BIOSPECIFICS TECHNOLOGIES CORP
Form 10KSB
May 13, 2002

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

FORM 10-KSB

(Mark One)
[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended January 31, 2002

[ ] 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 X 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 $8,210,000. The aggregate market value of common voting stock held by

non-affiliates of the Issuer was approximately $3,500,000 computed by reference to the last sale price at which the stock was sold on April 25, 2002 as reported by Nasdaq. As of April 25, 2002, 4,550,836 shares of common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required in Part III by Items 9, 10, 11, and 12 is incorporated by reference to the Registrant's proxy statement in connection with the 2002 annual meeting of shareholders, which will be filed by the Registrant within 120 days after the close of its fiscal year.

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 7 Management's Discussion and Analysis of Financial Condition and Results of Operations, 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

We are engaged in the business of producing and licensing for sale a fermentation derived enzyme named Collagenase ABC, approved by the U.S. Food and Drug Administration ("FDA") for debriding chronic dermal ulcers and severely burned areas. We are also researching and developing additional products derived from this enzyme for potential use as pharmaceuticals.

We derive substantially all of our revenues through an exclusive license agreement 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 U.S. sales of Collagenase Santyl(R) Ointment, which contains the product, to distributors. Since 1972, we have sold Collagenase ABC, our only commercial product to date, principally in the United States through exclusive license agreements with Abbott.

In January 2000, KPC, prior to its being acquired by Abbott, sublicensed its exclusive marketing rights to Smith & Nephew, Inc. ("S&N") with our permission.

See "Sale and Distribution of Collagenase ABC".

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 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 necrotic tissue in 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.

Sale and Distribution of Collagenase ABC

Collagenase ABC enzyme powder (the "product" or the "enzyme") is the active pharmaceutical ingredient of a topical ointment. We do not directly market the product to end-users. We 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. Our production of the product was voluntarily suspended in March 2000 due to an upgrade program at our manufacturing facilities in Curacao and Lynbrook to address various FDA concerns. The physical upgrades at the Curacao and Lynbrook facilities have been completed and subsequent validation substantially completed. The upgraded Curacao facility commenced limited production during the fiscal year ended January 31, 2002. However, it must still be inspected and approved by the FDA before we can supply Abbott with the product being produced there. Since March 2000, we supplied Abbott with the product from an inventory built up in anticipation of the upgrade. See "Manufacturing" and "Government Regulation." Pursuant to the agreement with Abbott, the Company supplies Abbott with the product and monitors the production by Abbott of an ointment containing the product. KPC marketed this 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 the product under the sublicensing agreement with Abbott.

Abbott Agreement and Sublicense

We have an agreement with Abbott (the "Abbott Agreement"), which runs through August 2003 and automatically renews for an additional 10-year period unless Abbott notifies us, at least 6 months prior to the renewal date, of its intention to terminate at the conclusion of the initial term. 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 fiscal 2002 and 2001 were approximately $2,269,000 and $2,095,000, 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.

In January 2000, pursuant to a sublicense and assignment agreement (the "Sublicense Agreement"), to which we are not a party, KPC (acquired by Abbott in March 2001) sublicensed its exclusive marketing rights to S&N with our consent. Under the sublicense, Abbott continues to purchase the product from us and contract manufacture Santyl(R). S&N markets Santyl(R) and sells it to distributors. In connection with the sublicense, we entered into several agreements with Abbott and S&N. These included an agreement allocating responsibility under the Abbott Agreement among us, Abbott, and S&N for both the sublicense and license period. Another agreement imposes certain obligations on us to address the FDA issues concerning the Curacao and Lynbrook manufacturing facilities. Abbott will assign its license rights (as opposed to the current sublicense arrangement) in the Abbott Agreement to S&N in the event of FDA approval of a

compliance program being undertaken by ABC. See "Government Regulation". If the license rights are assigned to S&N, the Abbott agreement will be extended at that time until 2013, and automatically renew for an additional 10-year term unless S&N notifies us, at least 6 months prior to the renewal date, of its intention to terminate at the conclusion of the 2013 term.

Abbott accounted for approximately $7,177,000 and $4,970,000 in product sales and royalties of the Company for the fiscal years ended January 31, 2002 and 2001, respectively. These amounts were approximately 87% and 90% of the Company's revenues during the fiscal years ended January 31, 2002 and 2001, respectively. As of January 31, 2002, we had approximately $700,000 of firm booked orders with Abbott for the product, which represents the value of all inventory available for sale to Abbott as of January 31, 2002, compared to approximately $2.2 million of firm booked orders with Abbott as of January 31, 2001. The Company's product is approved in two other countries, Brazil and India, and sold to commercial customers in those countries, who compound the product into ointment. In fiscal 2002 and 2001, sales to the customers in Brazil and India represented approximately 12% and 10% of total revenues, respectively. The Company has a license agreement with the customer in India. There is no license and supply agreement with the customer in Brazil. The product and purified collagenase are also sold for non-sponsored research purposes.

Other Agreements for the distribution of Collagenase ABC

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 calls 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. Our German subsidiary (see "Marketing") submitted collagenase ointment to the German health authority

for marketing approval in 1997, whose final decision is pending.

In 1994, we entered into a 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. The agreement runs for ten years from first market introduction of the product in each country. We recognized no revenue from this agreement in fiscal years ended January 31, 2002 and 2001.

In June 1994, we entered into a multi-year license with an Italian pharmaceutical company that has agreed to market an ointment containing the product in Italy subject to the receipt of requisite Italian governmental approval. The licensee has agreed to purchase the product in agreed minimum amounts increasing in each of the three years following such approval. For the fiscal years ended January 31, 2002 and 2001, we recognized no revenues from this contract.

PROPOSED PRODUCTS AND USES FOR PRODUCTS

Injectable Collagenase ABC

We have developed a non-patented, proprietary process to further purify Collagenase ABC. We have investigated using this purified form of collagenase as an injectable to remove collagen tissue that interferes with normal bodily functioning or is unsightly. 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 New York that is being used in U.S. clinical trials. We have renovated the pilot facility in Lynbrook for manufacture of purified

injectable collagenase in order to support plans for Phase 3 trials for Dupuytren's disease. 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 has completed testing.

Dupuytren's Disease

Dupuytren's disease is a deforming condition of the hand in which one or more fingers, usually 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 its 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 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") and the results were submitted to FDA in support of concluding Phase 2. An end of Phase 2 meeting was held with FDA to discuss how to proceed with Phase 3 studies. The investigators at Stony Brook received a grant from the FDA to conduct Phase 3 clinical trials to determine safety and efficacy of collagenase for this use.

Frozen Shoulder

A double 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". 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.

Lipolysis

A clinical investigation is currently being performed with collagenase injection in the treatment of skin lipomas. Lipomas are benign fatty tumors that occur as bulges under the skin. The concept of using collagenase for removal of fat is discussed in a European Patent Application we filed. Dr Anne Marie covered the story for ABC News in June 2001 and discussed the potential for "chemical liposuction."

Peyronie's Disease

We are developing 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 were awarded a patent for this use in March 2000 and received "orphan drug" designation from the FDA in March 1996. We believe that no other pharmaceutical treatment for this condition has been proven to be effective. 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

Peyronie's disease. In August 1999, the trial's investigator reported on 27 patients who were treated in an open label trial. The investigator reported encouraging results and additional trials are planned.

OTHER PROPOSED PRODUCTS AND USES

Treatment of Burns

Collagenase Santyl(R) has 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. We are collaborating with S&N in this area. Preclinical experiments are being conducted and 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 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 have been accepted for publication in 2002 by the Archives of Ophthamology.

We explored the possible use of purified injectable Collagenase ABC for the treatment of opaque scar tissue in the vitreous humor of the eye. Its use may assist in the surgical removal of scar tissue without tearing the retina to which the tissue is attached. If effective, this use may be beneficial in the treatment of blindness resulting from diabetes and certain other causes. Prior to 2000, approximately 20 persons have been treated with this product on an experimental basis. We are currently seeking a marketing partner in an effort to explore this potential use.

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.

MANUFACTURING

We produce Collagenase ABC, the active ingredient of a topical ointment, and supply it in powder form to pharmaceutical companies that compound it into the ointment and market the ointment to end-users. Our production of the product was voluntarily suspended in March 2000 due to renovation at the manufacturing facilities in Curacao and Lynbrook to address various FDA concerns, although final stage testing continues at the Lynbrook facility. We completed the upgrade renovation at the Curacao and Lynbrook facilities and have substantially completed validating the enzyme production process at the upgraded facilities. (In this context, the words "validating" or "validation" means demonstrating that the production process is reliably performing as intended. Such demonstration must be documented with data, process capability studies, and other appropriate means. The concept of validation is a requirement to demonstrate that what is being employed (e.g. a production process) has been investigated and proven to be reliable.) Once the validations are completed, FDA

approval will be required before enzyme produced at the facilities can be sold to Abbott. Until FDA approval of the facility we will supply customers with the product from our inventory. See "Government Regulation". Pursuant to the agreements with Abbott and S&N, we supply Abbott with the product and monitor the production by Abbott of Santyl(R), which since February 2000 has been marketed by S&N.

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 those of 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. 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") marketed an ointment substantially similar to our Collagenase Santyl(R) Ointment under the trade name "Iruxol(R)". In January 2000, Smith & Nephew plc acquired worldwide marketing rights to Iruxol(R) excluding the United States and Canada, as that ointment is not FDA approved for sale in the United States. KAG, which as part of the global pharmaceutical business of BASF, was acquired by Abbott in March 2001. We, through our foreign licensees for topical collagenase, will compete with Smith & Nephew plc in Europe if and when the licensees receive marketing and pricing approval from their respective health agencies. (See "Collagenase ABC - Agreements for the Distribution of Collagenase ABC").

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

MARKETING

We do not have our own sales staff and instead rely on licensees who have recognition and acceptance in the marketplace. By licensing those companies, which already have a strong marketing and sales force dedicated to specialties, we have very limited selling costs, while the licensee enhances the efficacy of its sales and marketing staff by adding additional products.

In the United States, we are gaining recognition as the manufacturer of Collagenase Santyl(R) as our name and that of our U.S. subsidiary are required to appear on the end-use package sold by Smith & Nephew.

The European Union ("EU") is the second largest pharmaceutical market in the world. We are seeking approval in certain countries within the EU through European licensees.

In November 1995, we established a German subsidiary, Biospecifics Pharma GmbH. Its purpose is 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. 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 $24.4 million in research on collagenase and other products. We incurred approximately $1,067,000 and $1,313,000 in research and development activities during its fiscal years ended January 31, 2002 and 2001, 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 periodic inspection and regulation 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.

Our manufacturing facilities in New York and Curacao are registered with, and licensed by, the FDA. In March 2000, our production of the product was voluntarily suspended due to upgrade renovation at our manufacturing facilities in Curacao and Lynbrook to address various FDA concerns. During fiscal 2002, the physical upgrade was completed and the Curacao facility went back into limited production, however, none of that production can be sold to Abbott until FDA approves the upgrade and any product already produced there for Abbott. Final stage processing and testing of previously produced inventory continues at the Lynbrook facility.

In January and March of 1999, we were issued a List of Inspectional Observations on FDA Form 483 (the "Form 483") from FDA inspectors, citing numerous inspectional observations relating to deficiencies in our compliance with FDA regulations at our Lynbrook, New York and Curacao, Netherlands Antilles facilities. In addition, on May 10, 1999, we received a letter from the FDA (the "FDA Letter") citing certain inspectional observations relating to deficiencies at its Lynbrook, New York facility, Curacao, Netherlands Antilles facility, and contract manufacturing facility at Abbott. The FDA Letter advised us that the FDA would institute formal proceedings to revoke our Product and Establishment Licenses to manufacture Collagenase Santyl(R) Ointment unless we provided satisfactory assurances to the FDA, including submitting to the FDA a comprehensive plan of corrective action to address the observations listed in the Form 483 and the FDA Letter, and otherwise demonstrate compliance with applicable regulatory requirements. We provided the FDA with a plan of corrective action and have had a number of meetings with the FDA to discuss the plan of corrective action and the upgrade renovation of the Curacao production facility. We submitted a number of periodic updates to the FDA on progress under the plan, hired outside consultants and employed additional staff for our Quality Unit.

We started renovating the Curacao facility in March 2000 and, as a result, suspended production of enzyme at that location. We also voluntarily suspended the production of enzyme at our Lynbrook facility, although final-stage testing continues there. Although renovations at the Curacao and Lynbrook facilities were substantially completed by March 2001, we cannot sell to Abbott enzyme now being produced at the Curacao facility until the FDA approves a prior approval supplement ("PAS") to our Establishment License. As part of the approval process for the PAS, the FDA will review and inspect the modifications of the Curacao facility. In anticipation of the renovations and suspension of manufacturing operations, we accumulated an inventory of the product, on which we conduct final stage testing at the Lynbrook facility, that we estimate Abbott can use to compound Santyl(R) into the third quarter of calendar 2002. We estimate that this would permit Abbott to supply S&N with Santyl(R) into the second quarter of calendar 2003.

We have spent approximately $4.7 million in capital improvements to upgrade both facilities and anticipate we may spend approximately $100,000 more to complete the renovations. In addition, we incurred consulting fees and other expenses of approximately $1.3 million since May 1999, including approximately $112,000 during the fiscal year ended January 31, 2002 and $215,000 during the fiscal year ended January 31, 2001. We may incur additional consulting and other expenses of approximately $100,000 during the fiscal year that will end January 31, 2003. During the fiscal years ended January 31, 2000, 2001, and 2002, we estimate that our personnel costs dedicated to the upgrade and addressing the FDA's observations were approximately $923,000, which were recorded in general and administrative expenses. We believe that the plant upgrade program and changes in our quality control policies and procedures outlined in the

corrective plan will adequately address the FDA's

concerns, although there can be no assurances that additional expenditures and time will not be required as a result of any FDA concerns. We believe the capital-spending plan modernized our facilities and improved operational efficiency.

While we believe that we have made considerable progress in addressing the FDA concerns addressed in the Form 483 and the FDA Letter, if we are unable to further address these matters in a timely manner, there may be delays in the delivery of product produced in the renovated facilities to Abbott for use to contract manufacture Collagenase Santyl(R) Ointment. Such delays could have a material adverse effect on our future operating results.

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".

PATENT AND TRADEMARK PROTECTION

Patents

We are the assignee or licensee of eleven U.S. patents. We are not able to ascertain whether these patents will provide any value either prior to their expirations or at any time thereafter. We are the assignee of additional U.S. patent rights that have expired as well as certain foreign patent rights corresponding to certain of the foregoing patents. We have other patents under active preparation for filing. 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. We are obligated to engage in research and development of certain products or uses underlying the patent rights licensed or assigned 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 42 full-time employees, of which 28 are located at the Lynbrook facility, 13 are at the Curacao facility, and 1 is in Germany. There are also 6 part-time employees in Lynbrook and 2 in Curacao. None of

these employees are represented by a union. We consider our relationship with our employees to be excellent.

We have entered into confidentiality agreements with most of our employees, other than executive officers. Pursuant to such agreements, each employee in New York agrees to keep all of our proprietary and other information secret and confidential and to return the same 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 of such agreements.

Our subsidiary in Germany, Bio Pharma, is managed by Rainer Friedel, MD., Ph.D. Dr. Friedel is a member of our board of directors. Dr. Friedel and the Company have executed an employment agreement, as mandated by German law.

Consulting Agreement

During the fiscal years ended January 31, 2002 and 2001, we incurred consulting fees in the amount of $0 and $35,000, respectively, for services provided by a son of a former director.

RISK FACTORS RELATED TO OUR BUSINESS

Reliance on a Single Product for Revenues

Collagenase ABC enzyme is our sole source of revenues.

Uncertainty of Government Regulatory Requirements and Future Production of the Enzyme

The production 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 production of the enzyme and began upgrading the Curacao facility in March 2000. In May 2001 we completed the upgrade and went back into limited production. In April 2002 we filed with the FDA a "Prior Approval Supplement" ("PAS") for the Curacao facility upgrade. Although it is difficult to predict with any certainty the time at which the PAS approval can be obtained, we believe the following could happen by the end of the fiscal year that will end January 31, 2003:

[ ] FDA comments on PAS
[ ] FDA inspects Curacao facility
[ ] FDA comments on inspection of Curacao facility
[ ] BioSpecifics responds to FDA comments
[ ] FDA approves PAS for Curacao facility

While we are producing enzyme at the upgraded Curacao facility, the enzyme being produced for Abbott must be held in quarantine and can only be sold to Abbott if and when the FDA approves the PAS and any enzyme already produced at the facility for Abbott. There can be no assurance when the FDA will approve our PAS, if at all.

Expected Operating Losses for the Fiscal Year Ended January 31, 2003

Since we began upgrading the Curacao facility in March 2000, we have not produced any new enzyme that we can currently sell to Abbott. The enzyme we processed and sold to Abbott in fiscal 2001 and fiscal 2002, which it used to make Collagenase Santyl(R) Ointment ("Santyl(R)"), was from an inventory of enzyme we built up at the Curacao facility prior to the start of the upgrade. This inventory will be depleted during the first half of fiscal 2003. Revenues from this inventory and royalties on sales of Santyl(R) will be insufficient to cover our operating expenses, resulting in an operating loss for the fiscal year that will end January 31, 2003.

Need for Additional Capital

We expect to have cash to fund operations during the fiscal year ended January 31, 2003 from royalties from sales of Santyl(R), the sale of the remaining enzyme inventory to Abbott, the production and sale of enzyme to foreign customers, and cash currently on hand. We estimate that Abbott can supply S&N with Santyl(R) through March 2003, based on its inventory of enzyme it has already purchased from us, our remaining inventory of enzyme, and S&N's rate of Santyl(R) sales. If we are able to get approval of the PAS by the end of the fiscal year ended January 31, 2003, we may also be able to sell quarantine enzyme already produced and planned to be produced for Abbott. However, if approval is significantly delayed and we cannot sell quarantine product, we will be unable to fund operations beyond the first quarter of calendar 2003 unless we are able to raise additional capital. In addition, we need funds to continue development of our proposed products.

Dependence on Abbott Laboratories and Smith & Nephew Inc.

We are dependent on Abbott to buy enzyme, contract manufacture Santyl(R) and provide it to S&N ready for distribution. We are dependent on S&N for the distribution of Santyl(R), which provides us with royalty revenue. Abbott and S&N have a Sublicense and Assignment agreement whereby Abbott will assign to S&N its rights in our exclusive license agreement by December 31, 2002. S&N has the option to terminate its agreement with Abbott if the Curacao facility PAS is not approved by the FDA by December 31, 2002. There can be no assurance that S&N will not terminate its agreement with Abbott if the PAS for Curacao is not received by December 31, 2002. In the event S&N terminates, our exclusive license agreement with Abbott automatically extends for 10 more years in August 2003, unless Abbott exercises its right not to extend our exclusive license agreement. In that event, Abbott would have to notify us six months in advance, or February 2003.

We are not aware of either party's current intentions. If S&N were to terminate, and Abbott exercises its right, we would have to find another licensee with a sufficient sales force. We would also have to use another trade name for ointment containing our Collagenase ABC, as the trade name Santyl(R) is owned by

Abbott. There can be no assurance that we would be successful in finding another licensee or that a new licensee could achieve S&N's current level of sales.

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 10,500 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 January 31, 2002 and 2001, the Company paid rent of $125,000 and real estate taxes of approximately $36,000 relating to this lease agreement. 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.

We also lease a building in Brievengat, Curacao, Netherlands Antilles from a 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 $30,000 per year.

ITEM 3. LEGAL PROCEEDINGS.

None.

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

None.

PART II

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

Our Common Stock trades on The Nasdaq SmallCap Market tier of the Nasdaq Stock Market ("Nasdaq") under the Symbol "BSTC". On April 25, 2002, the closing price for our Common Stock was $2.10. The table below sets forth the high and low sale prices for our Common Stock for the period February 1, 2000 through January 31, 2002, as reported by Nasdaq.

QUARTER ENDED	HIGH	LOW

April 30, 2000	$8.75	$2.08
July 31, 2000	$3.69	$2.03
October 31, 2000	$4.06	$1.06
January 31, 2001	$2.72	$0.81
April 30, 2001	$1.75	$0.75
July 31, 2001	$3.50	$0.94
October 31, 2001	$2.92	$2.00
January 31, 2002	$2.55	$1.50

On April 25, 2002, there were 110 stockholders of record of our Common Stock. We believe we have approximately 1,000 beneficial owners of our Common Stock.

Trading in our securities was transferred to The Nasdaq SmallCap Market on May 25, 2001 from The Nasdaq National Market because we no longer satisfied the requirements for listing on that market.

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 CONDITION AND RESULTS OF OPERATIONS.

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, government regulation, our ability to obtain the approval of our production facilities, our estimate that our inventory of product for Abbott is sufficient until the product being produced at the upgraded facilities is approved and can be sold to Abbott, changing market conditions, the impact of competitive products and pricing, the timely development and approval by the 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. 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.

CRITICAL ACCOUNTING POLICIES

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 BioSpecifics.

Revenue Recognition

Net sales include the sales of Collagenase ABC enzyme, which are recognized at the time the enzyme is shipped to Abbott and foreign customers. Net sales also include testing fees we charge Abbott for testing Collagenase Santyl(R) Ointment contract manufactured by Abbott. Net sales from testing fees are recognized when Santyl(R) is released for distribution. We earn royalties on Santyl(R) distributed in the United States by S&N. Royalties are recognized when S&N delivers Santyl(R) to distributors in the United States, as reported and paid to us by Abbott.

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 in a specific period.

RESULTS OF OPERATIONS

Net product sales were $5,940,637 and $3,437,083 for the fiscal years ended January 31, 2002 and 2001, respectively, an increase in fiscal 2002 of $2,503,554 or 73% from fiscal 2001. Sales of the product, Collagenase ABC, to Abbott increased by approximately $2 million, or 72%, and sales to the Company's customers in Brazil and India increased by approximately $400,000 or 76%. The increase in sales to Abbott was due to availability of the inventory and therefore timing of deliveries. Since the start of the Curacao facility upgrade, Abbott instructed us to deliver any and all product as it became available. The bulk of our inventory accumulated prior to the renovation became available during fiscal 2002 and was therefore delivered to Abbott. The increase is also due to a significant price increase that Abbott agreed to at the start of fiscal 2002. The increase in sales to our foreign customers was due to sale of product produced during the fiscal year at the upgraded Curacao facility. At January 31, 2001 we had approximately $2.2 million of deliveries in arrears due to the product not being ready for delivery, which was part of the fiscal 2002 deliveries. Net sales includes testing of Collagenase Santyl(R) Ointment compounded by Abbott during both periods presented.

Royalties earned on Collagenase Santyl(R) Ointment sales by S&N were $2,269,048 and $2,094,622 for the fiscal years ended January 31, 2002 and 2001, respectively, representing an increase in fiscal 2002 of $174,426 or 8%. S&N achieved higher sales in the second year of marketing the ointment over the first as it has developed its marketing program.

Cost of sales was $5,106,234 and $2,503,906 respectively, in fiscal 2002 and 2001, an increase in fiscal 2002 of $2,602,328 or 104% from fiscal 2001. The gross profit percentage decreased by 13 percentage points in fiscal 2002 (14%) versus fiscal 2001 (27%) because our production continued to be limited due to the recent completion of the Curacao facility upgrade.

General and administrative expenses ("G&A") were $2,319,853 and $2,659,621 respectively, in fiscal 2002 and 2001, a decrease in fiscal 2002 of $339,768, or 13% from fiscal 2001. Since May 1999, we have engaged consultants to assist in responding to FDA observations from FDA inspectors made on FDA's Form 483 ("483's), the cost of which is included in SG&A, though such costs were lower in fiscal 2002 versus fiscal 2001. We do anticipate that we will continue to incur considerable consultation costs and the involvement of laboratory personnel in responding to the 483's through the foreseeable future, although such involvement is expected to continue to gradually decline in future periods. See "Liquidity, Capital Resources, and Changes in Financial Condition".

Research and development expenses ("R&D") were $1,067,450 and $1,313,099 respectively, in fiscal 2002 and 2001, a decrease in fiscal 2002 of $245,649 or 19%. In fiscal 2001, we sponsored two Phase 2 clinical trials of injectable collagenase for Dupuytren's disease, which were completed early in Fiscal 2002. Most of the expenses relating to these trials were incurred in fiscal 2001. In fiscal 2001 we also sponsored a Phase 1 trial for Peyronie's disease. Both indications have been granted Orphan Drug status by the FDA. Internal

R&D costs have declined as development moves to clinics. For the fiscal year that will end January 31, 2003, we expect R&D expenditures to approximate $1 million.

Other income (expense), net was $8,636 and ($278,865) respectively, in fiscal 2002 and 2001, an increase in other income net in fiscal 2002 of $287,501. In fiscal 2001, we recorded the decrease in the market value of our investments in equity securities held as trading securities during that year. For all of fiscal 2002, we no longer had significant investments in equity securities, and therefore no material gains or losses. Interest expense increased due to the take down of the 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, during the fourth quarter of fiscal 2002.

The (provision) benefit for income taxes was $17,130 and $(276,695) respectively in fiscal 2002 and 2001. The benefit in fiscal 2002 relates to orphan drug tax credits. The fiscal 2001 provision represents an increase in our deferred tax valuation allowance recognized in the fourth quarter of fiscal 2001 due to the uncertainty with respect to the timing of future utilization of Orphan Drug tax credits and other tax benefits. The principal reason for the difference between the United States Federal statutory tax rate of 34% and the effective tax rate in fiscal 2002 is due to the tax effect of foreign sourced losses for which no benefit can be taken. The principal reason for the difference between the United States Federal statutory tax rate of 34% and the effective tax rate in fiscal 2001 is due to the above-mentioned increase in the deferred tax valuation allowance. 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.

LIQUIDITY, CAPITAL RESOURCES AND CHANGES IN FINANCIAL CONDITION

Our primary source of working capital is from operations, which includes sales of product, royalties, and periodic license fees. At January 31, 2002, we had working capital of approximately $2.4 million, which includes cash and cash equivalents, and marketable securities of approximately $693,000. The principal use of cash in fiscal 2002 was approximately $607,000 used to purchase plant, property and equipment for the upgraded Curacao and Lynbrook facilities. These uses were offset by the loan from Korpodeko, and cash provided by operating activities.

As discussed in the section titled "Risk Factors Related to our Business" in section in Item 1 of this report, Collagenase ABC enzyme is our only product and sole source of revenues. The production and marketing of Collagenase ABC enzyme is subject to regulation in the United States by the federal government, principally the FDA. We stopped production of the enzyme and began upgrading the Curacao facility in March 2000. In May 2001 we completed the upgrade and went back into limited production. In April 2002 we filed with the FDA a "Prior Approval Supplement" ("PAS") for the Curacao facility upgrade. Although it is difficult to predict with any certainty the time at which the PAS approval can be obtained, we believe the following could happen by the end of the fiscal year that will end January 31, 2003:

[ ] FDA comments on PAS
[ ] FDA inspects Curacao facility
[ ] FDA comments on inspection of Curacao facility
[ ] BioSpecifics responds to FDA comments
[ ] FDA approves PAS for Curacao facility

While we are producing enzyme at the upgraded Curacao facility, the new enzyme production for Abbott must be held in quarantine and can only be sold to Abbott if and when the FDA approves the PAS and any

enzyme already produced at the facility for Abbott. There can be no assurance if or when the FDA will approve our PAS according to our schedule, if at all.

Since we began upgrading the Curacao facility in March 2000, we have not produced any new enzyme that we can currently sell to Abbott. The enzyme we processed and sold to Abbott in fiscal 2001 and fiscal 2002, which it used to make Collagenase Santyl(R) Ointment ("Santyl(R)"), was from an inventory of enzyme we built up at the Curacao facility prior to the start of the upgrade. This inventory will be depleted during the first half of fiscal 2003. Revenues from this inventory and royalties on sales of ointment will be insufficient to cover our operating expenses, resulting in an operating loss for the fiscal year that will end January 31, 2003.

We expect to have cash to fund operations during the fiscal year ended January 31, 2003 from royalties from sales of Santyl(R), the sale of the remaining enzyme inventory to Abbott, the production and sale of enzyme to foreign customers, and cash currently on hand. We estimate that Abbott can supply S&N with Santyl(R) through March 2003, based on its inventory of enzyme it has already purchased from us, our remaining inventory of enzyme, and S&N's rate of Santyl(R) sales. If we are able to get approval of the PAS by the end of the fiscal year ended January 31, 2003, we may also be able to sell quarantined enzyme already produced and planned to be produced. However, if approval is significantly delayed and we cannot sell quarantined product, we will be unable to fund operations beyond the first quarter of calendar 2003 unless we are able to raise additional capital.

We are dependent on Abbott to buy enzyme, contract manufacture Santyl(R) and provide it to S&N ready for distribution. We are dependent on S&N for the distribution of Santyl(R), which provides us with royalty revenue. Abbott and S&N have a Sublicense and Assignment agreement whereby Abbott will assign to S&N its rights in our exclusive license agreement by December 31, 2002. S&N has the option to terminate its agreement with Abbott if the FDA approval of the Curacao facility PAS is not received by December 31, 2002. There can be no assurance that S&N will not terminate its agreement with Abbott if the PAS is not approved by December 31, 2002. In the event S&N terminates, our exclusive license agreement with Abbott automatically extends for 10 more years in August 2003, unless Abbott exercises its right not to extend our exclusive license agreement, in which event it would have to notify us six months in advance, or February 2003.

If S&N were to terminate, and Abbott exercise its right, we would have to find another licensee for Santyl(R) with a sufficient sales force. We might also have to use another trade name for ointment containing our Collagenase ABC, as the trade name Santyl(R) is owned by Abbott. There can be no assurance that we would be successful in finding another licensee or that a new licensee could achieve S&N's current level of sales.

While we believe we have made considerable progress in addressing the FDA concerns addressed in the Form 483 and the FDA Letter, if we are unable to further address these matters in a timely manner, there may be delays in the delivery of the product produced in the renovated facilities to Abbott for use to contract manufacture Collagenase Santyl(R) Ointment. Such delays could have a material adverse effect on our future operating results.

In connection with the Korpodeko loan, our subsidiary AB-Curacao agreed to pledge as collateral substantially all of our production assets located in Curacao, with a book value of approximately $4.5 million. BioSpecifics has also guaranteed the Korpodeko loan. We drew down this loan in November 2001. Through our subsidiary ABC-Curacao, we also maintain a line of credit with a Netherlands Antilles bank under which the bank will lend up to $110,000 to ABC-Curacao, with interest at the bank's prime lending rate (12% at January 31, 2002). Drawings under the line of credit would be secured by investment assets

and cash on deposit at the bank, is payable on demand, and is guaranteed by another of our subsidiaries, ABC-New York.

We believe that our capital resources, together with anticipated proceeds from the fiscal 2003 sales of available inventory, related royalty income from Abbott, and sales to foreign customers of inventory that will be produced are adequate to sustain the business at least through January 31, 2003 and complete the steps necessary to obtain FDA approval of our upgraded production facilities by that date. We believe we have made substantial progress in addressing the FDA's inspectional observations and that we may be able to resume normal operations by January 31, 2003. However, we are dependent on the FDA's approval of the upgraded plant in Curacao for the resumption of normal operations.

Although we believe our capital resources are adequate and that we have made substantial progress toward addressing the FDA's concerns, there can be no assurance that unforeseen circumstances will not have a material adverse effect on our financial condition and that the time required to get FDA approval of the upgraded Lynbrook and Curacao plants will not exceed our estimates. There can be no assurance that the FDA will not have additional inspectional observations

that could result in delaying its approval of the PAS for the Curacao facility an or that the FDA will approve the upgraded facility and permit us to resume our normal operations at all.

In addition to obligations previously discussed, long-term capital requirements at January 31, 2002 include a non-amortizing loan of $455,000 at 6.5% interest due in November 2003. The Company also has operating leases of approximately $191,000 annually through fiscal 2006.

ITEM 7. FINANCIAL STATEMENTS

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

In December 2001, with Board approval, the Company decided to change accountants. There were no disagreements with the previous accountant on any matter of accounting principal or practices, financial statement disclosure, or auditing scope or procedures. Information in response to this item has been reported on the Company's Current Report of Form 8-K dated December 12, 2001.

PART III

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

The information required by Item 9 as to directors is incorporated by reference to the information captioned "Election of Directors" to be included in the Registrant's definitive proxy statement in connection with the 2002 meeting of shareholders. The information regarding compliance with Section 16 of the Securities Exchange Act of 1934 and the Rules promulgated thereunder is incorporated by reference therein to the Company's definitive proxy statement in connection with the 2002 meeting of shareholders.

ITEM 10. EXECUTIVE COMPENSATION.

The information required by Item 10 is incorporated by reference to the information captioned "Remuneration and Other Transactions with Management" to

be included in the Registrant's definitive proxy statement in connection with the 2002 meeting of shareholders.

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

The information required by Item 11 is incorporated by reference to the information captioned "Voting Securities" to be included in the Registrant's definitive proxy statement in connection with the 2002 meeting of shareholders.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information required by Item 12 is incorporated by reference to the information captioned "Remuneration and Other Transactions with Management" to be included in the Registrant's definitive proxy statement in connection with the 2002 meeting of shareholders.

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 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 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.)
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.)
Exhibit 10.10	Regulatory Compliance Agreement between Advance Biofactures Corp., Knoll Pharmaceutical Company, and Smith and Nephew, Inc. (Previously filed on the Registrant's Form 8-K dated March 3, 2000 and incorporated herein by reference.)
Exhibit 10.11	Allocation of Responsibilities Agreement between Advance Biofactures Corp., Knoll Pharmaceutical Company, and Smith and Nephew, Inc. (Previously filed on the Registrant's Form 8-K dated March 3, 2000 and incorporated herein by reference.)
Exhibit 10.12	Adverse Event ("AE") Agreement between Advance Biofactures Corp., Knoll Pharmaceutical Company, and Smith and Nephew, Inc. (Previously filed on the Registrant's Form 8-K dated March 3, 2000 and incorporated herein by reference.)
Exhibit 10.13	Recourse Secured Demand Note between BioSpecifics Technologies Corp. and Edwin H. Wegman
Exhibit 10.14	Stock Pledge Agreement between BioSpecifics Technologies Corp. and Edwin H. Wegman
Exhibit 10.15	Form of 2001 Stock Option Plan of Registrant
Exhibit 10.16	Loan agreement between Advance Biofactures of Curacao, NV and

Korpodeko Curacao Development Corporation dated August 6, 2001 and Letter of Intent dated May 15, 2001.*

Exhibit 22 Subsidiaries of the Registrant. (Previously filed as exhibit 22 to Registrant's 10-KSB for the year ended January 31, 1996 and incorporated herein by reference.)

Exhibit 23.1 Consent of BDO Seidman LLP.*

Exhibit 23.2 Consent of Grant Thornton, LLP.*

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* Filed herewith

(B) REPORTS ON FORM 8-K

In an 8-K report dated December 10, 2001, the Company reported a change in certifying accountant from Grant Thornton LLP to BDO Seidman LLP.

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: May 13, 2002 By: 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.

Edwin H. Wegman Edwin H. Wegman	Chairman of the Board, President and Director (Principal Executive Officer)	May
Albert Horcher Albert Horcher	Secretary, Treasurer, Principal Financial and Chief Accounting Officer	May
Thomas L. Wegman Thomas L. Wegman	Executive Vice President and Director	May

Paul A. Gitman, M.D. --- Paul A. Gitman, M.D.	Director	May
Henry Morgan --- Henry Morgan	Director	May
Louis Lasagna, M.D. --- Louis Lasagna, M.D.	Director	May
Rainer Friedel, M.D. --- Rainer Friedel, M.D.	Director	May
John T. Lane --- John T. Lane	Director	May

Report of Independent Certified Public Accountants

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 January 31, 2002, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss) and cash flows for the year then ended. 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 audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BioSpecifics Technologies Corp. and subsidiaries at January 31, 2002, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO SEIDMAN, LLP

Melville, New York
April 5, 2002

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

To the Board of Directors and Stockholders of Biospecifics Technologies Corp. and Subsidiaries

We have audited the accompanying consolidated statements of operations, stockholders' equity and cash flows of Biospecifics Technologies Corp. and Subsidiaries for the year ended January 31, 2001. 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 audit.

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

In our opinion, the consolidated statements of operations, stockholders' equity and cash flows referred to above present fairly, in all material respects, the consolidated results of operations of Biospecifics Technologies Corp. and Subsidiaries for the year ended January 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

/s/ GRANT THORNTON LLP

Melville, New York
April 23, 2001

BIOSPECIFICS TECHNOLOGIES CORP.
AND SUBSIDIARIES

Consolidated Balance Sheet

January 31, 2002

Assets

Current assets:	
Cash and cash equivalents	$
Marketable securities	
Accounts receivable, net	2
Inventories, net	
Prepaid expenses and other current assets	
Total current assets	4
Property, plant and equipment, net	5
Deferred income taxes	
	$ 9

Liabilities and Stockholders' Equity

Current liabilities:	
Accounts payable and accrued expenses	$ 1
Notes payable to related parties	
Deferred revenue	
Total current liabilities	1
Long-term debt	
Minority interest in subsidiaries	
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; 4,912,216 shares issued	
Additional paid-in capital	3
Retained earnings	6
Accumulated other comprehensive income	
Treasury stock, 361,380 shares at cost	(1
Notes receivable from chairman and other related party	(1
Total stockholders' equity	6
	$ 9

See accompanying notes to consolidated financial statements.

Consolidated Statements of Operations
Years ended January 31,

	2002	2001
Revenues:		
Net sales	$ 5,940,637	3,437,083
Royalties	2,269,048	2,094,622
	8,209,685	5,531,705
Costs and expenses:		
Cost of sales	5,106,234	2,503,906
General and administrative	2,319,853	2,659,621
Research and development	1,067,450	1,313,099
	8,493,537	6,476,626
Loss from operations	(283,852)	(944,921)
Other income (expense):		
Investment income (expense)	21,551	(272,971)
Interest expense	(12,915)	(5,894)
	8,636	(278,865)
Loss before benefit (provision) for income taxes and minority interest	(275,216)	(1,223,786)
Income tax benefit (provision)	17,130	(276,695)
Loss before minority interest	(258,086)	(1,500,481)
Minority interest in loss of subsidiaries	770	32,000
Net loss	$ (257,316)	(1,468,481)
Basic and diluted net loss per share	$ (.06)	$ (.32)
Weighted-average common shares outstanding	4,539,325	4,529,766

See accompanying notes to consolidated financial statements.

BIOSPECIFICS TECHNOLOGIES CORP. AND
Consolidated Statements of Stockholders' Equity and

Common Stock		Additional Paid in	Retained	Accumulated other compre-hensive Income	
Shares	Amount	Capital	earnings	(loss)	Trea s

Balance at January 31, 2000	4,891,146	$ 4,891	$ 3,734,375	$7,826,812	$ 7,412	$(1,911
Stock options granted for services			14,000			
Change in cumulative translation adjustment						10
Notes receivable from chairman						
Net loss				(1,468,481)		
Balance at January 31, 2001	4,891,146	4,891	3,748,375	6,358,331	18,151	(1,911
Stock option exercises	6,750	7	6,743			
Stock options granted for services			5,000			
Stock granted for services	14,320	14	39,986			
Change in cumulative translation adjustment					(2,340)	
Net paydown of notes receivable from chairman and other related party						
Reclassification of Due from related party (note 15)						
Net loss				(257,316)		
Balance at January 31, 2002	4,912,216	$ 4,912	$ 3,800,104	$6,101,015	$15,811	$(1,911

See accompanying notes to consolidated financial statements.

BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
Years ended January 31,

	2002	
Cash flows from operating activities:		
Net loss	$ (257,316)	(1
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	437,350	
Options issued for services	5,000	
Issuance of stock for services	40,000	
Realized and unrealized loss on marketable securities, net	1,320	
Minority interest in loss of subsidiaries	(770)	
Provision (benefit) for deferred taxes	(28,330)	
Changes in operating assets and liabilities:		
Accounts receivable	(1,440,480)	
Inventories	1,145,880	
Prepaid expenses and other current assets	15,065	
Other assets	28,812	
Net change in trading securities	109,841	
Accounts payable and accrued expenses	(101,683)	
Income taxes	150,000	
Net cash provided by operating activities	104,689	
Cash flows from investing activities:		
Due from related party	10,028	
Net paydown of notes receivable from chairman and other related party	156,916	
Expenditures for property, plant and equipment	(607,498)	(3
Net cash used in investing activities	(440,554)	(4
Cash flows from financing activities:		
Increase in notes payable to related parties	500	
Exercise of stock options	6,750	
Increase in long-term debt	455,000	
Net cash provided by financing activities	462,250	
Effect of exchange rates on cash and equivalents	(2,340)	
Increase (decrease) in cash and cash equivalents	124,045	(3
Cash and cash equivalents at beginning of year	569,170	4
Cash and cash equivalents at end of year	$ 693,215	
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	$ 12,915	
Income taxes	$ 1,188	

See accompanying notes to consolidated financial statements.

BIOSPECIFICS TECHNOLOGIES CORP.
AND SUBSIDIARIES

Notes to Consolidated Financial Statements
January 31, 2002 and 2001

1. 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") which 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.

For the fiscal years ended January 31, 2002 and 2001, 87% and 90%, respectively, of the Company's revenues were from one customer in the United States, Abbott Laboratories ("Abbott") who, pursuant to an exclusive licensing 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 Company also earns royalties on the sale of Santyl(R) to distributors by Smith & Nephew, Inc. ("S&N") (Note 10).

2. Liquidity and Financial Condition

In 1999, the Company was issued a list of inspectional observations made by the FDA in Form 483 citing numerous deficiencies in the Company's compliance with FDA regulations at its production plants in Lynbrook and Curacao and at Abbott's contract manufacturing facility. The FDA advised the Company that they would revoke the Company's license to produce the enzyme and ointment unless the Company 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 regulations. The Company responded to the FDA by submitting a comprehensive plan of corrective action providing for (i) the renovation of the Lynbrook and Curacao production plants, (ii) the reorganization of the Company's quality control and quality assurance departments, (iii) an upgrade of quality control standards and procedures and (iv) the hiring of additional personnel in the quality control and quality assurance departments. The Company has retained an outside consulting firm with expertise in FDA regulatory compliance matters to assist in developing and implementing the corrective action plan.

The Company started renovating the Curacao plant in March 2000 and as a result suspended the production of enzyme at that location. The Company completed the renovation at the Curacao and Lynbrook facilities in March 2001 and has substantially validated the facilities. In April 2002, the Company filed with the FDA a "Prior Approval Supplement ("PAS") for the Curacao facility upgrade. FDA inspection and approval of the Curacao facility will be required before enzyme produced at the facilities can be sold to Abbott. In anticipation of the renovations and suspension of production operations, the Company accumulated an inventory of the product, which it continues to process at the Lynbrook facility and currently sells to Abbott when processing is completed. The Company

estimates that its inventory on hand at January 31, 2002 and Abbott's inventory on hand at January 31, 2002 can be used by Abbott to contract manufacture Santyl(R) into the third quarter of calendar 2002. The Company estimates that this inventory is sufficient to enable Abbott to supply S&N with Santyl(R) into the second quarter of calendar 2003.

The Company has invested approximately $4.7 million in plant, property and equipment to upgrade both plants and anticipates it will spend approximately $100,000 more to completion. In addition, the Company incurred consulting fees and other expenses of approximately $1.3 million since May 1999 including $112,000 during the fiscal year ended January 31, 2002, and believes it will incur additional expenses of approximately $100,000 during the fiscal year that will end January 31, 2003. During the fiscal years ended January 31, 2000, 2001, and 2002, we estimate that our personnel costs dedicated to the upgrade and addressing the FDA's observations were approximately $923,000, which were recorded in general and administrative expenses. The Company believes that the plant upgrades and changes in the Company quality control policies and procedures outlined in the corrective plan will adequately address the FDA's concerns, although there can be no assurances that additional expenditures and time will not be

required as a result of any FDA concerns. Management also believes that the capital-spending plan modernized the Company's facilities and improved operational efficiency.

While the Company believes that it has made considerable progress in addressing the FDA concerns addressed in the Form 483 and the FDA Letter, if the Company is unable to further address these matters in a timely manner, there may be delays in the approval of the PAS and delivery of product produced in the upgraded facilities to Abbott for use to contract manufacture Collagenase Santyl(R) Ointment. Such delays could have a material adverse effect on the Company's future operating results. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the incurrence of liabilities in the normal course of business.

For the year ended January 31, 2002, the Company incurred a net loss of approximately $257,000, generated operating cash flow of $104,689, raised approximately $455,000 by financing activities, primarily from long-term debt borrowings, and incurred $607,498 of expenditures relating to the facility upgrades. At January 31, 2002 the Company has approximately $2.4 million of working capital available, including approximately $784,000 of available inventory, which would generate proceeds from net sales, and royalty revenue to fund its operations and continue to address FDA concerns through January 31, 2003. The Company borrowed $455,000 from an industrial development agency in Curacao (Note 9) in fiscal 2002, and has a $110,000 line of credit with the Company's bank in Curacao.

The Company believes that its capital resources, together with anticipated proceeds from the sales of available inventory and related royalty income from Abbott, and sales to foreign customers of inventory that will be produced will be adequate to sustain the business at least through January 31, 2003 and complete the approval of the PAS for its production facilities by that date. The Company believes it has made substantial progress in addressing the FDA's inspectional observations and that it will be able to resume normal operations by January 31, 2003. However, the Company is dependent on the FDA's approval of

its PAS for the upgraded plant in Curacao for the resumption of normal operations and the sale to Abbott of Collagenase ABC enzyme produced there.

Although management believes that the Company's capital resources are adequate and that it has made satisfactory progress toward addressing the FDA's concerns, there can be no assurance that unforeseen circumstances will not have a material adverse effect on the Company's financial condition and that the cost of completing the upgrade of the Lynbrook and Curacao plants will not exceed management's estimates. There can be no assurance that the FDA will not have additional inspectional observations that could result in the delay of approval of the PAS for the upgraded plants and permit the Company to resume its normal operations at all.

3. 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.

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 their estimated useful lives of

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. 121, "Accounting for the Impairment of Long-Lived Assets to be Disposed of" ("SFAS 121"), relying on a number of factors including operating results, business plans, economic projections and anticipated future cash flows. SFAS 121 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. Impairment losses have not been incurred for the years ended January 31, 2002 and 2001.

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 functional currency of Bio Pharma GmbH is the Euro and its assets and liabilities are translated into the U.S. dollar at year-end exchange rates and income and expense items are translated at average exchange rates for the period. Gains and losses resulting from translation are included in stockholders' equity as accumulated other comprehensive income (loss). The assets and liabilities of ABC Curacao are denominated in U.S. dollars. ABC-Curacao conducts local transactions in local currency and translates them at average exchange rates for the period.

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 fees the Company charges Abbott for testing Ointment contract manufactured by Abbott. Net sales from testing are recognized when the ointment is released 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.

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 for potential products are recognized as income in the year agreements are entered into if related license fees are non-refundable. License fees attributable to agreements that contain refund provisions are deferred until all provisions of the agreements are fulfilled. The Company did not recognize any license fee revenue during the periods ended

January 31, 2002 and 2001.

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 $1,067,450 and $1,313,099 in 2002 and 2001, respectively.

Net Loss Per Share

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

Diluted net income 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 January 31, 2002 and 2001, as their effect is antidilutive. If the Company had reported net income for the year ended January 31, 2002, diluted earnings per share for the period would have included the number of shares used in the computation of basic net loss per share, plus common equivalent shares that would relate to 1,100,500 options outstanding at January 31, 2002. For the year ended January 31, 2001, the number of options outstanding was 721,300.

Stock Based Compensation

The Company has adopted the disclosure provisions of SFAS No. 123 "Accounting for Stock-Based Compensation", and therefore applies the intrinsic value method of accounting for employee stock options as prescribed under Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees" ("APB 25"). Under APB 25, when the exercise price of an employee stock option granted by the Company is equal to or greater than the market price of the underlying stock on the date of grant, no compensation expense is recognized. The Company discloses pro forma net loss and net loss per share for the years ended January 31, 2002 and 2001 as if the fair value method had been applied.

Compensation is recognized on options issued to nonemployees based on the fair value of the consideration received or the fair value of the option, whichever is more readily measurable.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America 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.

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. The fair value of notes receivable due from the chairman and other related party, and notes payable to related parties, approximate their carrying values based upon their stated interest rates and the underlying collateral pledged.

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 10.)

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets" effective for fiscal years beginning after December 15, 2001. Under the new standards, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized but will be subject to annual impairment tests. Other intangible assets will continue to be amortized over their useful lives. The Company does not expect the adoption of SFAS No. 141 and 142 to have a material impact on its financial position and results of operations.

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". The new guidance resolves significant implementation issues related to SFAS No. 121, "Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of". SFAS No. 144 supersedes SFAS No. 121, but it retains its fundamental provisions. SFAS No. 144 retains the requirements of SFAS No. 121 to recognize an impairment loss only if the carrying amount of a long-lived asset within the scope of SFAS No. 144 is not recoverable from its undiscounted cash flows and exceeds its fair value. It also amends Accounting Research Bulletin No. 51, "Consolidated Financial Statements" to eliminate the exception to consolidate a subsidiary for which control is likely to be temporary. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001. The Company plans to adopt its provisions in the Company's fiscal year

ending January 31, 2003. The Company does not expect the adoption of SFAS No. 144 to have a material impact on its financial position and results of operations.

4. Marketable Securities

Marketable securities at January 31, 2002 consist of common and preferred stock, with a cost basis of $256,953 unrealized holding losses of $253,927, and fair market value of $3,026. Fair values are based upon quoted market prices.

5. Inventories

Inventories at January 31, 2002 consist of:

Raw materials	$101,573
Work-in-process	682,591
	$784,164

6. Property, Plant and Equipment, net

Property, plant and equipment at January 31, 2002 consist of:

Machinery and equipment	$2,381,845
Furniture and fixtures	362,435
Leasehold improvements	4,027,760
Automobiles	11,743
	6,783,783
Less accumulated depreciation and amortization	(1,720,470)
	$5,063,313

The Company placed production equipment and related leasehold improvements at the upgraded Curacao and Lynbrook facilities into service during the year ended January 31, 2002. Depreciation and amortization expense amounted to $437,350 and $150,735 for the years ended January 31, 2002 and 2001, respectively.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

Trade accounts payable and accrued expenses	$ 829,763
Accrued legal and other professional fees	411,183
Accrued payroll and related costs	439,683
	$1,680,629

8. Income Taxes

The (provision) benefit for income taxes consists of the following:

	2002	2001
Current:		

Federal	$ (8,700)	$ 82,995
State	(2,500)	(9,690)
Foreign	--	--
	(11,200)	73,305
Deferred:		
Federal	25,620	(317,000)
State	2,710	(33,000)
	28,330	(350,000)
	$ 17,130	$(276,695)

The effective income tax rate of the Company differs from the federal statutory tax rate of 34% in fiscal 2002 and 2001 as a result of the effect of the following items:

	2002	2001
Computed tax benefit at statutory rate	$93,310	$409,000
Tax effect of foreign sourced loss, net of foreign taxes	(172,650)	(98,000)
State income taxes, net of federal benefit	130	27,705
Non-deductible expenses	(13,660)	(26,100)
Orphan drug and other tax credits	110,000	162,700
Increase in valuation allowance	-	(752,000)
	$17,130	$(276,695)

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

	2002	2001
Orphan Drug Credit	$742,000	$632,000
Inventory	84,000	76,000
Accrued expenses	193,000	194,000
Depreciation and amortization	25,000	21,000
Capital loss carryforward	54,000	79,000
Other	18,536	86,206
Net deferred tax assets before valuation allowance	1,116,536	1,088,206
Valuation allowance	(952,000)	(952,000)
Net deferred tax asset	$164,536	$136,206

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 $752,000 during the fourth quarter of the year ended January 31, 2001. The valuation allowance at January 31, 2002 and 2001 primarily pertains to uncertainties with respect to the timing of future utilization of Orphan Drug Credits and other tax benefits. The Company believes it will utilize the benefit of net deferred tax assets based on recognition of future income.

The Company has reinvested the accumulated earnings of its foreign subsidiaries, mostly in the form of plant, property and equipment, and therefore does not plan to repatriate the balance of such earnings (approximately $4.7 million as of January 31, 2002) 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%.

9. Credit Facilities

The Company, through its subsidiary ABC-Curacao, drew down in November 2001 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 is due November 2003. The Company, also through its subsidiary, ABC-Curacao, has a $110,000 line of credit with a Netherlands Antilles bank, with interest at the bank's prime lending rate (12% at January 31, 2002). Substantially all of the Company's fixed assets located in Curacao, with a book value of $4.3 million, are pledged as collateral for these obligations. The Company has also guaranteed the Korpodeko loan.

10. Major Customer and Royalty and License Agreements

The Company's primary royalty and license agreements are for its FDA approved product, Collagenase ABC.

In the fiscal years ended January 31, 2002 and 2001, the Company derived 83% of its net sales of product and 100% of its royalties from an exclusive license agreement with Abbott Laboratories ("Abbott", which acquired Knoll Pharmaceutical Company ("KPC"), the Company's original licensee, in March 2001). Abbott acts as the Company's contract manufacturer by compounding the product into Collagenase Santyl(R) ("Santyl(R)"), an ointment used to treat various types of skin wounds, particularly chronic dermal ulcers and severely burned areas. The exclusive licensing agreement provides Abbott with exclusive rights to market Santyl(R) ointment in North America in exchange for purchases of the product and royalties on Santyl(R) sales to distributors by Smith & Nephew Inc. ("S&N"). The license agreement, with an expiration date of August 2003, has an automatic ten-year renewal clause unless Abbott elects not to renew the agreement. The rest of the Company's revenues come from product sales to pharmaceutical companies in Brazil and India.

In January 2000, pursuant to a sublicense and assignment agreement, to which the Company is not a party, KPC sublicensed its rights to Smith & Nephew, Inc. ("S&N") with the consent of the Company. Under the sublicense, Abbott continues to purchase the product from the Company and manufacture the ointment. S&N markets the ointment and sells it to distributors. In connection with the sublicense, the Company entered into several agreements with Abbott and S&N.

These include an agreement allocating responsibility under the Abbott Agreement among the Company, Abbott, and S&N for both the sublicense and license period. Another agreement imposes certain obligations upon the Company to address the FDA issues concerning the Curacao and Lynbrook production facilities. Abbott will assign its license rights (as opposed to the current sublicense agreement) in the Abbott Agreement to S&N in the event of FDA approval of a compliance program being undertaken by the Company, including the upgrade of its production facilities. If the license rights are assigned to S&N, the Abbott agreement will be automatically extended at that time until 2013, and automatically renew for an additional 10-year term unless S&N notifies the Company, at least 6 months prior to the renewal date, of its intention to terminate at the conclusion of the 2013 term.

The minimum annual royalty is $60,000 per year. Royalties from Abbott were $2,269,048 and $2,094,622 in fiscal 2002 and 2001, 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 January 31, 2002 is $45,000 from this agreement. The deferred revenue is refundable if approval in Germany is not obtained.

11. Stockholders' Equity

Stock Option Plans

In April 1991, the Company established a stock option plan (the "1991 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 1991 plan, qualified incentive stock options and non-qualified stock options may be granted to purchase up to an aggregate of 220,000 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 1991 plan, no option shall be granted under the plan subsequent to ten years after its effective date, or November 2001.

In July 1994, the Company's stockholders approved a stock option plan (the "1993 plan") with terms identical to the 1991 plan. The 1993 plan authorizes the granting of awards of up to an aggregate of 200,000 shares of the Company's common stock, subject to certain anti-dilution provisions.

In July 1997, the Company's stockholders approved a stock option plan (the "1997 plan") with terms identical to the 1991 and 1993 plans. 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 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.

The Company has adopted the disclosure provisions of SFAS No. 123 "Accounting for Stock Based Compensation" ("SFAS 123"). It applies APB 25 and related interpretations in accounting for its plans and does not recognize compensation expense since its plans provide for the granting of options with prices equal to or greater than the fair market value of the Company's common stock at the date of grant. Had compensation cost been recognized consistent with SFAS 123, the Company's consolidated net loss in fiscal 2002 would have increased by $271,160 to a loss of ($528,476) and consolidated net loss in fiscal 2001 would have increased by $185,678 to a loss of ($1,654,159). Basic and diluted loss per share in fiscal 2002 and 2001 would have been increased to a loss of ($0.12) per share and ($0.37) per share, respectively.

The per share weighted average fair value of stock options issued to employees by the Company during fiscal 2002 and 2001 was $0.64 and $0.91, respectively, on the date of grant. In fiscal 2002 and 2001, the assumptions of no dividends, expected volatility of approximately 60%, and an average expected life of 5 years were used by

the Company in determining the fair value of the stock options granted using the Black Scholes option pricing model. In addition, the calculations assumed a risk-free interest rate of 5.0% in fiscal 2002 and 2001.

The summary of the stock options activity is as follows:

	Fiscal 2002		Fiscal 2
	Shares	Weighted Average Exercise Price	
Outstanding at beginning of year	721,300	$3.41	
Options granted	430,250	1.03	
Options exercised	(6,750)	1.00	
Options canceled or expired	(44,300)	3.11	
Outstanding at end of year	1,100,500	2.64	
Options exercisable at year end	986,500	2.66	
Shares available for future grant	434,050	-	

During fiscal 2002 and 2001, the Company granted 5,000 and 10,000 options, respectively, to medical consultants at an exercise price of $1.25 and $2.875

per share, respectively. These options vest at the rate of 25% per year. In connection with these options, the Company recorded in fiscal 2002 and 2001 an expense of $5,000 and $14,000, respectively, representing the estimated fair value of the options. During fiscal 2002 and 2001, the Company granted 425,250 and 205,050 options, respectively, to employees of the Company at prices ranging from $1.00 to $3.00.

The following table summarizes information relating to stock options by exercise price as at January 31, 2002:

	Outstanding			Exercisable	
		Weighted Average			Weighted Average
Option exercise price	Shares	Life (years)	Exercise price	Shares	O exercise
$1.00-1.10	587,200	9.8	$1.02	483,200	
1.88	125,450	8.0	1.88	125,450	
2.00-2.88	66,950	8.8	2.57	63,950	
3.00-3.88	44,200	6.5	3.33	44,200	
4.00-4.63	105,500	5.4	4.36	98,500	
5.81-7.25	115,500	2.4	6.13	115,500	
8.00	5,700	3.0	8.00	5,700	
9.13	50,000	2.5	9.13	50,000	
	1,100,500	7.7	$2.64	986,500	

12. Net Loss Per Share

Net loss per share for the years ended January 31, 2002 and 2001 is presented in the accompanying statement of operations. Diluted loss per share is the same as basic loss per share for the years ended January 31, 2002 and 2001, as the effect of dilutive securities would be anti-dilutive.

13. 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 January 31,

2003	191,000
2004	191,000
2005	191,000
2006	30,000

Rent expense under all operating leases amounted to approximately $191,000 in

both fiscal 2002 and 2001, 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 real estate taxes to WSC in each of fiscal 2002 and 2001.

ABC-Curacao leases a building in Brievengat, Curacao, Netherlands Antilles from a 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 fiscal 2002 and 2001.

(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 each of fiscal 2002 and 2001, the Company recorded approximately $24,000 for payments to Board members under these agreements. The Company has oral agreements with two of the eight members of the Board and a written agreement with two other members providing for honoraria of approximately $6,000 each, terminable at the option of the Company.

(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.

(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.

14. Segment Information

The Company is engaged in one segment, specifically research, development, production and distribution 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 January 31, 2002:	North America	S.A. and Europe	Eliminations
Revenues from unaffiliated customers	$7,248,547	$961,138	
Intercompany revenue between geographic regions		395,780	(395,780)
Income (loss) from operations	218,335	(502,187)	
Income (loss) before taxes	233,344	(507,790)	
Identifiable assets	4,024,090	5,414,197	(110,743)
Capital expenditures	187,952	419,546	
Depreciation and amortization	160,405	276,945	

Year ended January 31, 2001:	North America	S.A. and Europe	Eliminations
Revenues from unaffiliated customers	$4,986,194	$545,511	
Intercompany revenue between geographic regions		1,088,508	(1,088,508)
Loss from operations	(779,039)	(165,882)	
Loss before taxes	(947,439)	(244,347)	
Identifiable assets	4,840,975	4,823,570	(520,801)
Capital expenditures	464,216	3,358,350	
Depreciation and amortization	114,480	36,255	

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 at arms-length.

15. Related Party Transactions

The Company has two loans to the Company's chairman. One loan, whose principal

balance at January 31, 2002 is $941,306 is a demand promissory note, bears interest at 9% per annum, is collateralized by approximately 1,800,000 shares of the Company's stock. Another loan, whose principal balance at January 31, 2002 is $56,820 is a demand promissory note, bears interest at 9% per annum, an 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 which amount to $35,646. For financial statement purposes, all these loans, which aggregate $1,116,378 are classified as components of stockholders' equity in the balance sheet and appear as "Notes due from chairman and other related party". Interest income accrued for these loans but not recognized for financial statement purposes aggregated approximately $105,000 and $72,000 for the years ended January 31, 2002 and 2001, 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 $14,010 at January 31, 2002. The notes, which bear interest at 9% per annum, are payable on demand.

During the fiscal years ended January 31, 2002 and 2001 the Company incurred consulting fees in the amount of $0 and $35,000 for services provided by a son of a former director. During the fiscal year ended January 31, 2001, the Company paid $92,650 for the use of an entertainment facility formerly owned by an affiliate of the Company's chairman and chief executive officer.

16. 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 the years ended January 31, 2002 and 2001.

EXHIBIT INDEX

EXHIBIT

Exhibit 10.16	Loan agreement between Advance Biofactures of Curacao, NV and Korpodeko Curacao Development Corporation dated August 6, 2001 and Letter of Intent dated May 15, 2001.
Exhibit 23.1	Consent of BDO Seidman LLP
Exhibit 23.2	Consent of Grant Thornton, LLP