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BIOSPECIFICS TECHNOLOGIES CORP
Form 10QSB
December 23, 2002

U.S. SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549

FORM 10-QSB

(Mark One)

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

For the quarterly period ended: OCTOBER 31, 2002

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 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, 2002, was 4,577,836.

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

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PART I. FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

BioSpecifics Technologies Corp. and Subsidiaries Consolidated Balance Sheets

ASSETS	(Unaudited) October 31, 2002	January 31, 2002
	-----	-----
Cash and cash equivalents	\$ 453,523	\$ 693,215
Marketable securities	3,026	3,026
Accounts receivable	910,073	2,606,412
Inventory, net	588,736	784,164
Prepaid expenses and other current assets	56,265	12,878
	-----	-----

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TOTAL CURRENT ASSETS	2,011,623	4,099,695
Property, plant, and equipment - net	4,613,781	5,063,313
Deferred tax assets	164,536	164,536
	-----	-----
	\$ 6,789,940	\$ 9,327,544
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	\$ 1,554,763	\$ 1,680,629
Notes payable to related parties	14,385	14,010
Deferred revenue	45,000	45,000
	-----	-----
TOTAL CURRENT LIABILITIES	1,614,148	1,739,639
Long-term debt	455,000	455,000
Minority interest in subsidiaries	172,178	238,678
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; 4,939,216 shares issued at October 31, 2002 and 4,912,216 issued at January 31, 2002	4,950	4,912
Additional paid-in capital	3,834,665	3,800,104
Retained earnings	3,736,764	6,101,015
Accumulated other comprehensive income	13,781	15,811
Treasury stock - 361,380 shares, at cost	(1,911,237)	(1,911,237)
Notes receivable from chairman and other related party	(1,130,309)	(1,116,378)
	-----	-----
STOCKHOLDERS' EQUITY	4,548,614	6,894,227
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 6,789,940	\$ 9,327,544
	=====	=====

See accompanying notes to consolidated financial statements.

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Biospecifics Technologies Corp. and Subsidiaries
Consolidated Statements of Operations

	(Unaudited) Three months ended October 31,		(Unaudited) Nine months end October 31,	
	2002	2001	2002	2001
Revenues:				
Net sales	\$ 305,086	\$ 235,260	\$ 1,698,587	\$ 4,099,695
Royalties	525,774	559,149	1,558,124	1,558,124
	-----	-----	-----	-----

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Total Revenues	830,860	794,409	3,256,711	5

Costs and Expenses:				
Cost of sales	455,040	346,227	2,338,551	3
General and administrative	896,740	630,791	2,419,334	1
Research and development	253,563	371,791	914,907	

Total costs and expenses	1,605,343	1,348,809	5,672,792	6

Loss from operations	(774,483)	(554,400)	(2,416,081)	
Other income (expense)				
Investment and other income	3,308	453	16,270	
Interest expense	(8,669)	(2,260)	(30,936)	

Total other income (expense) - net	(5,361)	(1,807)	(14,666)	

Loss before provision for income taxes	(779,844)	(556,207)	(2,430,747)	
Income tax expense	0	0	0	

Loss before minority interest	(779,844)	(556,207)	(2,430,747)	
Minority interest in losses	(21,200)	(10,000)	(66,500)	

Net loss	(\$758,644)	(\$546,207)	(\$2,364,247)	(
=====				
Basic net loss per common share	(\$0.17)	(\$0.12)	(\$0.52)	
Weighted-average common shares outstanding	4,577,836	4,549,063	4,559,836	4
=====				
Diluted net loss per common share	(\$0.17)	(\$0.12)	(\$0.52)	
=====				
Weighted-average common and dilutive potential common shares outstanding	4,577,836	4,549,063	4,559,836	4
=====				

See accompanying notes to consolidated financial statements

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BioSpecifics Technologies Corp. and Subsidiaries
Consolidated Statements of Cash Flows

(Unaudited)
Nine months ended
October 31,
2002 2001

CASH FLOWS FROM OPERATING ACTIVITIES:

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Net loss	(\$2,364,247)	(\$241,469)
ADJUSTMENTS TO RECONCILE NET LOSS		
TO CASH PROVIDED BY OPERATING ACTIVITIES:		
Depreciation	489,166	291,749
Options and stock issued for services	0	45,000
Loss on marketable securities - net	0	1,320
Minority interest	(66,500)	(1,500)
CHANGES IN OPERATING ASSETS & LIABILITIES:		
Accounts receivable	1,696,339	135,999
Marketable securities - net	0	109,841
Inventory	195,428	521,025
Prepaid expenses and other current assets	(43,387)	1,362
Accounts payable and accrued expenses	(125,871)	(284,074)
Income taxes payable	0	38,067
	-----	-----
Net cash provided by operating activities	(219,072)	617,320
	-----	-----
CASH FLOWS FROM INVESTING ACTIVITIES:		
Decrease in notes receivable from chairman - net	(13,931)	165,066
Due from related parties	0	10,028
Expenditures for plant, property and equipment	(39,634)	(591,830)
	-----	-----
Net cash used in investing activities	(53,565)	(416,736)
	-----	-----
CASH FLOWS FROM FINANCING ACTIVITIES:		
Increase in notes payable to related parties	375	375
Exercises of stock options	34,600	6,750
	-----	-----
Net cash provided by financing activities	34,975	7,125
	-----	-----
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(2,030)	(2,678)
	-----	-----
CHANGE IN CASH AND CASH EQUIVALENTS	(239,692)	205,031
CASH AND EQUIVALENTS:		
Beginning of Period	693,215	569,170
	-----	-----
End of Period	\$ 453,523	\$ 774,201
	=====	=====
SUPPLEMENTAL DISCLOSURE		
Cash paid during the period for interest	\$ 30,936	\$ 5,277
	=====	=====
Cash paid during the period for income taxes	\$ 14,050	\$ 1,188
	=====	=====

See accompanying notes to consolidated financial statements

BioSpecifics Technologies Corp. ("the Company") was incorporated under the laws of the State of Delaware in 1990. The Company produces a fermentation-derived enzyme named Collagenase ABC (the "product" or "enzyme") that is licensed by the U.S. Food and Drug Administration (the "FDA"). The Company operates production facilities in Lynbrook, New York (the "Lynbrook Plant or Facility") and in Curacao, Netherlands Antilles, the Company's primary production facility (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 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 royalty revenues from Abbott are earned on sales of Santyl(R) to distributors by Smith & Nephew, Inc. ("S&N").

The accompanying consolidated financial statements include the accounts of BioSpecifics Technologies Corp. (the "Company"), 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.

As of the date of this quarterly report, we have limited cash resources available to fund our operations. If we are unable to obtain funding in the next few months, our cash reserves will be depleted, and we may have to cease operations or explore available alternatives.

The accompanying consolidated financial statements have been prepared on a going concern basis. As discussed in "Liquidity, Capital Resources, and Changes in Financial Condition", the Company must get approval of its Curacao facility in order to generate revenues sufficient to cover operating expenses in the near term. Management's plans in regard to this matter are discussed in that section. The consolidated financial statements do not include any adjustments that might result from the ultimate timing of the facility's approval.

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 adjustments, considered necessary to present fairly, in all material respects, the Company's balance sheet as of October 31, 2002, the statements of operations for the three and nine months ended October 31, 2002 and 2001, and statements of cash flows for the nine months ended October 31, 2002 and 2001. 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 Form 10-KSB for the fiscal year ended January 31, 2002.

3. Net loss per share

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Basic net loss per share ("EPS") excludes dilution and is computed by dividing 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, 2002, and 2001, common stock equivalents 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, 2002, identifiable assets in the United States of America approximated \$2.4 million and identifiable assets in Curacao, Netherlands Antilles approximated \$4.4 million. There are minimal assets and operations in Germany. For the three and nine months ended October 31, 2002, total revenues derived from Abbott in the United States of America approximated \$0.6 million and \$2.5 million, respectively, and \$240,000 and \$696,000, respectively from international customers. For the three 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 \$576,000, respectively from international. Total accounts receivable at October 31, 2002 are comprised of amounts due from three customers.

5. Stockholders' equity and other comprehensive income

The change to stockholders' equity during the periods presented were primarily decreases to retained earnings due to net losses and increases in additional paid in capital resulting from the exercise of options and the issuance of fully vested and non-forfeitable stock options granted to non-employees. Other comprehensive income represents gains and losses resulting from translation of foreign subsidiaries' assets, liabilities, revenues and expenses into the U.S. dollar at period-end exchange rates.

6. Liquidity and Financial Condition

As of the date of this quarterly report, we have limited cash resources available to fund our operations. If we are unable to obtain funding in the next few months, our cash reserves will be depleted, and we may have to cease operations or explore available alternatives. We are currently engaged in various efforts to obtain liquidity. There can be no assurances that any of these efforts will be successful.

See "Liquidity, Capital Resources, and Changes in Financial Condition" for a discussion about the upgrade and FDA inspection of the Curacao facility, the Company's planned response to FDA inspectional observations, and the effects on the Company's financial condition.

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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, our liquidity in light of the depletion of our stockpiled inventory and our inability to distribute newly produced enzyme to Abbott until the Curacao facility is approved, 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 Food and Drug Administration ("FDA") and foreign health authorities of potential products, market acceptance of our potential products, and other risks detailed herein and in other filings we make with the Securities and Exchange Commission. 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.

The Company incorporates by reference the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in its Form 10-KSB for the fiscal year ended January 31, 2002.

Summary

We are a biopharmaceutical company focusing on wound healing and tissue remodeling. We produce Collagenase ABC enzyme, (the "enzyme") which is the active ingredient in the prescription drug Collagenase Santyl(R) Ointment sold in the United States and indicated for debriding chronic dermal ulcers and second and third degree burns. We are developing an injectable form of our enzyme for treating Dupuytren's disease, Peyronie's disease, frozen shoulder, and lipomas. We have completed Phase 2 clinical trials for Dupuytren's disease and Phase 1 trials for Peyronie's disease. A Phase 2 trial for frozen shoulder is ongoing. Clinical trials investigating the use of injectable collagenase for lipoma reduction have been initiated.

Revenues recorded the nine months ended October 31, 2002 and 2001 were from sales of stockpiled enzyme inventory to Abbott Laboratories ("Abbott"), which as contract manufacturer makes Collagenase Santyl(R) Ointment (the "ointment"), and royalties on distribution of the ointment by Smith and Nephew, Inc. ("S&N"). We depleted our stockpiled enzyme inventory available for use by Abbott during the fiscal quarter ended July 31, 2002, although Abbott has an inventory of our enzyme and the ointment, which we believe is sufficient to supply S&N with ointment for distribution through April 2003, on which we will earn royalties. Through October 31, 2002, our revenues were insufficient to cover our expenses, and we expect operating losses to continue while we attempt to get our upgraded manufacturing facility in Curacao approved by the U.S. Food and Drug Administration ("FDA"). Historically, approximately 90% of our net sales and royalties are derived from Collagenase Santyl(R) Ointment sold in the United States.

As of the date of this quarterly report, we have limited cash resources available to fund our operations. If we are unable to obtain funding in the next few months, our cash reserves will be depleted, and we may have to cease operations or explore available alternatives. We are currently engaged in various efforts to obtain liquidity. There can be no assurances that any of these efforts will be successful.

Results of Operations

Net sales - Net sales include the sales of Collagenase ABC enzyme powder recognized at the time the product is shipped to customers, primarily Abbott. Net sales also include fees we charge Abbott for testing Collagenase Santyl(R) Ointment contract manufactured by Abbott. Net sales for the three and nine months ended October 31, 2002 were \$305,086 and \$1,645,967, respectively, as compared to \$235,260 and \$4,007,578 for the same periods in 2001. The increase during the three month period ended October 31, 2002 of \$69,826 was due to higher sales of enzyme to our foreign customers. The decrease in net sales for the nine month period ended October 31, 2002 of \$2,308,991 was due to much higher levels of stockpiled inventory available and delivered to Abbott during the 2001 period, and the depletion of the stockpiled inventory. Testing fees included in net sales for the three and nine months ended October 31, 2002 were \$62,000 and \$250,000, respectively, compared to \$53,000 and \$256,000 for the same periods in 2001.

During the second fiscal quarter ended July 31, 2002, we delivered to Abbott all the remaining stockpiled inventory of enzyme powder accumulated for it prior to the Curacao facility upgrade, which began in March 2000. The upgraded facility in Curacao is now producing enzyme powder. However, we cannot deliver to Abbott any of that inventory until the FDA approves the Curacao facility and the quarantine inventory now being produced in Curacao. See "Liquidity, Capital Resources, and Changes in Financial Position".

During the three and nine months ended October 31, 2002 we had net sales of approximately \$241,000 and \$696,000, respectively to customers in Brazil and India, compared to \$227,000 and \$576,000 for the same periods in 2001. We can sell enzyme produced at the renovated facility in Curacao to these customers.

Royalties - Royalties for the three and nine months ended October 31, 2002 and 2001 were \$525,774 and 1,558,124, respectively, compared to \$559,149 and \$1,738,147 for the same periods in 2001. The decrease for both the three and nine months ended October 31, 2002 of \$33,375 and \$180,023 was due to lower sales of Collagenase Santyl(R) Ointment to wholesalers in the United States by S&N during the 2002 periods, as reported to the Company by Abbott. We expect Abbott's inventory of our enzyme powder, including that which was delivered during the six months ended July 31, 2002, will enable Abbott to supply Collagenase Santyl(R) Ointment to Smith & Nephew, which will support distribution of the ointment, and royalties thereon, through April 2003.

Cost of sales - Cost of sales for the three and nine months ended October 31, 2002 were \$455,040 and \$2,338,551, respectively, compared to \$346,227 and \$3,469,319 for the same periods in 2001. The increase of \$108,813 during the three month period ended October 31, 2002 was due to higher sales of enzyme during the 2002 period and warranty accruals. We had a negative gross profit margin in the current three and nine month periods due to fixed production costs, compared to a gross profit percentage of 13% during the nine months ended October 31, 2001.

We have produced new enzyme powder inventory at the upgraded Curacao facility for all our customers. The inventory produced for Abbott is work in process inventory that must undergo additional processing. Since FDA has not yet approved the Curacao facility, that inventory will remain in quarantine until approval, if obtained. The carrying value of this quarantine inventory for Abbott is being partially reserved against because approval cannot be assured. These reserves also negatively affect the cost of sales margin. We are dependent

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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 Position").

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General and administrative - General and administrative ("G&A") expenses for the three and nine months ended October 31, 2002 were \$896,740 and \$2,419,334, respectively, compared to \$630,791 and \$1,592,944 for the same periods in 2001. The increase for both the three and nine month periods ended October 31, 2002 of \$265,949 and \$826,390, respectively is attributable to the continued effort to gain approval of the upgraded production facility in Curacao. During the nine months ended October 31, 2002, a significant portion of our lab and production personnel time was spent on preparing for the FDA inspection of the Curacao facility, including travel, which took place at the end of July 2002. During the year ago period, the upgraded facility's construction had just been completed and therefore the FDA inspection was not pending. Since such a significant portion of laboratory and production personnel was devoted to this effort, their costs were allocated from cost of sales to general and administrative. We expect this effort to continue; therefore we expect to allocate these costs to general and administrative throughout the fiscal year ending January 31, 2003.

Research and development - Research and development ("R&D") expenses for the three and nine months ended October 31, 2002 were \$253,563 and \$914,907, respectively, compared to \$371,791 and \$939,575 for the same periods in 2001. During 2001, Phase 2 clinical trials for Cordase(TM), our injectable collagenase for Dupuytren's disease were completed. The decrease of \$118,228 during the three months ended October 31, 2002 is due to less external costs incurred for the development of Cordase(TM), as we prepare for the initiation of Phase 3 clinical trials for this potential product. We will need to raise considerable additional funds to continue the development of Cordase(TM) and other product candidates.

Other income (expense)- net - Other income (expense)- net for the three and nine months ended October 31, 2002 were (\$5,361) and (\$14,666), respectively, compared to (\$1,807) and \$13,144 for the same periods in 2001. The increase in other (expense) - net during the 2002 periods was primarily attributable to interest expense on our loan with an industrial development agency in Curacao ("Korpodeko"), which was drawn down in November 2001 (see "Liquidity, Capital Resources and Changes in Financial Condition").

Income tax - No income tax was recorded for the three and nine months ended October 31, 2002 and 2001. No income tax benefit for income tax loss carryforwards was recorded because of uncertainties with respect to the timing of future utilization of that tax benefit.

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 October 31, 2002, the Company had working capital of approximately \$397,000, which includes cash and cash equivalents, and marketable securities of approximately \$450,000. The principal use of cash during the nine months ended October 31, 2002 was approximately \$219,000 from operating activities. Within the operating activities, we had non-cash expenses, such as depreciation of approximately \$489,000, and a decrease of approximately \$1.7 million in accounts receivable. These sources were offset by the net loss of approximately \$2.4 million.

As of the date of this quarterly report, we have limited cash resources

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available to fund our operations. If we are unable to obtain funding in the next few months, our cash reserves will be depleted, and we may have to cease operations or explore available alternatives. We are currently engaged in various efforts to obtain liquidity. There can be no assurances that any of these efforts will be successful.

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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. In March 2000 we stopped production of the enzyme and began upgrading our primary production facility, located in Curacao, Netherlands Antilles. In May 2001 we completed the upgrade and went back into limited enzyme production, which we cannot distribute to Abbott until approval. In April 2002 we filed with the FDA a "Prior Approval Supplement" ("PAS") for the upgraded Curacao facility.

In July 2002, the FDA completed a Pre-Approval Inspection of this facility. At the conclusion of the inspection, the FDA inspectors provided us with a list of observations on FDA Form 483, which we responded to in November 2002. In August 2002, FDA issued a "Complete Response" letter with respect to the Pre-Approval Inspection, and with outside assistance, we expect to respond to the FDA in the coming weeks with a plan that is aimed at addressing issues raised in the "Complete Response" letter and obtaining approval by the end of February 2003. Of course, no assurances can be given that the FDA will accept the plan or approve the facility by the end of February 2003.

While we have produced enzyme at the upgraded Curacao facility, the new enzyme produced for Abbott must be held in quarantine and can only be distributed by S&N 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. Enzyme produced at the Curacao facility can be sold to international customers.

Since we began upgrading the Curacao facility in March 2000, we have not produced any new enzyme that we can currently sell to Abbott. Enzyme now being produced cannot be sold to Abbott until we obtain approval. The enzyme we processed and have sold to Abbott in fiscal 2001, fiscal 2002, and fiscal 2003, which it is has used and is continuing to use 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. The last of this stockpiled inventory was delivered to Abbott during the second fiscal quarter ended July 31, 2002. Revenues from this inventory and royalties on sales of ointment that will be manufactured from this and other inventory we have already delivered to Abbott will be insufficient to cover our operating expenses, resulting in an operating loss for the fiscal year that will end January 31, 2003.

We estimate that Abbott can supply S&N with Santyl(R) through April 2003, based on its inventory of enzyme it has already purchased from us and S&N's rate of Santyl(R) sales. If we are able to get approval of the PAS, we may also be able to sell quarantined enzyme already produced and planned to be produced. However, if approval is delayed and we cannot sell quarantined product, we do not expect that cash generated from royalties, the sale of enzyme to foreign customers, collection of our accounts receivable, and cash currently on hand is sufficient to fund operations, in their current form, through March 2003, without additional financing.

We are dependent on Abbott to buy enzyme from us, 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

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its rights in our exclusive license agreement by December 31, 2002. If approval of the plant is obtained, the license agreement rights will be assigned to S&N and the agreement will automatically extend to August 2013. 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. We do not expect approval of the PAS by December 31, 2002. There can be no assurance that S&N will not terminate its agreement with Abbott since approval of the PAS is not expected 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.

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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 to the satisfaction of the FDA, there may be delays in the approval of the Curacao facility and the delivery of the enzyme powder produced there for Abbott to use to contract manufacture Collagenase Santyl(R) Ointment. Such delays would have a material adverse effect on our future operating results.

In November 2001, ABC Curacao borrowed a non-amortizing loan of \$455,000 at 6.5% interest due in November 2003 from Korpodeko. In connection with this loan, ABC-Curacao agreed to pledge as collateral substantially all of our production assets located in Curacao, with a book value of approximately \$4.0 million. BioSpecificals has also guaranteed the Korpodeko loan. Through 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). Borrowings 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. In addition to the Korpodeko loan, long-term obligations at October 31, 2002 include operating leases of approximately \$191,000 annually through fiscal 2006.

There can be no assurance that unforeseen circumstances will not have a material adverse effect on our financial condition and that the time required getting FDA approval of our PAS will not exceed our estimates. There can be no assurance that the FDA will not have additional comments or requests that could result in delaying its approval of the PAS for the Curacao facility or that the FDA will permit us to resume our normal operations at all.

Claims asserted by Abbott and Smith & Nephew

In September 2002, we, S&N, Abbott, and a consulting firm entered into a Memorandum of Understanding ("MOU") in which all parties agreed to work on a plan (the "plan") intended to address issues and observations made by the FDA relating to the upgraded Curacao facility. In the MOU, any of the parties was entitled to withdraw its cooperation if it believed that the required level of progress to the plan was not forthcoming. In the event of such withdrawal by either Abbott, S&N, or both, those parties, or party, would have no further legal or financial obligation towards us, the consultant, or any other third

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party consultant hired to assist with the plan, other than to pay any previously agreed share of work performed through the date of withdrawal. None of the parties withdrew its cooperation.

In December 2002, S&N and Abbott informed us in separate letters that while they intend to pay for the consulting costs each incurred and was billed for, they expect us to reimburse them. S&N informed us that they expect us to reimburse them for \$350,000 within 12 months of the approval of the Curacao facility by the FDA. Abbott informed us that they expect us to reimburse them for \$439,757.23 no later than the end of 2003.

We believe the matter will be resolved after the facility is approved and we resume normal operations. However, we believe we have no legal obligation with respect to this matter, and therefore have not recorded any liability for these amounts claimed, totaling \$789,757.23, as of October 31, 2002.

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ITEM 3: CONTROLS AND PROCEDURES

Within the 90 days prior to the date of this report, our Chief Executive Officer and Chief Financial Officer, with the participation of other members of management, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-14 of the Securities Exchange Act of 1934). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are adequately designed to ensure that the information required to be included in this report has been recorded, processed, summarized and reported on a timely basis. There have been no significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation. There have been no corrective actions taken with regard to significant deficiencies and material weaknesses subsequent to the date of our most recent evaluation.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For a discussion of our 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."

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SIGNATURES

In accordance with Section 13 or 15(d) of the 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: December 23, 2002

By: /s/Edwin H. Wegman

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Edwin H. Wegman
Chairman and President

Date: December 23, 2002

By: /s/Albert Horcher

Albert Horcher
Treasurer, Principal Financial and
Chief Accounting Officer

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CERTIFICATIONS

Certification Pursuant to
18 U.S.C. Section 1350,
As adopted pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Edwin H. Wegman, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of BioSpecifics Technologies Corp. ("BioSpecifics");
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of BioSpecifics as of, and for, the periods presented in this quarterly report.

Date: December 23, 2002

/s/Edwin H. Wegman

Edwin H. Wegman
President and Chief Executive Officer

Certification Pursuant to
18 U.S.C. Section 1350,
As adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with this quarterly report on Form 10-QSB of BioSpecifics Technologies Corp. ("BioSpecifics"), I, Edwin H. Wegman, President and Chief Executive Officer of BioSpecifics, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of BioSpecifics.

Date: December 23, 2002

/s/Edwin H. Wegman

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Edwin H. Wegman
President and Chief Executive Officer

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Certification Pursuant to
18 U.S.C. Section 1350,
As adopted pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Albert Horcher, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of BioSpecifics Technologies Corp. ("BioSpecifics");
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of BioSpecifics as of, and for, the periods presented in this quarterly report.

Date: December 23, 2002

/s/Albert Horcher

Albert Horcher
Secretary, Treasurer and
Principal Accounting Officer

Certification Pursuant to
18 U.S.C. Section 1350,
As adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with this quarterly report on Form 10-QSB of BioSpecifics Technologies Corp. ("BioSpecifics"), I, Albert Horcher, Secretary, Treasurer and Principal Accounting Officer of BioSpecifics, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of BioSpecifics.

Date: December 23, 2002

/s/Albert Horcher

Albert Horcher
Secretary, Treasurer and
Principal Accounting Officer

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