

BIOSPECIFICS TECHNOLOGIES CORP  
Form 10-Q  
August 09, 2010

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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 June 30, 2010**

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**001-34236**

(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

Smaller reporting company

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(Do not check if a smaller reporting company)

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

Yes [ ] No [X]

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

<u>Class of Stock</u>	<u>Outstanding August 3, 2010</u>
<b>Common Stock (\$.001 par value)</b>	<b>6,275,758</b>

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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 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 discussed in Item 1A, Risk Factors , included in our Annual Report on Form 10-K for the year ended December 31, 2009, and for the reasons described elsewhere in this Report. All forward-looking statements and reasons why actual 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**

	<b>June 30, 2010</b>	<b>December 31, 2009</b>
	(unaudited)	(audited)
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 5,304,216	\$ 3,950,389
Short-term investments	4,548,541	4,548,541
Accounts receivable, net	609,182	1,295,399
Income tax receivable	418,605	416,821
Prepaid expenses and other current assets	169,851	63,260
<b>Total current assets</b>	<b>11,050,395</b>	<b>10,274,410</b>
Deferred royalty buy-down	1,250,000	1,250,000
Property, plant and equipment, net	202	610
Patent costs, net	182,766	223,458
<b>Total assets</b>	<b>12,483,363</b>	<b>11,748,478</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	837,469	584,509
Accrued third-party development expenses	3,527,732	2,965,225
Deferred revenue	623,769	877,778
Accrued liabilities of discontinued operations	78,138	78,138
<b>Total current liabilities</b>	<b>5,067,108</b>	<b>4,505,650</b>
Long-term deferred revenue	932,170	1,150,721
<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; 6,425,743 and 6,327,318 shares issued at June 30, 2010 and December 31, 2009, respectively	6,426	6,327
Additional paid-in capital	17,139,776	15,164,727
Accumulated deficit	(9,549,403)	(8,384,990)
Treasury stock, 149,985 and 131,267 shares at cost at June 30, 2010 and December 31, 2009, respectively	(1,112,714)	(693,957)
<b>Total stockholders' equity</b>	<b>6,484,085</b>	<b>6,092,107</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 12,483,363</b>	<b>\$ 11,748,478</b>

See accompanying notes to consolidated financial statements



**BioSpecifics Technologies Corp.**  
**Consolidated Statements of Operations**  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
<b>Revenues:</b>				
Net sales	\$ 18,209	\$ 9,914	\$ 27,145	\$ 17,105
Royalties	507,322	375,400	539,134	375,400
Licensing fees	259,276	766,281	2,807,560	1,032,562
Consulting fees	70,000	70,000	140,000	140,000
<b>Total Revenues</b>	<b>854,807</b>	<b>1,221,595</b>	<b>3,513,839</b>	<b>1,565,067</b>
<b>Costs and expenses:</b>				
Research and development	144,799	124,192	1,041,616	240,063
General and administrative	1,646,165	1,140,485	3,680,343	2,307,456
<b>Total Cost and Expenses</b>	<b>1,790,964</b>	<b>1,264,677</b>	<b>4,721,959</b>	<b>2,547,519</b>
<b>Operating loss</b>	<b>(936,157)</b>	<b>(43,082)</b>	<b>(1,208,120)</b>	<b>(982,452)</b>
<b>Other income (expense):</b>				
Interest income	25,925	1,688	51,775	4,545
Interest expense	-	(39)	-	(39)
Other	-	-	-	(9,463)
	25,925	1,649	51,775	(4,957)
Loss before expense for income tax	(910,232)	(41,433)	(1,156,345)	(987,409)
Income tax expense	-	(46,376)	(8,067)	(46,376)
<b>Net loss</b>	<b>\$ (910,232)</b>	<b>\$ (87,809)</b>	<b>\$ (1,164,412)</b>	<b>\$ (1,033,785)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.15)</b>	<b>\$ (0.01)</b>	<b>\$ (0.19)</b>	<b>\$ (0.17)</b>
<b>Shares used in computation of basic and diluted net loss per share</b>	<b>6,273,945</b>	<b>6,014,312</b>	<b>6,244,136</b>	<b>6,011,588</b>

See accompanying notes to consolidated financial statements

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

	Six Months Ended June 30,	
	2010	2009
<b>Cash flows from operating activities:</b>		
Net loss	\$ (1,164,412)	\$ (1,033,785)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	509	16,312
Stock-based compensation expense	1,321,772	882,891
Changes in operating assets and liabilities:		
Deferred revenue	(472,560)	(472,563)
Accounts receivable	686,218	6,078,109
Prepaid expenses and other current assets	(108,375)	(67,554)
Accounts payable and accrued expenses	856,057	(59,942)
<b>Net cash provided by operating activities</b>	<b>1,119,209</b>	<b>5,343,468</b>
<b>Cash flows from investing activities:</b>		
Maturities of marketable securities	-	900,000
Purchases of marketable securities	-	(499,379)
<b>Net cash provided by investing activities</b>	<b>-</b>	<b>400,621</b>
<b>Cash flows from financing activities:</b>		
Proceeds from stock option exercises	653,375	86,260
Purchase of treasury stock	(418,757)	-
<b>Net cash provided by financing activities</b>	<b>234,618</b>	<b>86,260</b>
Increase in cash and cash equivalents	1,353,827	5,830,349
Cash and cash equivalents at beginning of year	3,950,389	3,494,150
<b>Cash and cash equivalents at end of year</b>	<b>\$ 5,304,216</b>	<b>\$ 9,324,499</b>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid during the year for:		
Interest	\$ -	\$ -
Taxes	\$ 9,851	\$ 361,228

**Supplemental disclosures of non-cash transactions:**

Under the Auxilium Agreement certain patent costs paid by Auxilium on behalf of the Company are creditable against future royalties. The patent costs and related accrued liability for the six months ended June 30, 2010 decreased by \$40,592 as compared to an increase of \$53,021 in the related 2009 period.

See accompanying notes to consolidated financial statements



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

**June 30, 2010**  
**(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 an Amended and Restated Development and License Agreement with Auxilium Pharmaceuticals, Inc. ( Auxilium ), which became effective on December 17, 2008 (the Auxilium Agreement ). Pursuant to the Auxilium Agreement, we have licensed to Auxilium our injectable collagenase (which Auxilium has named XIAFLEX® (formerly known as AA4500 )) for clinical indications in Dupuytren s contracture, Peyronie disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including lipomas and cellulite. Auxilium has an agreement with Pfizer, Inc. ( Pfizer ) pursuant to which Pfizer has the right to market XIAFLEX for the treatment of Dupuytren s contracture and Peyronie s disease in 27 member countries of the European Union and 19 other European and Eurasian countries.

Auxilium announced on July 12, 2010 that it held its end of phase II meeting with the U.S. Food and Drug Administration ( FDA ) in late June 2010 regarding development of XIAFLEX for the treatment of Peyronie's disease and that, as a result, Auxilium is reaffirming its plan to initiate phase III pivotal trials by the end of 2010.

Auxilium announced on February 2, 2010 that it received marketing approval from the FDA for XIAFLEX for the treatment of adult Dupuytren s contracture patients with a palpable cord. XIAFLEX, the only drug approved by the FDA for the treatment of Dupuytren s contracture, became available by prescription for such treatment in March 2010. In its May 2010 presentation materials, Auxilium stated, We believe worldwide peak revenues for XIAFLEX could be in excess of \$1 Billion annually.

Auxilium also announced the list price to distributors of XIAFLEX. In a February 17, 2010 press release, Auxilium stated this list price will be \$3,250 and that it anticipates that Dupuytren s contracture patients treated with XIAFLEX will have 1.5 cords treated, on average, and that each cord will be treated with an average of 1.1 vials of XIAFLEX.

Pfizer and Auxilium announced, on January 21, 2010, that the scientific/technical review procedure for the Marketing Authorization Approval for XIAFLEX for Dupuytren s contracture in Europe had begun.

**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 United States generally accepted accounting principles ( GAAP ) 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 Report on Form 10-Q for the quarterly period ended March 31, 2010 filed with the SEC on May 10, 2010 and Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC on March 15, 2010.

**Principles of Consolidation**

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

## Management Estimates

The preparation of consolidated financial statements in conformity with GAAP requires the use of management's estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

## Cash, Cash Equivalents and Short-term Investments

Cash, cash equivalents and short-term investments 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 short-term investments by placing its investments with banks it believes are highly creditworthy and with highly rated money market funds, United States government securities, or certificates of deposit.

## 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 June 30, 2010:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash and cash equivalents	\$ 5,304,216	-	-
Certificates of Deposit	4,548,541	-	-

## Revenue Recognition

We currently recognize revenues resulting from product sales, the licensing and sublicensing of the use of our technology and from 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 collagenase for laboratory use that are recognized at the time the product is shipped to customers for laboratory use.

### ***Royalty/ Mark-up on Cost of Goods Sold / Earn-Out Revenue***

For those arrangements for which royalty, mark-up on cost of goods sold or earn-out payment information becomes available and collectability is reasonably assured, we recognize revenue during the applicable period earned. For interim quarterly reporting purposes, when collectability is reasonably assured but a reasonable estimate of royalty, mark-up on cost of goods sold or earn-out payment revenues cannot be made, the royalty, mark-up on cost of goods sold or earn-out payment revenues are generally recognized in the quarter that the applicable licensee provides the written report and sufficient related information to us.

Under the Auxilium Agreement, we do not participate in the selling, marketing or manufacturing of products for which we receive royalties and a mark-up of the cost of goods sold revenues. Under the Auxilium Agreement, the royalty and mark-up of cost of goods sold reports from Auxilium are required to be submitted approximately 30 - 60 days in arrears. On August 3, 2010, we received an incomplete royalty and mark up on cost of goods sold report from Auxilium. Because we have no other reliable information and the report contains insufficient data on which to estimate the amount of royalties and mark-up on cost of goods sold owed by Auxilium, we will record no revenues for royalties and a mark-up of the cost of goods sold under the Auxilium Agreement until such time as we can make a reliable estimate.

Under a March 2006 agreement (the DFB Agreement ), pursuant to which we sold our topical collagenase business to DFB Biotech, Inc. and its affiliates ( DFB ), we have the right to receive earn-out payments in the future based on sales of certain products. Generally, under the DFB Agreement we would receive payments and a report within ninety (90) days from the end of each calendar year after DFB has sold the royalty-bearing product. Currently, DFB is providing us reliable earn-out reports on a quarterly basis.

### ***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 for which we are providing continuing services related to product development, are 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 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 consulting and technical assistance contracts primarily as a result of the DFB Agreement. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations to DFB expire during March 2011.

### **Accounts Receivable and Allowance for Doubtful Accounts**

The Company performs ongoing credit evaluations of its customers and maintains allowances for potential credit losses which when realized have been within the range of management's expectations. Our policy is to write off bad debts as uncollectible when it is determined that they cannot be collected.

### **Reimbursable Third Party Development Costs**

We accrue expenses for research and development and capitalize certain patent costs related to estimated third party development costs that are reimbursable under the Auxilium Agreement. 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 or decrease 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 expenses which are creditable against future royalty revenues. Auxilium has advised us that certain patent costs may have been invoiced to us in error. In August 2010, we received an updated invoice from Auxilium for approximately \$3.5 million which represents a decrease of approximately \$0.2 million in the total amount due that Auxilium believes is owed by us through June 30, 2010 under this provision. The \$0.2 million decrease was primarily due to a reduction in certain patent costs. Based upon the updated invoice, we changed our estimates for reimbursable third party development and certain patent costs to approximately \$3.5 million.

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 and certain patent expenses may increase based upon a resolution of certain patent matters, and therefore, we reserve all rights related to this matter, including but not limited to our right to contest the amount charged by Auxilium. In addition, we believe that this matter will be settled within calendar year 2010, and we have re-classified accrued third party development costs from long-term liabilities to current liabilities on our balance sheet as of June 30, 2010 and December 31, 2009, accordingly.

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 and preclinical 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 agreement to agreement and may result in uneven payment flows. Payments under such agreements 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

The Company has two stock-based compensation plans in effect. Under 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 Company did not grant any stock options during the six months ended June 30, 2010.

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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Research and development	\$ 31,516	\$ 29,728	\$ 55,153	\$ 43,644
General and administrative	515,188	423,576	1,266,619	839,247
<b>Total stock-based compensation expense</b>	<b>\$ 546,704</b>	<b>\$ 453,304</b>	<b>\$ 1,321,772</b>	<b>\$ 882,891</b>

### Stock Option Activity

A summary of our stock option activity during the six months ended June 30, 2010 is presented below:

Options	Total Number of Shares	Weighted-Average Exercise Price
Outstanding as of December 31, 2009	1,464,850	\$ 7.64
Granted	-	-
Forfeited	-	-
Exercised	(98,425)	\$ 6.74
Expired	-	-
<b>Outstanding as of June 30, 2010</b>	<b>1,366,425</b>	<b>\$ 7.71</b>
<b>Exercisable as of June 30, 2010</b>	<b>1,178,925</b>	<b>\$ 5.50</b>

The Company did not grant stock options during the first and second quarters of 2010. The total number of outstanding options as of June 30, 2010 was 1,366,425.

During the six months ended June 30, 2010 and 2009, \$653,375 and \$86,260, respectively, were received from stock options exercised by option holders.

The aggregate intrinsic value of options outstanding and exercisable as of June 30, 2010 was approximately \$17.0 million. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our common stock of \$19.88 on June 30, 2010, 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 June 30, 2010 was approximately \$1.2 million which we expect to recognize over a weighted-average period of 1.0 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 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 asset and 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 basis of assets and liabilities at the statutory rates enacted for future periods. In accordance with Accounting Standards Codification 740-10-45-25, *Income Statement Classification of Interest and Penalties*, we classify interest associated with income taxes under interest expense and tax penalties under other.

### **Recent Accounting Pronouncements**

In January 2010, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2010-06, *Improving Disclosures about Fair Value Measurements* ( ASU 2010-06 ). ASU 2010-06 requires disclosing the amounts of significant transfers in and out of Level 1 and 2 fair value measurements and describing the reasons for the transfers. These disclosure requirements were effective for reporting periods beginning after December 15, 2009, and had no material impact on the Company's financial statements for the period ended March 31, 2010. Additionally, ASU 2010-06 requires disclosure of the gross purchases, sales, issuances and settlements activity in Level 3 fair value measurements for fiscal years beginning after December 15, 2010. The Company does not expect the provisions of ASU 2010-06 to have a material effect on its consolidated results of operations, financial position or liquidity.

In February 2010, FASB issued ASU 2010-09, *Subsequent Events (Topic 855): Amendments to Certain Recognition and Disclosure Requirements*, which, among other things, amended FASB Accounting Standards Codification 855 to remove the requirement for an SEC filer to disclose the date through which subsequent events have been evaluated. The Company has incorporated this guidance into this Report.

In April 2010, FASB issued ASU 2010-17, *Revenue Recognition Milestone Method (Topic 605): Milestone Method of Revenue Recognition* ( ASU 2010-17 ). ASU 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. ASU 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The Company is currently evaluating the impact of the provisions of ASU 2010-17 on its consolidated results of operations, financial position or liquidity.

**3. NET LOSS PER SHARE**

In accordance with Accounting Standards Codification 260, *Earnings Per Share*, 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 months and six months ended June 30, 2010 and 2009, 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		Six Months Ended	
	June 30,		June 30,	
	2010	2009	2010	2009
Stock options	939,276	1,014,917	945,713	1,017,570

**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		Six Months Ended	
	June 30,		June 30,	
	2010	2009	2010	2009
Net loss	\$ (910,232)	\$ (87,809)	\$ (1,164,412)	\$ (1,033,785)
Other comprehensive loss:				
Change in unrealized losses on marketable securities	-	-	-	-
<b>Total Comprehensive Loss</b>	<b>\$ (910,232)</b>	<b>\$ (87,809)</b>	<b>\$ (1,164,412)</b>	<b>\$ (1,033,785)</b>

**5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consisted of the following:

	June 30,	December 31,
	2010	2009
Trade accounts payable and accrued expenses	\$ 554,162	\$ 378,872
Accrued legal and other professional fees	137,478	70,935
Accrued payroll and related costs	145,829	134,702
<b>Total</b>	<b>\$ 837,469</b>	<b>\$ 584,509</b>

**6. PATENT COSTS**

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 4 to 12 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 June 30, 2010, the Company capitalized certain patent costs, paid by Auxilium on behalf of the Company. These costs are reimbursable to Auxilium under the Auxilium Agreement and are creditable against future royalty revenues.

Our Net patent costs consisted of:

	June 30, 2010	December 31, 2009
Patents	\$ 241,705	\$ 282,297
Accumulated Amortization	(58,939)	(58,839)
	\$ 182,766	\$ 223,458

The amortization expense for patents decreased by \$40,692 for the six months ended June 30, 2010 due the adjusted invoice received from Auxilium for certain patent matters (See Note 1: **Reimbursable Third Party Development Costs** for a more detailed description of the change) In the comparable period of 2009, the amortization expense for patents was \$15,469. The estimated aggregate amortization expense for each of the next five years is approximately as follows:

2011	\$ 36,000
2012	33,000
2013	31,000
2014	24,000
2015	9,000

## 7. INCOME TAXES

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

	June 30 2010	December 31, 2009
Computed tax expense at statutory rate	(34.0)%	(34.0)%
Deferred revenues	(15.6)%	(17.1)%
Stock-based compensation	38.6%	23.9%
Tax benefit of NOL	11.0%	-%
Tax refund 2008	-%	(3.2)%
Other	-%	1.4%
Increase (decrease) in valuation allowance	-%	25.8%
Effective tax rate (benefit)	-%	(3.2)%

The significant components of the Company's deferred tax assets (liabilities), pursuant to Accounting Standards Codification 740-10-50 are summarized as follows:

	June 30, 2010	December 31, 2009
Tax Credit carryforward	1,039,390	1,039,390
Deferred revenues	461,216	741,714
Other	-	54,846
Options	1,985,327	406,517
Net operating loss carryforward	1,713,785	556,504
Net deferred tax assets before valuation allowance	5,199,719	2,798,971
Valuation allowance	(5,199,719)	(2,798,971)
Net deferred tax asset	-	-

For the six month period ended June 30, 2010, the valuation allowance increased by approximately \$2.4 million. The change from December 31, 2009 reflects an increase of \$1.6 million in deferred tax assets related to the exercise of disqualified and non-qualified stock options. A decrease of \$0.3 million in deferred tax assets related to deferred

revenue recognized during the period. A decrease of \$0.1 million in other and an increase in the net operating loss carry-forward of \$1.1 million which was applied to the current period federal and state income taxes.

## 8. RELATED PARTY TRANSACTIONS

In connection with the settlement of the previously reported dispute between ABC-NY (together with the Company, the Tenant ) and Wilbur St. Corp. (the Landlord ) regarding payments of amounts due under the Extension and Modification Agreement dated July 1, 2005 (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 Modification Agreement, subject to the terms thereof, and agreed to a \$15,000 reduction in the annual rental price of the Company's premises located at 35 Wilbur Street, Lynbrook, NY 11563 from \$150,000 to \$135,000. The underlying lease agreement expired on June 30, 2010, and the Company is holding over on a month-to-month basis at the same monthly rental rate.

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, and is qualified by reference to them.*

#### **Overview**

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. Pursuant to the Auxilium Agreement, we have licensed to Auxilium our injectable collagenase (which Auxilium has named XIAFLEX® (formerly known as AA4500 )) for clinical indications in Dupuytren's contracture, Peyronie's disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including lipomas and cellulite. Auxilium has an agreement with Pfizer pursuant to which Pfizer has the right to market XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in 27 member countries of the European Union and 19 other European and Eurasian countries.

Auxilium announced on July 12, 2010 that it held its end of phase II meeting with the FDA in late June 2010 regarding development of XIAFLEX for the treatment of Peyronie's disease and that, as a result, Auxilium is reaffirming its plan to initiate phase III pivotal trials by the end of 2010.

Auxilium announced on February 2, 2010 that it received marketing approval from the FDA for XIAFLEX for the treatment of adult Dupuytren's contracture patients with a palpable cord, and XIAFLEX became available by prescription for such treatment in March 2010. In its May 2010 presentation materials, Auxilium stated, "We believe worldwide peak revenues for XIAFLEX could be in excess of \$1 Billion annually."

Auxilium has also announced the list price to distributors of XIAFLEX. In a February 17, 2010 press release, Auxilium stated this list price will be \$3,250 and that it anticipates that Dupuytren's contracture patients treated with XIAFLEX will have 1.5 cords treated, on average, and that each cord will be treated with an average of 1.1 vials of XIAFLEX.

Pfizer and Auxilium announced, on January 21, 2010, that the scientific/technical review procedure of the Marketing Authorization Application for XIAFLEX for Dupuytren's contracture in Europe had begun.

#### **Outlook**



We foresee the potential to generate income from limited sources in the next several years. In connection with the sale of our topical collagenase business to DFB in March 2006, we continue to receive payments for certain technical assistance and certain transition services that we provide to DFB, as well as earn-out payments based on the sales of certain products. Under the Auxilium Agreement, in 2009 we received \$6.375 million of the \$75 million upfront payment paid to Auxilium by Pfizer. In March 2010, we received \$1.275 million of the \$15 million paid to Auxilium by Pfizer. We will receive 8.5% of the \$395 million in potential additional milestone payments that may be made by Pfizer to Auxilium under the Pfizer Agreement. Of these additional milestones, \$135 million are tied to regulatory milestones and \$260 million are based on sales milestones. In addition to the payments already received by us with respect to the Dupuytren's contracture indication, Auxilium will be obligated to make contingent milestone payments, with respect to each of the Peyronie's disease and frozen shoulder indications, upon the acceptance of the regulatory filing and receipt by Auxilium, its affiliate or sublicensee of regulatory approval.

Based on our current business model, we expect to have adequate cash reserves until at least the second half of 2012. 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 June 30, 2010, we had an accumulated deficit from continuing operations of approximately \$9.5 million.

We are dependent to a significant extent on third parties, and our principal licensee, Auxilium, may not be able to successfully commercialize XIAFLEX for Dupuytren's contracture, successfully develop XIAFLEX for additional indications, obtain required regulatory approvals, manufacture XIAFLEX 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.

### **Critical Accounting Policies, Estimates and Assumptions**

The preparation of unaudited consolidated financial statements in conformity with 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 June 30, 2010 and for the three and six months ended June 30, 2010 and 2009 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, 2009 balance sheet amounts and disclosures included herein have been derived from the Company's December 31, 2009 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, 2009 included in the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2010 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 filed with the SEC on May 10, 2010. 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, 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 for which 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/ Mark-up on Cost of Goods Sold / Earn-Out Revenue***

For those arrangements for which royalty, mark-up on cost of goods sold or earn-out payment information becomes available and collectability is reasonably assured, we recognize revenue during the applicable period earned. For interim quarterly reporting purposes, when collectability is reasonably assured but a reasonable estimate of royalty, mark-up on cost of goods sold or earn-out payment revenues cannot be made, the royalty, mark-up on cost of goods sold or earn-out payment revenues are generally recognized in the quarter that the applicable licensee provides the written report and related information to us.

Under the Auxilium Agreement, we do not participate in the selling, marketing or manufacturing of products for which we receive royalties and a mark-up of the cost of goods sold revenues. Under the Auxilium Agreement, the royalty and mark-up of cost of goods sold reports from Auxilium are required to be submitted approximately 30 - 60 days in arrears. On August 3, 2010, we received an incomplete royalty and mark up on cost of goods sold report from Auxilium. Because we have no other reliable information and the report contains insufficient data on which to estimate the amount of royalties and mark-up on cost of goods sold owed by Auxilium, we will record no revenues for royalties and a mark-up of the cost of goods sold under the Auxilium Agreement until such time as we can make a reliable estimate.

Under a March 2006 agreement (the DFB Agreement ), pursuant to which we sold our topical collagenase business to DFB Biotech, Inc. and its affiliates ( DFB ), we have the right to receive earn-out payments in the future based on sales of certain products. Generally, under the DFB Agreement we would receive payments and a report within ninety (90) days from the end of each calendar year after DFB has sold the royalty-bearing product. Currently, DFB is providing us earn-out reports on a quarterly basis.

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

***Reimbursable Third Party Development Costs.*** We accrue expenses for research and development and capitalize certain patent costs related to estimated third party development costs that are reimbursable under the Auxilium Agreement. 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 or decrease 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 expenses which are creditable against future royalty revenues. Auxilium has advised us that certain patent costs may have been invoiced to us in error. In August 2010, we received an updated invoice from Auxilium for approximately \$3.5 million which represents a decrease of approximately \$0.2 million in the total amount due that Auxilium believes is owed by us through June 30, 2010 under this provision. The \$0.2 million decrease was primarily due to a reduction in certain patent costs. Based upon the updated invoice, we changed our estimates for reimbursable third party development and certain patent costs to approximately \$3.5 million.

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 and certain patent expenses may increase based upon a resolution of certain patent matters, and therefore, we reserve all rights related to this matter, including but not limited to our right to contest the amount charged by Auxilium. In addition, we believe that this matter will be settled within calendar year 2010, and we have re-classified accrued third party development costs from long-term liabilities to current liabilities on our balance sheet as of December 31, 2009, accordingly.

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 the DFB Agreement, we agreed to provide certain technical assistance and transitional services in consideration of fees and costs totaling over \$1.4 million. At the closing of the DFB Agreement, DFB made a partial payment to us of \$400,000 in respect of the technical assistance to be provided by us. To date, we have received a total of \$1.4 million in payments from DFB. The consulting obligations expire during March 2011.

**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 June 30, 2010, 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*, 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 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 June 30, 2010 and 2009

#### Revenues

##### *Product Revenues, net*

Product revenues include the sales of the collagenase for laboratory use 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 June 30, 2010 and 2009, product revenues were \$18,209 and \$9,914, respectively. This increase of \$8,295, or 84%, was primarily related to the amount of material required to perform testing by our customers.

##### *Royalties/Earn-out*

We receive royalty revenues from DFB under the earn-out payment provision of the DFB Agreement, after certain net sales levels are achieved. Royalty revenues recognized under the DFB Agreement for the three months ended June 30, 2010 were \$507,322 and \$375,400 for the same period in 2009. This increase of \$131,922 or 35% is mainly related to the increase in net sales during the 2010 period reported to us by DFB.

As of June 30, 2010, we have not recorded royalties and the mark-up on cost of goods sold due to us under the terms of the Auxilium Agreement. For interim quarterly reporting purposes, when collectability is reasonably assured but a reasonable estimate of royalty and the mark-up on cost of goods sold revenues cannot be made, the royalty and mark-up on cost of goods sold revenues are generally recognized in the quarter that the applicable licensee provides the written report and related information to us. Under the Auxilium Agreement, the royalty and mark-up of cost of goods sold reports from Auxilium are required to be submitted approximately 30 - 60 days in arrears. On August 3, 2010, we received an incomplete royalty and mark up on cost of goods sold report from Auxilium. Because we have no other reliable information and the report contains insufficient data on which to estimate the amount of royalties and mark-up on cost of goods sold owed by Auxilium, we will record no revenues for royalties and a mark-up of the cost of goods sold under the Auxilium Agreement until such time as we can make a reliable estimate.

*Licensing, Sublicensing and Milestone Revenues*

For the three months ended June 30, 2010 and 2009, we recognized total licensing and milestone revenue of \$259,276 and \$766,281, 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. Licensing revenue recognized for the three months ended June 30, 2010 was \$109,276 and \$266,281 for the same period in 2009. The decrease of \$157,006, or 59%, was mainly due to the completed recognition of licensing revenue associated with the Dupuytren's contracture indication during the first quarter of 2010. Auxilium received marketing approval from the FDA for XIAFLEX for the treatment of Dupuytren's contracture on February 2, 2010.

Milestone revenue recognized for the three months ended June 30, 2010 and 2009 was \$150,000 and \$0.5 million, respectively. In the second quarter of 2010, we received and recognized the remaining \$150,000 of a \$1.0 million milestone related to the FDA's approval of XIAFLEX for Dupuytren's contracture in February 2010 in connection with our notification to Auxilium of our election not to commercially manufacture XIAFLEX. In the second quarter of 2009, we recognized \$500,000 related to a milestone received under the Auxilium Agreement for the filing and acceptance of a new drug application for Dupuytren's contracture.

Under current accounting guidance, nonrefundable upfront license fees for product candidates for which 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 DFB Agreement. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations under the DFB Agreement expire during March 2011. For the three months ended June 30, 2010 and 2009 consulting revenues were \$70,000 in each period.

**Costs and Expenses**

*Research and Development Activities*

Research and development expenses were \$144,799 and \$124,192, respectively, for the three months ended June 30, 2010 and 2009. This increase of \$20,608, or 17%, in research and development expenses was primarily due to preclinical expenses related to our animal study.

*General and Administrative Expenses*

General and administrative expenses were \$1,646,165 and \$1,140,485, respectively, for the three months ended June 30, 2010 and 2009. The increase in general and administrative expenses of \$505,690 or 44%, was due to legal expenses, stock based compensation, consulting services, and services related to investor relations partially offset by a decrease in patent costs.

*Other Income (expense), net*

Other income, net, was \$25,925 for the three months ended June 30, 2010 as compared to \$1,649 for the same period in 2009, representing a change of \$24,276. Components of other income, net, consist of investment income, interest expense and other, net. Investment income for the three months ended June 30, 2010 was \$25,925 as compared to \$1,688 for the same period in 2009. This increase of \$24,237 was primarily due to higher invested balances during the 2010 period. Interest expense for the three months ended June 30, 2010 was zero, and \$39 for the same period in



2009.

### *Income Taxes*

Income tax expense for the three months ended June 30, 2010 and 2009 was zero and \$46,376, respectively. The income tax expense for the 2009 period was due to tax allowance reserve in connection with the recognition of a deferred tax asset arising from the exercise and sale of employee stock options during that period.

### *Net Loss*

As a result of the above discussion, we recorded a net loss of \$0.9 million for the three months ended June 30, 2010, or \$0.15 per basic and diluted common share, compared to a net loss of \$0.1 million, or \$0.01 per basic and diluted common share, for the same period in 2009.

## **SIX-MONTHS ENDED June 30, 2010 and 2009**

### **Revenues**

#### *Product Revenues, net*

Product revenues include the sales of the collagenase for laboratory use 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 six months ended June 30, 2010 and 2009, product revenues were \$27,145 and \$17,105, respectively. This increase of \$10,040, or 59%, was primarily related to the amount of material required to perform testing by our customers.

#### *Royalties/Earn-out*

We receive royalty revenues from DFB under the earn-out payment provision of the DFB Agreement after certain net sales levels are achieved. Royalty revenues recognized under the DFB Agreement for the six months ended June 30, 2010 were \$539,134 and \$375,400, respectively. This increase of \$163,734, or 44%, is mainly related to the increase in net sales during the 2010 period reported to us by DFB.

As of June 30, 2010, we have not recorded royalties and the mark-up on cost of goods sold due to us under the terms of the Auxilium Agreement. For interim quarterly reporting purposes, when collectability is reasonably assured but a reasonable estimate of royalty and the mark-up on cost of goods sold revenues cannot be made, the royalty and mark-up on cost of goods sold revenues are generally recognized in the quarter that the applicable licensee provides the written report and related information to us. Under the Auxilium Agreement, the royalty and mark-up of cost of goods sold reports from Auxilium are required to be submitted approximately 30 - 60 days in arrears. On August 3, 2010, we received an incomplete royalty and mark up on cost of goods sold report from Auxilium. Because we have no other reliable information and the report contains insufficient data on which to estimate the amount of royalties and mark-up on cost of goods sold owed by Auxilium, we recorded no royalties and a mark-up of the cost of goods sold revenues under this agreement until such time as we can make a reliable estimate.

#### *Licensing, Sublicensing and Milestone Revenues*

For the six months ended June 30, 2010 and 2009, we recognized total licensing and milestone revenue of \$2,807,560 and \$1,032,562, 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. Licensing revenue recognized for the six months ended June 30, 2010 and 2009 was \$532,560 and \$532,562, respectively.

Milestone revenue recognized for the six months ended June 30, 2010 and 2009 was \$2.275 million and \$0.5 million, respectively. In the 2010 period, we received and recognized \$1.275 million of the \$15 million paid to Auxilium by Pfizer for the scientific/technical review procedure of the Marketing Authorization Application for XIAFLEX for

Dupuytren's contracture in Europe. We also received and recognized a milestone of \$1.0 million related to the FDA's approval of XIAFLEX for Dupuytren's contracture in February 2010 of which payment of the remaining \$150,000 was in connection with our notification in June 2010 to Auxilium of our election not to commercially manufacture XIAFLEX. In the comparable 2009 period, we recognized \$500,000 related to a milestone received under the Auxilium Agreement for the filing and acceptance of a new drug application for Dupuytren's contracture.

Under current accounting guidance, nonrefundable upfront license fees for product candidates for which 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 DFB Agreement. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations under the DFB Agreement expire during March 2011. For the six months ended June 30, 2010 and 2009 consulting revenues were \$140,000 in each period.

### **Costs and Expenses**

#### *Research and Development Activities*

Research and development expenses were \$1,041,616 and \$240,063, respectively, for the six months ended June 30, 2010 and 2009. This increase of \$801,553 or 334%, in research and development expenses was primarily due to third party development costs that are reimbursable under the Auxilium Agreement.

#### *General and Administrative Expenses*

General and administrative expenses were \$3,680,343 and \$2,307,456, respectively, for the six months ended June 30, 2010 and 2009. The increase in general and administrative expenses of \$1,372,887 or 59%, was due to legal fees, stock based compensation, consulting services, and services related to investor relations partially offset by lower patent costs.

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

Other income, net, was \$51,775 for the six months ended June 30, 2010 as compared to other expense, net, of \$4,957 for the same period in 2009, representing a change of \$56,732. Components of other income, net, consist of investment income, interest expense and other, net. Investment income for the six months ended June 30, 2010 was \$51,775 as compared to \$4,545 for the same period in 2009. This increase of \$47,230 was primarily due to higher invested balances during the 2010 period. Interest expense for the six months ended June 30, 2010 and 2009 was zero and \$39, respectively. Other expense for the six months ended June 30, 2010 was zero as compared to \$9,463 for the same period in 2009. The amount of other expense in the 2009 period was primarily related to tax penalties due in connection with our prior year delinquent federal and state tax returns.

#### *Income Taxes*

Income tax expense for the six months ended June 30, 2010 and 2009 was \$8,067 and \$46,376, respectively. The income tax expense for the 2010 period is primarily related to the payment of New York state taxes. The income tax expense for the 2009 period was due to tax allowance reserve in connection with the recognition of a deferred tax asset arising from the exercise and sale of employee stock options during that period.

#### *Net Loss*

As a result of the above discussion, we recorded a net loss of \$1.2 million for the six months ended June 30, 2010, or \$0.19 per basic and diluted common share, compared to a net loss of \$1.0 million, or \$0.17 per basic and diluted common share, for the same period in 2009.

### **Liquidity and Capital Resources**

To date, we have financed our operations primarily through product sales, debt instruments, licensing revenues and royalties under agreements with third parties and sales of our common stock. At June 30, 2010 and December 31, 2009, we had cash and cash equivalents in the aggregate of approximately \$5.3 million and \$4.0 million, respectively.

*Continuing Operations*

Net cash provided by operating activities for the six months ended June 30, 2010 was \$1.1 million as compared to \$5.3 million for the same period in 2009. The decrease in the 2010 period as compared to the same period in 2009 was primarily attributable to a reduction in accounts receivable in the 2009 period due to the receipt of a payment for a sublicense fee of \$6.4 million partially offset by an increase in accounts payable and accrued expenses.

Net cash provided by investing activities for the six months ended June 30, 2010 and 2009 was zero and \$0.4 million, respectively. The change in net cash provided by investing activities between the 2010 and 2009 periods reflects the redemption of marketable securities in 2009 partially offset by the purchase of marketable securities.

Net cash provided by financing activities for the six months ended June 30, 2010 was \$234,618 as compared to \$86,260 for the same period in 2009. The change in net cash provided by financing activities between these periods was due to stock repurchases of \$418,757, or 18,718 shares of our common stock, under our stock repurchase program announced in May 2010 and an increase in proceeds received from stock option exercises, with \$653,375 for the 2010 period, and \$86,260 for the 2009 period.

### ***Off-Balance Sheet Arrangements***

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

### **Item 3: Quantitative and Qualitative Disclosures About Market Risk.**

We do not use derivative financial instruments or derivative commodity instruments for trading purposes. Our financial instruments consist of cash, cash equivalents, short-term investments, trade accounts receivable, accounts payable and long-term obligations. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents.

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments. The maximum allowable duration of a single issue is twelve months.

Our investment portfolio is subject to interest rate risk, although limited given the nature of the investments, and will fall in value in the event market interest rates increase. All our cash and cash equivalents and short-term investments at June 30, 2010, amounting to approximately \$9.9 million, were maintained in bank demand accounts, money market accounts, and certificates of deposit through the Certificate of Deposit Account Registry Service (CDARS). We do not hedge our interest rate risks, as we believe reasonably possible near-term changes in interest rates would not materially affect our results of operations, financial position or cash flows.

We are subject to market risks in the normal course of our business, including changes in interest rates. There have been no significant changes in our exposure to market risks since December 31, 2009.

### **Item 4. 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 June 30, 2010 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 1A. Risk Factors**

There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K filed with the SEC on March 15, 2010.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.****ISSUER PURCHASES OF EQUITY SECURITIES**

<b>Period</b>	<b>(a) Total Number of Shares (or Units) Purchased</b>	<b>(b) Average Price Paid per Share (or Unit)</b>	<b>(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</b>	<b>(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs</b>
June 8, 2010 - June 16, 2010	18,718	\$ 22.37	18,718	\$ 1,581,242
<b>Total</b>	<b>18,718</b>	<b>\$ 22.37</b>	<b>18,718</b>	<b>\$ 1,581,242</b>

On June 4, 2010, we announced that our Board of Directors authorized the repurchase of up to \$2.0 million of our outstanding common stock over the next year.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. (Removed and Reserved).****Item 5. Other Information**

None.

**Item 6. Exhibits**

- 3.1 Registrant's Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 of the Registrant's Form 10-KSB filed with the SEC on March 2, 2007).
- 3.2 Registrant's Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Registrant's Form 10-KSB filed with the SEC on March 2, 2007).
- 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: August 9, 2010

/s/ Thomas L. Wegman

Thomas L. Wegman

President and Principal Executive and Financial Officer

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