

BIOSPECIFICS TECHNOLOGIES CORP  
Form 10QSB  
August 14, 2003  
Index

**United States**

**Securities And Exchange Commission**

**Washington, DC 20549**

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**FORM 10-QSB**

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Quarterly Period Ended **June 30, 2003**

Or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Transition Period From \_\_\_\_\_ to \_\_\_\_\_

Commission file number **0-19879**

**BioSpecifics Technologies Corp.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
Incorporation or organization)

**11-3054851**  
(I.R.S. Employer  
Identification Number)

**35 Wilbur St.**

**Lynbrook, NY 11563**

(Address of principal executive offices)(Zip Code)

**(516) 593-7000**

(Registrant's telephone number, including area code)

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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:**

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: **4,888,148 shares of Common Stock, \$0.001 par value as of August 1, 2003**

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

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**BioSpecifics Technologies Corp.**

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**FORM 10-QSB**

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**PART I. FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**BIOSPECIFICS TECHNOLOGIES CORP.**

**AND SUBSIDIARIES**

**Consolidated Balance Sheet**

(Unaud

June

200

## Assets

## Current assets:

Cash and cash equivalents	\$	0
Marketable securities		7
Accounts receivable, net		4
Inventories, net		2,000
Income tax refund receivable		4
Prepaid expenses and other current assets		2,000
Total current assets		2,000
Other assets - loan costs		4,000
Property, plant and equipment, net	\$	6,000

## Liabilities and Stockholders' Equity

## Current liabilities:

Accounts payable and accrued expenses	1,000
Notes payable to related parties	4,000
Deferred revenue	4,000
Short-term debt - Korpodeko	4,000
Short-term debt - promissory note	2,000
Total current liabilities	2,000

Senior secured convertible 12% note, net	1,000
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Minority interest in subsidiaries

Commitments and contingencies

## Stockholders' equity:

Series A Preferred stock, \$.50 par value, 700,000 shares authorized;

none outstanding

Common stock, \$.001 par value; 10,000,000 shares authorized;

5,249,528 shares issued at June 30, 2003

Additional paid-in capital	4,000
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Retained earnings	1,000
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Accumulated other comprehensive income

Treasury stock, 361,380 shares at cost	(1,000)
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Notes receivable from chairman and other related party	(
Total stockholders' equity	3,
	\$ 6,

See accompanying notes to consolidated financial statements.

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**BIOSPECIFICS TECHNOLOGIES CORP.**

**AND SUBSIDIARIES**

**Consolidated Statements of Operations**

	<b>(Unaudited)</b>		<b>(Unaudited)</b>		<b>(Unaudited)</b>
	<b>Three Months Ended</b>		<b>Six Months Ended</b>		<b>Five Months</b>
	<b>June 30,</b>	<b>July 31,</b>	<b>June 30,</b>	<b>July 31,</b>	<b>Ended</b>
	<b>2003</b>	<b>2002</b>	<b>2003</b>	<b>2002</b>	<b>June 30,</b>
					<b>2003</b>
<b>Revenues:</b>					
Net sales	\$ 143,629	\$ 1,051,607	\$ 395,131	\$ 1,393,501	\$ 172,
Royalties	664,249	472,222	1,138,057	1,032,350	970,
	807,878	1,523,829	1,533,188	2,425,851	1,142,
<b>Costs and Expenses:</b>					
Cost of sales	504,865	1,114,635	1,146,201	1,883,511	974,
General and administrative	651,359	781,364	1,447,261	1,522,594	1,049,
Research and development	187,503	300,134	435,756	661,344	357,
	1,343,727	2,196,133	3,029,218	4,067,449	2,381,

Loss from operations	(535,849 )	(672,304 )	(1,496,030 )	(1,641,598 )	(1,239,000 )
Other income (expense):					
Investment and other income	12,068	(4,015 )	22,361	12,962	19,000
Interest expense	(12,800 )	(9,670 )	(30,807 )	(22,267 )	(28,000 )
	(732 )	(13,685 )	(8,446 )	(9,305 )	(9,000 )
Loss before income taxes and minority interest	(536,581 )	(685,989 )	(1,504,476 )	(1,650,903 )	(1,248,000 )
Income tax benefit (expense)	0	0	7,000	0	(13,000 )
Loss before minority interest	(536,581 )	(685,989 )	(1,497,476 )	(1,650,903 )	(1,261,000 )
Minority interest in net loss of subsidiaries	8,200	18,000	35,183	45,300	28,000
Net loss	\$ (528,381 )	\$ (667,989 )	\$ (1,462,293 )	\$ (1,605,603 )	\$ (1,232,000 )
Basic and diluted net loss per common share	\$ (0.11 )	\$ (0.15 )	\$ (0.32 )	\$ (0.35 )	\$ (0.10 )
Weighted-average common shares outstanding	4,614,180	4,555,058	4,597,258	4,552,947	4,597,000

See accompanying notes to consolidated financial statements

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**BIOSPECIFICS TECHNOLOGIES CORP.**

**AND SUBSIDIARIES**

**Consolidated Statements of Cash Flows**

	(Unaudited)		(Unaudited)
	Six Months Ended		Five Months
	June 30, 2003	July 31, 2002	Ended June 30, 2002
Cash flows from operating activities:			
Net loss	\$ (1,462,293 )	\$ (1,605,603 )	\$ (1,232,9
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization	269,518	325,795	220,4
Options issued for services	14,000	0	14,0
Issuance of stock for services	15,000	0	15,0
Minority interest in loss of subsidiaries	(35,183 )	(45,300 )	(28,5
Changes in operating assets and liabilities:			
Accounts receivable	193,763	1,143,635	314,7
Inventories	(52,662 )	278,858	(22,0
Prepaid expenses and other current assets	1,143	(18,746 )	1,1
Accounts payable and accrued expenses	26,491	(139,950 )	(189,7
Income taxes receivable	5,000	0	13,0
Net cash used by operating activities	(1,025,223 )	(61,311 )	(895,4
Cash flows from investing activities:			
Paydown of notes receivable from chairman	153,946	(13,931 )	48,9
Expenditures for property, plant and equipment	0	(22,027 )	
Net cash provided by (used) in investing activities	153,946	(35,958 )	48,9
Cash flows from financing activities:			
Interest accrued on notes payable to related parties	250	250	2
Exercises of stock options	0	27,000	
Increase in short-term debt	100,000	0	100,0
Increase in senior secured convertible debt	1,575,000	0	1,575,0
Other assets - loan costs	(180,276 )	0	(180,2
Stock issued to senior secured debt	295	0	2
Net cash provided by financing activities	1,495,269	27,250	1,495,2
Effect of exchange rates on cash and equivalents	(4,366 )	(3,578 )	(4,3
Increase (decrease) in cash and cash equivalents	619,626	(73,597 )	644,3
Cash and cash equivalents at beginning of period	50,899	693,215	26,1



Cash and cash equivalents at end of period	\$	670,525	\$	619,618	\$	670,5
Supplemental disclosures of cash flow information:						
Cash paid during the year for:						
Interest	\$	30,807	\$	22,266	\$	10,9
Income taxes	\$	0	\$	14,050	\$	

See accompanying notes to consolidated financial statements

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**BIOSPECIFICS TECHNOLOGIES CORP.**

**NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

**JUNE 30, 2003**

**(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 manufacturing facilities in Lynbrook, New York (the Lynbrook facility ) and in Curacao, Netherlands Antilles, the Company s primary manufacturing facility (the Curacao 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 the product and all of its royalty revenues from one customer in the United States, Abbott Laboratories ( Abbott ) who, pursuant to an exclusive licensing agreement (the Agreement ),

compounds the product into Collagenase Santyl® Ointment ( Santyl® or ointment ), a prescription drug used to treat dermal ulcers and burns. The royalty revenues from Abbott are earned on North American sales of Santyl® to distributors made by Smith & Nephew, Inc. ( S&N ).

The FDA notified us in writing on July 28, 2003 that our request to supplement our biologics license for collagenase ABC was approved ( FDA approval ). The supplement included major renovations to the manufacturing facility, utility systems, and process equipment at our Curacao facility. The FDA notification acknowledged our written commitments to provide additional information regarding ongoing studies and when to submit this information to our biologics license for review.

With FDA approval, inventory of enzyme product manufactured at the Curacao facility can be distributed to Abbott when the manufacturing process is completed.

In 1999, as a result of inspectional observations made by the FDA in Form 483 citing numerous deficiencies in the Company's compliance with FDA regulations at its Lynbrook and Curacao facilities and at the contract manufacturing facility used by the Company, the FDA advised the Company in a letter (the FDA letter ) that it would revoke the Company's license to produce the enzyme and ointment unless the Company could immediately provide satisfactory assurance to the FDA (including submitting a comprehensive plan of corrective action) addressing the FDA's observations and demonstrate compliance with the applicable regulations. Regardless of the recent FDA approval described above, the FDA letter will remain in effect until we demonstrate compliance with the applicable federal standards and regulations, which the Company understands to be two satisfactory annual GMP inspections of our Lynbrook and Curacao manufacturing facilities. The Company believes it has made progress in complying with the applicable federal standards and regulations, although there can be no assurances as to when the FDA letter will be rescinded, if at all.

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.

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The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not purport to represent realizable or settlement values. The Company was dependent on the FDA approval it received. The Company has incurred significant operating losses since the period of Curacao facility renovation and currently has limited liquidity. These factors raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of those uncertainties.

As of the date of this report, the Company has limited cash resources available to fund its operations. Over the past few months, the Company has been able to fund operations by (1) borrowings: \$100,000 from an unaffiliated individual (described below), an aggregate of \$500,000 from April through the first half of June 2003, advanced to the Company by a principal (a principal) of Bio Partners LP, a private investment group and unrelated third party (Bio Partners), and net \$890,000 from Bio Partners on June 19, 2003, described below (after the payment of loan expenses and taking into account the aggregate \$500,000 previously advanced to the Company by a principal), (2) receiving early payment of royalties from Abbott Laboratories, the Company's major customer, in May 2003 earned from distribution of Santyl® Ointment from a supply that will be depleted in August 2003, (3) our chairman's deferring salary of approximately \$100,000 during the three months ended June 30, 2003, (4) our chairman's repaying \$153,946 from January 2003 through June 30, 2003, and in July 2003 repaying an additional \$307,000 obtained by his refinancing the mortgage on the administrative headquarters in Lynbrook, New York, which is owned by his affiliate and leased to the Company, and (5) deferring or making partial payments to creditors.

On June 19, 2003, the Company entered into a financing transaction with Bio Partners LP, a private investor group, pursuant to which the Company sold to Bio Partners in a private placement (i) a \$1.575 million convertible note, issued at face value (the Note), and (ii) 295,312 restricted shares of Company common stock, issued at par value, or \$.001 per share. The net proceeds to the Company were approximately \$890,000, after the payment of loan expenses and taking into account the aggregate \$500,000 that was previously advanced to the Company by a principal of Bio Partners. Based on operating projections made in January 2003 and updated through July 2003, the Company projects that these funds will enable it to continue operations at least to December 31, 2003.

These projections assume or assumed that, among other things:

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- the Company obtain FDA approval of the Curacao facility, which it did in July 2003
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the Company can timely sell to Abbott inventory manufactured prior to FDA approval of the Curacao facility, its primary manufacturing facility;

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our chairman repay to the Company \$325,000 of the amount he and his affiliate owe the Company by the end of July 2003, which he did in July 2003 in the amount of \$307,000; and

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The Company receives a tax refund of approximately \$412,000 in September 2003, on a refund filing made in July 2003.

If any of the remaining assumptions on which our projections are based do not occur, the Company may not be able to fund operations past the next several months. In addition, it cannot be assured that the Company will be able to obtain any additional financing on acceptable terms, if at all. The Company is attempting to license its injectable collagenase product under development. Our projections do not assume such a transaction.

The Note matures on June 19, 2005 and bears interest at a rate of 12% per annum. Interest-only payments under the Note are payable monthly in arrears and the entire principal amount is payable at maturity. Up to \$1,141,875 aggregate principal amount of the Note is convertible into the Company's common stock at any time, at a conversion price of \$2.50 per share, subject to customary adjustments. The Note also contains restrictions on the Company's ability to incur debt as long as the Note is outstanding. The Note is secured by a pledge of substantially

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all of the assets of the Company and the Company's New York subsidiary, Advance Biofactures Corporation ( ABC ). The Company has committed to filing a registration statement for the common shares issued in connection with the Note and issuable upon conversion of the Note. In addition, ABC has guaranteed the obligations of the Company under the Note and our chairman, Edwin H. Wegman, has personally guaranteed 50% of the obligations of the Company under the Note. The loan discount of approximately \$281,000 and loan costs of approximately \$180,000 on the Note will be amortized over the two-year life of the Note.

The Abbott Agreement's initial term expires in August 2003. However, because Abbott did not exercise its right to terminate the Agreement by providing the Company with notice six months before the August 2003 expiration date, the Agreement will automatically renew for an additional 10-year period, to August 2013. Notwithstanding, should the Company be unable to provide enzyme under terms of the Agreement, the Company may be required to provide Abbott with necessary technical information and manufacturing know-how to permit Abbott to manufacture our enzyme until the Company can again supply. In addition, the Company cannot assure you that Abbott will not claim that any inability to deliver the enzyme to it is an event of default under terms of the Agreement or claim that they have the right to terminate the Agreement because of default.

Historically, the Company has derived substantially all of its revenues from the topical ointment business, through the Agreement with Abbott Laboratories. Revenues from this business are derived from two sources i.) sales of Collagenase ABC enzyme in powder form to Abbott and to a lesser extent foreign pharmaceutical companies, and ii.) royalties paid by Abbott on U.S. sales of Collagenase Santyl® Ointment, which contains the product, to distributors in North America. Our manufacture of new product was voluntarily suspended in March 2000 due to a major renovation program at our Curacao facility to address various FDA concerns. Since March 2000, the Company supplied Abbott with the product from an inventory stockpiled in anticipation of the renovation program. This stockpiled inventory was depleted in July 2002. The Company received FDA approval of the Curacao facility in July 2003. The approved Curacao facility has been in limited production of quarantine inventory since the fiscal year ended January 31, 2002. However, FDA approval was required before Santyl® can be made from finished inventory produced at the Curacao facility. There is no assurance when the inventory manufactured at the Curacao will be finished and distributed to Abbott, or if the Company will be able to manufacture adequate levels of inventory on a timely basis, or what the impact of delays could have on the market for Santyl® Ointment.

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 the assets owned by ABC-Curacao, including the upgraded facility's manufacturing assets with a book value of approximately \$3.5 million at June 30, 2003. BioSpecifics has also guaranteed the Korpodeko loan. Long-term obligations at June 30, 2003 include operating leases of approximately \$191,000 annually through January 2005.

On March 11, 2003, the Company borrowed \$100,000 from an individual lender, evidenced by a one-year promissory note, bearing interest of 8% per annum, and personally guaranteed by our chairman. The Company also granted to the lender warrants to purchase up to 10,000 common shares of BioSpecifics at \$1.18, the closing price on that day, until March 11, 2008. The cost associated with these warrants, based on Black-Scholes methodology, is \$5,000 and was recorded as interest expense during the quarter ended March 31, 2003.

The accompanying consolidated financial statements have been prepared on a going concern basis. The Company was dependent on FDA approval of its Curacao facility in order to generate revenues sufficient to cover operating expenses in the near term. The Company must continue to obtain liquidity. The consolidated financial statements do not include any adjustments that might result from the ultimate timing of obtaining additional liquidity.

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2. Interim Financial Statements

In March 2003 we changed our fiscal year end from January 31 to December 31. Our first fiscal year using this new basis will be the eleven months ending December 31, 2003. In this report we compare the three and six months ended June 30, 2003 to the three and six months ended July 31, 2002, because it is not practical to recast the prior comparative periods ended June 30, 2002. The five months period ended June 30, 2003 is also presented.

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 June 30, 2003, the statements of operations for the three and six months ended June 30, 2003, and the three and six months ended July 31, 2002, and statements of cash flows for the six months ended June 30, 2003 and July 31, 2002 and five months ended June 30, 2003. 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, 2003.

3. Net loss per share

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 six months ended June 30, 2003 and July 31, 2002, 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 June 30, 2003, tangible assets in the United States of America approximated \$2.7 million and tangible assets in Curacao, Netherlands Antilles approximated \$4.0 million. There are minimal assets and operations in Germany. For the three and six months ended June 30, 2003, total revenues derived from Abbott in North America approximated \$707,000 and \$1.2 million, respectively, and \$101,000 and \$289,000, respectively from international customers. For the three and six months ended July 31, 2002, total revenues derived from Abbott in North America approximated \$1.3 million and \$1.97 million, respectively, and \$256,000 and \$455,000 respectively from international customers. Total accounts receivable at June 30, 2003 are comprised of amounts due from two 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 issuance of the Note, fully vested and non-forfeitable stock options granted to non-employees, and issuance of restricted stock for services. 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.

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6. Liquidity and Financial Condition

As of the date of this quarterly report, we have limited cash resources available to fund our operations. Although we obtained FDA approval of our Curacao manufacturing facility, we must obtain additional funding by the end of 2003, at which time our cash reserves will be nearly depleted based on our projections. We are engaged in efforts to obtain more capital through various alternatives. There can be no assurances that these efforts will be successful.

See Liquidity, Capital Resources, and Changes in Financial Condition .

7. Stock Based Compensation

The Company has three stock-based employee compensation plans in effect. The Company accounts for all transactions under which employees receive shares of stock or other equity instruments in the Company based on the price of its stock in accordance with the provisions of Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees." No stock-based employee compensation cost is reflected in net loss, as all options granted under the plan had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123 Accounting for Stock-Based Compensation .

	Three months ended June 30, 2003	Three months ended July 31, 2002	Six months ended June 30, 2003	Six months ended July 31, 2002
Net loss as reported	(\$528,381)	(\$667,989)	(\$1,462,293)	(\$1,605,603)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net effect of minority interest and related tax effects	(937)	=	(937)	=
Proforma net loss	(\$529,318)	(\$667,989)	(\$1,463,230)	(\$937,619)
Basic and diluted net loss per share:				
As reported	(\$0.11)	(\$0.15)	(\$0.32)	(\$0.35)
Proforma SFAS 123	(\$0.11)	(\$0.15)	\$(0.32)	\$(0.35)

The fair value for each option granted was estimated at the date of grant using the Black-Scholes option-pricing model, one of the allowable valuation methods under SFAS 123, with the following assumptions:

	Three months ended June 30, 2003	Three months ended July 31, 2002	Six months ended June 30, 2003	Six months ended July 31, 2002
Average risk free interest rates	4.50%	5.50%	4.50%	5.50%



Average expected life

(in years)	5.00	5.00	5.00	5.00
Volatility	82%	74%	82%	74%

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The Company granted 25,000 options that vest over four years to an employee during the three months ended June 30, 2003 and none during the six months ended July 31, 2002. The Company recorded an expense of \$9,000 and \$0 during the six months ended June 30, 2003 and July 31, 2002, respectively, for options granted to a research consultant. During the six months ended June 30, 2003, the Company issued 15,000 shares of restricted stock to a third party in lieu of cash payment for financial consulting services. The Company recorded an expense of \$15,000 for these shares issued.

8. New Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46 "Consolidation of Variable Interest Entities" ( FIN 46 ). FIN 46 explains the concept of variable interest entity and requires consolidation by the primary beneficiary where the variable interest entity does not have sufficient equity at risk to finance its activities without additional subordinated financial support from other parties. This interpretation applies immediately to any variable interest entities created after January 31, 2003 and to variable interest entities in which an interest is obtained after that date. The Company believes that the lessor of its operating facility is a variable interest entity and that the Company is the primary beneficiary. Under FIN 46 the lessor will be consolidated in the Company's consolidated balance sheet. The Company is in the process of determining the impact of this interpretation on its financial position and results of operations, as it will have effect in the third quarter 2003.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ( FAS 150 ). This statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. In accordance with the standard, financial instruments that embody obligations for the issuer are required to be classified as liabilities. This statement shall be effective for financial instruments entered into or modified after May 31, 2003 and otherwise shall be effective at the beginning of the first interim period beginning after June 15, 2003. The

Company does not expect the provisions of this statement to have a significant impact on the statement of financial position.

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**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

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

Information provided by us or statements contained in this report or made by our employees, if not historical, are forward looking information, which involve uncertainties and risks.

We caution readers that important factors may affect our actual results and could cause such results to differ materially from forward-looking statements made by us or on our behalf. Such factors include, but are not limited to, our liquidity in light of the depletion of our stockpiled inventory, government regulation, our ability to continue to manufacture the product at the recently FDA approved Curacao facility and at the Lynbrook facility, changing market conditions, the impact of competitive products and pricing, the results of clinical trials for potential products, the timely development and approval by the (FDA) and foreign health authorities of potential products, market acceptance of our potential products, and other risks detailed herein and in other filings we make with the Securities and Exchange Commission. Further, any forward looking statement or statements speak only as of the date on which such statements were made, and we undertake no obligation to update any forward looking statement or statements to reflect events or circumstances after the date on which such statement or statements were made.

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, 2003.

Summary

We are a biopharmaceutical company focusing on wound healing and tissue remodeling. We manufacture Collagenase ABC enzyme, (the enzyme) which is the active ingredient in the prescription drug Collagenase Santyl® 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, lipomas, and other conditions. 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.

The Company derives most of its net sales of the product and all of its royalty revenues from one customer in the United States, Abbott Laboratories (Abbott) who, pursuant to an exclusive licensing agreement (the Agreement), compounds the product into Collagenase Santyl® Ointment (Santyl® or ointment), a prescription drug used to treat dermal ulcers and burns. The royalty revenues from Abbott are earned on North American sales of Santyl® to distributors made by Smith & Nephew, Inc. (S&N). Historically, approximately 90% of our net sales and all royalties are derived from Collagenase Santyl® Ointment sold in North America.

The Food and Drug Administration (FDA) notified us in writing on July 28, 2003 that our request to supplement our biologics license for collagenase ABC was approved (FDA approval). The supplement included major renovations to the manufacturing facility, utility systems, and process equipment at our Curacao facility. The FDA notification acknowledged our written commitments to provide additional information regarding ongoing studies and when to submit this information to our biologics license for review.

With FDA approval, inventory of enzyme product manufactured at the Curacao facility can be distributed to Abbott when the manufacturing process is completed.

In 1999, as a result of inspectional observations made by the FDA in Form 483 citing numerous deficiencies in the Company's compliance with FDA regulations at its Lynbrook and Curacao facilities and at the contract manufacturing facility used by the Company, the FDA advised the Company in a letter (the FDA letter) that it would revoke the Company's license to produce the enzyme and ointment unless the Company could immediately provide satisfactory assurance to the FDA (including submitting a comprehensive plan of corrective action) addressing the FDA's observations and demonstrate compliance with the applicable regulations. Regardless of the

recent FDA approval described above, the FDA letter will remain in effect until we demonstrate compliance with the applicable federal standards and regulations, which the Company understands to be two satisfactory annual GMP inspections of our Lynbrook and Curacao manufacturing facilities. The Company believes it has made progress in complying with the applicable federal standards and regulations, although there can be no assurances as to when the FDA letter will be rescinded, if at all.

Revenues recorded for the six months ended July 31, 2002 were from sales of stockpiled enzyme inventory to Abbott Laboratories ( Abbott ), which as contract manufacturer makes Collagenase Santyl® Ointment (the ointment ), and royalties on distribution of the ointment in North America 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, and therefore had no sales of product to Abbott since then, including the six months ended June 30, 2003. Abbott's inventory of the ointment, which it supplies to S&N for distribution and on which we earn royalties, will be depleted during August 2003.

Since February 1, 2000, our revenues have been insufficient to cover our expenses, and we expect operating losses to continue while we attempt to return to normal manufacturing operations. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not purport to represent realizable or settlement values. The Company was dependent on the FDA approval it received and has suffered operating losses over the period of Curacao facility renovation. The Company currently has limited liquidity. These factors raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of those uncertainties.

As of the date of this quarterly report, we have limited cash resources available to fund our operations. Although we obtained FDA approval of our Curacao manufacturing facility, we must obtain additional funding by the end of 2003, at which time our cash reserves will be nearly depleted based on our projections. We are engaged in efforts to obtain more capital through various alternatives. There can be no assurances that these efforts will be successful.

The Company was notified by The Nasdaq Stock Market that the Nasdaq Listing Qualifications Panel (the Panel ) determined to continue the listing of the Company's common stock on The Nasdaq SmallCap Market pursuant to the following exception:

On or before August 14, 2003 and November 14, 2003, BioSpecifics must file the Forms 10-QSB for the quarters ending June 30, 2003 and September 30, 2003, respectively with the Securities and Exchange Commission and Nasdaq, evidencing continued compliance with all requirements for continued listing on The Nasdaq SmallCap Market.

The Panel reserved the right to terminate or otherwise modify the terms of this exception subsequent to a review of BioSpecifics' publicly filed financial statements. In order to fully comply with the terms of this exception, BioSpecifics must be able to demonstrate compliance with all requirements for continued listing on The Nasdaq SmallCap Market. In the event BioSpecifics fails to comply with any of the terms of this exception, its securities will be delisted from The Nasdaq SmallCap Market. There can be no assurances that BioSpecifics will be able to meet the requirements of the Nasdaq exception.

### Results of Operations

In March 2003 we changed our fiscal year end from January 31 to December 31. Our first fiscal year using this new basis will be the eleven months ending December 31, 2003. In this report we compare the three and six months ended June 30, 2003 to the three and six months ended July 31, 2002, because it is not practical to recast the prior comparative periods ended June 30, 2002. The five months period ended June 30, 2003 is also presented.

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#### **Three months ended June 30, 2003 and July 31, 2002**

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® Ointment contract manufactured by Abbott. Net sales for the three months ended June 30, 2003 and July 31, 2002 were \$143,629 and \$1,051,607, respectively, a decrease of \$907,978. As previously noted, net sales recorded for the three months ended July 31, 2002 were from delivery of stockpiled enzyme inventory to Abbott. We depleted that stockpiled enzyme inventory for Abbott during the fiscal quarter ended July 31, 2002, and therefore had no sales of product to Abbott since then, including the three months ended June 30, 2003. During the 2003 period, most of our net sales were to an international customer, to whom we have sold limited amounts of enzyme produced at the renovated facility in Curacao, though historically international sales have represented approximately 10% of total revenues. The decrease in net sales is also due to less testing fees earned from Collagenase Santyl® Ointment contract manufactured by Abbott, as their inventory of our product used to make Santyl® is depleted.

As a result of FDA approval, enzyme inventory manufactured at the Curacao facility can be distributed to Abbott when the manufacturing process is completed. Abbott will use this inventory to contract manufacture Collagenase

Santyl® Ointment.

Royalties - Royalties for the three months ended June 30, 2003 and July 31, 2002 were \$664,249 and \$472,222 respectively, an increase of \$192,027 or 41%. The increase was due to higher sales of Collagenase Santyl® Ointment to wholesalers in the United States by S&N during the three months ended June 30, 2003, as reported to the Company by Abbott. The Company believes S&N fulfilled distributor back orders for the ointment during the more recent three month period.

The supply of Collagenase Santyl® Ointment made from our stockpiled inventory will be depleted during August 2003. As a result of FDA approval, enzyme inventory manufactured at the Curacao facility can be distributed to Abbott when the manufacturing process is completed. However, there will be some delay in the time we had expected to deliver enzyme to Abbott after FDA approval, and by virtue of the ointment manufacturing process, there is a delay between the time we deliver our enzyme product to Abbott and the time Collagenase Santyl® Ointment can be distributed. As a result, we expect reduced royalties during the remainder of 2003 due to reduced sales of Collagenase Santyl®.

Cost of Sales - Cost of sales for the three months ended June 30, 2003 and July 31, 2002 were \$504,865 and \$1,114,635, respectively, a decrease of \$609,770 or 55%. During the three month period ended June 30, 2003, we made no shipments of Collagenase ABC to Abbott but had fixed production costs. During the three months ended July 31, 2002, we delivered the last of our stockpiled inventory. We had a negative gross profit margin in both periods due to fixed production costs. The recently approved Curacao facility has been in limited production of enzyme inventory as we attempt to resume normal operations. Enzyme produced for Abbott is work in process inventory that must undergo additional processing.

General and administrative - General and administrative expenses for the three months ended June 30, 2003 and July 31, 2002 were \$651,359 and \$781,364 respectively, a decrease of \$130,005 or 17%. The decrease during the June 30, 2003 period is due to reduced legal and consulting professional fees, as well as reduced travel fees. During the three months ended July 31, 2002, the Curacao facility was inspected by the FDA, which required substantial travel and related costs.

Research and development - Research and development ("R&D") expense for the three months ended June 30, 2003 and July 31, 2002 were \$187,503 and \$300,134 respectively, representing a decrease of \$112,631 or 38%. Costs incurred during the more recent quarter represent mostly fixed costs for our R&D department. We will need to raise considerable funds to continue the development of Cordase™, our injectable collagenase for Dupuytren's disease, and other potential product candidates.

Other income (expense), net - Other income (expense), net for the three months ended June 30, 2003 and July 31, 2002 was \$(732) and \$(13,685) respectively. The decrease in other (expense) of \$12,953 was primarily attributable to the receipt of a state tax refund.

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We expect other (expense) to greatly increase in future quarters due to the June 2003 financing transaction with Bio Partners LP, a private investor group, pursuant to which the Company sold to Bio Partners in a private placement a \$1.575 million convertible note, issued at face value, which bears interest of 12% per annum. See Liquidity, Capital Resources and Changes in Financial Condition .

Income tax benefit We recorded no income tax benefit for the three months ended June 30, 2003 and July 31, because of uncertainties with respect to the timing of future utilization of net operating loss benefit.

**Six Months Ended June 30, 2003 and July 31, 2002**

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® Ointment contract manufactured by Abbott. Net sales for the six months ended June 30, 2003 and July 31, 2002 were \$395,131 and \$1,393,501, respectively, a decrease of \$998,370. As previously noted, net sales recorded for the six months ended July 31, 2002 were from delivery of stockpiled enzyme inventory to Abbott. We depleted that stockpiled enzyme inventory for Abbott during the fiscal quarter ended July 31, 2002, and therefore had no sales of product to Abbott since then, including the six months ended June 30, 2003. During the 2003 period, most of our net sales were to an international customer, to whom we have sold limited amounts of enzyme produced at the renovated facility in Curacao, though historically international sales have represented approximately 10% of total revenues. The decrease in net sales is also due to less testing fees earned from Collagenase Santyl® Ointment contract manufactured by Abbott, as their inventory of our product used to make Santyl® is depleted.

As a result of FDA approval, enzyme inventory manufactured at the Curacao facility can be distributed to Abbott when the manufacturing process is completed. Abbott will use this inventory to contract manufacture Collagenase Santyl® Ointment.

Royalties - Royalties for the six months ended June 30, 2003 and July 31, 2002 were \$1,138,057 and \$1,032,350 respectively, an increase of \$105,707 or 10%. The increase was due to higher sales of Collagenase Santyl® Ointment

to wholesalers in the United States by S&N during the six months ended June 30, 2003, as reported to the Company by Abbott. The Company believes S&N fulfilled distributor back orders for the ointment during the three months ended June 30, 2003.

The supply of Collagenase Santyl® Ointment made from our stockpiled inventory will be depleted during August 2003. As a result of FDA approval, enzyme inventory manufactured at the Curacao facility can be distributed to Abbott when the manufacturing process is completed. However, there will be some delay in the time we had expected to deliver our enzyme to Abbott after FDA approval, and by virtue of the ointment manufacturing process, there is a delay between the time we deliver our enzyme product to Abbott and the time Collagenase Santyl® Ointment can be distributed. As a result, we expect reduced royalties during the remainder of 2003 due to reduced sales of Collagenase Santyl®.

Cost of Sales - Cost of sales for the six months ended June 30, 2003 and July 31, 2002 were \$1,146,201 and \$1,883,511, respectively, a decrease of \$737,310 or 39%. During the six month period ended June 30, 2003, we made no shipments of Collagenase ABC to Abbott but had fixed production costs. During the six months ended July 31, 2002, we delivered the last of our stockpiled inventory. We had a negative gross profit margin in both periods due to fixed production costs. The recently approved Curacao facility has been in limited production of enzyme inventory as we attempt to resume normal operations. Enzyme produced for Abbott is work in process inventory that must undergo additional processing.

General and administrative - General and administrative expenses for the six months ended June 30, 2003 and July 31, 2002 were \$1,447,261 and \$1,522,594 respectively, a decrease of \$75,333 or 5%. The decrease during the June 30, 2003 period is due to reduced legal and consulting professional fees, as well as reduced travel fees. During the six months ended July 31, 2002, the Curacao facility was inspected by the FDA, which required substantial travel and related costs.

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Research and development - Research and development ("R&D") expense for the six months ended June 30, 2003 and July 31, 2002 were \$435,756 and \$661,344 respectively, representing a decrease of \$225,588 or 34%. Costs incurred during the more recent period represent mostly fixed costs for our R&D department. We will need to raise considerable funds to continue the development of Cordase™, our injectable collagenase for Dupuytren's disease, and other potential product candidates.



Other income (expense), net - Other income (expense), net for the six months ended June 30, 2003 and July 31, 2002 was \$(8,446) and \$(9,305) respectively. The decrease in other (expense) of \$859 was primarily attributable to the receipt of a state tax refund during the three months ended June 30, 2003.

We expect other (expense) to greatly increase in future quarters due to the June 2003 financing transaction with Bio Partners LP, a private investor group, pursuant to which the Company sold to Bio Partners in a private placement a \$1.575 million convertible note, issued at face value, which bears interest of 12% per annum. See Liquidity, Capital Resources and Changes in Financial Condition .

Income tax benefit We recorded no income tax benefit for the six months ended June 30, 2003 and July 31, because of uncertainties with respect to the timing of future utilization of net operating loss benefit.

### **Liquidity, Capital Resources and Changes in Financial Condition**

Our primary source of working capital is from operations, which includes sales of product, testing fees, royalties, and periodic license fees. At June 30, 2003, we had working capital of approximately \$197,000. The principal use of cash in during the six months ended June 30, 2003 was approximately \$1,025,000 for operating activities. Sources of cash included approximately \$153,000 of repayments by our chairman of his notes, an increase of \$100,000 in short term debt, and proceeds from a \$1,575,000 two year senior secured convertible note bearing 12% interest, described below.

As of the date of this quarterly report, we have limited cash resources available to fund our operations. Although we obtained FDA approval of our Curacao manufacturing facility, we must obtain additional funding by the end of 2003, at which time our cash reserves will be nearly depleted based on our projections. We are engaged in efforts to obtain more capital through various alternatives. There can be no assurances that these efforts will be successful.

On June 19, 2003, the Company entered into a financing transaction with Bio Partners LP, a private investor group, pursuant to which the Company sold to Bio Partners in a private placement (i) a \$1.575 million convertible note (the Note ), issued at face value, and (ii) 295,312 shares of Company common stock, issued at par value, or \$.001 per share. The net proceeds to the Company were approximately \$890,000, after the payment of loan expenses and taking into account the aggregate \$500,000 that was previously advanced to the Company by a principal of Bio Partners.

The Note matures on June 19, 2005 and bears interest at a rate of 12% per annum. Interest-only payments under the Note are payable monthly in arrears and the entire principal amount is payable at maturity. Up to \$1,141,875 aggregate principal amount of the Note is convertible into the Company's common stock at any time, at a conversion price of \$2.50 per share, subject to customary adjustments. The Note also contains restrictions on the Company's

ability to incur debt as long as the Note is outstanding. The Note is secured by a pledge of substantially all of the assets of the Company and the Company's New York subsidiary, Advance Biofactures Corporation ( ABC ). The Company has committed to filing a registration statement for the common shares issued in connection with the Note and issuable upon conversion of the Note. In addition, ABC has guaranteed the obligations of the Company under the Note and our chairman, Edwin H. Wegman, has personally guaranteed 50% of the obligations of the Company under the Note. The loan discount of approximately \$281,000 and loan costs of approximately \$185,000 on the Note will be amortized over the two-year life of the Note.

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 the assets owned by ABC-Curacao, including the upgraded facility's manufacturing assets with a book value of

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approximately \$3.5 million at June 30, 2003. BioSpecifics has also guaranteed the Korpodeko loan. Long-term obligations at June 30, 2003 include operating leases of approximately \$191,000 annually through January 2005. On March 11, 2003, we borrowed \$100,000 from an individual lender, personally guaranteed by the Company's chairman and evidenced by a one-year promissory note, bearing interest of 8% per annum. We also granted to the lender warrants to purchase up to 10,000 common shares of BioSpecifics at \$1.18, the closing price on that day, until March 11, 2008. The cost associated with these warrants, based on Black-Scholes methodology, is \$5,000 was recorded as interest expense for the three months ended March 31, 2003.

### **ITEM 3. CONTROLS AND PROCEDURES**

#### **Controls and Procedures.**

As of the end of the period covered by this report, the Company conducted an evaluation, under the supervision and with the participation of the principal executive officer and principal financial officer, of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act )). Based on this evaluation, the principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and

reported within the time periods specified in Securities and Exchange Commission rules and forms. There was no change in the Company's internal control over financial reporting during the Company's most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## **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 Changes in Financial Condition .

### **ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

a)

Exhibit 31.1, Exhibit 31.2, Exhibit 32.1, Exhibit 32.2

b)

Form 8-K dated March 17, 2003, Form 8-K dated May 16, 2003, Form 8-K dated June 19, 2003, Form 8-K dated July 29, 2003, Form 8-K dated August 1, 2003

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**BIOSPECIFICS TECHNOLOGIES CORP.**

Date: August 14, 2003

By: /s/ EDWIN H. WEGMAN

Edwin H. Wegman

Chairman, President, and

Chief Executive Officer

Date: August 14, 2003

By: /s/ ALBERT HORCHER

Albert Horcher

Secretary, Treasurer and Principal Financial

And Chief Accounting Officer

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**EXHIBIT INDEX**

No.	Description
<u>31.1</u>	Certification Pursuant to Section 302 of The Sarbanes-Oxley Act Of 2002 by Edwin H. Wegman, Chief Executive Officer
<u>31.2</u>	Certification Pursuant to Section 302 of The Sarbanes-Oxley Act Of 2002 by Albert Horcher, Principal Accounting Officer
<u>32.1</u>	Certification Pursuant to 18 U.S.C. Section 1350 by Edwin H. Wegman, Chief Executive Officer
<u>32.2</u>	Certification Pursuant to 18 U.S.C. Section 1350 by Albert Horcher, Principal Accounting Officer