after its effective date, or July 2004.

In July 1997, the Company's stockholders approved a stock option plan (the "1997 plan") with terms identical to the 1993 plan. The 1997 plan authorizes the granting of awards of up to an aggregate of 500,000 shares of the Company's common stock, subject to certain anti-dilution provisions.

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In August 2001, the Company's stockholders approved a stock option plan (the "2001 plan"), with terms similar to the 1997 plan. The 2001 plan authorizes the granting of awards of up to an aggregate of 750,000 shares of the Company's common stock, subject to certain anti-dilution provisions. On December 16, 2003, stockholders approved an amendment to the 2001 stock option plan which increased the number of shares authorized for grant from 750,000 shares to 1,750,000 shares, an increase of 1,000,000 shares. A total of 1,750,000 shares of common stock are now authorized for issuance under the amended 2001 plan, of which 775,000 were subject to outstanding options at December 31, 2003. There are a total of 1,018,650 shares available for grant from the 1993, 1997, and 2001 plans.

The summary of the stock options activity is as follows:

Year ended	December 31, 2003		January 31, 2003	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	1,358,325	\$ 1.98	1,100,500	\$ 2.00
Options granted	50,000	1.28	427,750	1.00
Options exercised	--	--	(27,000)	1.00
Options canceled or expired	(57,700)	2.77	(142,925)	4.20

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Outstanding at end of year	1,350,625	\$ 1.77	1,358,325	1.98
	-----	-----	-----	-----
Options exercisable at year end	1,250,625	1.86	1,269,325	1.98
Shares available for future grant	1,006,150	--	56,150	--

During calendar 2003 and fiscal 2003, the Company granted 15,000 and 11,000 options, respectively, to consultants at an exercise price of \$1.23 and \$1.00 per share, respectively. In connection with these options, the Company recorded in calendar 2003 and fiscal 2003 an expense of \$14,000 and \$7,600, respectively, representing the estimated fair value of the options. During calendar 2003 and fiscal 2003, the Company granted 35,000 and 416,750 options, respectively, to employees of the Company at prices ranging from \$1.00 to \$3.00. The calendar 2003 options vest over 4 years and the fiscal 2003 options immediately vest. The following table summarizes information relating to stock options by exercise price as at December 31, 2003:

Option exercise price	Shares	Outstanding		Exercisable	
		Weighted Average Life (years)	Exercise price	Weighted Average Shares	Option price
-----	-----	-----	-----	-----	-----
\$1.00-1.38	973,600	7.8	\$ 1.04	873,600	\$ 1.00
1.88	108,250	6.0	1.88	108,250	1.88
2.00-2.88	54,750	6.8	2.63	54,750	2.63
3.00-3.88	48,300	4.5	3.04	48,300	3.04
4.00-4.63	97,425	3.4	4.17	97,425	4.17
5.81-7.25	23,000	1.0	6.32	23,000	6.32
8.00	5,300	1.0	8.00	5,300	8.00
9.13	40,000	0.5	9.13	40,000	9.13
	-----	-----	-----	-----	-----
	1,350,625	6.8	\$ 1.77	1,250,625	\$ 1.86
	-----	-----	-----	-----	-----

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11. Commitments and Contingencies

(a) Lease Agreements

The Company's operations are principally conducted in leased premises. Future minimum annual rental payments required under noncancellable operating leases are approximated as follows:

Year ending December 31,

2004	\$159,000
2005	47,000
2006	6,000

Rent expense under all operating leases amounted to approximately \$191,000 in both calendar 2003 and fiscal 2003, respectively. The S.J. Wegman Company, which is owned by the Company's President and certain of his relatives, is the 100% shareholder of the Wilbur Street Corporation ("WSC"), which owns and leases a facility to ABC-New York.

In January 1998, WSC and the Company entered into a triple net lease agreement that provides for an annual rent starting at \$125,000, which can increase annually by the amount of the annual increase in the consumer price index for the greater New York metropolitan region. The lease term is 7 years, expiring January 31, 2005. The Company paid approximately \$161,000 representing rent and

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real estate taxes to WSC in each of calendar 2003 and fiscal 2003.

ABC-Curacao leases a building in Brievengat, Curacao, Netherlands Antilles from an unrelated company wholly owned by the Insular Territory of Curacao. The lease term, which originally commenced on January 1, 1977, is automatically renewed upon the same terms every five years, unless either party gives three months notice prior to the expiration of the five-year period. The lessor is entitled to revalue the rent for each successive five-year period. The lease has been renewed through March 1, 2006. Rent expense amounted to approximately \$30,000 in calendar 2003 and fiscal 2003.

(b) Scientific Advisory Board

The Company has an eight member Scientific Advisory Board ("the Board") that provides research and consultation services to the Company. In fiscal 2003, the Company recorded approximately \$24,000 for payments to Board members under these agreements. In calendar 2003, the Company made no payments to the Board.

(c) Potential Product Liability

The sale of Collagenase ABC, as well as the development and marketing of any potential products of the Company, expose the Company to potential product liability claims both directly from patients using the product or products in development, as well as from the Company's agreement to indemnify certain distributors of the product for claims made by others. The Company has product liability insurance which covers the use of the licensed product, Collagenase Santyl(R), and clinical experiments of potential products in the United States. No known claims are pending against the Company at the current time.

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(d) Employment Agreement

The Company has an employment agreement with the managing director of its German subsidiary, Bio Pharma. The Company or the managing director upon one year's written notice can terminate the contract. The agreement provides for an annual salary, currently \$195,000, and a like severance payment if the agreement is terminated by the Company without cause. The managing director left the employ of the Company in January 2004 and resigned as a Director effective April 30, 2004.

(e) FDA Observation

In 1999, the FDA advised the Company, as a result of their inspectional observations, that it would revoke its license to manufacture the enzyme and ointment unless the Company could immediately provide satisfactory assurance of its compliance with the applicable GMP regulations. The Company submitted such a plan in 1999.

The FDA notified the Company on July 28, 2003 that its request to supplement its biologics license for collagenase ABC was approved ("FDA approval"). The FDA notification acknowledged the Company's written commitments to provide additional information regarding ongoing studies and when to submit this information to its biologics license for review. Regardless of this FDA approval, the FDA letter will remain in effect until the Company demonstrates compliance with the applicable federal standards and regulations, which the Company understands to be two "satisfactory annual GMP inspections" of its Lynbrook and Curacao manufacturing facilities. The Company believes that it has made progress in complying with the applicable federal standards and regulations, although there can be no assurances as to when the FDA letter will be rescinded, if at all. During the quarter ended June 30, 2004, the FDA

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completed an inspection of the Company's Lynbrook facility. The Company is hopeful that after the next FDA inspection is completed at its Lynbrook facility, the Company will be eligible to have the FDA letter rescinded. In May 2004, the FDA inspected the facility of the Company's Subcontractor. To the best of the Company's knowledge, the FDA has not commented on the inspection, nor is the FDA obligated to do so. The FDA has not conducted an inspection of the Company's Curacao facility since July 2002.

12. Segment Information

The Company is engaged in one segment, specifically research, development, and production of pharmaceutical products. Operations in this business segment are summarized below by geographic area. All unaffiliated revenues from South America are generated by ABC-Curacao and primarily represent export sales made to Brazil and India ("S.A. ").

Year ended December 31, 2003: -----	North America -----	S.A. and Europe -----	Eliminations -----
Revenues	\$2,905,765	\$333,775	
Intercompany revenue between geographic regions		764,471	(764,471)
Loss from operations	(1,652,836)	(1,451,237)	
Loss before taxes	(1,784,230)	(1,447,370)	
Identifiable assets	2,141,223	3,541,657	(127,909)
Capital expenditures	(7,960)	24,149	
Depreciation and amortization	117,670	581,459	

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Year ended January 31, 2003: -----	North America -----	S.A. and Europe -----	Eliminations -----
Revenues	\$3,196,356	\$882,884	
Intercompany revenue between geographic regions		629,640	(629,640)
Loss from operations	(2,299,442)	(940,917)	
Loss before taxes	(2,234,994)	(950,239)	
Identifiable assets	2,614,313	4,284,218	(262,520)
Capital expenditures	3,885	48,383	
Depreciation and amortization	125,199	511,458	

The information presented above may not be indicative of results if the geographic areas were independent organizations. Intercompany transactions are made at transfer prices which management believes to be equivalent to those made

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at arms-length.

13. Related Party Transactions

The Company has two loans to the Company's chairman. One loan, whose principal balance at December 31, 2003 is \$494,302 is a demand promissory note, bears interest at 9% per annum, and is collateralized by approximately 1,800,000 shares of the Company's stock. Another loan, whose principal balance at December 31, 2003 is \$56,820 is a demand promissory note, bears interest at 9% per annum, and is uncollateralized. The Company also has two loans with Wilbur St. Corporation ("WSC"), an affiliate of the chairman. One loan is a non-amortizing loan from WSC in the amount of \$82,606 and bears interest at 9% per annum; the other is for advances to WSC in the amount of \$15,647. For financial statement purposes, all these loans, which aggregate \$649,375 of principal, are classified as components of stockholders' equity in the balance sheet and appear as "Notes due from chairman and other related party". During calendar 2003, the Chairman repaid net principal of \$375,935 on these loans. There is no assurance that the Company will be able to collect on these notes. Interest income accrued for these loans but not recognized for financial statement purposes aggregated approximately \$42,000 and \$101,000 for the calendar year 2003 and fiscal 2003, respectively.

ABC-New York has notes payable to a former director of the Company and to a partner of the S.J. Wegman Company, an affiliate, amounting to \$15,010 at December 31, 2003. The notes, which bear interest at 9% per annum, are payable on demand.

14. Employee Benefit Plan

ABC-New York has a 401(k) Profit Sharing Plan for employees who meet minimum age and service requirements. Contributions to the plan by ABC - New York are discretionary and subject to certain vesting provisions. The Company made no contributions to this plan for calendar 2003 or fiscal 2003.

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15. Subsequent Events

In June 2004, the Company entered into a development and license agreement Auxilium Pharmaceuticals, Inc. ("the Auxilium Agreement"). Under the agreement, the Company has granted Auxilium the rights to develop products containing its enzyme ("AA4500") for the treatment of Peyronie's and Dupuytren's disease. The Company has granted Auxilium the exclusive world-wide license to any products developed under the agreement other than dermal formulations labeled for topical administration. The Company also granted Auxilium the option to develop and license the technology for use in other indications other than dermal formulations labeled for topical administration. The agreement extends, on a country-by-country and product-by-product basis, for the longer of the patent life, the expiration of any regulatory exclusivity period or 12 years. Auxilium may terminate the agreement with 90 days written notice. Auxilium is obligated to pay all clinical and regulatory development costs on an on-going basis, to purchase commercial inventory from the Company and to pay royalties based on product sales. In addition, Auxilium is obligated to make milestone payments for contract initiation, receipt of technical data, manufacturing process development, the one-year anniversary date, filing of regulatory applications and receipt of regulatory approval.

In June 2004, we received an up-front payment under the agreement totalling \$2,500,000. In August 2004, we received an additional \$2,500,000 for delivery of all in-process research and development material product data relating to Dupuytren's and Peyronie's disease. We may also receive up to \$10,500,000 of

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contingent milestone payments under this agreement if all existing conditions are met. Additional milestone obligations may be due if Auxilium exercises an option to develop and license our enzyme for additional medical indications.

In March 2004, the chairman's deferred salary of \$100,000 during the three months ended June 2003 has been applied against the chairman's note receivable.

On March 22, 2004 the Nasdaq Listings Qualifications Panel (the "Panel") informed the Company in writing of its determination to delist the Company's common stock from The NASDAQ SmallCap Market effective with the open of business on March 24, 2004. The Nasdaq notice stated that the Panel's determination was based on the Company's failure to satisfy the \$2.5 million shareholders' equity requirement as of December 31, 2003. The Company's common stock was immediately eligible for quotation on the OTC Bulletin Board effective with the open of business on March 24, 2004. The OTC Bulletin Board symbol assigned to the Company is BSTC. No application was required to be filed for inclusion on the OTC Bulletin Board.

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