BIOSPECIFICS TECHNOLOGIES CORP
Form 10QSB
December 20, 2001

U.S. Securities and Exchange Commission
Washington D.C. 20549

FORM 10-QSB

(Mark One)

[x] QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: October 31, 2001

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

Commission File number: 0-19879

BioSpecifics Technologies Corp.
(Exact name of Small Business Issuer as Specified in Its Charter)

Delaware	11-3054851
(State of Incorporation)	(IRS Employer I.D. Number)

35 Wilbur St.
Lynbrook, NY 11563
(Address of principal executive offices)

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

Check whether the issuer: (1) has filed all reports required by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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

APPLICABLE ONLY TO CORPORATE ISSUERS:

The number of shares outstanding of the issuer's common stock, par value $0.001 per share as of December 1, 2001, was 4,550,836.

Transitional Small Business Disclosure Format (check one): Yes No X

BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES

INDEX

2

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

BioSpecifics Technologies Corp. and Subsidiaries
Consolidated Balance Sheets

	(Unaudited) October 31, 2001	Januar 200
ASSETS		
Cash and cash equivalents	$ 774,201	$ 569

Marketable securities	3,026	114
Accounts receivable	1,029,933	1,165
Inventory	1,409,019	1,930
Income tax refund receivable	111,933	150
Prepaid expenses and other current assets	26,581	27
Total current assets	3,354,693	3,957
Property, plant, and equipment - net	5,193,247	4,893
Deferred tax assets	136,206	136
Due from related parties	118,252	128
Other assets	28,812	28
TOTAL ASSETS	$ 8,831,210	$ 9,143
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 1,498,239	$ 1,782
Notes payable to related parties	13,885	13
Deferred revenue	45,000	45
Total current liabilities	1,557,124	1,840
Minority interest in subsidiaries	237,948	239
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 at October 31, 2001 and 4,891,146 shares issued at January 31, 2001	4,912	4
Additional paid-in capital	3,800,104	3,748
Retained earnings	6,116,862	6,358
Accumulated other comprehensive income	15,473	18
Treasury stock - 361,380 shares, at cost	(1,911,237)	(1,911
Notes receivable from chairman	(989,976)	(1,155
Total stockholders' equity	7,036,138	7,063
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 8,831,210	$ 9,143

See accompanying notes to consolidated financial statements.

Biospecifics Technologies Corp. and Subsidiaries
Consolidated Statements of Operations

(Unaudited)

	Three months ended October 31,		
	2001	2000	2
Revenues:			
Net sales	$ 235,260	$ 69,434	$ 4,
Royalties	559,149	503,414	1,
Total Revenues	794,409	572,848	5,
Costs and Expenses:			
Cost of sales	346,227	340,705	3,
Selling, general and administrative	630,791	788,615	1,
Research and development	371,791	252,127	
Total costs and expenses	1,348,809	1,381,447	6,
Loss from operations	(554,400)	(808,599)	(
Other income (expense)			
Investment and other income (loss)	453	(66,975)	
Interest expense	(2,260)	(952)	
Total other income (expense) - net	(1,807)	(67,927)	
Loss before provision for income taxes	(556,207)	(876,526)	(
Income tax expense (benefit)	0	(92,100)	
Income (loss) before minority interest	(556,207)	(784,426)	(
Minority interest in losses	(10,000)	(20,100)	
Net loss	$ (546,207)	$ (764,326)	$ (
Basic net loss per common share	$ (0.12)	$ (0.17)	$
Weighted-average common shares outstanding	4,549,063	4,529,766	4,
Diluted net loss per common share	$ (0.12)	$ (0.17)	$
Weighted-average common and dilutive potential common shares outstanding	4,549,063	4,529,766	4,

See accompanying notes to consolidated financial statements

BioSpecifics Technologies Corp. and Subsidiaries
Consolidated Statements of Cash Flows

	(Unaudited) Nine months ended October 31, 2001	2000
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (241,469)	$ (742,825)
Adjustments to reconcile net loss		
to cash provided by operating activities:		
Depreciation	291,749	115,193
Options and stock issued for services	45,000	17,500
Loss on marketable securities - net	1,320	441,811
Minority interest	(1,500)	(14,200)
Deferred tax assets	--	(75,000)
Changes in operating assets & liabilities:		
Accounts receivable	135,999	591,574
Marketable securities - net	109,841	(17,133)
Inventory	521,025	(241,922)
Prepaid expenses and other current assets	1,362	93,586
Accounts payable and accrued expenses	(284,074)	73,499
Income taxes payable	38,067	(3,970)
Deferred revenue	--	421,978
Net cash provided by operating activities	617,320	660,091
CASH FLOWS FROM INVESTING ACTIVITIES:		
Decrease in notes receivable from chairman - net	165,066	(336,886)
Due from related parties	10,028	(8,500)
Expenditures for plant, property and equipment	(591,830)	(2,856,910)
Net cash used in investing activities	(416,736)	(3,202,296)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Increase in notes payable to related parties	375	375
Exercises of stock options	6,750	--
Net cash provided by financing activities	7,125	375
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(2,678)	(1,915)
CHANGE IN CASH AND CASH EQUIVALENTS	205,031	(2,543,745)
CASH AND EQUIVALENTS:		
Beginning of Period	569,170	4,221,447
End of Period	$ 774,201	$,677,702
SUPPLEMENTAL DISCLOSURE		
Cash paid during the period for interest	$ 5,277	$ 3,797
Cash paid during the period for income taxes	$ 1,188	$ 33,563

========== ==========

See accompanying notes to consolidated financial statements

BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES
NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS
OCTOBER 31, 2001
(UNAUDITED)

1. Description of Business and Basis of Presentation

The accompanying consolidated financial statements include the accounts of BioSpecifics Technologies Corp. (the "Company"), its 97.2% majority-owned subsidiaries, Advance Biofactures Corp. ("ABC") 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.

The Company produces a fermentation-derived enzyme named Collagenase ABC (the "product" or "enzyme") that is licensed by the U.S. Food and Drug Administration (the "FDA") and is indicated for topical debridement of dermal ulcers and burn wounds. The Company operates a production facility 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.

The Company derives most of its net sales of product revenues and all of its royalty revenues from one customer, Knoll Pharmaceutical Company ("KPC"). KPC 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 Company and KPC are parties to a licensing agreement expiring in August 2003 providing KPC with exclusive rights to market Santyl(R) in North America in exchange for purchases of the product and royalties on KPC's Santyl(R) sales to distributors. The license agreement has an automatic ten-year renewal clause unless KPC 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, KPC sublicensed its rights to Smith & Nephew, Inc. ("S&N") with the consent of ABC. Under the sublicense, KPC will continue to purchase the product from the Company and manufacture Santyl(R). S&N will market the Santyl(R). In connection with the sublicense, the Company entered into several contemporaneous agreements with KPC and S&N. These agreements included one allocating responsibility under the KPC Agreement among ABC, KPC, and S&N for both the sublicense and license period. Another agreement imparts certain obligations upon ABC to address the FDA issues concerning the Curacao and Lynbrook manufacturing facilities. (See "Liquidity, Capital Resources, and Changes in Financial Condition".) KPC will assign its license rights in the KPC Agreement to S&N in the event of FDA approval of a compliance program being undertaken by ABC. If the license rights are assigned to S&N, the KPC agreement will be automatically extended at that time until 2013.

In March 2001, KPC became an indirect wholly owned subsidiary of Abbott Laboratories ("Abbott"). Therefore, all ensuing references, which in the past were made to "KPC", have been changed to "Abbott".

2. Interim Financial Statements

In the opinion of management, the accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and reflect all adjustments, consisting of normal recurring accrual adjustments, considered necessary to present fairly, in all material respects, the Company's consolidated balance sheet as of October 31, 2001, the consolidated statements of operations for the three and nine months ended

October 31, 2001 and 2000, and consolidated statements of cash flows for the nine months ended October 31, 2001 and 2000.

The results of operations for interim periods are not necessarily indicative of the results to be expected for an entire fiscal year, and the results for the current interim period are not necessarily indicative of results to be expected in other interim periods. These interim financial statements should be read in conjunction with the Company's annual report on Form 10-KSB for the fiscal year ended January 31, 2001.

3. Net income (loss) per share

Basic net income (loss) per share ("EPS") excludes dilution and is computed by dividing earnings (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the 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. As a result of the net loss for the three and nine months ended October 31, 2001 and 2000, common stock options have not been included in the diluted EPS calculation, as their effect would have been antidilutive.

4. Segment Information

The Company is engaged in one segment, specifically research, development and production of pharmaceutical products. Operations in this business segment take place in one location in the United States of America, one location in Curacao, Netherlands Antilles, and one location in Germany. As of October 31, 2001, identifiable assets in the United States of America approximated $3.6 million and identifiable assets in Curacao, Netherlands Antilles approximated $5.2 million. For the three months and nine months ended October 31, 2001, total revenues derived from Abbott in the United States of America approximated $0.5 million and $5.1 million, respectively, and $227,000 and $579,000, respectively from customers in Brazil and India. For the three and nine months ended October 31, 2000, total revenues derived from Abbott in the United States of America approximated $0.5 million and $3.5 million, respectively, and $49,000 and $531,000, respectively from customers in Brazil and India. There are minimal assets and operations in Germany.

5. Stockholders' equity and other comprehensive income

The change to stockholders' equity during the periods presented includes decreases to retained earnings due to net losses. Increases in common stock and additional paid in capital include the issuance of common stock for services, fully vested and non-forfeitable stock options granted to non-employees, and the

issuance of common stock resulting from the exercise of stock options. Other comprehensive income represents gains and losses resulting from translation of a foreign subsidiary's balance sheet and statement of operations.

6) 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 first quarter of the Company's fiscal year ending January 31, 2002. The Company does not expect the adoption of SFAS No. 144 to have a material impact on its financial position and results of operations.

7. Regulatory Matter

See "Liquidity, Capital Resources, and Changes in Financial Condition" in Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations below for a discussion regarding the effect of this regulatory matter on the Company's financial condition.

Item 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

RESULTS OF OPERATIONS

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

Information provided by the Company or statements contained in this report or made by its employees, if not historical, are forward looking information, which involve uncertainties and risk. The Company cautions readers that important factors may affect the Company's actual results and could cause such results to differ materially from forward-looking statements made by or on behalf of the Company.

Such factors include, but are not limited to, government regulation, the ability of the Company to complete the renovation of its production facilities and comply with the Form 483 and FDA Letter, the Company's estimate that its inventory of product is sufficient until the renovated facilities can release product again, 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 in development, market acceptance of the Company's potential products, and other risks detailed herein and in other filings the Company makes 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 the Company undertakes 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.

The Company incorporates by reference the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in its annual report on Form 10-KSB for the fiscal year ended January 31, 2001.

Three months ended October 31, 2001 and 2000

Net sales - Net sales for the three months ended October 31, 2001 and 2000 were $235,260 and $69,434 respectively, representing an increase of $165,826 or 239%.

During both the three months ended October 31, 2001 and 2000 none of the Company's inventory of enzyme product, Collagenase ABC, was in the finished stage and available for delivery to KPC, due to the implementation of new production controls. These controls lengthened the production cycle and the impact was felt during both three month periods. The Company is delivering to Abbott Collagenase ABC inventory that was produced prior to the voluntary

closure and renovation of production facilities that began in March 2000 ("previously produced work in process inventory"). The Company anticipates that much of this inventory will be finished and delivered to Abbott in the fourth quarter of this fiscal year (ended January 31, 2002), although there can be no assurance as to the exact timing. The timing of deliveries to Abbott depends upon when the final stage processes for this previously produced work in process inventory are complete. Abbott has indicated that the Company may deliver any of the enzyme product in inventory as soon as it is finished. Net sales include testing of ointment compounded by Abbott during both periods presented, and sales of Collagenase ABC to foreign customers from inventory not designated for Abbott.

Royalties - Royalties for the three months ended October 31, 2001 and 2000 were $559,149 and $503,414 respectively, representing an increase of $55,735 or 11%. As reported to the Company by Abbott, S&N sold greater amounts of Collagenase Santyl(R) Ointment, on which the royalty is earned, during the three months ended October 31, 2001 than it did in the year ago period. We consider the calendar year 2000 to have been a transition year in which S&N began marketing Collagenase Santyl(R) Ointment, as discussed in Note 1 to the Company's Consolidated Interim Financial Statements.

Cost of sales - Cost of sales for the three months ended October 31, 2001 and 2000 were $346,227 and $340,705, respectively, representing an increase of $5,522, or 2%. The gross profit margin was negative during both three months ended October 31, 2001 and 2000 due to sales to foreign customers of higher cost previously produced work in process inventory and declining levels of this inventory being processed in the final stages. During the quarter ended July 31, 2001, the Company began producing new inventory at the renovated Curacao

facility (which is subject to FDA approval, as described below), besides continuing the processing of previously produced work in process inventory.

From March 2000 to April 30, 2001, the Company renovated its Collagenase ABC production facilities and thus could not produce any new inventory (see "Liquidity, Capital Resources, and Changes in Financial Position"). Production costs, primarily wages, benefits, and production overhead during that period were allocated to the Company's previously produced work in process inventory that was and still is being processed, but at more limited levels than could be during normal production.

In May 2001, the Company resumed Collagenase ABC enzyme production at its renovated facility in Curacao at a limited level. The Company cannot sell enzyme it is now producing at the renovated facility to Abbott until the FDA approves a supplement (the "supplement') to ABC's Establishment License. While we allocated certain production costs to this new inventory, the remaining costs went to selling, general and administrative, as the Company is dependent on the FDA's approval of the renovated plant in Curacao for the resumption of normal operations. See "Liquidity, Capital Resources, and Changes in Financial Condition".

Selling, general and administrative - Selling, general and administrative ("SG&A") expenses for the three months ended October 31, 2001 and 2000 were $630,791 and $788,615, respectively, representing a decrease of $157,824 or 20%. During the prior year quarter ended October 31, 2000, the Company engaged, to a greater extent versus the current period, consultants to assist in responding to FDA inspectional observations on FDA's Form 483 ("483's") from FDA inspectors, and the associated costs were included in SG&A. During both periods, however, production lab personnel have been highly involved in the response effort and validation of the Curacao production facility. These costs usually allocated to production are included in SG&A. The Company will continue to incur into the foreseeable future consultation costs and involvement of its lab personnel in responding to the 483s and validating the Curacao production facility. See "Liquidity, Capital Resources, and Changes in Financial Condition".

Research and development - Research and development ("R&D") expenses for the three months ended October 31, 2001 and 2000 were $371,791 and $252,127, respectively, representing an increase of $119,664, or 47%. During the quarter ended October 31, 2001, the Company began planning and preparation for Phase 3

trials of its injectable collagenase for the treatment of Dupuytren's disease, resulting in greater costs than incurred in the prior period. The Company anticipates that R&D expenses may begin to increase again as trials for Dupuytren's are initiated.

Other income (expense)- net - Other income (expense)- net for the three months ended October 31, 2001 and 2000 was ($1,807) and ($67,927) respectively. The decrease of 66,120 in the loss was primarily due to the recognition of losses in the prior comparative period from decreasing values of equity securities held as trading security investments. There was an insignificant level of funds available for investment during the three months ended October 31, 2001 versus the prior comparative period due to expenditures for renovation of facilities.

Income tax benefit - The income tax benefit for the three months ended October 31, 2001 and 2000 was $0 and $92,100, respectively, a decrease of $92,100. The Company recognized tax credits for research and development in the year-ago period.

Nine months ended October 31, 2001 and 2000

Net sales - Net sales for the nine months ended October 31, 2001 and 2000 were $4,007,578 and $2,644,817, respectively, representing a $1,362,761 or 52% increase. The increase was primarily due to a 63% increase in deliveries of Collagenase ABC to Abbott in the United States. There was also a 9% increase in deliveries to pharmaceutical companies in countries outside the United States.

As explained above, during both periods the Company delivered to Abbott Collagenase ABC inventory that was produced prior to the voluntary closure and renovation of production facilities that began in March 2000 ("previously produced work in process inventory"). The timing of deliveries to Abbott depends upon when the final stage processes for this previously produced work in process inventory are complete. There were no deliveries to Abbott during the fiscal third quarters ended October 31, 2001 and 2000 because remaining previously produced work in process inventory had not completed final stage processing by the end of the period. The Company anticipates that much of this inventory will be completed and delivered to Abbott during the fiscal fourth quarter of the year ending January 31, 2002, although there can be no assurance that it will be able to do so.

Royalties - Royalties for the nine months ended October 31, 2001 and 2000 were $1,738,147 and $1,431,425, respectively, representing a $306,722 or 21% increase. As reported to the Company by Abbott, S&N sold greater amounts of Collagenase Santyl(R) Ointment, on which the royalty is earned, during the nine months ended October 31, 2001 than it did in the year ago transition period of 2000, the year when S&N began marketing Collagenase Santyl(R) Ointment, as discussed in Note 1 to the Company's Consolidated Interim Financial Statements.

Cost of sales - Cost of sales for the nine months ended October 31, 2001 and 2000 were $3,469,319 and $1,584,062, respectively, representing an increase of $1,885,257 or 119% due to higher net sales, and a lower gross profit margin. The gross profit margin decreased to 13% during the nine months ended October 31, 2001 compared to 40% for the nine months ended October 31, 2000 due to sales of higher cost previously produced work in process inventory, declining levels of this inventory being processed in the final stages, and provision for potential warranty costs. During the nine months ended October 31, 2001, the Company began producing new inventory at the renovated Curacao facility, besides continuing the processing of the previously produced work in process inventory.

From March 2000 to April 30, 2001, the Company renovated its Collagenase ABC production facilities and thus could not produce any new inventory (see "Liquidity, Capital Resources, and Changes in Financial Position"). Production costs, primarily wages, benefits, and production overhead during that period were allocated to the Company's previously produced work in process inventory that was and still is being processed, but at more limited levels than could be during normal production.

Starting in May 2001, the Company resumed Collagenase ABC enzyme production at its renovated facility in Curacao at a limited level. The Company cannot sell the enzyme it is now producing at the renovated facility to Abbott until the FDA approves a supplement (the "supplement') to ABC's Establishment License. While we allocated certain production costs to this new inventory, the remaining costs were allocated to selling, general and administrative, as the Company is dependent on the FDA's approval of the renovated plant in Curacao for the resumption of normal operations. See "Liquidity, Capital Resources, and Changes in Financial Condition".

Selling, general and administrative - SG&A expenses for the nine months ended October 31, 2001 and 2000 were $1,592,944 and $2,043,167, respectively, representing a $450,223, or 22% decrease. As explained above, during the prior year nine month period ended October 31, 2000, the Company engaged, to a greater extent versus the current period, consultants to assist in responding to FDA inspectional observations on FDA's Form 483 ("483's") from FDA inspectors, the cost of which were included in SG&A. During both periods, however, production lab personnel have been highly involved in the response effort and validation of the Curacao production facility. These costs usually allocated to production are included in SG&A. The Company will continue to incur into the foreseeable future consultation costs and involvement of its lab personnel in responding to the 483s and validating the Curacao production facility. See "Liquidity, Capital Resources, and Changes in Financial Condition".

Research and development - R&D expenses for the nine months ended October 31, 2001 and 2000 were $939,575 and $1,028,757, respectively, representing a decrease of $89,182 or 9%. During the nine months ended October 31, 2001, mid-stage clinical trials that were underway during the prior year period for Dupuytren's disease and Peyronie's disease were mostly completed, hence the decline in expense. The Company anticipates that R&D expenses will increase again as trials for Dupuytren's disease advance to Phase 3.

Other income (expense) - net - Other income (expense) - net for the nine months ended October 31, 2001 and 2000 was $13,144 and ($272,281), respectively. The change of $285,425 was due primarily the recognition of losses in the prior comparative period from decreasing values of equity securities held as trading security investments. There was an insignificant level of funds available for investment during the nine months ended October 31, 2001 versus the prior comparative period due to expenditures for renovation of facilities.

Income tax benefit - The income tax benefit for the nine months ended October 31, 2001 and 2000 was $0 and $95,000, respectively, a decrease of $95,000. The Company recognized tax credits for research and development in the year-ago period.

Liquidity, Capital Resources, and Changes in Financial Condition
---

The Company's primary source of working capital is from operations, which includes sales of product, royalties, and periodic license fees. At October 31, 2001, the Company had working capital of approximately $1.8 million, which includes cash and cash equivalents, and marketable securities of approximately $774,000. The principal sources of cash during the nine months ended October 31, 2001 were approximately $617,000 from operating activities, and net repayment of notes due from chairman of approximately $165,000. The principal use of cash during the nine months ended October 31, 2001 was approximately $592,000 invested in plant, property and equipment for the Curacao and Lynbrook facilities.

The Company's manufacturing facilities in New York and Curacao are registered with, and licensed by, the FDA. As previously disclosed, in January and March of 1999, ABC was issued a List of Inspectional Observations on FDA Form 483 (the "Form 483") from FDA inspectors, citing numerous inspectional observations relating to deficiencies in the Company's compliance with FDA regulations at its Lynbrook, New York and Curacao, Netherlands Antilles facilities. In addition, in

May 1999, ABC 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 KPC.

The FDA Letter advised ABC that the FDA would institute formal proceedings to revoke ABC's Establishment License to manufacture Collagenase Santyl(R) Ointment unless ABC 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.

The Company provided the FDA with a plan of corrective action and had a number of meetings with the FDA to discuss the plan of corrective action and the renovation of the Curacao production facility. ABC has submitted a number of periodic updates to the FDA on progress under the plan. ABC hired outside consultants and employed additional staff for its reorganized Quality Unit. 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 produced the enzyme Collagenase ABC (the "enzyme"), the active ingredient in Collagenase Santyl(R) Ointment, at its Lynbrook and Curacao facilities. The Company started extensive renovations at the Curacao facility in March 2000, which resulted in the suspension of enzyme production there. Production at the Curacao facility resumed in May 2001. The Company also voluntarily suspended the production of the enzyme at the Lynbrook facility, although final stage testing on previously produced work in process inventory continues there.

The Company has spent approximately $5.4 million through October 31, 2001 in new equipment and leasehold improvements and anticipates it could invest approximately $75,000 more to completion. This investment is intended to address matters described in the Form 483 and the FDA Letter, as well as to modernize and ensure the efficiency of the Company's production process in the future. During the fiscal year ended January 31, 2000 the Company had spent approximately $1,000,000 for professional fees and other expenses in connection with the remediation of the FDA's deficiency observations, approximately $215,000 during the fiscal year ended January 31, 2001, and approximately $75,000 during the nine months ended October 31, 2001. The Company estimates it could spend an additional $50,000 in professional fees in connection with the remediation of the FDA's deficiency observations.

Although renovations at the Curacao and Lynbrook facilities were substantially completed by May 2001 and resumed production in Curacao, the Company cannot release enzyme now being produced at these facilities for sale as a pharmaceutical in the United States until the FDA approves a supplement (the "supplement') to ABC's Establishment License. As part of the approval process for the supplement, the FDA will conduct an inspection of the Curacao facility and inspect the Lynbrook facility. In anticipation of the renovation and suspension of manufacturing operations, the Company accumulated an inventory of the product (the "previously produced work in process inventory"), which it continues to test, and estimates can be used by Abbott to contract manufacture Collagenase Santyl(R) Ointment into the second quarter of calendar 2002. In the opinion of the Company, Abbott will be able to supply S&N with the Santyl(R) ointment made from previously produced work in process inventory into the beginning of calendar 2003 (or the fourth quarter of our fiscal year ending January 31, 2003).

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 delivery of the Collagenase ABC enzyme 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 the Company's future operating results.

In November 2001, the Company, through its subsidiary ABC - Curacao, drew down a two-year, non-amortizing loan of $450,000 at 6.5% interest from Korpodeko, a Curacao development corporation established to develop industry on the island of Curacao. The entire principal will come due in two years or November 2003. In connection with this loan, ABC-Curacao pledged as collateral substantially all of the Company's fixed assets located in Curacao, with a book value of approximately $4.3 million. The Company has also guaranteed the Korpodeko loan.

The Company, through its subsidiary, ABC-Curacao, also maintains 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 October 31, 2001). 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 ABC-New York.

The Company believes that its capital resources, together with anticipated proceeds from the sales of available inventory and related royalty income, are adequate to sustain the business through October 31, 2002. In addition, the Company also believes that it has made substantial progress in addressing the FDA's inspectional observations and that it may be able to resume normal operations during the second quarter of calendar year 2002 (or the second quarter of our fiscal year ending January 31, 2003). However, the Company is dependent on the FDA's approval of its renovated plant in Curacao for the resumption of normal operations and the release for sale of Collagenase ABC enzyme to Abbott.

Although management believes that the Company's capital resources are adequate and that it has made satisfactory progress toward completing the Corrective Action Plan and 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 renovation of the Lynbrook and Curacao plants will not exceed management's estimates. In addition there can be no assurance that the FDA will not have additional inspectional observations that could result in the delay of completing the Corrective Action Plan or that the FDA will approve the renovated plant and permit the Company to resume its normal operations at all. In July 2001, we retained a strategic advisor with experience in biotechnology joint ventures and alliances to assist us in evaluating strategic opportunities. There can be no assurance that we will be able to enter into any joint ventures or alliances with other companies in the healthcare industry.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

For a discussion of the Company's progress concerning inspectional observations from the U.S. Food and Drug Administration, see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity, Capital Resources, and Change in Financial Condition."

Item 6. Filings 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 the requirements of the Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioSpecifics Technologies Corp.
(The Registrant)

Date: December 20, 2001

By: /s/ Edwin H. Wegman
Edwin H. Wegman
Chairman and President

Date: December 20, 2001

By: /s/ Albert Horcher
Albert Horcher
Treasurer, Principal Financial and
Chief Accounting Officer