BIOSPECIFICS TECHNOLOGIES CORP
Form 10-Q
November 09, 2010

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

**For the quarterly period ended September 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** | **11-3054851** |
|---|---|
| *(State or Other Jurisdiction of Incorporation or Organization)* | *(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 [X] 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 [X]

Non-accelerated filer [ ] Smaller reporting company [ ]
(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:

| Class of Stock | Outstanding November 4, 2010 |
|---|---|
| **Common Stock ($.001 par value)** | **6,275,758** |

**BIOSPECIFICS TECHNOLOGIES CORP.**

**TABLE OF CONTENTS**

**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**

| | September 30, 2010 (unaudited) | December 31, 2009 (audited) |
|---|---|---|
| **Assets** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 3,299,628 | $ 3,950,389 |
| Short-term investments | 5,360,970 | 4,548,541 |
| Accounts receivable, net | 1,176,650 | 1,295,399 |
| Income tax receivable | 418,605 | 416,821 |
| Prepaid expenses and other current assets | 130,940 | 63,260 |
| **Total current assets** | **10,386,793** | **10,274,410** |
| | | |
| Deferred royalty buy-down | 1,250,000 | 1,250,000 |
| Property, plant and equipment, net | - | 610 |
| Patent costs, net | 177,963 | 223,458 |
| **Total assets** | **11,814,756** | **11,748,478** |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | 648,179 | 584,509 |
| Accrued third-party development expenses | 3,322,766 | 2,965,225 |
| Deferred revenue | 553,769 | 877,778 |
| Accrued liabilities of discontinued operations | 78,138 | 78,138 |
| **Total current liabilities** | **4,602,852** | **4,505,650** |
| | | |
| Long-term deferred revenue | 822,894 | 1,150,721 |
| | | |
| **Stockholders' equity:** | | |
| Series A Preferred stock, $.50 par value, 700,000 shares authorized; none outstanding | - | - |
| Common stock, $.001 par value; 10,000,000 shares authorized; 6,425,743 and 6,327,318 shares issued at September 30, 2010 and December 31, 2009, respectively | 6,426 | 6,327 |
| Additional paid-in capital | 17,528,996 | 15,164,727 |
| Accumulated deficit | (10,033,698) | (8,384,990) |
| Treasury stock, 149,985 and 131,267 shares at cost at September 30, 2010 and December 31, 2009, respectively | (1,112,714) | (693,957) |
| **Total stockholders' equity** | **6,389,010** | **6,092,107** |
| | | |
| **Total liabilities and stockholders equity** | **$ 11,814,756** | **$ 11,748,478** |

**See accompanying notes to consolidated financial statements**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2010** | **2009** | **2010** | **2009** |
| **Revenues:** | | | | |
| Net sales | $ 5,183 | $ 19,089 | $ 32,328 | $ 36,194 |
| Royalties | 819,639 | 481,197 | 1,358,773 | 856,597 |
| Licensing fees | 109,275 | 266,282 | 2,916,835 | 1,298,844 |
| Consulting fees | 70,000 | 70,000 | 210,000 | 210,000 |
| **Total Revenues** | **1,004,097** | **836,568** | **4,517,936** | **2,401,635** |
| | | | | |
| **Costs and expenses:** | | | | |
| Research and development | 216,571 | 112,920 | 1,258,187 | 352,983 |
| General and administrative | 1,289,310 | 1,176,885 | 4,969,653 | 3,484,341 |
| **Total Cost and Expenses** | **1,505,881** | **1,289,805** | **6,227,840** | **3,837,324** |
| | | | | |
| **Operating loss** | **(501,784)** | **(453,237)** | **(1,709,904)** | **(1,435,689)** |
| | | | | |
| **Other income (expense):** | | | | |
| Interest income | 17,487 | 24,140 | 69,262 | 28,685 |
| Interest expense | - | - | - | (39) |
| Other | - | 600 | - | (8,863) |
| | 17,487 | 24,740 | 69,262 | 19,783 |
| | | | | |
| Loss before expense for income tax | (484,297) | (428,497) | (1,640,642) | (1,415,906) |
| Income tax benefit (expense) | - | 46,376 | (8,067) | - |
| | | | | |
| **Net loss** | **$ (484,297)** | **$ (382,121)** | **$ (1,648,709)** | **$ (1,415,906)** |
| | | | | |
| **Basic and diluted net loss per share** | **$ (0.08)** | **$ (0.06)** | **$ (0.26)** | **$ (0.23)** |
| | | | | |
| **Shares used in computation of basic and diluted net loss per share** | **6,275,758** | **6,075,758** | **6,254,792** | **6,034,301** |

**See accompanying notes to consolidated financial statements**

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2010** | **2009** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (1,648,709) | $ (1,415,906) |
| Adjustments to reconcile net loss to net cash provided by operating activities: | | |
| Depreciation and amortization | 9,770 | 25,737 |
| Stock-based compensation expense | 1,710,992 | 1,201,075 |
| Changes in operating assets and liabilities: | | |
| Deferred revenue | (651,836) | (808,844) |
| Accounts receivable | 116,965 | 5,668,405 |
| Prepaid expenses and other current assets | (67,679) | (28,053) |
| Accounts payable and accrued expenses | 457,547 | 20,957 |
| **Net cash provided by (used in) operating activities** | **(72,950)** | **4,663,371** |
| | | |
| **Cash flows from investing activities:** | | |
| Maturities of marketable securities | 4,548,541 | 900,000 |
| Purchases of marketable securities | (5,360,970) | (5,022,854) |
| **Net cash used in investing activities** | **(812,429)** | **(4,122,854)** |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from stock option exercises | 653,375 | 232,924 |
| Purchase of treasury stock | (418,757) | 0 |
| **Net cash provided by financing activities** | **234,618** | **232,924** |
| | | |
| Increase (decrease) in cash and cash equivalents | (650,761) | 773,441 |
| Cash and cash equivalents at beginning of year | 3,950,389 | 3,494,150 |
| **Cash and cash equivalents at end of year** | **$ 3,299,628** | **$ 4,267,591** |
| | | |
| **Supplemental disclosures of cash flow information:** | | |
| 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 nine months ended September 30, 2010 decreased by $45,495 as compared to an increase of $53,440 in the related 2009 period.

**See accompanying notes to consolidated financial statements**

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

**September 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 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, Inc. ( Pfizer ) pursuant to which Pfizer has the right to market XIAFLEX and will do so under the name XIAPEX 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 October 11, 2010 that the first subject has been dosed in the global Phase III program of XIAFLEX for the treatment of Peyronie's disease. The stage global development plan for XIAFLEX will consist of four clinical studies and will be known by the acronym IMPRESS - The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies. There will be two randomized, double-blind, placebo-controlled phase III studies, which are expected to enroll at least 600 patients at approximately 70 sites in the U.S. and Australia, with a 2:1 ratio of XIAFLEX to placebo. There also will be one open label study, which is expected to enroll at least 250 patients, at approximately 30 sites in the U.S., EU and New Zealand, and one pharmacokinetic study, which it expected to enroll approximately 16 patients.

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.

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 Reports on Form 10-Q for the quarterly periods ended March 31, 2010 and June 30, 2010 filed with the SEC on May 10, 2010 and August 9, 2010 respectively, and our 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 September 30, 2010:

| | Level 1 | Level 2 | Level 3 |
|---|---|---|---|
| Cash and cash equivalents | $ 3,299,628 | - | - |
| Certificates of Deposit | 5,360,970 | - | - |

**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. In October 2010, we received information from Auxilium clarifying the royalty and mark-up on cost of goods sold reports from Auxilium for the first and second quarters of 2010. We recognized revenue from the first and second quarters of 2010 in the third quarter of 2010. For future periods, the royalty, mark-up on cost of goods sold revenues will generally be recognized in the quarter that Auxilium provides the written reports and related information to us, that is, royalty and mark up on cost of goods sold revenues are generally recognized one quarter following the quarter in which sales by Auxilium occurred.

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. In October 2010, we received an updated invoice from Auxilium for approximately $3.5 million which represents an increase of approximately $13,000 in the total amount due that Auxilium believes is owed by us through September 30, 2010 under this provision. The increase was primarily due to certain patent costs. Any amount ultimately agreed as being owed by us to Auxilium for lyophilization expenses and patent expenses are creditable against future royalties payable by Auxilium on net sales of XIAFLEX. We recognized approximately $0.2 million related to royalty revenue from the sale of XIAFLEX in the first and second quarters of 2010. Based upon the updated invoice and the royalty revenue reported to us, we reduced our estimates for reimbursable third party development and certain patent costs to approximately $3.3 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 the next twelve months, and we have re-classified accrued third party development costs from long-term liabilities to current liabilities on our balance sheet as of September 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 nine months ended September 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2010** | **2009** | **2010** | **2009** |
| Research and development | $ 27,116 | $ 33,305 | $ 82,269 | $ 76,948 |
| General and administrative | 362,104 | 284,879 | 1,628,724 | 1,124,126 |
| **Total stock-based compensation expense** | **$ 389,220** | **$ 318,184** | **$ 1,710,993** | **$ 1,201,074** |

*Stock Option Activity*

A summary of our stock option activity during the nine months ended September 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 | - | - |
| **Outstanding as of September 30, 2010** | **1,366,425** | **$ 7.71** |
| | | |
| **Exercisable as of September 30, 2010** | **1,223,925** | **$ 6.16** |

The Company did not grant stock options during the nine months ended September 30, 2010. The total number of outstanding options as of September 30, 2010 was 1,366,425.

During the nine months ended September 30, 2010 and 2009, $653,375 and $232,924, respectively, were received from stock options exercised by option holders.

The aggregate intrinsic value of options outstanding and exercisable as of September 30, 2010 was approximately $25.5 million. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our common stock of $26.92 on September 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 September 30, 2010 was approximately $0.9 million which we expect to recognize over a weighted-average period of 1.2 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 October 2010, the FASB issued a proposed Accounting Standards Update (ASU), “Receivables (Topic 310): Clarifications to Accounting for Troubled Debt Restructurings (“TDR”) by Creditors” to assist creditors in determining whether a modification is a TDR. Currently, there is diversity in practice in identifying loan modifications that constitute TDRs, particularly when determining whether a concession has been granted. The clarifications are proposed to be effective for interim and annual periods ending after June 15, 2011, and would be applied retrospectively to restructurings occurring on or after the beginning of the earliest period presented. The Company does not expect ASU-310 will have a material effect on its consolidated results of operations, financial position or liquidity.

In September 2010, the FASB issued ASU-2010-25, Plan Accounting—Defined Contribution Pension Plans (Topic 962). The objective of the amendments in this Update is to clarify how loans to participants should be classified and measured by defined contribution pension benefit plans. Participant loans are currently classified as investments in accordance with the defined contribution pension plan guidance in paragraph 962-325-45-10. Subtopic 962-325 requires most investments held by a plan, including participant loans, to be presented at fair value. Topic 820, Fair Value Measurements and Disclosures, provides specific guidance on how fair value should be measured.

The amendments in this Update require that participant loans be classified as notes receivable from participants, which are segregated from plan investments and measured at their unpaid principal balance plus any accrued but unpaid interest. The Company does not believe ASU-2010-25 will have any material effect on its consolidated results of operations, financial position or liquidity.

In July 2010, the FASB issued an additional disclosure requirement regarding credit quality and the allowance for credit losses. The new disclosures will require significantly more information about credit quality in a financial institution's portfolio. Although this statement addresses only disclosures and does not seek to change recognition or measurement, the disclosure represents a meaningful change in practice. The new disclosure requirement affects loans, trade accounts receivable, notes receivable, credit cards, leveraged leases, direct financing leases, and sales-type leases. It requires two levels of disaggregation for disclosure: portfolio segment and class of financing receivable, such as commercial, consumer or residential loans. It will be effective for interim and annual reporting periods ending after December 15, 2010. The Company does not expect the provisions of this requirement will have a material effect 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 nine months ended September 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2010** | **2009** | **2010** | **2009** |
| **Stock options** | **902,134** | **1,025,466** | **936,615** | **983,828** |

**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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2010** | **2009** | **2010** | **2009** |
| Net loss | $ (484,297) | $ (382,121) | $ (1,648,709) | $ (1,415,906) |
| Other comprehensive loss: | | | | |
| Change in unrealized losses on marketable securities | **-** | - | **-** | - |
| **Total Comprehensive Loss** | **$ (484,297)** | **$ (382,121)** | **$ (1,648,709)** | **$ (1,415,906)** |

**5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consisted of the following:

| | **September 30, 2010** | **December 31, 2009** |
|---|---|---|
| Trade accounts payable and accrued expenses | $ 466,553 | $ $ 378,872 |
| Accrued legal and other professional fees | 43,016 | 70,935 |
| Accrued payroll and related costs | 138,610 | 134,702 |
| **Total** | **$ 648,179** | **$ 584,509** |

**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 September 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:

| | September 30, 2010 | December 31, 2009 |
|---|---|---|
| Patents | $ 245,962 | $ 282,297 |
| Accumulated Amortization | (67,999) | (58,839) |
| | $ 177,963 | $ 223,458 |

The amortization expense for patents was $9,160 for the nine months ended September 30, 2010. (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 $24,472. The estimated aggregate amortization expense for each of the next five years is approximately as follows:

| | |
|---|---|
| 2011 | $ 36,000 |
| 2012 | 34,000 |
| 2013 | 31,000 |
| 2014 | 25,000 |
| 2015 | 10,000 |

**7. INCOME TAXES**

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

| | September 30 2010 | December 31, 2009 |
|---|---|---|
| Computed tax expense at statutory rate | (34.0)% | (34.0)% |
| Deferred revenues | (13.2)% | (17.1)% |
| Stock-based compensation | 35.2% | 23.9% |
| Tax benefit of NOL | 12.0% | -% |
| 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:

| | September 30, 2010 | December 31, 2009 |
|---|---|---|
| Tax Credit carryforward | 1,128,724 | 1,039,390 |
| Deferred revenues | 536,899 | 741,714 |
| Other | - | 54,846 |
| Options | 1,985,327 | 406,517 |
| Net operating loss carryforward | 1,841,808 | 556,504 |
| Net deferred tax assets before valuation allowance | 5,492,758 | 2,798,971 |
| Valuation allowance | (5,492,758) | (2,798,971) |

| | | |
|---|---|---|
| Net deferred tax asset | - | - |

For the nine month period ended September 30, 2010, the valuation allowance increased by approximately $2.7 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 $0.2 million in deferred tax assets related to deferred revenue recognized during the period. An increase of $0.1 million in the tax credit carry-forward relating to a portion of the general business credit which was freed-up with the NOL carry-back. A decrease of $0.1 million in other and an increase in the net operating loss carry-forward of $1.3 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**

On November 3, 2010, we announced that we received $426,000 in grant funding under the Qualifying Therapeutic Discovery Project (QTDP) Program. The program, funded through the US Patient Protection and Affordable Care Act of 2010, supports therapeutic discovery programs.

We received two separate grants of $244,000 and $182,000, respectively. The first grant is for the clinical development of injectable collagenase in human lipomas. The second grant will fund a project related to the development of improved collagenases for tissue disassociation related to cellular therapy. Two partial grant payments were authorized on October 29, 2010 and the remaining allocated amounts will be authorized for payment no later than 30 days after the end of the 2010 calendar year.

**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. 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'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, Inc. ("Pfizer") pursuant to which Pfizer has the right to market XIAFLEX and will do so under the name XIAPEX 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 October 11, 2010 that the first subject has been dosed in the global Phase III program of XIAFLEX for the treatment of Peyronie's disease. The stage global development plan for XIAFLEX will consist of four clinical studies and will be known by the acronym IMPRESS - The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies. There will be two randomized, double-blind, placebo-controlled phase III studies, which are expected to enroll at least 600 patients at approximately 70 sites in the U.S. and Australia, with a 2:1 ratio of XIAFLEX to placebo. There also will be one open label study, which is expected to enroll at least 250 patients, at approximately 30 sites in the U.S., EU and New Zealand, and one pharmacokinetic study, which is expected to enroll approximately 16 patients.

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.

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.

**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 earn-out payments based on the sales of certain products, as well as revenue related to certain technical assistance and certain transition services that we provide to DFB. 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. 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 September 30, 2010, we had an accumulated deficit from continuing operations of approximately $10.0 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 September 30, 2010 and for the three and nine months ended September 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 quarters ended March 31, 2010 and June 30, 2010 filed with the SEC on May 10, 2010 and August 9, 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. In October 2010, we received information from Auxilium clarifying the royalty and mark-up on cost of goods sold reports from Auxilium for the first and second quarters of 2010. We recognized revenue from the first and second quarters of 2010 in the third quarter of 2010. For future periods, the royalty, mark-up on cost of goods sold revenues will generally be recognized in the quarter that Auxilium provides the written reports and related information to us, that is, royalty and mark up on cost of goods sold revenues are generally recognized one quarter following the quarter in which sales by Auxilium occurred.

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. In October 2010, we received an updated invoice from Auxilium for approximately $3.5 million which represents an increase of approximately $13,000 in the total amount due that Auxilium believes is owed by us through September 30, 2010 under this provision. The increase was primarily due to certain patent costs. Any amount ultimately agreed as being owed by us to Auxilium for lyophilization expenses and patent expenses are creditable against future royalties payable by Auxilium on net sales of XIAFLEX. We recognized approximately $0.2 million related to royalty revenue from the sale of XIAFLEX in the first and second quarters of 2010. Based upon the updated invoice and the royalty revenue reported to us, we reduced our estimates for reimbursable third party development and certain patent costs to approximately $3.3 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 the next twelve months, 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 September 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 SEPTEMBER 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 September 30, 2010 and 2009, product revenues were $5,183 and $19,089, respectively. This decrease of $13,906, or 73%, was primarily related to the amount of material required to perform testing by our customers.

*Royalties/Earn-out*

Total royalty and earn-out revenues for the three months ended September 30, 2010 were $819,639 as compared to $481,197 in the 2009 period. 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 September 30, 2010 were $592,793 and $481,197 for the same period in 2009. This increase of $111,556 or 23% is mainly related to the increase in net sales during the 2010 period reported to us by DFB.

As of September 30, 2010, we began to recognize royalties and the mark-up on cost of goods sold due to us under the terms of the Auxilium Agreement. Royalty and cost of goods sold revenues recognized under the Auxilium Agreement for the three months ended September 30, 2010 were $226,886 and zero in the comparable period of 2009. The increase was due to the net sales of XIAFLEX during the first two quarters of 2010 reported to us by Auxilium. Auxilium received marketing approval from the FDA for XIAFLEX for the treatment of adult Dupuytren's contracture patients with palpable cord in February 2010.

*Licensing, Sublicensing and Milestone Revenues*

For the three months ended September 30, 2010 and 2009, we recognized licensing revenue of $109,275 and $266,282, 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. The decrease of $157,007, 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 in February 2010.

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 September 30, 2010 and 2009 consulting revenues were $70,000 in each period.

**Costs and Expenses**

*Research and Development Activities*

Research and development expenses were $216,571 and $112,920, respectively, for the three months ended September 30, 2010 and 2009. This increase of $103,651, or 92%, in research and development expenses was primarily due to preclinical expenses and consulting services related to our animal study.

*General and Administrative Expenses*

General and administrative expenses were $1,289,310 and $1,176,885, respectively, for the three months ended September 30, 2010 and 2009. The increase in general and administrative expenses of $112,425 or 10% was due to legal expenses and stock based compensation partially offset by lower consulting services.

*Other Income (expense), net*

Other income, net, was $17,487 for the three months ended September 30, 2010 as compared to $24,740 for the same period in 2009, representing a change of $7,253. Components of other income, net, consist of investment income, interest expense and other, net. Investment income for the three months ended September 30, 2010 was $17,487 as compared to $24,140 for the same period in 2009. This decrease of $6,653 was primarily due to lower interests rates during the 2010 period. Interest expense for the three months ended September 30, 2010 was zero and $600 for the same period in 2009.

*Income Taxes*

Income tax benefit for the three months ended September 30, 2010 and 2009 was zero and $46,376, respectively. The tax benefit in 2009 was due to a carry back of the windfall tax deductible expenses resulting from the exercise and sale of non-qualified employee stock options during the 2009 period.

*Net Loss*

As a result of the above discussion, we recorded a net loss of $0.5 million for the three months ended September 30, 2010, or $0.08 per basic and diluted common share, compared to a net loss of $0.4 million, or $0.06 per basic and diluted common share, for the same period in 2009.

**NINE-MONTHS ENDED SEPTEMBER 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 nine months ended September 30, 2010 and 2009, product revenues were $32,328 and $36,194, respectively. This decrease of $3,866, or 11%, was primarily related to the amount of material required to perform testing by our customers.

*Royalties/Earn-out*

Total royalty and earn-out revenues for the nine months ended September 30, 2010 were $1,358,773 as compared to $856,597 in the 2009 period. 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 nine months ended September 30, 2010 were $1,131,887 and $856,597 for the same period in 2009. This increase of $275,290 or 32% is mainly related to the increase in net sales during the 2010 period reported to us by DFB.

As of September 30, 2010, we began to recognize royalties and the mark-up on cost of goods sold due to us under the terms of the Auxilium Agreement. Royalty and cost of goods sold revenues recognized under the Auxilium Agreement for the nine months ended September 30, 2010 were $226,886 and zero in the comparable period of 2009. The increase was due to the net sales of XIAFLEX during the first two quarters of 2010 reported to us by Auxilium. Auxilium received marketing approval from the FDA for XIAFLEX for the treatment of adult Dupuytren's contracture patients with palpable cord in February 2010.

*Licensing, Sublicensing and Milestone Revenues*

For the nine months ended September 30, 2010 and 2009, we recognized total licensing and milestone revenue of $2,916,835 and $1,298,844, 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. Licensing revenue recognized for the nine months ended September 30, 2010 and 2009 were $641,835 and $798,845, respectively. The decrease of $157,010, or 20%, was mainly due to the completed recognition of licensing revenue associated with the Dupuytren's contracture indication during the first quarter of 2010.

Milestone revenue recognized for the nine months ended September 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 and 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 nine months ended September 30, 2010 and 2009 consulting revenues were $210,000 in each period.

**Costs and Expenses**

*Research and Development Activities*

Research and development expenses were $1,258,187 and $352,983, respectively, for the nine months ended September 30, 2010 and 2009. This increase of $905,204 or 256%, 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 $4,969,653 and $3,484,341, respectively, for the nine months ended September 30, 2010 and 2009. The increase in general and administrative expenses of $1,485,312 or 30%, was due to legal fees, stock based compensation, services related to investor relations and consulting services and partially offset by lower patent costs.

*Other Income (expense), net*

Other income, net, was $69,262 for the nine months ended September 30, 2010 as compared to other expense, net, of $19,783 for the same period in 2009, representing a change of $49,479. Components of other income, net, consist of investment income, interest expense and other, net. Investment income for the nine months ended September 30, 2010 was $69,262 as compared to $28,685 for the same period in 2009. This increase of $40,577 was primarily due to higher invested balances during the 2010 period. Interest expense for the nine months ended September 30, 2010 and 2009 was zero and $39, respectively. Other expense for the nine months ended September 30, 2010 was zero as compared to $8,863 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 nine months ended September 30, 2010 and 2009 was $8,067 and zero, respectively. The income tax expense for the 2010 period is primarily related to the payment of New York state taxes.

*Net Loss*

As a result of the above discussion, we recorded a net loss of $1.6 million for the nine months ended September 30, 2010, or $0.26 per basic and diluted common share, compared to a net loss of $1.4 million, or $0.23 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 September 30, 2010 and December 31, 2009, we had cash and cash equivalents in the aggregate of approximately $3.3 million and $4.0 million, respectively.

***Continuing Operations***

Net cash used in operating activities for the nine months ended September 30, 2010 was $0.1 million as compared to net cash provided by operating activities of $4.7 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 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 an increase in accounts payable and accrued expenses.

Net cash used in investing activities for the nine months ended September 30, 2010 and 2009 was $0.8 million and $4.1 million, respectively. The change in net cash used in investing activities reflects the redemption of marketable securities of $4.5 million in the 2010 period as compared to $0.9 million in the 2009 period.

Net cash provided by financing activities for the nine months ended September 30, 2010 and 2009 was $0.2 million in each period. The change in net cash provided by financing activities was due to stock repurchases of $0.4 million, 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 of $0.7 million in the 2010 period as compared to $0.2 million in 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 September 30, 2010, amounting to approximately $8.7 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 September 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. None 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 Rule13a-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 8, 2010

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