

BIOSPECIFICS TECHNOLOGIES CORP  
Form 10-Q  
November 06, 2009

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**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 September 30, 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 ☒

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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:

Class of Stock

Outstanding November 2, 2009

Common Stock (\$.001 par value)

**6,299,818**

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**BIOSPECIFICS TECHNOLOGIES CORP.****TABLE OF CONTENTS**

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**Introductory Comments   Terminology**

Throughout this quarterly report on Form 10-Q (this Report ), the terms BioSpecifics, Company, we, our, and to BioSpecifics Technologies Corp. and its subsidiary, Advance Biofactures Corp. ( 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, estimates, potential, or continue or the negative thereof or other 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 as discussed in Item 1A, Risk Factors , included in our Annual Report on Form 10-K for the year ended December 31, 2008, 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.

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**PART I FINANCIAL INFORMATION****Item 1: Consolidated Financial Statements**

**BIOSPECIFICS TECHNOLOGIES CORP.**  
**Consolidated Balance Sheets**

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
	(unaudited)	(audited)
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 4,267,591	\$ 3,494,150
Short-term investments	5,022,854	900,000
Accounts receivable, net	882,369	6,912,001
Income tax receivable	600,247	40,780
Prepaid expenses and other current assets	95,762	67,709
<b>Total current assets</b>	<b>10,868,822</b>	<b>11,414,640</b>
Deferred royalty buy-down	1,250,000	1,250,000
Property, plant and equipment, net	1,031	2,297
Patent costs, net	217,864	164,424
<b>Total assets</b>	<b>12,337,717</b>	<b>12,831,361</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	607,273	642,465
Deferred revenue	1,026,282	1,271,792
Accrued liabilities of discontinued operations	78,138	78,138
<b>Total current liabilities</b>	<b>1,711,693</b>	<b>1,992,395</b>
Accrued third-party development expenses	2,892,655	2,758,595
Long-term deferred revenue	1,338,499	1,901,832
<b>Stockholders' equity:</b>		
Series A Preferred stock, \$.50 par value, 700,000 shares authorized; none outstanding	-	-
Common stock, \$.001 par value; 10,000,000 shares authorized; 6,238,318 shares and 6,140,068 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	6,238	6,140
Additional paid-in capital	14,926,942	13,294,803
Accumulated deficit	(7,844,353)	(6,428,447)
Treasury stock, 131,267 shares at cost at September 30, 2009 and December 31, 2008	(693,957)	(693,957)
<b>Total stockholders' equity</b>	<b>6,394,870</b>	<b>6,178,539</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 12,337,717</b>	<b>\$ 12,831,361</b>

**See accompanying notes to consolidated financial statements**

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**BIOSPECIFICS TECHNOLOGIES CORP.**  
**Consolidated Statements of Operations**  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
<b>Revenues:</b>				
Net sales	\$ 19,089	\$ 13,042	\$ 36,194	\$ 29,841
Royalties	481,197	-	856,597	2,028
Licensing fees	266,282	266,281	1,298,844	798,844
Consulting fees	70,000	70,000	210,000	354,185
<b>Total Revenues</b>	<b>836,568</b>	<b>349,323</b>	<b>2,401,635</b>	<b>1,184,898</b>
<b>Costs and expenses:</b>				
Research and development	112,920	71,737	352,983	260,440
General and administrative	1,176,885	866,574	3,484,341	2,840,346
<b>Total Cost and Expenses</b>	<b>1,289,805</b>	<b>938,311</b>	<b>3,837,324</b>	<b>3,100,786</b>
<b>Operating loss</b>	<b>(453,237)</b>	<b>(588,988)</b>	<b>(1,435,689)</b>	<b>(1,915,888)</b>
<b>Other income (expense):</b>				
Interest income	24,140	31,511	28,685	89,314
Interest expense	-	46,979	(39)	46,528
Other, net	600	104,203	(8,863)	108,730
	<b>24,740</b>	<b>182,693</b>	<b>19,783</b>	<b>244,572</b>
Loss before benefit for income tax	<b>(428,497)</b>	<b>(406,295)</b>	<b>(1,415,906)</b>	<b>(1,671,316)</b>
Income tax benefit	46,376	192,287	-	192,287
<b>Net loss</b>	<b>\$ (382,121)</b>	<b>\$ (214,008)</b>	<b>\$ (1,415,906)</b>	<b>\$ (1,479,029)</b>
<b>Basic and diluted net loss per share</b>				
	<b>\$ (0.06)</b>	<b>\$ (0.04)</b>	<b>\$ (0.23)</b>	<b>\$ (0.25)</b>
<b>Shares used in computation of basic and diluted net loss per share</b>				
	<b>6,075,758</b>	<b>5,976,937</b>	<b>6,034,301</b>	<b>5,803,497</b>

See accompanying notes to consolidated financial statements

**BioSpecifics Technologies Corp.**  
**Consolidated Statements of Cash Flows**  
(unaudited)

	<b>Nine Months Ended September 30,</b>	
<b>Cash flows from operating activities:</b>	<b>2009</b>	<b>2008</b>
Net loss	\$ (1,415,906)	\$ (1,479,029)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of fixed asset	-	(5,535)
Depreciation and amortization	25,737	23,487
Stock-based compensation expense	1,201,075	1,054,147
Deferred revenue	(808,844)	(808,844)
Changes in operating assets and liabilities:		
Accounts receivable	6,029,633	38,550
Prepaid expenses and other current assets	(28,053)	(220,366)
Income tax receivable	(361,228)	(11,531)
Accounts payable and accrued expenses	20,957	(652,868)
<b>Net cash provided by (used in) operating activities</b>	<b>4,663,371</b>	<b>(2,061,989)</b>
<b>Cash flows from investing activities:</b>		
Maturities of marketable securities	900,000	1,600,000
Purchases of marketable securities	(5,022,854)	(2,000,000)
Payment for royalty buydown	-	(1,250,000)
Proceeds from sale of fixed asset	-	8,000
<b>Net cash used in investing activities</b>	<b>(4,122,854)</b>	<b>(1,642,000)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of capital stock	-	6,007,047
Proceeds from stock option exercises	232,924	247,388
Proceeds from pay-off of notes receivable from former CEO and Chairman	-	1,116,558
<b>Net cash provided by financing activities</b>	<b>232,924</b>	<b>7,370,993</b>
Increase in cash and cash equivalents	773,441	3,667,004
Cash and cash equivalents at beginning of year	3,494,150	68,564
<b>Cash and cash equivalents at end of year</b>	<b>\$ 4,267,591</b>	<b>\$ 3,735,568</b>

**Supplemental disclosures of cash flow information:**

Cash paid during the year for:

Interest	\$ -	\$ 33,880
Taxes	\$ 361,228	\$ 225,824

**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 September 30, 2009 we accrued \$267,192 related to this issue of which \$24,472 was amortized in the 2009 period and zero in the 2008 comparable period.
- The Company recognized \$198,238 of windfall tax benefits associated with the exercise of non-qualified stock options directly to additional paid in capital and tax refunds receivable for the nine months ended September 30,



2009.

**See accompanying notes to consolidated financial statements**

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

**September 30, 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 XIAFLEX<sup>™</sup> (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, in its entirety, the Prior Auxilium Agreement (such restated 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.

On April 28, 2009, Auxilium announced that the United States Food and Drug Administration (the FDA ) has accepted for filing and granted priority review status to its Biologics License Application ( BLA ) for XIAFLEX. On September 16, 2009, the Arthritis Advisory Committee, appointed by the Division of Anesthesia, Analgesia and Rheumatology Products of the FDA, recommended by a unanimous vote of 12 to 0 that XIAFLEX be granted marketing approval by the FDA for the treatment of Dupuytren s disease. The Arthritis Advisory Committee s recommendation, although not binding, will be considered by the FDA in its review of the BLA submitted for XIAFLEX by the Company s partner, Auxilium. The FDA has not updated the Prescription Drug User Fee Act date of August 28, 2009.

**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 generally accepted accounting principles ( 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 Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2009 and June 30, 2009 filed with the SEC on May 12, 2009 and August 13, 2009 and 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, Advanced Biofactures Corp. ( ABC-NY ).

### **Management Estimates**

The preparation of unaudited consolidated financial statements in conformity with U.S. GAAP 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 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.

### **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**

Accounting Standards Codification 820, *Fair Value Measurements and Disclosures* ( ASC 820 ), requires expanded disclosures about fair value measurements. We adopted these provisions 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.

ASC 820 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. ASC 820 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 September 30, 2009:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash and cash equivalents	\$ 4,267,591	-	-
Certificates of Deposit	4,523,102	-	-
U.S Treasuries	499,752	-	-

**Auction Rate Securities**

As of September 30, 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. 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 Accounting Standards Codification 605, *Revenue Recognition* ( ASC 605 ).

If we determine that separate elements exist in a revenue arrangement under ASC 605, 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 active pharmaceutical ingredient for topical collagenase (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 (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 the Asset Purchase Agreement with DFB, 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. Currently, we receive quarterly royalty reports. Our right to receive earn out payments under our Asset Purchase Agreement with DFB will expire in 2013. We recognize royalty revenues when we can reliably estimate such amounts and collectability is reasonably assured.

***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 licenses 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 a 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 and are creditable against future royalty revenues. Estimates are based on contractual terms, historical development costs, review of 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 and expenses.

On October 13, 2009, we received an updated invoice from Auxilium for approximately \$50,000 increasing the total amount due that Auxilium believes is owed by us to approximately \$2.9 million through September 30, 2009. The increase in the third quarter was primarily due to patent and related legal fees. Based upon the updated invoice, we recorded an additional liability of \$50,000 for reimbursable third party patent expenditures.



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.

### **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 expenses, 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 may 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 Accounting Standards Codification 718, *Compensation - Stock Compensation* ( ASC 718 ), 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 an 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. When there is uncertainty in the factors used to determine the expected term of an award, we use the simplified method in accordance with SEC Staff Accounting Bulletin 107. 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. The weighted-average assumptions used were as follows:



	<b>Nine Months Ended September 30, 2009</b>
<b>Stock Option Plans</b>	
Expected life, in years	5.0
Risk free interest rate	2.47 %
Volatility	53 %
Dividend yield	

ASC 718 requires that employee stock-based compensation costs 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.

Stock-based compensation expense recognized was as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b><u>2009</u></b>	<b><u>2008</u></b>	<b><u>2009</u></b>	<b><u>2008</u></b>
Research and development	\$ 33,305	\$ 20,468	\$ 76,948	\$ 30,426
General and administrative	284,879	295,888	1,124,126	1,023,721
<b>Total stock-based compensation expense</b>	<b>\$ 318,184</b>	<b>\$ 316,356</b>	<b>\$ 1,201,074</b>	<b>\$ 1,054,147</b>

*Stock Option Activity*

A summary of our stock option activity during the nine months ended September 30, 2009 is presented below:

<b>Options</b>	<b>Total Number of Shares</b>	<b>Weighted-Average Exercise Price</b>
Outstanding as of December 31, 2008	1,477,100	\$ 4.82
Granted	115,000	23.42
Forfeited	-	-
Exercised	(98,250)	\$ 2.37
Expired	-	-
<b>Outstanding as of September 30, 2009</b>	<b>1,493,850</b>	<b>\$ 5.71</b>
<b>Exercisable as of September 30, 2009</b>	<b>1,235,100</b>	<b>\$ 4.42</b>

During the third quarter of 2009, the Company granted 60,000 stock options to its directors with a one year vesting period at an average exercise price of \$27.52. The total number of outstanding options as of September 30, 2009 was 1,493,850.

The weighted-average grant-date fair value for options granted during the nine months ended September 30, 2009 and 2008 was \$23.42 and \$16.00 per share respectively. During the nine months ended September 30, 2009 and 2008, \$232,924 and \$247,388 were received from stock options exercised by option holders, respectively.



The aggregate intrinsic value of options outstanding and exercisable as of September 30, 2009 was approximately \$39.5 million. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our common stock of \$32.01 on September 30, 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 September 30, 2009 was approximately \$1.5 million which we expect to recognize over a weighted-average period of 1.3 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 remaining life of the lease, which is less than 1 year.

### **Income Taxes**

Deferred tax assets and liabilities are recognized based on the expected future tax consequences, using current tax rates, of temporary differences between the financial statement carrying amounts and the income tax basis of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We use the liability method of accounting for income taxes, as set forth in Accounting Standards Codification 740-10-25-2. 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. In accordance with Codification section 740-10-45-25, interest and penalties paid for an underpayment of income taxes are included in Other Income and Expense under interest expense and other income (expense), respectively.

When the non-qualified stock options are exercised, the company compares the allowable tax deduction to the related compensation expense recorded for financial statement purposes. If the tax deduction exceeds the compensation expense, the tax benefit associated with any excess deduction is considered an excess tax benefit, or windfall. The Company follows the U.S. tax law to determine the sequence of tax benefits being utilized for book purposes. Under U.S. tax law, the current-year stock compensation deduction (which would include the windfall) would be used to offset taxable income before the net operating loss ( NOL ) carryforwards because all current-year deductions take priority over NOL carryforwards. Thus, for current-year stock option deductions, this would result in a credit to Additional Paid in Capital ( APIC ) being recorded in the financial statements in the year in which the windfall reduces taxable income.

### **Recent Accounting Pronouncements**

In June 2009, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 168, *The FASB Accounting Standard Codification and the Hierarchy of the Generally Accepted Accounting Principles* a replacement of SFAS No. 162 ( SFAS 168 ), to become the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company's adoption of SFAS 168 did not have a material impact on our consolidated financial statements.

**3. NET LOSS PER SHARE**

In accordance with Accounting Standard Codification 260, *Earnings Per Share* ( ASC 260 ), 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 using the converted method. For the three and nine months ended September 30, 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:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
<b>Stock options</b>	1,025,466	1,355,912	983,828	1,270,527

**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):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Net loss	\$ (382,121)	\$ (214,008)	\$ (1,415,906)	\$ (1,479,029)
Other comprehensive gain:				
Change in unrealized gain on marketable securities	-	354,572	-	-
<b>Total</b>	<b>\$ (382,121)</b>	<b>\$ 140,564</b>	<b>\$ (1,415,906)</b>	<b>\$ (1,479,029)</b>

**Comprehensive Gain (loss)**

**5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consisted of the following:

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
Trade accounts payable and accrued expenses	\$ 433,363	\$ 409,433
Accrued legal and other professional fees	54,785	117,837
Accrued payroll and related costs	119,125	115,195
<b>Total</b>	<b>\$ 607,273</b>	<b>\$ 642,465</b>

**6. PATENT COSTS**



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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 September 30, 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. Net patent costs consisted of:

	September 30, 2009	December 31, 2008
Patents	\$ 267,192	\$ 189,280
Accumulated Amortization	(49,328)	( 24,856)
	\$ 217,864	\$ 164,424

The amortization expense for patents was \$24,472, for the nine months ended September 30, 2009 and zero for the 2008 period. The estimated aggregate amortization expense for each of the next five years is approximately as follows:

2010	\$37,000
2011	37,000
2012	34,000
2013	32,000
2014	27,000

## 7. INCOME TAXES

The reconciliation of statutory to effective tax rate is as follows:

Tax at statutory rate	0%
Deferred revenues	(28)%
Other	(2)%
Windfall- exercise of options	24%
Non-qualified options	30%
Net operating loss carry-forward	31%
Increase in allowance	(42)%

Effective tax benefit rate 13%

As of September 30, 2009 and December 31, 2008, the Company's deferred tax assets were as follows

	9/30/2009	12/31/2008
Tax Credit carryforward	1,039,390	1,039,390
Deferred revenues	837,838	1,231,287
Other	13,293	37,736
Non-qualified incentive options exercised	143,445	-
Options (Black-Scholes comp. expense)	1,239,086	815,686
Net operating loss carry-forward	560,994	128,775
Net deferred tax assets before valuation allowance	3,834,046	3,252,874
Valuation allowance	(3,834,046)	(3,252,874)
	-0-	-0-



We prepared and filed our tax returns for the years ended December 31, 2003 to 2007, on September 15, 2008. In the tax return for 2006, we utilized \$686,097 of our orphan tax credit and reduced our income tax payable to \$220,366. We had already estimated and recorded our Federal tax at \$195,002. We simultaneously filed a form 1139, Corporation Application for a Tentative Refund, to carryback a part of our 2007 net operating loss and recognized \$1,108,729 related tax asset and requested a refund of \$220,366.

As a result of the delinquent filing of our Federal and State tax returns, tax years 2003 through 2008 remain open to examination by taxing authorities.

#### *2008 Interest and Penalty*

After finalizing our delinquent prior year tax filings, for 2003 to 2007 in 2008, our estimated federal and state tax penalties and interest were reduced by \$103,203 and \$77,250, respectively, for the year ended December 31, 2008. The decreases in penalties and interest were included in Other Income and Expense under interest expense and other income (expense), for the year ended December 31, 2008.

In 2008, the Company has estimated that it is likely that the full amount of its tax position will be realized and accordingly has recognized the full amount of the tax position in its financial statements.

### **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.

As previously reported, ABC-NY (together with the Company, the *Tenant*), and Wilbur St. Corp. (the *Landlord*), entered into a Commercial Lease Agreement on January 30, 1998 (the *Commercial Lease Agreement*), pursuant to which the Landlord leased to ABC-NY the premises located at 35 Wilbur Street, Lynbrook, NY 11563 (the *Premises*) for a term of 7 years or until January 31, 2005 and for an annual rental price of \$125,000.

As previously reported, the Tenant, without the approval of the board of directors of the Company, and the Landlord entered into an Extension and Modification Agreement on July 1, 2005 (the *Modification Agreement* and together with the Commercial Lease Agreement, the *Lease Agreement*), pursuant to which the term of the Commercial Lease Agreement was extended for an additional 5 years or until June 30, 2010 and the annual rental price for the Premises increased to \$150,000.

In connection with the settlement of the previously reported dispute between the Tenant and the Landlord regarding payments of amounts due under the Modification Agreement, the parties entered into a Lease Modification Agreement dated June 22, 2009 and effective as of June 24, 2009 (the *LMA*). Pursuant to the LMA, the Tenant ratified the Lease Agreement, including the Modification Agreement, subject to the terms thereof, and agreed to a \$15,000 reduction in the annual rental price of the Premises to \$135,000.



The foregoing description of the LMA does not purport to be complete and is qualified in its entirety by reference to the full text of the agreement, which was filed as Exhibit 10.1 to our Current Report on Form 8-K on June 29, 2009.

## 9. SUBSEQUENT EVENTS

None

### 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<sup>™</sup> (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, in its entirety, the Prior Auxilium Agreement (such restated 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.

On April 28, 2009, Auxilium announced that the United States Food and Drug Administration (the "FDA" ) has accepted for filing and granted priority review status to its Biologics License Application ( "BLA" ) for XIAFLEX. On September 16, 2009, the Arthritis Advisory Committee appointed by the Division of Anesthesia, Analgesia and Rheumatology Products of the FDA recommended by a unanimous vote of 12 to 0 that XIAFLEX be granted marketing approval by the FDA for the treatment of Dupuytren's disease. The Arthritis Advisory Committee's recommendation, although not binding, will be considered by the FDA in its review of the BLA submitted for XIAFLEX by the Company's partner, Auxilium. The FDA has not updated the Prescription Drug User Fee Act date of August 28, 2009.

#### Outlook

We foresee the potential to generate income from limited sources in the next several years. Under the terms of our Asset Purchase Agreement (the "Asset Purchase Agreement" ) with DFB Biotech, Inc. ( "DFB" ), we receive certain contractual anniversary payments and, if DFB exceeds a certain sales target, the Company is 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.



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 September 30, 2009 we had an accumulated deficit from continuing operations of \$7,844,353.

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 September 30, 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. 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 U.S. generally accepted accounting principles ( GAAP ) 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 September 30, 2009 and for the three and nine months ended September 30, 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, 2009 and June 30, 2009. 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. 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.

**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.

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 a 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. 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 Asset Purchase 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 September 30, 2009 and 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 and are creditable against future royalty revenues. Estimates are based on contractual terms, historical development costs, the review of 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 and expenses.

On October 13, 2009, we received an updated invoice from Auxilium for approximately \$50,000 increasing the total amount due that Auxilium believes is owed by us to approximately \$2.9 million through September 30, 2009. The increase in the third quarter was primarily due to patent and related legal fees. Based upon the updated invoice, we recorded an additional liability of \$50,000 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.

**Receivables and Deferred Revenue.** Under our Asset Purchase 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 September 30, 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 September 30, 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 Accounting Standards Codification 350, *Intangibles, Goodwill and Other* (ASC 350), 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 Accounting Standards Codification, *Compensation - Stock Compensation* (ASC 718), 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 an 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, ASC 718 requires that employee stock-based compensation costs 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 SEPTEMBER 30, 2009 and 2008

#### Revenues

##### *Product Revenues, net*

Product revenues include the sales of the active pharmaceutical ingredient for topical collagenase (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 September 30, 2009 and 2008 product revenues were \$19,089 and \$13,042, respectively. This increase of \$6,046 or 46% 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 were achieved. Royalty revenues recognized under our Asset Purchase Agreement with DFB for the three months ended September 30, 2009 were \$481,197 and zero in the 2008 period. This increase is mainly related to the increase in net sales during the period reported to us by DFB.

##### *Licensing and Milestone Revenues*

For the three months ended September 30, 2009 and 2008, we recognized licensing and milestone revenue of \$266,282 and \$266,281, respectively. 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 with DFB 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 with DFB generally expire during March 2011. For the three months ended September 30, 2009 and 2008 consulting revenues were \$70,000 in each period.

## Costs and Expenses

### *Research and Development Activities*

Research and development expenses were \$112,920 and \$71,737 respectively, for the three months ended September, 2009 and 2008. This increase of \$41,183 or 57% in research and development expenses was primarily due to the Company incurring certain employee costs which were previously reimbursable under our transition services agreement with DFB, which expired in October 2008, and stock-based compensation expense.

### *General and Administrative Expenses*

General and administrative expenses were \$1,176,885 and \$866,574 for the three months ended September, 2009 and 2008, respectively. The increase in general and administrative expenses of \$310,311 or 36% was due to outside consulting, Board Member service, legal fees and the Company incurring certain facility costs which were previously reimbursable under our transition services agreement with DFB, which expired in October 2008.

### *Other Income (expense), net*

Other income, net, was \$24,740 for the three months ended September, 2009 as compared to other income, net of \$182,693 for the 2008 period. Components of other income, net, consist of investment income, interest expense and other, net. Investment income for the three months ended September 30, 2009 was \$24,140 as compared to \$31,511 in the comparable period of 2008. This decrease of \$7,371 or 23% was primarily due to lower interest rates during the 2009 period. Interest expense for the three months ended September 30, 2009 was zero as compared to an interest expense reduction of \$46,979 in the 2008 period. This reduction in interest expense in the 2008 period is primarily the result of lower than previously estimated accrued interest associated with our delinquent federal and state tax returns. Other expense, net for the three months ended September 30, 2009 was \$600 as compared to \$104,203 in the 2008 period. The decrease in other expense, net was primarily due to lower than previously estimated tax penalties due in connection with our delinquent federal and state tax returns.

### *Income Taxes*

The tax benefit for the three months ended September 30, 2009 was \$46,376 as compared to a benefit for income taxes of \$192,287 in the comparable period of 2008. The tax benefit in 2009 was due to carrying back to 2008 of the windfall tax deductible expenses resulting from the exercise and sale of non-qualified employee stock options during the 2009 period. The Company reduced the valuation allowance against its previously recognized tax asset recognizing a benefit of \$46,376, recorded \$151,862 additional paid in capital and a tax refund receivable of \$198,238 for the taxes paid for 2008.

In the 2008 period, we filed our federal and state tax returns in September 2008 for the years ended 2003, 2004, 2005, 2006 and 2007. We paid federal and state taxes of approximately \$225,000 related to our federal and state tax returns for the years ended 2003, 2004, 2005 and 2006. We accrued an additional \$28,079 in federal and state taxes related to previous years for the three months ended September 30, 2008. In connection with the filing of our 2007 federal tax return, we applied for a refund of approximately \$220,000 and recorded a receivable under prepaid expenses and other current assets on our Balance Sheet at that time resulting in a net tax benefit of \$192,287 for the three months ended September 30, 2008.



**NINE-MONTHS ENDED SEPTEMBER 30, 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 nine months ended September 30, 2009 and 2008 product revenues were \$36,194 and \$29,841, respectively. This increase of \$6,353 or 21% 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 were achieved. Royalty revenues recognized under our Asset Purchase Agreement with DFB for the nine months ended September 30, 2009 were \$856,597 and \$2,028 in the 2008 period. This increase is mainly related to the increase in net sales during the period reported to us by DFB.

*Licensing and Milestone Revenues*

For the nine months ended September 30, 2009 and 2008, we recognized licensing and milestone revenue of \$1,298,844 and \$798,844, respectively. Licensing revenues recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period. This increase of \$500,000 was related to a milestone received and recognized in the in the 2009 period under our agreement with Auxilium.

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 with DFB 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 nine months ended September 30, 2009 and 2008 consulting revenues were \$210,000 and \$354,185, respectively. This decrease of \$144,185 or 41% in 2009 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 \$352,983 and \$260,440 respectively, for the nine months ended September 30, 2009 and 2008. This increase of \$92,543 or 36% in research and development expenses was primarily due to the Company incurring certain employee costs which were previously reimbursable under our transition services agreement with DFB, which expired in October 2008, and stock-based compensation expense partially offset by decreases in external study development costs.

*General and Administrative Expenses*

General and administrative expenses were \$3,484,341 and \$2,840,346 for the nine months ended September 30, 2009 and 2008, respectively. The increase in general and administrative expenses of \$643,995 or 23% was primarily due to outside consulting services, the Company incurring certain facility costs which were previously reimbursable under our transition services agreement with DFB, which expired in October 2008, stock-based compensation expense, Board Member service, employee costs and patent related fees partially offset by a decrease in legal fees.

*Other Income (expense), net*

Other income, net, was \$19,783 for the nine months ended September 30, 2009 as compared to other income, net of \$244,572 for the 2008 period. Components of other income, net, consist of investment income, interest expense and other, net. Investment income for the nine months ended September 30, 2009 was \$28,685 as compared to \$89,314 in the comparable period of 2008. This decrease of \$60,629 was primarily due to lower interest rates and invested balances during the 2009 period. Interest expense for the nine months ended September 30, 2009 was minimal as compared to an interest expense reduction for the nine months ended September 30, 2009 of \$46,528. This reduction in interest expense is primarily the result of lower than previously estimated accrued interest associated with our delinquent federal and state tax returns. Other expense, net for the nine months ended September 30, 2009 was \$8,863 as compared to other expense, net of \$108,730 in the 2008 period. The change in other income and expense, net was primarily due to a penalty related to our delinquent tax filings from previous periods partially offset by the sale of a company owned vehicle in the 2008 period.

*Income Taxes*

The tax benefit for the nine months ended September 30, 2009 was zero as compared to a benefit for income taxes of \$192,287 in the comparable period of 2008. The tax benefit in 2009 was due to carrying back to 2008 of the windfall tax deductible expenses resulting from the exercise and sale of non-qualified employee stock options during the 2009 period. The Company recorded \$198,238 additional paid in capital and a tax refund receivable of \$198,238 for the taxes paid for 2008. The Company plans to file for the refund of 2008 taxes.

In the 2008 period, we filed our federal and state tax returns in September 2008 for the years ended 2003, 2004, 2005, 2006 and 2007. We paid federal and state taxes of approximately \$225,000 related to our federal and state tax returns for the years ended 2003, 2004, 2005 and 2006. We accrued an additional \$28,079 in federal and state taxes related to previous years for the nine months ended September 30, 2008. In connection with the filing of our 2007 federal tax return, we applied for a refund of approximately \$220,000 and recorded a receivable under prepaid expenses and other current assets on our Balance Sheet at that time resulting in a net tax benefit of \$192,287 for the nine months ended September 30, 2008.

**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 September 30, 2009 and December 31, 2008, we had cash and cash equivalents in the aggregate of \$4,267,591 and \$3,494,150, respectively.

*Continuing Operations*

Net cash provided by operating activities for the nine months ended September 30, 2009 was \$4,663,371 as compared to net cash used in operating activities in the 2008 period of \$2,061,989. 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 income tax receivable resulting from the exercise and sale of non-qualified employee stock options during the 2009 period partially offset by non-cash stock compensation expense and accounts payable and accrued expenses.

Net cash used in investing activities for the nine months ended September 30, 2009 was \$4,122,854 as compared to net cash used in investing activities in the 2008 period of \$1,642,000. The change in net cash used in investing activities for the 2009 period reflect our purchase of marketable securities of \$5,022,854 partially offset by the redemption of marketable securities of \$900,000. In the 2008 period, we had purchases of marketable securities of \$2,000,000 as well as a one-time cash payment related to our future royalty obligations for Peyronie's disease of \$1,250,000 which were partially offset by maturities of marketable securities of \$1,600,000.

Net cash provided by financing activities for the nine months ended September 30, 2009 was \$232,924 as compared to the 2008 period of \$7,370,993. The change in net cash provided by financing activities for the 2009 consisted of proceeds received from stock option exercises and excess tax benefits related to the sale by employees of certain stock options. Net cash provided by financing activities in the 2008 period consisted of proceeds from the sale of our common stock of \$6,007,047, repayment of an outstanding loan from our former Chairman and CEO of \$1,116,558 and proceeds received from stock option exercises of \$247,388.

### **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 and nine month periods ended September 30, 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**

None.

**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).
- 31\* Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).
- 32\* Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002.

\* 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: November 6, 2009

/s/ Thomas L. Wegman  
Thomas L. Wegman  
President  
(Principal Executive and Financial Officer)

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