BIOSPECIFICS TECHNOLOGIES CORP
Form 10QSB
November 14, 2003

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

FORM 10-QSB

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

For the quarterly period ended: SEPTEMBER 30, 2003

[ ] 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: 4,888,148 shares of Common Stock, $0.001 par value as of November 1, 2003

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



INDEX

BIOSPECIFICS TECHNOLOGIES CORP.
AND SUBSIDIARIES

Consolidated Balance Sheet

| | September 30, 2003 (Unaudited) |
|---|---|
| **Assets** | |
| Current assets: | |
| Cash and cash equivalents | $ 551,507 |
| Marketable securities | 3,026 |
| Accounts receivable, net | 674,620 |
| Inventories, net | 728,634 |
| Prepaid expenses and other current assets | 33,655 |
| Total current assets | 1,991,442 |
| Other assets - loan costs | 225,992 |
| Property, plant and equipment, net | 4,068,140 |
| | $ 6,285,574 |
| **Liabilities and Stockholders' Equity** | |
| Current liabilities: | |
| Accounts payable and accrued expenses | 1,699,022 |
| Notes payable to related parties | 14,885 |
| Deferred revenue | 45,000 |
| Short-term debt - Korpodeko | 91,000 |
| Short-term debt - promissory note | 100,000 |

| | |
|---|---|
| Total current liabilities | 1,949,907 |
| Long-term debt less current portion - Korpodeko | 364,000 |
| Senior secured covertible 12% note, net | 1,329,522 |
| Minority interest in subsidiaries | 107,188 |
| 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 September 30, 2003 | 5,249 |
| Additional paid-in capital | 4,144,207 |
| Retained earnings | 961,683 |
| Accumulated other comprehensive income | 4,430 |
| Treasury stock, 361,380 shares at cost | (1,911,237) |
| Notes receivable from chairman and other related party | (669,375) |
| Total stockholders' equity | 2,534,957 |
| | $ 6,285,574 |

See accompanying notes to consolidated financial statements.



Biospecifics Technologies Corp.
and Subsidiaries
Consolidated Statements of Operations

| Revenues: | Three Months Ended September 30, 2003 (Unaudited) | Three Months Ended October 31, 2002 (Unaudited) |
|---|---|---|
| Net sales | $ 525,746 | $ 305,086 |
| Royalties | 266,290 | 525,774 |
| | 792,036 | 830,860 |
| Costs and Expenses: | | |
| Cost of sales | 754,983 | 455,040 |
| General and administrative | 759,348 | 896,740 |
| Research and development | 181,222 | 253,563 |
| | 1,695,553 | 1,605,343 |
| Loss from operations | (903,517) | (774,483) |
| Other income (expense): | | |

| | | |
|---|---|---|
| Investment and other income | 10 | 3,308 |
| Interest expense | (102,836) | (8,669) |
| | (102,826) | (5,361) |
| Loss before income taxes and minority interest | (1,006,343) | (779,844) |
| Income tax benefit (expense) | 0 | 0 |
| Loss before minority interest | (1,006,343) | (779,844) |
| Minority interest in net loss of subsidiaries | 24,770 | 21,200 |
| Net loss | ($ 981,573) | ($ 758,644) |
| Basic and diluted net loss per common share | ($ 0.21) | ($ 0.17) |
| Weighted-average common shares outstanding | 4,888,148 | 4,577,836 |

| Revenues: | Nine Months Ended October 31, 2002 (Unaudited) | Eight Months Ended September 30, 2003 (Unaudited) |
|---|---|---|
| Net sales | $ 1,698,587 | $ 698,014 |
| Royalties | 1,558,124 | 1,236,363 |
| | 3,256,711 | 1,934,377 |
| Costs and Expenses: | | |
| Cost of sales | 2,338,551 | 1,629,043 |
| General and administrative | 2,419,334 | 1,909,341 |
| Research and development | 914,907 | 538,605 |
| | 5,672,792 | 4,076,989 |
| Loss from operations | (2,416,081) | (2,142,612) |
| Other income (expense): | | |
| Investment and other income | 16,270 | 19,317 |
| Interest expense | (30,936) | (131,538) |
| | (14,666) | (112,221) |
| Loss before income taxes and minority interest | (2,430,747) | (2,254,833) |
| Income tax benefit (expense) | 0 | (13,000) |
| Loss before minority interest | (2,430,747) | (2,267,833) |
| Minority interest in net loss of subsidiaries | 66,500 | 53,270 |
| Net loss | ($2,364,247) | ($2,214,563) |
| Basic and diluted net loss per common share | ($ 0.52) | ($ 0.48) |
| Weighted-average common shares outstanding | 4,559,836 | 4,683,773 |

See accompanying notes to consolidated financial statements

Biospecifics Technologies Corp.
and Subsidiaries
Consolidated Statements of Cash Flows

| | Nine Months Ended September 30, 2003 | Nine Month October 3 |
|---|---|---|
| | (Unaudited) | (Unaudi |
| Cash flows from operating activities: | | |
| Net loss | ($2,443,866) | ($2,364 |
| Adjustments to reconcile net loss to net cash used by operating activities: | | |
| Depreciation and amortization | 468,751 | 489 |
| Options issued for services | 14,000 | |
| Issuance of stock for services | 15,000 | |
| Minority interest in loss of subsidiaries | (59,953) | (66 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 194,190 | 1,696 |
| Inventories | (79,754) | 195 |
| Prepaid expenses and other current assets | 493 | (43 |
| Accounts payable and accrued expenses | 42,474 | (125 |
| Income taxes receivable | 417,000 | |
| Net cash used by operating activities | (1,431,665) | (219 |
| Cash flows from investing activities: | | |
| Paydown of notes receivable from chairman | 460,934 | (13 |
| Expenditures for property, plant and equipment | (8,849) | (39 |
| Net cash provided by (used) in investing activities | 452,085 | (53 |
| Cash flows from financing activities: | | |
| Interest accrued on notes payable to related parties | 375 | |
| Exercises of stock options | 0 | 34 |
| Decrease in short-term debt | (264,000) | |
| Increase in long term debt | 364,000 | |
| Increase in senior secured convertible debt | 1,575,000 | |
| Other assets - loan costs | (225,992) | |
| Amortization of loan discount | 35,068 | |
| Stock issued to senior secured debt | 295 | |
| Net cash provided by financing activities | 1,484,746 | 34, |
| Effect of exchange rates on cash and equivalents | (4,558) | (2 |
| Increase (decrease) in cash and cash equivalents | 500,608 | (239 |
| Cash and cash equivalents at beginning of period | 50,899 | 693 |
| Cash and cash equivalents at end of period | $551,507 | $453 |
| Supplemental disclosures of cash flow information: | | |
| Cash paid during the year for: | | |
| Interest | $131,539 | $30 |
| Income taxes | 0 | $14 |

See accompanying notes to consolidated financial statements



BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES
NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS
SEPTEMBER 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(R) Ointment ("Santyl(R)" or "ointment"), a prescription drug used to treat dermal ulcers and burns. The royalty revenues from Abbott were earned on North American sales of Santyl(R) to distributors by Smith & Nephew, Inc. ("S&N").

The FDA notified us 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 sub-license agreement under which Smith & Nephew marketed Santyl(R) ointment terminated on June 30, 2003 but it was agreed they would continue to market

through the end of 2003. The Ross Products Division of Abbott Laboratories Inc. will assume United States marketing responsibility for Collagenase Santyl(R) Ointment effective January 1, 2004.

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 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(R) Ointment from a supply that was 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 notes repayments of $153,934 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 October 2003, the Company projects that these funds will enable it to continue operations to December 31, 2003.

If any of the 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, and attempting to obtain an additional loan, which would require the permission of Bio

Partners. Our projections do not assume such transactions.



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 $258,000 incurred on the Note will be amortized over the two-year life of the Note.

The Abbott Agreement automatically renewed for an additional 10-year period, to August 2013. The sub-license agreement under which Smith & Nephew marketed Santyl(R) ointment terminated on June 30, 2003 but it was agreed they would continue to market through the end of 2003. The Ross Products Division of Abbott Laboratories Inc. will assume all marketing responsibility for Collagenase Santyl(R) Ointment effective January 1, 2004. 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 and the predecessor company Knoll Pharmaceutical Company. 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(R) 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. FDA approval was required before Santyl(R) could be made from inventory manufactured at the renovated Curacao facility. Inventory manufactured at the renovated Curacao facility was delivered to Abbott during the three months ended September 30, 2003. There is no assurance when other inventory manufactured at the Curacao facility 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 how substantial the impact of delays will have on the market for Santyl(R) 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 $3.4 million at September 30, 2003. BioSpecifics has also guaranteed the Korpodeko loan. In September 2003, Korpodeko agreed to modify the terms of the loan. Korpodeko will permit the Company to repay 20%, or $91,000 of the loan principal in November 2003, and pay the remaining principal, or $364,000 in November 2004. In return, the Company agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004. On the consolidated balance sheet as of September 30, 2003, short-term liabilities include the $91,000 due November 2003, and long-term liabilities include the remaining



$364,000 due November 2004. Long-term obligations at September 30, 2003 include operating leases of approximately $191,000 payable 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, was $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 its efforts to obtain additional working capital and maintain liquidity. The consolidated financial statements do not include any adjustments that might result from the ultimate timing of obtaining additional liquidity.

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 nine months ended September 30, 2003 to the three and nine months ended October 31, 2002, because it is not practical to recast the prior comparative periods ended September 30, 2002. The eight months period ended September 30, 2003 is also presented.

In the opinion of management, the accompanying consolidated interim 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 September 30, 2003, the statements of operations for the three and nine months ended September 30, 2003, and the three and nine months ended October 31, 2002, and statements of cash flows for the nine months ended September 30, 2003 and October 31, 2002 and eight months ended September 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 nine months ended September 30, 2003 and October 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 September 30, 2003, tangible assets in the United States of America approximated $2.3 million and tangible assets in Curacao, Netherlands Antilles approximated $3.7 million. There are minimal assets and



operations in Germany. For the three and nine months ended September 30, 2003, total revenues derived from Abbott in North America approximated $800,000 and $2.0 million, respectively, and $0 and $289,000, respectively from international customers. For the three and nine months ended October 31, 2002, total revenues derived from Abbott in North America approximated $0.6 million and $2.5 million, respectively, and $240,000 and $696,000 respectively from international customers. Total accounts receivable at September 30, 2003 are primarily due from Abbott.

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 Bio Partners 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.

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, in particular licensing our injectable collagenase under development, and obtaining an additional loan. 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 September 30, 2003 | Three months ended October 31, 2002 | Nine months ended September 30, 2003 |
|---|---|---|---|
| Net loss as reported | ($981,573) | ($758,644) | ($2,443,866) |
| 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 | (73,787) | (29,515) | (221,361) |
| Proforma net loss | ($1,055,360) | ($788,159) | ($2,665,227) |
| Basic and diluted net loss per share: | | | |
| As reported | ($0.21) | ($0.17) | ($0.53) |
| Proforma SFAS 123 | ($0.22) | ($0.17) | $(0.57) |



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 September 30, 2003 | Three months ended October 31, 2002 | Nine months ended September 30, 2003 |
|---|---|---|---|
| Average risk free interest rates | 4.50% | 5.50% | 4.50% |
| Average expected life (in years) | 5.00 | 5.00 | 5.00 |
| Volatility | 82% | 74% | 82% |

The Company granted 20,000 options that vest over four years to an employee during the nine months ended September 30, 2003 and granted 425,000 options to employees during the nine months ended October 31, 2002 which vested in October 2003. The Company recorded an expense of $9,000 and $0 during the nine months ended September 30, 2003 and October 31, 2002, respectively, for options granted to a research consultant. During the nine months ended September 30, 2003, the Company issued 15,000 shares of restricted stock to a third party non-employee 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. A determination has been made that although the lessor of its operating facility is a variable interest entity, the Company is not the primary beneficiary. Under FIN 46 the lessor will not be consolidated in the Company's consolidated balance sheet. The required disclosures for this entity have been included in the Company's 10-KSB for the fiscal year ended January 31, 2003.

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 manufacture the product at adequate levels at the recently FDA approved Curacao facility and at the Lynbrook facility, changing market conditions, the impact that delivery delays of our enzyme to Abbott will have on the market for Collagenase Santyl(R) Ointment, 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(R) Ointment sold in the United States and indicated for debriding chronic dermal ulcers and second and third degree burns. We are developing an injectable form of our enzyme for treating Dupuytren's disease, Peyronie's disease, frozen shoulder, lipomas, and other conditions. We have initiated Phase 3 clinical trials for Dupuytren's disease. A clinical trial for Peyronie's disease is scheduled for December 2003. 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(R) Ointment ("Santyl(R)" or "ointment"), a prescription drug used to treat dermal ulcers and burns. The royalty revenues from Abbott were earned on North American sales of Santyl(R) to distributors by Smith & Nephew, Inc. ("S&N"). Historically, approximately 90% of our net sales and all royalties are derived from Collagenase Santyl(R) Ointment sold in North America.

The sub-license agreement under which Smith & Nephew marketed Santyl(R) ointment terminated on June 30, 2003 but it was agreed they would continue to market through the end of 2003. The Ross Products Division of Abbott Laboratories Inc. will assume United States marketing responsibility for Collagenase Santyl(R) Ointment effective January 1, 2004.

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 manufactured at the Curacao facility can be distributed to Abbott when the manufacturing process is completed. We did not achieve our 2003 enzyme manufacturing and inventory



level goals due to manufacturing difficulties, but are working to solve such difficulties and expect improvement in 2004.

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(R) 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 from then until the middle of September 2003, when deliveries of available enzyme resumed. Abbott's inventory of the ointment, which it supplies to S&N for distribution and on which we earn royalties, was depleted by the end of July 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.

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 "12% 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 November 2003, the Company projects that these funds and funds provided by operations will enable it to continue operations at least to December 31, 2003.

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. BioSpecifics filed Form 10-QSB for the quarter ended June 30, 2003 on August 14, 2003 and has filed this report on Form 10-QSB by November 14, 2003. There can be no assurances that BioSpecifics will be able to continue to meet other requirements of continued Nasdaq listing.

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 nine months ended September 30, 2003 to the three and nine months ended October 31, 2002, because it is not practical to recast the prior period results into comparative periods ended September 30, 2002. The eight months period ended September 30, 2003 is also presented.

THREE MONTHS ENDED SEPTEMBER 30, 2003 AND OCTOBER 31, 2002

Net Sales - Net sales include the sales of Collagenase ABC enzyme recognized at the time it is shipped to customers, primarily Abbott. Net sales also include fees we charge Abbott for testing Collagenase Santyl(R) Ointment it contract manufactures. Net sales for the three months ended September 30, 2003 and October 31, 2002 were $525,746 and $305,086, respectively, an increase of $220,660 or 72%.

As a result of the FDA approval, we can distribute to Abbott enzyme inventory manufactured at the renovated Curacao facility when the manufacturing process is completed, which Abbott can then use to contract manufacture Collagenase Santyl(R) Ointment. In September 2003, we delivered the first available enzyme manufactured at the renovated Curacao facility to Abbott. As previously noted, we depleted stockpiled enzyme inventory for Abbott during the fiscal quarter ended July 31, 2002, and therefore had no sales of product to Abbott subsequently, including the three months ended October 31, 2002. During the 2002 period, net sales of enzyme were to an international customer, to whom we have sold limited amounts of enzyme produced at the renovated facility in Curacao, though international sales have historically represented approximately 10% of total revenues. During the three months ended September 30, 2003, there were no sales to international customers and none are expected for the remainder of 2003. We expect more enzyme inventory to be available for delivery to Abbott in December 2003, though there can be no assurances.

During the 2002 period, we earned higher testing fees because Abbott contract manufactured more Collagenase Santyl(R) Ointment than in the 2003 period, because we had and delivered to Abbott more of the stockpiled enzyme.

Royalties - Royalties for the three months ended September 30, 2003 and October 31, 2002 were $266,290 and $525,774 respectively, a decrease of $259,484 or 49%. As previously noted, Abbott's inventory of Santyl(R) ointment, which it has supplied to S&N for distribution and on which we earn



royalties, was depleted by the end of July 2003. Therefore, no royalties were earned during August and September 2003.

In September 2003, we delivered the first available enzyme manufactured at the renovated Curacao facility to Abbott, which Abbott contract manufactured into Santyl(R) ointment. We expect this ointment to be distributed during 2003. However, Santyl(R) sales during 2003 will be significantly lower than 2002 levels because of lack of sufficient enzyme, resulting in significantly lower royalties. We expect Santyl(R) sales to continue to be negatively impacted in

2004, because we did not achieve our 2003 enzyme manufacturing and inventory level goals due to manufacturing difficulties. We are working to solve production difficulties and expect improvement in enzyme production levels in 2004 by adding new staffing, although there can be no assurances.

The sub-license agreement under which Smith & Nephew marketed Santyl(R) ointment terminated on June 30, 2003 but it was agreed they would continue to market through the end of the 2003. The Ross Products Division of Abbott Laboratories Inc. will assume United States marketing responsibility for Collagenase Santyl(R) Ointment effective Jan. 1, 2004.

Cost of Sales - Cost of sales for the three months ended September 30, 2003 and October 31, 2002 were $754,983 and $455,040, respectively, an increase of $299,943 or 66%, partially due to the higher level of net sales of enzyme described above. 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 September 30, 2003 and October 31, 2002 were $759,348 and $896,740 respectively, a decrease of $137,392 or 15%. The decrease during the September 30, 2003 period is due to reduced legal and consulting professional fees.

Research and development - Research and development ("R&D") expense for the three months ended September 30, 2003 and October 31, 2002 were $181,222 and $253,563 respectively, representing a decrease of $72,341 or 29%. 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(TM), 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 September 30, 2003 and October 31, 2002 was ($102,826) and ($5,361) respectively. The increase in other (expense) of $97,465 was primarily attributable to interest expense on the 12% Note and the promissory note totaling approximately $55,000 and amortization of the 12% Note discount of approximately $35,000. The quarterly amortization of the loan costs of approximately $32,000 is included in General and Administrative expenses.

Interest expense will be at these levels in future quarters due to the 12% Note and the promissory note. See "Liquidity, Capital Resources and Changes in Financial Condition".

Income tax benefit - We recorded no income tax benefit for the three months ended September 30, 2003 and October 31, 2002 because of uncertainties with respect to future utilization of net operating loss benefit.

NINE MONTHS ENDED SEPTEMBER 30, 2003 AND OCTOBER 31, 2002

Net Sales - Net sales include the sales of Collagenase ABC enzyme recognized at the time it is shipped to customers, primarily Abbott. Net sales also include fees we charge Abbott for testing Collagenase



Santyl(R) Ointment it contract manufactures. Net sales for the nine months ended September 30, 2003 and October 31, 2002 were $920,877 and $1,698,587, respectively, a decrease of $777,710, or 46%.

As a result of the FDA approval, we can distribute to Abbott enzyme inventory manufactured at the renovated Curacao facility when the manufacturing process is completed, which Abbott can then use to contract manufacture Collagenase Santyl(R) Ointment. In September 2003, we delivered the first available enzyme manufactured at the renovated Curacao facility to Abbott

As previously noted, net sales recorded for the nine months ended October 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 subsequent to September 2003. During the 2003 period, we have sold limited amounts of enzyme produced at the renovated facility in Curacao to an international customer, though international sales have historically represented approximately 10% of total revenues. We expect no further sales to international customers for the remainder of 2003. We expect more enzyme inventory to be available for delivery to Abbott in December 2003, though there can be no assurances.

During the 2002 period, we earned higher testing fees because Abbott contract manufactured more Collagenase Santyl(R) Ointment than in the 2003 period, because we had and delivered to Abbott more of the stockpiled enzyme.

Royalties - Royalties for the nine months ended September 30, 2003 and October 31, 2002 were $1,404,347 and $1,558,124 respectively, a decrease of $153,777 or 10%. As previously described, Abbott's inventory of Santyl(R) ointment, which it has supplied to S&N for distribution and on which we earn royalties, was depleted by the end of July 2003. Therefore, no royalties were earned during August and September 2003.

In September 2003, we delivered the first available enzyme manufactured at the renovated Curacao facility to Abbott, which Abbott contract manufactured into Santyl(R) ointment. We expect this ointment to be distributed during 2003. However, Santyl(R) sales during 2003 will be significantly lower than 2002 levels because of lack of sufficient enzyme, resulting in significantly lower royalties. We expect Santyl(R) sales to continue to be negatively impacted in 2004, because we did not achieve our 2003 enzyme manufacturing and inventory level goals due to manufacturing difficulties. We are working to solve production difficulties and expect improvement in enzyme production levels in 2004 by adding new staffing, although there can be no assurances.

The sub-license agreement under which Smith & Nephew marketed Santyl(R) ointment terminated on June 30, 2003 but it was agreed they would continue to market through the end of the 2003. The Ross Products Division of Abbott Laboratories Inc. will assume United States marketing responsibility for Collagenase Santyl(R) Ointment effective January 1, 2004.

Cost of Sales - Cost of sales for the nine months ended September 30, 2003 and October 31, 2002 were $1,901,184 and $2,338,551, respectively, a decrease of $437,367 or 19%, partially due to the lower level of net sales of enzyme previously described. 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 nine months ended September 30, 2003 and October 31, 2002 were $2,206,609 and $2,419,334 respectively, a decrease of $212,725 or 9%. The decrease during the September 30, 2003 period is due to reduced legal and consulting professional fees, as well as reduced travel fees. During the nine months ended October 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 nine months ended September 30, 2003 and October 31, 2002 were $616,978 and $914,907 respectively, representing a decrease of $297,929 or 33%. 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(TM), our injectable collagenase for Dupuytren's disease, and other potential product candidates.

Other income (expense), net - Other income (expense), net for the nine months ended September 30, 2003 and October 31, 2002 was $(111,272) and $(14,666) respectively. The increase in other (expense) of $96,606 was primarily attributable to the interest expense on the 12% Note and the promissory note totaling approximately $75,000 and amortization of the 12% Note discount of approximately $35,000. The amortization of the loan costs of approximately $32,000 is included in General and Administrative expenses.

Interest expense will be at these levels in future quarters due to the 12% Note and the promissory note. See "Liquidity, Capital Resources and Changes in Financial Condition".

Income tax benefit - We recorded no income tax benefit for the nine months ended September 30, 2003 and October 31, 2002 because of uncertainties with respect to 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, and borrowings. At September 30, 2003, we had working capital of approximately $42,000. The principal use of cash during the nine months ended September 30, 2003 was approximately $1.4 million for operating activities. Sources of cash included approximately $461,000 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 $258,000 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 approximately $3.4 million at September 30, 2003. BioSpecifics has also guaranteed the Korpodeko loan. In September 2003, Korpodeko agreed to modify the terms of the loan. Korpodeko will permit the Company will repay 20%, or $91,000 of the loan principal in November 2003, and pay the remaining principal, or $364,000 in November 2004. In return, the Company agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004. On the consolidated balance sheet as of September 30, 2003, short-term liabilities include the $91,000 due November 2003, and long-term liabilities include the remaining $364,000 due November 2004. Long-term obligations at September 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

Exhibit 31.1 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Edwin H. Wegman, Chief Executive Officer.

Exhibit 31.2 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Albert Horcher, Principal Accounting Officer.



Exhibit 32.1 Certification Pursuant to 18 U.S.C. Section 1350 by Edwin H. Wegman, Chief Executive Officer.

Exhibit 32.2 Certification Pursuant to 18 U.S.C. Section 1350 by Albert Horcher, Principal Accounting Officer.

Form 8-K dated July 29, 2003, and Form 8-K dated August 1, 2003



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: November 14, 2003

By: /s/ Edwin H. Wegman
---
Edwin H. Wegman
Chairman, President, and
Chief Executive Officer

Date: November 14, 2003

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