BIOSPECIFICS TECHNOLOGIES CORP
Form 10QSB
June 18, 2002

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: April 30, 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 X No

APPLICABLE ONLY TO CORPORATE ISSUERS:

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 4,550,836 shares of Common Stock, $0.001 par value as of June 1, 2002

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

INDEX

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

BioSpecifics Technologies Corp. and Subsidiaries
Consolidated Balance Sheets

	(Unaudited) April 30, 2002
Cash and cash equivalents	$ 1,317,488
Marketable securities	3,026
Accounts receivable	1,027,640
Inventory, net	813,943
Prepaid expenses and other current assets	29,303
Total current assets	3,191,400

Property, plant, and equipment - net	4,922,916
Deferred tax assets	164,536
	$ 8,278,852
LIABILITIES AND STOCKHOLDERS' EQUITY	
Accounts payable and accrued expenses	$ 1,606,558
Notes payable to related parties	14,135
Deferred revenue	45,000
Total current liabilities	1,665,693
Long-term debt	455,000
Minority interest in subsidiaries	211,378
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 April 30, 2002 and January 31, 2002	4,912
Additional paid-in capital	3,800,104
Retained earnings	5,163,396
Accumulated other comprehensive income	12,384
Treasury stock - 361,380 shares, at cost	(1,911,237)
Notes receivable from chairman and other related party	(1,122,778)
Stockholders' equity	5,946,781
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 8,278,852

See accompanying notes to consolidated financial statements.

Biospecifics Technologies Corp.
and Subsidiaries
Consolidated Statements of Operations

	(Unaudited) Three Months Ended April 30,	
	2002	2001
Revenues:		
Net sales	$ 341,894	$ 2,211,202
Royalties	560,128	581,270
	902,022	2,792,472

Costs and Expenses:		
Cost of sales	768,876	1,899,488
General and administrative	741,230	449,588
Research and development	361,210	276,121
	1,871,316	2,625,197
Income (loss) from operations	(969,294)	167,275
Other income (expense):		
Investment and other income	16,972	11,042
Interest expense	(12,597)	(1,084)
	4,375	9,958
Income (loss) before income taxes and minority interest	(964,919)	177,233
Income tax expense	0	0
Income (loss) before minority interest	(964,919)	177,233
Minority interest in net loss (income) of subsidiaries	27,300	(2,500)
Net income (loss)	($ 937,619)	$ 174,733
Basic net income (loss) per common share	($ 0.21)	$ 0.04
Weighted-average common shares outstanding	4,550,836	4,529,766
Diluted net income (loss) per common share	($ 0.21)	$ 0.04
Weighted-average common and dilutive potential common shares outstanding	4,550,836	4,563,406

See accompanying notes to consolidated financial statements

BioSpecifics Technologies Corp. and Subsidiaries
Consolidated Statements of Cash Flows

	(Unaudited) Three Months Ended April 30,	
CASH FLOWS FROM OPERATING ACTIVITIES:	2002	2001

Net income (loss)	($ 937,619)	$ 174,733
Adjustments to reconcile net income (loss)		
to net cash provided by operating activities:		
Depreciation and amortization	162,424	40,999
Loss on marketable securities - net	--	1,320
Minority interest in income (loss) of subsidiaries	(27,300)	2,500
Options issued for services	--	5,000
Changes in operating assets and liabilities:		
Accounts receivable	1,578,772	(882,792)
Marketable securities, net	109,841	
Inventory	(29,779)	869,488
Prepaid expenses and other current assets	(16,425)	5,540
Accounts payable and accrued expenses	(74,071)	(229,573)
Net cash provided by operating activities	656,002	97,056
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in notes receivable from chairman and other related party	(6,400)	(24,067)
Expenditures for plant, property and equipment	(22,027)	(329,227)
Net cash used in investing activities	(28,427)	(353,294)
CASH FLOWS FROM FINANCING ACTIVITIES		
Increase in notes payable to related parties	125	125
Effect of exchange rates on cash and cash equivalents	(3,427)	1,617
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	624,273	(254,496)
CASH AND CASH EQUIVALENTS:		
Beginning of period	693,215	569,170
End of period	$ 1,317,488	$ 314,674
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 12,597	$ 1,085
Cash paid during the period for income taxes	$ 14,050	$ 1,188

See accompanying notes to consolidated financial statements

BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES
NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS
APRIL 30, 2002
(UNAUDITED)

1. Description of Business and Basis of Presentation

BioSpecifics Technologies Corp. ("the Company") was incorporated under the laws of the State of Delaware in 1990. The Company produces a fermentation-derived

enzyme named Collagenase ABC (the "product" or "enzyme") that is licensed by the U.S. Food and Drug Administration (the "FDA"). The Company operates production facilities in Lynbrook, New York (the "Lynbrook Plant or Facility") and in Curacao, Netherlands Antilles (the "Curacao Plant or Facility"). The Company is also researching and developing additional products derived from this enzyme for potential use as pharmaceuticals.

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.

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 April 30, 2002, the statements of operations for the three months ended April 30, 2002 and 2001, and statements of cash flows for the three months ended April 30, 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 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 months ended April 30, 2002, common stock equivalents have not been included in the diluted EPS calculation, as their effect would have been antidilutive. During the three months ended April 30, 2001, dilutive common stock options included in diluted EPS amounted to 33,640.

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 April 30, 2002, identifiable assets in the United States of America approximated $3.0 million and identifiable assets in Curacao, Netherlands Antilles and Germany approximated $5.3 million. For the three months ended April 30, 2002, total revenues derived from a customer in the United States of America approximated $646,000 and $256,000 from customers in Brazil and India. For the three months ended April 30, 2001, total revenues derived from a customer in the United States of America approximated $2.7 million and $100,000 from customers in Brazil and India. Total accounts receivable at April 30, 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 increases (decreases) to retained earnings due to net income (loss) and increases in additional paid in capital resulting from 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

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

Three months ended April 30, 2002 and 2001

Net Sales - Net sales include the sales of Collagenase ABC 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 months ended April 30, 2002 and 2001 were $341,894 and $2,211,202, respectively, a decrease of $1,869,308 or 85%. The decrease is due to the timing of product shipments made to Abbott, which depends on when the product is complete and thereby ready for shipment to Abbott. During the three months ended April 30, 2002, none of our Collagenase ABC was ready for delivery, versus the three months ended April 30, 2001, when we made two large shipments to Abbott of inventory accumulated in anticipation of the suspension of manufacturing operations, that became available during that period. We expect to make the last delivery of available inventory to Abbott during the second fiscal quarter ended July 31, 2002. After that, we do not expect to make any more deliveries to Abbott until the Curacao facility is approved and quarantine inventory now being produced there is approved. During the three months ended April 30, 2002 we had sales of approximately $256,000 to our customers in Brazil and India versus $100,000 during the quarter ended April 30, 2001.

Royalties - Royalties for the three months ended April 30, 2002 and 2001 were $560,128 and $581,270 respectively, a decrease of $21,142 or 4%. The decrease was due to lower sales of Collagenase ointment (Collagenase Santyl(R)) to wholesalers in the United States by S&N during the 2002 first fiscal quarter, as reported to the Company by Abbott.

Cost of Sales - Cost of sales for the three months ended April 30, 2002 and 2001 were $768,876 and $1,899,488 respectively, a decrease of $1,130,612 or 60%. As discussed above, during the three months ended April 30, 2002, we made no shipments of Collagenase ABC to Abbott because none was available for delivery. During the three months ended April 30, 2001, we made two large shipments to Abbott of accumulated product in inventory. We had a negative gross profit margin in the current quarter due to fixed production costs, compared to a gross profit percentage of 15% during the three months ended April 30, 2001.

We are producing new inventory at the upgraded Curacao facility for all our customers. The inventory being produced for Abbott is work in process inventory that must undergo additional processing. Since the Curacao facility has not yet been inspected and approved by FDA, that inventory will remain in quarantine until approval, if obtained. We are 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 Position").

General and administrative - General and administrative expenses for the three months ended April 30, 2002 and 2001 were $741,230 and $449,588 respectively, an increase of $291,642 or 65%. During the quarter ended April 30, 2002, a significant portion of our lab and production personnel time has been on preparing for the pending FDA inspection of the Curacao facility. 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 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 will allocate these costs to general and administrative throughout the fiscal year ending January 31, 2003.

Research and development - Research and development ("R&D") expense for the three months ended April 30, 2002 and 2001 were $361,210 and $276,121 respectively, representing an increase of $85,089 or 31%. The increase is due to higher costs incurred for development of Cordase(TM), our injectable collagenase for Dupuytren's disease, as we prepare for the initiation of Phase 3 clinical trials for this potential product.

Other income (expense), net - Other income (expense), net for the three months ended April 30, 2002 and 2001 was $4,375 and $9,958 respectively. The decrease of $5,583 was attributable to interest expense on our loan with Korpodeko (see "Liquidity, Capital Resources and Changes in Financial Condition").

Income tax (expense) benefit - We recorded no income tax expense or benefit for the three months ended April 30, 2002 and 2001. We did not record a tax benefit for the net loss during the quarter ended April 30, 2002 because the loss can only be applied to future earnings, which we do not forecast for the fiscal year ended January 31, 2003. We believe we will utilize the benefit of net deferred tax assets based on recognition of future taxable income.

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 April 30, 2002, the Company had working capital of approximately $1.5 million, which includes cash and cash equivalents, and marketable securities of approximately $1.3 million. The principal source of cash during the three months ended April 30, was approximately $656,000 provided by operating activities, primarily from a decrease of approximately $1.6 in accounts receivable partially offset by the net loss of approximately $938,000.

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 we could obtain approval of the PAS and Curacao facility by the end of the fiscal year that will end January 31, 2003.

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 second fiscal quarter ended July 31, 2002. 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, collection of our accounts receivable, 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 ending 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 funds.

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 to the satisfaction of the FDA, 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.

Our subsidiary in Curacao borrowed a non-amortizing loan of $455,000 at 6.5% interest due in November 2003 from an industrial development agency there ("Korpodeko") during the fiscal year ended January 31, 2002. In connection with this 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 $4.1 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 obligations at April 30, 2002 include operating leases of approximately $191,000 annually through fiscal 2006.

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."

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: June 18, 2002

By:/s/ Edwin H. Wegman

Edwin H. Wegman
Chairman, President, and
Chief Executive Officer

Date: June 18, 2002

By: /s/ Albert Horcher

Albert Horcher
Secretary, Treasurer and Principal
Financial and Chief Accounting Officer