BIOSPECIFICS TECHNOLOGIES CORP
Form 10QSB
June 19, 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: April 30, 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:

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 4,529,766 shares of Common Stock, $0.001 par value as of June 1, 2001

Transitional Small Business Disclosure Format (check one):

Yes No X

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BioSpecifics Technologies Corp. and Subsidiaries
Consolidated Balance Sheets

	(Unaudited) April 30, 2001	Janu 2

ASSETS		
Cash and cash equivalents	$ 314,674	$ 5
Marketable securities	3,026	1
Accounts receivable	2,048,724	1,1
Inventory	1,060,556	1,9
Income tax refund receivable	150,000	1
Prepaid expenses and other current assets	22,406	
Total current assets	3,599,386	3,9
Property, plant, and equipment - net	5,181,395	4,8
Deferred tax assets	136,206	1
Due from related parties	128,280	1
Other assets	28,812	
TOTAL ASSETS	$ 9,074,079	$ 9,1
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 1,552,744	$ 1,7
Notes payable to related parties	13,635	
Deferred revenue	45,000	
Total current liabilities	1,611,379	1,8
Minority interest in subsidiaries	241,948	2
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; 4,891,146 shares issued at April 30, 2001 and January 31, 2001	4,891	
Additional paid-in capital	3,753,375	3,7
Retained earnings	6,533,064	6,3
Accumulated other comprehensive income	19,768	
Treasury stock - 361,380 shares, at cost	(1,911,237)	(1,9
Notes receivable from chairman	(1,179,109)	(1,1
Stockholders' equity	7,220,752	7,0
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 9,074,079	$ 9,1

See accompanying notes to consolidated financial statements.

Biospecifics Technologies Corp.
and Subsidiaries
Consolidated Statements of Operations

Unaudited
Three Months Ended

	April 30, 2001	2000
Revenues:		
Net sales	$ 2,211,202	$ 989,805
Royalties	581,270	449,198
	2,792,472	1,439,003
Costs and Expenses:		
Cost of sales	1,899,488	479,787
Selling, general and administrative	449,588	552,327
Research and development	276,121	411,679
	2,625,197	1,443,793
Income (loss) from operations	167,275	(4,790)
Other income (expense):		
Investment and other income (loss)	11,042	(56,515)
Interest expense	(1,084)	(1,583)
	9,958	(58,098)
Income (loss) before income taxes and minority interest	177,233	(62,888)
Income tax expense	0	(3,030)
Income (loss) before minority interest	177,233	(65,918)
Minority interest in net income of subsidiaries	(2,500)	--
Net income (loss)	$ 174,733	($65,918)
Basic net income (loss) per common share	$ 0.04	($0.01)
Weighted-average common shares outstanding	4,529,766	4,529,766
Diluted net income (loss) per common share	$ 0.04	($0.01)
Weighted-average common and dilutive potential common shares outstanding	4,563,406	4,529,766

See accompanying notes to consolidated financial statements

BioSpecifics Technologies Corp. and Subsidiaries
Consolidated Statements of Cash Flows

	(unaudited) Three Months Ended April 30, 2001	2000
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 174,733	$ (65,918)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	40,999	37,292
Loss on marketable securities - net	1,320	141,938
Minority interest in income of subsidiaries	2,500	--
Options issued for services	5,000	--
Deferred tax benefit	--	(52,970)
Changes in operating assets and liabilities:		
Accounts receivable	(882,792)	508,708
Marketable securities, net	109,841	(237,495)
Inventory	869,488	(168,790)
Prepaid expenses and other current assets	5,540	12,671
Accounts payable and accrued expenses	(229,573)	(332,197)
Income taxes	--	56,000
Deferred revenue	--	1,687,910
Net cash provided by operating activities	97,056	1,587,149
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in notes receivable from chairman	(24,067)	(215,000)
Increase in due from related parties	--	(4,000)
Expenditures for plant, property and equipment	(329,227)	(694,215)
Net cash used in investing activities	(353,294)	(913,215)
CASH FLOWS FROM FINANCING ACTIVITIES		
Increase in notes payable to related parties	125	125
Effect of exchange rates on cash and cash equivalents	1,617	(835)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(254,496)	673,224
CASH AND CASH EQUIVALENTS:		
Beginning of Period	569,170	4,221,447
End of Period	$ 314,674	$ 4,894,671
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 1,085	$ 1,583
Cash paid during the period for income taxes	$ 1,188	$ 82,847

See accompanying notes to consolidated financial statements

APRIL 30, 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 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.

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, to which ABC-New York is not a party, 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.

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, 2001, the statements of operations for the three months ended April 30, 2001 and 2000, and statements of cash flows for the three months ended April 30, 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 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 months ended April 30, 2000, 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, 2001, identifiable assets in the United States of America approximated $4.3 million and identifiable assets in Curacao, Netherlands Antilles and Germany approximated $4.8 million. 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. For the three months ended April 30, 2000, total revenues derived from a customer in the United States of America approximated $1.2 million and $239,000 from customers in Brazil and India.

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 and its effect 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 produce 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, 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 Form 10-KSB for the fiscal year ended January 31, 2001.

Three months ended April 30, 2001 and 2000

Net Sales - Net sales include the sales of Collagenase ABC recognized at the time the product is shipped to customers, primarily KPC. Net sales also includes fees the Company charges KPC for testing Collagenase Santyl(R) contract manufactured by KPC. Net sales for the three months ended April 30, 2001 and 2000 were $2,211,202 and $989,805, respectively, an increase of $1,221,397 or 123%. The increase is due to the timing of product shipments made to KPC, which is in turn due to the timing of when the product is complete and thereby ready for shipment to KPC. During the three months ended April 30, 2001, the Company made two large shipments of product to KPC that became available, versus one large shipment during the three months ended April 30, 2000. KPC has told the Company that it may deliver any of the enzyme product it accumulated in inventory, whenever it becomes available.

Royalties - Royalties for the three months ended April 30, 2001 and 2000 were $581,270 and $449,198 respectively, an increase of $132,072 or 29%. The increase was due to higher sales of Collagenase ointment (Collagenase Santyl(R)) to wholesalers in the United States by S&N during the 2001 first fiscal quarter, as reported to the Company by KPC. During the fourth quarter of calendar 1999, KPC initiated a sales promotion for Collagenase Santyl(R). Wholesalers responded to the promotion by buying at record levels. As a result, wholesalers purchased less during the subsequent period; which was the three months ended April 30, 2000.

Cost of Sales - Cost of sales for the three months ended April 30, 2001 and 2000

were $1,899,488 and $479,787 respectively, an increase of $1,419,701 or 296%. As discussed above, during the three months ended April 30, 2001, the Company made two large shipments to KPC of product in inventory that had been accumulated in anticipation of the suspension of manufacturing operations in March 2000. This inventory was substantially completed as of January 31, 2001. The gross profit percentage decreased to 15% during the three months ended April 30, 2001 compared to 52% for the 3 months ended April 30, 2000 due to lower inventory processing activity in this as well as prior periods and a provision for potential warranty costs provided for during the three months ended April 30, 2001. The Company has not produced any new inventory due to the renovation of the Curacao facility and only continued the processing and sale of the accumulated inventory. As a result, a significant portion of the Company's fixed production costs that had been absorbed into a lower number of inventory units processed were sold during the three months ended April 30, 2001, as compared to the three months ended April 30, 2000.

Since March 2000 and during the three months ended April 30, 2001, the Company has been renovating its Collagenase ABC production facilities and has not been able to produce any new inventory (see "Liquidity, Capital Resources, and Changes in Financial Position"). Production costs, primarily wages, benefits, and production overhead are being allocated to the Company's remaining inventory, 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, though at a limited level. The Company cannot sell the enzyme it is now producing at the renovated facility to KPC until the FDA approves a supplement (the "supplement') to ABC's Establishment License. While it may be possible to allocate production costs to this new inventory, 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 April 30, 2001 and 2000 were $449,588 and $552,327 respectively, a decrease of $102,739 or 19%. During the quarter ended April 30, 2000, the Company's use of consultants to assist in responding to FDA observations was higher than in the 2001 period.

Research and development - Research and development ("R&D") expense for the three months ended April 30, 2001 and 2000 were $276,121 and $411,679 respectively, representing a decrease of $135,558 or 33%. In both periods the Company sponsored Phase 2 clinical trials of injectable collagenase for Dupuytren's disease, which has been granted Orphan Drug status by the FDA. However, the clinical activity was greater during the year ago period. Also, internal R&D staff costs declined as development moved to outside clinics, and as the internal staff dedicated more of its efforts to addressing the inspectional observations made by the FDA (see "Liquidity, Capital Resources, and Changes in Financial Condition"). The Company is focusing its R&D on potential indications of its injectable collagenase. During the 2000 period, there was greater clinical activity, hence greater costs, than in the 2001 period.

Other income (loss), net - Other income (loss), net for the three months ended April 30, 2001 and 2000 was $9,958 and $(58,098) respectively. The increase of $68,056 was attributable to the decrease in the amount of the Company's investments in equity securities held as trading securities.

Income tax (expense) benefit - The income tax expense for the three months ended April 30, 2001 and 2000 was $0 and $3,030 respectively. The 2000 period expense

represents current tax liabilities for foreign income taxes, partially offset by an increase in deferred tax assets, principally relating to net operating loss carryback credits. The Company has a 2% tax rate ("tax holiday") applicable to pre-tax earnings from operations of its subsidiary in Curacao, in effect until the year 2016. The statutory tax rate in Curacao is normally 30%.

Liquidity, Capital Resources and Changes in Financial Condition
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The Company's primary source of working capital is from operations, which includes sales of product, royalties, and periodic license fees. At April 30, 2001, the Company had working capital of approximately $1.9 million, which includes cash and cash equivalents, and marketable securities of approximately $317,000. The principal use of cash during the three months ended April 30, was approximately $329,000 used to purchase plant, property and equipment for the Curacao and Lynbrook facilities. These uses were partially offset by cash provided by operating activities of approximately $197,000.

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 will 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 has provided the FDA with a plan of corrective action and has 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 has 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. The Company also voluntarily suspended the production of the enzyme at the Lynbrook facility, although final stage testing continues there.

The Company has spent approximately $4.4 million through April 30, 2001 in new equipment and leasehold improvements and anticipates it could invest approximately $200,000 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, and spent approximately $215,000 during the fiscal year ended January 31, 2001. The Company estimates it could spend an additional $200,000 in fees in connection with the remediation of the FDA's deficiency observations.

Although renovations at the Curacao and Lynbrook facilities were substantially completed in March 2001, the Company cannot sell to KPC enzyme it will produce at these facilities 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. In anticipation of the renovation and suspension of manufacturing operations, the Company accumulated an inventory of the product, which it continues to test, and it estimates KPC can use to contract manufacture Collagenase Santyl(R) Ointment into the second quarter of calendar 2002. In the opinion of the Company, this would permit KPC to supply S&N with the ointment into the third quarter of calendar 2002.

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 product produced in the renovated facilities to KPC for use to contract manufacture Collagenase Santyl(R) Ointment. Such delays could have a material adverse effect on the Company's future operating results.

The Company, through its subsidiary ABC - Curacao, has received a commitment for 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 would become due two years after the loan is drawn down. In connection with this loan, ABC-Curacao has agreed it will pledge as collateral substantially all of the Company's assets located in Curacao, with a book value of approximately $4.1 million. The Company has also agreed it would guarantee the Korpodeko loan. The Company expects to draw down this loan during the second calendar quarter of 2001.

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 April 30, 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 at least through April 30, 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 fourth quarter of calendar year 2001. However, the Company is dependent on the FDA's approval of its renovated plant in Curacao for the resumption of normal operations and the production of Collagenase ABC enzyme.

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.

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."

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 19, 2001

By: /s/ Edwin H. Wegman

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

Date: June 19, 2001

By: /s/ Albert Horcher

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