

BIOSPECIFICS TECHNOLOGIES CORP
Form 10-Q
May 12, 2009

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **March 31, 2009**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

0-19879

(Commission file number)

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 No.)

35 Wilbur Street Lynbrook, NY 11563
(Address of Principal Executive Offices) (Zip Code)

516.593.7000
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 12, 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 ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☒ [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

Indicate the number of shares outstanding of the issuer's classes of common stock, as of the latest practicable date:

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Class of Stock
Common Stock (\$.001 par value)

Outstanding April 23, 2009
6,014,801

BIOSPECIFICS TECHNOLOGIES CORP.

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Introductory Comments Terminology

Throughout this quarterly report on Form 10-Q (this Report), the terms BioSpecifics, Company, we, our, and us refer to BioS Technologies Corp. and its subsidiary, Advance Biofactures Corporation (ABC-NY).

Introductory Comments Forward-Looking Statements

This Report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimate, potential, or continue or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this Report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below, and for the reasons described elsewhere in this Report. All forward-looking statements and reasons why results may differ included in this Report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

PART I FINANCIAL INFORMATION**Item 1: Consolidated Financial Statements****BIOSPECIFICS TECHNOLOGIES CORP.
Consolidated Balance Sheets**

	March 31, 2009 (unaudited)	December 31, 2008 (audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,741,213	\$ 3,494,150
Short-term investments	-	900,000
Accounts receivable, net	66,834	6,952,781
Prepaid expenses and other current assets	68,824	67,709
Total current assets	10,876,871	11,414,640
Deferred royalty buy-down	1,250,000	1,250,000
Property, plant and equipment, net	1,875	2,297
Patent costs, net	186,066	164,424
Total assets	12,314,812	12,831,361
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	730,566	642,465
Deferred revenue	1,266,621	1,271,792
Accrued tax and other accrued liabilities of discontinued operations	78,138	78,138
Total current liabilities	2,075,325	1,992,395
Accrued third-party development expenses	2,803,616	2,758,595
Long-term deferred revenue	1,770,721	1,901,832
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; 6,143,068 shares and 6,140,068 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	6,143	6,140
Additional paid-in capital	13,727,387	13,294,803
Accumulated deficit	(7,374,423)	(6,428,447)
Treasury stock, 131,267 shares at cost at March 31, 2009 and December 31, 2008	(693,957)	(693,957)
Total stockholders' equity	5,665,150	6,178,539
Total liabilities and stockholders' equity	\$ 12,314,812	\$ 12,831,361

See accompanying notes to consolidated financial statements

BIOSPECIFICS TECHNOLOGIES CORP.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended	
	March 31,	
	2009	2008
Revenues:		
Net sales	\$ 7,191	\$ 12,753
Licensing fees	266,281	266,281
Consulting fees	70,000	122,185
Total Revenues	343,472	401,219
Costs and expenses:		
Research and development	115,871	94,271
General and administrative	1,166,971	800,456
Total Cost and Expenses	1,282,842	894,727
Operating loss	(939,370)	(493,508)
Other income (expense):		
Interest income	2,857	30,275
Interest expense	-	(451)
Other, net	(9,463)	-
	(6,606)	29,824
Loss before benefit (expense) for income tax	(945,976)	(463,684)
Income tax benefit (expense)	-	-
Net loss	\$ (945,976)	\$ (463,684)
Basic and diluted net loss per share	\$ (0.16)	\$ (0.08)
Shares used in computation of basic and diluted net loss per share	6,008,834	5,633,177
See accompanying notes to consolidated financial statements		

BioSpecifics Technologies Corp.
Consolidated Statements of Cash Flows

	Three Months Ended March 31,	
Cash flows from operating activities:	2009	2008
Net loss	\$ (945,976)	\$ (463,684)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,636	8,037
Stock-based compensation expense	429,587	158,579
Changes in operating assets and liabilities:		
Accounts receivable	6,885,947	17,231
Prepaid expenses and other current assets	(1,115)	16,600
Accounts payable and accrued expenses	104,265	224,003
Deferred revenue	(136,281)	(136,281)
Net provided by (used in) operating activities	6,344,063	(175,515)
Cash flows from investing activities:		
Maturities of marketable securities	900,000	-
Purchases of marketable securities	-	(750,000)
Net cash provided by (used in) investing activities	900,000	(750,000)
Cash flows from financing activities:		
Proceeds from issuance of capital stock	-	2,093,650
Proceeds from stock option exercises	3,000	198,925
Proceeds from pay-off of notes receivable from former CEO and Chairman	-	1,116,558
Net cash provided by financing activities	3,000	3,409,133
Increase (decrease) in cash and cash equivalents	7,247,063	2,483,618
Cash and cash equivalents at beginning of year	3,494,150	68,564
Cash and cash equivalents at end of year	\$ 10,741,213	\$ 2,552,182
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	\$ -	\$ 451
Taxes	\$ -	\$ -

Supplemental disclosures of non-cash transactions:

Under our agreement with Auxilium certain patent costs paid by Auxilium on behalf of the Company are creditable against future royalties. As of March 31, 2009 we accrued \$218,135 related to this issue of which \$7,214 was amortized in the 2009 period and zero in the 2008 comparable period.

See accompanying notes to consolidated financial statements

**BIOSPECIFICS TECHNOLOGIES CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2009
(Unaudited)**

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. (Auxilium) for injectable collagenase (which Auxilium has named XIAFLEXTM (formerly known as AA4500)) for clinical indications in Dupuytren s disease, Peyronie s disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas.

The most advanced indications are for the treatment of Dupuytren s disease, Peyronie s disease and frozen shoulder. On June 3, 2004, we entered into a development and license agreement with Auxilium, as amended on May 10, 2005 and December 15, 2005, respectively (the Prior Auxilium Agreement), pursuant to which we granted to Auxilium an exclusive worldwide license to develop products containing our injectable collagenase for the treatment of Dupuytren s disease, Peyronie's disease and frozen shoulder, as well as an exclusive option to develop and license the technology for use in additional indications other than dermal formulations labeled for topical administration.

On December 11, 2008, the parties amended and restated the development and license agreement (the Auxilium Agreement), which became effective on December 17, 2008 upon the execution and effectiveness of the Development, Commercialization and Supply Agreement, dated December 17, 2008 (the Pfizer Agreement) between Auxilium International Holdings, Inc., a wholly owned subsidiary of Auxilium, and Pfizer, Inc. (Pfizer), pursuant to which Pfizer will market XIAFLEX for the treatment of Dupuytren s disease and Peyronie s disease in Europe and various other territories. The Auxilium Agreement amends and restates in its entirety the Prior Auxilium Agreement.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements are unaudited, but include all adjustments (consisting only of normal, recurring adjustments) which we consider necessary for a fair presentation of our financial position at such dates and the operating results and cash flows for those periods. Although we believe that the disclosures in our financial statements are adequate to make the information presented not misleading, certain information normally included in financial statements prepared in accordance with accounting principles generally accepted (GAAP) in the United States (the U.S.) has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC) for quarterly reporting.

The information included in this Report should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2008 filed with the SEC on March 31, 2009.

Principles of Consolidation

The unaudited consolidated financial statements include the accounts of the Company and its subsidiary, ABC-NY.

Management Estimates

The preparation of unaudited consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires the use of management's estimates and assumptions that affect the amounts reported in the unaudited consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities are stated at market value. Cash equivalents include only securities having a maturity of three months or less at the time of purchase. The Company limits its credit risk associated with cash, cash equivalents and marketable securities by placing its investments with banks it believes are highly creditworthy.

Fair Value Measurements

SFAS 157 requires expanded disclosures about fair value measurements. SFAS 157 applies to other accounting pronouncements that require or permit fair value measurements, but does not require any new fair value measurements. We adopted the provisions of SFAS 157 relating to assets and liabilities recognized or disclosed in the financial statements at fair value on a recurring basis on January 1, 2008. The adoption of these provisions did not have a material effect on our consolidated financial statements.

SFAS 157 clarifies that fair value is an exit price, representing the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants based on the highest and best use of the asset or liability. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. SFAS 157 requires us to use valuation techniques to measure fair value that maximize the use of observable inputs and minimize the use of unobservable inputs. These inputs are prioritized as follows:

- Level 1: Observable inputs such as quoted prices for identical assets or liabilities in active markets
- Level 2: Other inputs that are observable directly or indirectly, such as quoted prices for similar assets or liabilities or market-corroborated inputs
- Level 3: Unobservable inputs for which there is little or no market data and which require us to develop our own assumptions about how market participants would price the assets or liabilities

The following table sets forth the fair value of our financial assets that were measured on a recurring basis as of March 31, 2009:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash and cash equivalents	10,741,213	-	-
Auction rate securities	-	-	-

Auction Rate Securities

As of March 31, 2009 we held no taxable auction rate securities, or ARS. As of December 31, 2008, we held \$0.9 million of ARS, which were classified as short-term investments. In October 2008, the Company received notice from UBS of a solution that provided us the option to continue to hold our ARS or sell the securities back to UBS at par value plus any accrued interest. On October 24, 2008 we accepted UBS's offer and instructed UBS that we would notify them if and when we want to exercise our rights and sell our ARS to UBS during the period January 2, 2009 through January 4, 2011. In early January 2009, we exercised our rights and instructed UBS to sell all our remaining ARS. On January 5, 2009, we received the remaining principal balance of our investment in auction rate securities of \$0.9 million.

Revenue Recognition

We recognize revenues resulting from product sales, royalties, from licensing and use of our technology, and from other services we sometimes perform in connection with the licensed technology under the guidance of Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition.

If we determine that separate elements exist in a revenue arrangement under Emerging Issues Task Force Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21), we recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete, when payment is reasonably assured and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement.

Revenues, and their respective treatment for financial reporting purposes, are as follows:

Product Sales

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed or determinable and collectability is reasonably assured. No right of return exists for our products except in the case of damaged goods. To date, we have not experienced any significant returns of our products.

Net sales include the sales of the API Enzyme that are recognized at the time the product is shipped to customers for laboratory use.

Royalty/Earn-Out Revenue

We recognize royalties under the earn-out provision of the Asset Purchase Agreement with DFB. We have the right to receive earn out payments in the future based on sales of certain products. Generally, under this agreement we would receive royalty payments and a report within ninety (90) days from the end of each calendar year after the licensee has sold the royalty-bearing product. Our right to receive earn out payments under our agreement with DFB will expire in 2013. We recognize royalty revenues when we can reliably estimate such amounts and collectability is reasonably assured.

License Fees

We include revenue recognized from upfront licensing and milestone payments in License Fees in our unaudited consolidated statements of operations in this Report.

License and Sublicense Fees

We include revenue recognized from upfront licensing, sublicensing and milestone payments in License Fees in our consolidated statements of operations in this Report.

Upfront License and Sublicensing Fees

We generally recognize revenue from upfront licensing and sublicensing fees when the agreement is signed, we have completed the earnings process and we have no ongoing performance obligation with respect to the arrangement. Nonrefundable upfront technology license for product candidates for which we are providing continuing services related to product development are deferred and recognized as revenue over the development period.

Milestones

Milestones, in the form of additional license fees, typically represent nonrefundable payments to be received in conjunction with the achievement of a specific event identified in the contract, such as completion of specified development activities and/or regulatory submissions and/or approvals. We believe that a milestone represents the culmination of a distinct earnings process when it is not associated with ongoing research, development or other performance on our part. We recognize such milestones as revenue when they become due and collection is reasonably assured. When a milestone does not represent the culmination of a distinct earnings process, we recognize revenue in a manner similar to that of an upfront license fee.

The timing and amount of revenue that we recognize from licenses of technology, either from upfront fees or milestones where we are providing continuing services related to product development, is primarily dependent upon our estimates of the development period. We define the development period as the point from which research activities commence up to regulatory approval of either our, or our partners' submission assuming no further research is necessary. As product candidates move through the development process, it is necessary to revise these estimates to consider changes to the product development cycle, such as changes in the clinical development plan, regulatory requirements, or various other factors, many of which may be outside of our control. Should the FDA or other regulatory agencies require additional data or information, we would adjust our development period estimates accordingly. The impact on revenue of changes in our estimates and the timing thereof is recognized prospectively over the remaining estimated product development period.

Consulting and Technical Assistance Services

We recognize revenues from a consulting and technical assistance contracts primarily as a result of our agreements with DFB and Auxilium. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations to DFB generally expire during March 2011.

Reimbursable Third Party Development Costs

We accrue expenses to research and development for estimated third party development costs and capitalize certain patent costs that are reimbursable under our agreement with Auxilium. Estimates are based on contractual terms, historical development costs, reviewing third party data and expectations regarding future development for certain products. Further, we monitor the activities and clinical trials of our development partners.

If conditions or other circumstances change, we may take actions to revise our reimbursable third party development cost estimates. These revisions could result in an incremental increase in research and development costs. For example, the Auxilium Agreement provides that Auxilium and BioSpecifics will share equally in third party costs for the development of the lyophilization of the injection formulation and certain patent fees.

On May 4, 2009, we received an updated invoice from Auxilium for approximately \$2.8 million which represents an increase of approximately \$45,000 in the total amount due that Auxilium believes is owed by us through March 31, 2009 under this provision. The increase in the first quarter was primarily due to patent and related legal fees. Based upon the updated invoice, we recorded an additional liability of \$45,000 for reimbursable third party patent expenditures.

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Based on our preliminary review, we believe that only a portion of the amount charged actually relates to the development of the lyophilization of the injection formulation as well as for patent and related legal fees and, therefore, reserve all rights related to this matter, including but not limited to our right to contest the amount charged by Auxilium.

Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

Research and Development Expenses

Our research and development (R&D) costs are expensed as incurred. R&D includes, but is not limited to, internal costs, such as salaries and benefits, costs of materials, lab expense, facility costs and overhead. R&D also consists of third-party costs, such as medical professional fees, contract manufacturing costs for material used in clinical trials, consulting fees and costs associated with clinical study R&D arrangements. We fund R&D at medical research institutions under agreements that are generally cancelable. All of these costs are charged to R&D as incurred, which may be measured by percentage of completion, contract milestones, patient enrollment, or the passage of time.

Clinical Trial Expenses

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with various clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the ongoing development of potential drugs. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, the completion of portions of the clinical trial, or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual cost of services received and efforts expended. As such, expenses related to each patient enrolled in a clinical trial are recognized ratably beginning upon entry into the trial and over the course of the patient's continued participation in the trial. In the event of early termination of a clinical trial, we accrue an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial. Our estimates and assumptions could differ significantly from the amounts that may actually be incurred.

Stock-Based Compensation

Under the provisions of Statement of Financial Accounting Standards (SFAS) No. 123(R), we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures) and the expected volatility. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. No stock options were granted during the first quarter of 2009.

Further, SFAS 123(R) requires that employee stock-based compensation costs to be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. The allocation of employee stock-based compensation costs to each operating expense line are estimated based on specific employee headcount information at each grant date and estimated stock option forfeiture rates and revised, if necessary, in future periods if actual employee headcount information or forfeitures differ materially from those estimates. As a result, the amount of employee stock-based compensation costs we recognize in each operating expense category in future periods may differ significantly from what we have recorded in the current period.

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Stock-based compensation expense recognized under SFAS 123(R) was as follows:

Three Months Ended			
March 31,			
	2009		2008
Research and development	\$ 13,916	\$	4,979
General and administrative	415,671		153,600
Total stock-based compensation expense	\$ 429,587	\$	158,579

Stock Option Activity

A summary of our stock option and warrant activity during the nine months ended March 31, 2009 is presented below:

Option	Total Number of Shares	Weighted-Average Exercise Price
Outstanding as of December 31, 2008	1,477,100	\$ 4.82
Granted	-	-
Forfeited	-	-
Exercised	(3,000)	\$ 1.00
Expired	-	-
Outstanding as of March 31, 2009	1,474,100	\$ 4.83
Exercisable as of March 31, 2009	1,262,850	\$ 3.61

The Company approved an award of options to purchase 50,000 shares of the Company common stock to the Company's President, in 2008. The vesting of this grant is contingent upon obtaining certain corporate milestones. As of March 31, 2009, the contingent grant milestone was not achieved and no employee stock-based compensation cost was recognized. The total number of outstanding options as of March 31, 2009 was 1,474,100.

No options were granted during the three months ended March 31, 2009. The weighted-average grant-date fair value for options granted during the three months ended March 31, 2008 was \$13.24 per share. During the three months ended March 31, 2009 and 2008, zero and \$198,925 were received from stock options exercised by employees, respectively.

The aggregate intrinsic value of options outstanding and exercisable as of March 31, 2009 was approximately \$21.0 million. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our common stock of \$20.5 on March 31, 2009, which would have been received by the option holders had all option holders exercised their options as of that date. Total unrecognized compensation cost related to non-vested stock options outstanding as of March 31, 2009 was approximately \$0.9 million which we expect to recognize over a weighted-average period of 1.8 years.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation. Machinery and equipment, furniture and fixtures, and autos are depreciated on the straight-line basis over their estimated useful lives of 5 to 10 years. Leasehold improvements are being amortized over the lesser of their estimated useful lives or the life of the lease, which is approximately 8 to 10 years.

Recent Accounting Pronouncements

In April 2008, the FASB issued FSP FAS 142-3, *Determination of Useful Life of Intangible Assets* (FSP FAS 142-3). FSP FAS 142-3 amends the factors that should be considered in developing the renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FAS 142, *Goodwill and Other Intangible Assets*. FSP FAS 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008. Earlier adoption is not permitted. The adoption of this FSP did not have a material effect on our consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. This Statement identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP in the United States (the GAAP hierarchy). This Statement will not have any impact on the Company's consolidated financial statements.

3. NET LOSS PER SHARE

In accordance with SFAS No. 128, *Earnings Per Share* (SFAS 128), basic net loss per share amount is computed using the weighted-average number of shares of common stock outstanding during the periods presented, while diluted net loss per share is computed using the sum of the weighted-average number of common and common equivalent shares outstanding. Common equivalent shares used in the computation of diluted earnings per share result from the assumed exercise of stock options, and warrants using the converted method. For the three ended March 31, 2009 and 2008, we incurred a net loss from continuing operations and, as such, we did not include the effect of outstanding stock options in the diluted net loss per share calculations, as their effect would have been anti-dilutive.

The following table summarizes the number of common equivalent shares excluded from the calculation of diluted net loss per share from continuing operations reported in the consolidated statement of operations as their effect would have been anti-dilutive:

Three Months Ended		
March 31,		
	2009	2008
Stock options	1,006,547	938,989
Total	1,006,547	938,989

4. TOTAL COMPREHENSIVE INCOME (LOSS)

Comprehensive loss is comprised of net loss and other comprehensive income. Specifically, we include in other comprehensive income the changes in unrealized gains and losses on our holdings of available-for-sale securities, which are excluded from our net loss. The following table presents the calculation of our comprehensive income (loss):

Three Months Ended		
March 31,		
	2009	2008
Net loss	\$ (945,976)	\$ (463,683)
Other comprehensive income:		
Change in unrealized loss on marketable securities	-	(212,388)
Total Comprehensive loss	\$ (945,976)	\$ (676,071)

5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	March 31, 2009	December 31, 2008
Trade accounts payable and accrued expenses	\$ 534,195	\$ 409,433
Accrued legal and other professional fees	50,110	117,837
Accrued payroll and related costs	146,261	115,195
Total	\$ 730,566	\$ 642,465

6. PATENT COSTS

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 5 to 13 years, and review for impairment on a quarterly basis and when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

As of March 31, 2009, the Company capitalized certain patent costs, paid by Auxilium on behalf of the Company. These costs are reimbursable to Auxilium under our agreement and are creditable against future royalty revenues. Patent costs consisted of:

	March 31, 2009	December 31, 2008
Patents	\$ 186,065	\$ 164,424

The amortization expense for patents was \$7,214, for the three months ended March 31, 2009 and zero for the 2008 period. The estimated aggregate amortization expense for each of the next five years is approximately as follows:

2010	\$ 30,000
2011	30,000
2012	28,000
2013	26,000
2014	26,000

7. INCOME TAXES

The Company uses the liability method of accounting for income taxes, as set forth in Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes. Under this method, deferred income taxes, when required, are provided on the basis of the difference between the financial reporting and income tax bases of assets and liabilities at the statutory rates enacted for future periods.

8. RELATED PARTY TRANSACTIONS

On February 1, 2008, the Estate of Edwin H. Wegman (the Estate) sold an aggregate of 344,114 shares of the Company's common stock, par value \$0.001, at a purchase price of \$12.00 per share to certain private investors. The Estate used certain of the proceeds of the transaction to repay the loan owed to the Company by Edwin H. Wegman, our former Chairman and CEO. The total loan repayment amount was \$1,116,558, which represents the principal amount of \$625,774 owed to the Company and accrued interest through January 31, 2008 of \$490,784.

9. SUBSEQUENT EVENTS

On April 28, 2009, Auxilium announced that the U.S. Food and Drug Administration (the FDA) has accepted for filing and granted priority review status to its Biologics License Application for XIAFLEX. Under the Prescription Drug User Fee Act (PDUFA), the FDA is expected to take action on the application by August 28, 2009.

Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with the consolidated financial statements and related notes thereto included elsewhere in this Report.

Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. (Auxilium) for injectable collagenase (which Auxilium has named XIAFLEX (formerly known as AA4500)) for clinical indications in Dupuytren's disease, Peyronie's disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas.

The most advanced indications are for the treatment of Dupuytren's disease, Peyronie's disease and frozen shoulder. On June 3, 2004, we entered into a development and license agreement with Auxilium, as amended on May 10, 2005 and December 15, 2005, respectively (the Prior Auxilium Agreement), pursuant to which we granted to Auxilium an exclusive worldwide license to develop products containing our injectable collagenase for the treatment of Dupuytren's disease, Peyronie's disease and frozen shoulder, as well as an exclusive option to develop and license the technology for use in additional indications other than dermal formulations labeled for topical administration.

On December 11, 2008, the parties amended and restated the development and license agreement (the Auxilium Agreement), which became effective on December 17, 2008 upon the execution and effectiveness of the Development, Commercialization and Supply Agreement, dated December 17, 2008 (the Pfizer Agreement) between Auxilium International Holdings, Inc., a wholly owned subsidiary of Auxilium, and Pfizer, Inc. (Pfizer), pursuant to which Pfizer will market XIAFLEX for the treatment of Dupuytren's disease and Peyronie's disease in Europe and various other territories. The Auxilium Agreement amends and restates in its entirety the Prior Auxilium Agreement.

Outlook

We foresee the potential to generate income from limited sources in the next several years. Under the terms of our agreement with DFB, we are scheduled to receive certain contractual anniversary payments and, if DFB exceeds a certain sales target, we would be entitled to an earn out on sales. Under the terms of our agreement with Auxilium, we may receive milestone payments upon their achieving certain regulatory progress and if Auxilium elects to pursue additional indications for injectable collagenase (Additional Indications) as well as 8.5% of all sublicense income that Auxilium may receive from Pfizer under the Pfizer Agreement.

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Based on our current business model, we expect to have adequate cash reserves until at least the first half of 2012 depending on the amount actually owed to Auxilium, as discussed in Item 1A, *Risk Factors*, included in our Annual Report on Form 10-K for the year ended December 31, 2008. As a significant portion of our revenues is tied directly to the success of Auxilium in commercializing XIAFLEX, we cannot reasonably forecast our financial condition beyond this time.

Significant Risks

In recent history we have had operating losses and may not achieve sustained profitability. As of March 31, 2009 we had an accumulated deficit from continuing operations of \$7,374,423.

We are dependent to a significant extent on third parties, and our principal licensee, Auxilium, may not be able to successfully develop products, obtain required regulatory approvals, manufacture products at an acceptable cost, in a timely manner and with appropriate quality, or successfully market products or maintain desired margins for products sold, and as a result we may not achieve sustained profitable operations.

As of March 31, 2009 we held no taxable auction rate securities, or ARS. As of December 31, 2008, we held \$0.9 million of ARS, which were classified as short-term investments. In October 2008, the Company received notice from UBS of a solution that provided us the option to continue to hold our ARS or sell the securities back to UBS at par value plus any accrued interest. On October 24, 2008 we accepted UBS's offer and instructed UBS that we would notify them if and when we want to exercise our rights and sell our ARS to UBS during the period January 2, 2009 through January 4, 2011. In early January 2009, we exercised our rights and instructed UBS to sell all our remaining ARS. On January 6, 2009, we received the remaining principal balance of our investment in auction rate securities of \$0.9 million.

Critical Accounting Policies, Estimates and Assumptions

The preparation of unaudited consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are based on historical experience and on various other assumptions that we believe are reasonable under the circumstances. The information at March 31, 2009 and for the three months ended March 31, 2009 and 2008 is unaudited but includes all adjustments (consisting only of normal recurring adjustments) which, in the opinion of management, are necessary to state fairly the financial information set forth herein. The December 31, 2008 balance sheet amounts and disclosures included herein have been derived from the Company's December 31, 2008 audited consolidated financial statements. The interim results are not necessarily indicative of results to be expected for the full fiscal year. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2008 included in the Company's Form 10-K filed with the SEC on March 31, 2009 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2008, June 30, 2008 and September 30, 2008. While our significant accounting policies are described in more detail in the notes to our unaudited consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our unaudited consolidated financial statements.

Revenue Recognition. We recognize revenues from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and payment is reasonably assured. We currently recognize revenues resulting from the licensing, sublicensing and use of our technology and from services we sometimes perform in connection with the licensed technology.

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We enter into product development licenses, and collaboration agreements that may contain multiple elements, such as upfront license and sublicense fees, and milestones related to the achievement of particular stages in product development and royalties. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple-element arrangement should be treated as separate units of accounting for revenue recognition purposes, and if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element.

We recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our licensee confirms that we have met the requirements under the terms of the agreement, and when payment is reasonably assured. Changes in the allocation of the contract value between various deliverable elements might impact the timing of revenue recognition, but in any event, would not change the total revenue recognized on the contract. For example, nonrefundable upfront product license fees, for product candidates where we are providing continuing services related to product development, are deferred and recognized as revenue over the development period.

Milestones, in the form of additional license fees, typically represent nonrefundable payments to be received in conjunction with the achievement of a specific event identified in the contract, such as completion of specified clinical development activities and/or regulatory submissions and/or approvals. We believe that a milestone represents the culmination of a distinct earnings process when it is not associated with ongoing research, development or other performance on our part. We recognize such milestones as revenue when they become due and payment is reasonably assured. When a milestone does not represent the culmination of a distinct earnings process, we recognize revenue in a manner similar to that of an upfront product license fee.

Royalty/Earn-Out Revenue. We recognize royalties under the earn-out provision of the Asset Purchase Agreement with DFB BioTech, Inc. (DFB). We have the right to receive earn out payments in the future based on sales of certain products. Generally, under this agreement we would receive royalty payments and a report within ninety (90) days from the end of each calendar year after the licensee has sold the royalty-bearing product. Our right to receive earn out payments under our agreement with DFB will expire in 2013. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured.

Consulting and Technical Assistance Services. We recognize revenues from a consulting and technical assistance contracts primarily as a result of our agreements with DFB and Auxilium. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations to DFB generally expire during March 2011.

Inventory and Warranty Provisions. Inventories are stated at the lower of cost or realizable market value. In assessing the ultimate realization of inventories, we are required to make judgments as to future demand requirements and compare that with the current inventory levels. In March 2006 we sold our topical collagenase business to DFB, including certain product inventory. As of a result of this sale our product inventory as of March 31, 2009 and December 31, 2008 was zero.

Reimbursable Third Party Development Costs. We accrue expenses to research and development and capitalize certain patent costs for estimated third party development costs that are reimbursable under our agreement with Auxilium. Estimates are based on contractual terms, historical development costs, reviewing third party data and expectations regarding future development for certain products. Further, we monitor the activities and clinical trials of our development partners.

If conditions or other circumstances change, we may take actions to revise our reimbursable third party development cost estimates. These revisions could result in an incremental increase in research and development costs. For example, the Auxilium Agreement provides that Auxilium and BioSpecifics will share equally in third party costs for the development of the lyophilization of the injection formulation and patent expenses.

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On May 4, 2009, we received an updated invoice from Auxilium for approximately \$2.8 million which represents an increase of approximately \$45,000 in the total amount due that Auxilium believes is owed by us through March 31, 2009 under this provision. The increase in the first quarter was primarily due to patent and related legal fees. Based upon the updated invoice, we recorded an additional liability of \$45,000 for reimbursable third party patent expenditures.

Based on our preliminary review, we believe that only a portion of the amounts invoiced actually relates to the development of the lyophilization of the injection formulation as well as for patent and related legal fees, and therefore, reserve all rights related to this matter, including but not limited to our right to contest the amount charged by Auxilium.

Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

Receivables and Deferred Revenue. Under our agreement with DFB, we agreed to provide certain technical assistance and transitional services in consideration of fees and costs totaling over \$1.4 million. At the closing, DFB paid to us a partial payment of \$400,000 in respect of the technical assistance to be provided by us. To date, we have received a total of \$1,200,000 in payments from DFB. The consulting obligations generally expire during March 2011. As of March 31, 2009 the remaining accounts receivable balance due was \$200,000 for future services and was offset by the associated deferred revenues to be recognized in future periods of \$200,000.

Royalty Buy-Down. In August 2008, we signed an agreement to significantly improve the deal terms related to our future royalty obligations for Peyronie's disease by buying down our future royalty obligations with a one-time cash payment. We modified our agreement to lower future royalties payable on net sales of injectable collagenase, XIAFLEX, for Peyronie's disease. In addition, we agreed to pay certain development milestones, if achieved.

As of March 31, 2009, we capitalized \$1,250,000 which will be amortized over approximately five years beginning on the date of the first commercial sale of XIAFLEX, for Peyronie's disease, which represents the period estimated to be benefited, using the straight-line method. In accordance with SFAS No. 142, *Goodwill and Other Intangibles*, the Company amortizes intangible assets with finite lives in a manner that reflects the pattern in which the economic benefits of the assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the assets are amortized using the straight-line method.

Stock Based Compensation. Under the provisions of SFAS 123(R), we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Expected volatility is based on the historical volatility of our common stock. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our historical experience of employee stock option exercises (including forfeitures) and the expected volatility. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, we are likely to change our valuation assumptions used to value employee stock-based awards granted in future periods.

Further, SFAS 123(R) requires that employee stock-based compensation costs to be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. The allocation of employee stock-based compensation costs to each operating expense line are estimated based on specific employee headcount information at each grant date and estimated stock option forfeiture rates and revised, if necessary, in future periods if actual employee headcount information or forfeitures differ materially from those estimates. As a result, the amount of employee stock-based compensation costs we recognize in each operating expense category in future periods may differ significantly from what we have recorded in the current period.

RESULTS OF OPERATIONS

THREE-MONTHS ENDED March 31, 2009 and 2008

Revenues

Product Revenues, net

Product revenues include the sales of the API Enzyme recognized at the time it is shipped to customers. We recognized a small amount of revenue from the sale of collagenase for laboratory use. For the three months ended March 31, 2009 and 2008 product revenues were \$7,191 and \$12,753, respectively. This decrease of \$5,562 or 44% was primarily related to the amount of material required to perform testing by our customers.

Royalties

We received all of our royalty revenues from DFB under the earn out payment provision of the Asset Purchase Agreement after certain net sales levels are achieved. Royalty revenues recognized under our agreement with DFB for the three months ended March 31, 2009 and 2008 were zero.

Licensing Revenues

For the three months ended March 31, 2009 and 2008, we recognized licensing revenue of \$266,281 in each period. Licensing revenues recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period.

Under current accounting guidance, nonrefundable upfront license fees for product candidates where we are providing continuing services related to product development, are deferred and recognized as revenue over the development period. The remaining balance will be recognized over the respective development periods or when we determine that we have no ongoing performance obligations.

Consulting Services

We recognize revenues from consulting and technical assistance contracts primarily as a result of the Asset Purchase Agreement and an Auxilium consulting agreement signed in October 2007 which terminated during the second quarter of 2008. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations under the Asset Purchase Agreement generally expire during March 2011. For the three months ended March 31, 2009 and 2008 consulting revenues were \$70,000 and \$122,185, respectively. This decrease of \$52,185 or 43% in was primarily due to the recognition in 2008 of revenues earned in connection with the October 2007 consulting agreement with Auxilium.

Costs and Expenses

Research and Development Activities

Research and development expenses were \$115,871 and \$94,271 respectively, for the three months ended March 31, 2009 and 2008. This increase of \$21,600 or 23% in research and development expenses was primarily due to certain employee costs which were reimbursable under our agreement with DFB which expired in October 2008 partially offset by decreases in external study development costs.

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General and Administrative Expenses

General and administrative expenses were \$1,166,971 and \$800,456 for the three months ended March 31, 2009 and 2008, respectively. The increase in general and administrative expenses of \$366,515 or 46% was primarily due to higher stock-based compensation expense and outside consulting expense partially offset by lower legal fees.

Other Income (expense), net

Other expense, net, was \$6,606 for the three months ended March 31, 2009 as compared to other income, net of \$29,824 for the 2008 period. Components of other income, net, consist of investment income, a reduction in interest expense and other, net. Investment income for the three months ended March 31, 2009 was \$2,857 as compared to \$30,275 in the comparable period of 2008. This decrease of \$27,418 or 91% was primarily due to lower interest rates and invested balances during the 2009 period. Interest expense for the three months ended March 31, 2009 was zero as compared to \$451 in the 2008 period. Other expense, net for the three months ended March 31, 2009 was \$9,463 as compared to zero in the 2008 period. The increase in other expense, net was primarily due to tax penalties in connection with our past delinquent federal tax returns.

Income Taxes

The expense for income taxes for the three months ended March 31, 2009 and 2008 was zero.

Liquidity and Capital Resources

To date, we have financed our operations primarily through product sales, debt instruments, licensing revenues, royalties under agreements with third parties and sales of our common stock. At March 31, 2009 and December 31, 2008, we had cash and cash equivalents in the aggregate of \$10,741,213 and \$3,494,150, respectively.

Continuing Operations

Net cash provided by operating activities for the three months ended March 31, 2009 was \$6,344,063 as compared to net cash used in operating activities in the 2008 period of \$175,515. In the 2009 period, as compared to the 2008 period, the changes in net cash provided by operating activities was primarily attributable to a the reduction in accounts receivable due to the receipt of a payment for a sublicense fee of \$ 6.4 million and non-cash stock compensation expense partially offset by increased expenses during the period 2009 period.

Net cash provided by investing activities for the three months ended March 31, 2009 was \$900,000 as compared to net cash used in investing activities in the 2008 period of \$750,000. The change in net cash provided by investing activities for the 2009 period reflect redemption of our investment in marketable securities compared to cash used in investing activities related to purchases of marketable securities in the 2008 period.

Net cash provided by financing activities for the three months ended March 31, 2009 was \$3,000 as compared to the 2008 period of \$3,409,133. The change in net cash provided by financing activities for the 2009 consisted of proceeds received from stock option exercises. Net cash provided by financing activities in the 2008 period consisted of proceeds from the sale of our common stock of \$2,093,650, repayment of an outstanding loan from our former Chairman and CEO of \$1,116,558 and proceeds received from stock option exercises of \$198,925.

Item 3: Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4T. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company, under the supervision and with the participation of Thomas L. Wegman, the Company's President, Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of its disclosure controls and procedures as of the end of the period covered by this Report. Based on that evaluation, management has concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to the Company's management to allow timely decisions regarding required disclosure. Because of the inherent limitations in all control systems, any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Furthermore, our controls and procedures can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control, and misstatements due to error or fraud may occur and not be detected on a timely basis.

Changes in Internal Controls

There were no changes in our internal controls over financial reporting during the three month period ended March 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

The Company sold shares of its common stock in the following transactions, in which its shares were offered and sold in reliance on Section 4(2) of the Securities Act of 1933 (the Act) as private placements of securities that are exempt from the registration requirements of the Act.

On January 14, 2008, the Company sold 200,000 shares of its common stock in a private placement offering to Apis Capital Advisors LLC on behalf of various funds advised by them at a purchase price of \$10.50 per share, for aggregate proceeds to the Company of \$2,100,000.

On May 30, 2008, the Company sold 100,000 shares of its common stock in a private placement offering to an investment fund at a purchase price of \$13.00 per share, for aggregate proceeds to the Company of \$1,300,000.

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On June 9, 2008, the Company sold 100,000 shares of its common stock in a private placement offering to certain private investors at a purchase price of \$15.00 per share, for aggregate proceeds to the Company of \$1,500,000.

On August 19, 2008, the Company sold 50,000 shares of its common stock in a private placement offering to an investment fund at a purchase price of \$22.50 per share, for aggregate proceeds to the Company of \$1,125,000.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None.

Item 6. Exhibits

- | | |
|------------|--|
| 3.1 | Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-KSB for the fiscal years ended December 31, 2005, 2004 and 2003). |
| 3.2 | Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-KSB for the fiscal years ended December 31, 2005, 2004 and 2003). |
| <u>31*</u> | <u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).*</u> |
| <u>32*</u> | <u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002.*</u> |

* filed herewith

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 thereunto duly authorized.

BIOSPECIFICS TECHNOLOGIES CORP.

(Registrant)

Date: May 12, 2009

/s/ Thomas L. Wegman

Thomas L. Wegman

President

(Principal Executive and Financial Officer)