

BIOSPECIFICS TECHNOLOGIES CORP  
Form 10-Q  
May 10, 2011

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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 March 31, 2011**

☐ 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 ☐  
Non-accelerated filer ☐

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:

Class of Stock

Outstanding May 6, 2011

Common Stock (\$.001 par value)

6,353,868

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**BIOSPECIFICS TECHNOLOGIES CORP.**

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**Introductory Comments   Terminology**

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

**Introductory Comments   Forward-Looking Statements**

This Report contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding BioSpecifics' strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, its expected revenue growth, and any other statements containing the words believes, expects, anticipates, plans, estimates and similar expressions, are forward-looking statements. There are a number of important factors that could cause its actual results to differ materially from those indicated by such forward-looking statements, including the statements made by BioSpecifics and by its partner Auxilium Pharmaceuticals, Inc. ( Auxilium ) regarding progress toward achievement of Auxilium's objectives for the US launch of XIAFLEX<sup>®</sup> for Dupuytren's contracture; the ability of Pfizer, Inc. to achieve its objectives for XIAPEX<sup>®</sup> in Europe; the ability of Asahi Kasei to achieve its objectives for XIAFLEX<sup>®</sup> in Japan; the success of the Phase 3 trials for XIAFLEX for the treatment of Peyronie's disease; the outcome of the dispute with Auxilium over the Company's right to conduct clinical trials; the Company's ability to restart the Chien-803 trial for injectable collagenase for the treatment of canine lipomas and the clinical success of that trial; the Company's ability to initiate and complete clinical trials in additional indications, all of which will determine the amount of milestone, royalty and sublicense income BioSpecifics may receive; and other risk factors identified in the Company's Form 10-K for the year ended December 31, 2010 and its reports on Form 8-K filed with the SEC. All forward-looking statements included in this Report are made as of the date hereof, and the Company assumes no obligation to update these forward-looking statements.

**PART I FINANCIAL INFORMATION****Item 1: Consolidated Financial Statements****BioSpecifics Technologies Corp.  
Consolidated Balance Sheets**

	<b>March 31, 2011</b> (unaudited)	<b>December 31, 2010</b> (audited)
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 3,145,359	\$ 2,470,852
Short-term investments	5,360,970	5,360,970
Accounts receivable, net	1,016,027	1,986,125
Income tax receivable	185,386	185,386
Deferred tax assets	2,321,286	-
Prepaid expenses and other current assets	80,489	91,925
<b>Total current assets</b>	<b>12,109,517</b>	<b>10,095,258</b>
Deferred royalty buy-down	1,250,000	1,250,000
Deferred tax assets long term	1,217,954	-
Patent costs, net	176,677	173,443
<b>Total assets</b>	<b>14,754,148</b>	<b>11,518,701</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	1,177,655	893,083
Accrued third-party development expenses	1,931,365	2,649,369
Deferred revenue	437,101	483,769
Accrued liabilities of discontinued operations	78,138	78,138
<b>Total current liabilities</b>	<b>3,624,259</b>	<b>4,104,359</b>
Long-term deferred revenue	604,344	713,619
<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; 6,445,743 shares issued at March 31, 2011 and December 31, 2010	6,446	6,446
Additional paid-in capital	17,889,930	17,739,765
Accumulated deficit	(6,202,407)	(9,893,530)
Treasury stock, 151,875 shares at cost at March 31, 2011 and December 31, 2010	(1,151,958)	(1,151,958)
<b>Total stockholders' equity</b>	<b>10,525,545</b>	<b>6,700,723</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 14,754,148</b>	<b>\$ 11,518,701</b>
<b>See accompanying notes to consolidated financial statements</b>		



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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Revenues:</b>		
Net sales	\$ 5,892	\$ 8,936
Royalties	945,081	31,812
Licensing revenues	859,275	2,548,284
Consulting fees	46,667	70,000
<b>Total Revenues</b>	<b>1,856,915</b>	<b>2,659,032</b>
<b>Costs and expenses:</b>		
Research and development	212,066	896,817
General and administrative	1,509,526	2,034,178
<b>Total Cost and Expenses</b>	<b>1,721,592</b>	<b>2,930,995</b>
<b>Operating income (loss)</b>	<b>135,323</b>	<b>(271,963)</b>
<b>Other income (expense):</b>		
Interest income	16,560	25,850
Income (loss) before expense for income tax	151,883	(246,113)
Income tax benefit (expense)	3,539,240	(8,067)
<b>Net income (loss)</b>	<b>\$ 3,691,123</b>	<b>\$ (254,180)</b>
<b>Basic net income (loss) per share</b>	<b>\$ 0.59</b>	<b>\$ (0.04)</b>
<b>Diluted net income (loss) per share</b>	<b>\$ 0.51</b>	<b>\$ (0.04)</b>
<b>Shares used in computation of basic net income (loss) per share</b>	<b>6,293,868</b>	<b>6,213,995</b>
<b>Shares used in computation of diluted net income (loss) per share</b>	<b>7,203,324</b>	<b>6,213,995</b>

See accompanying notes to consolidated financial statements

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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ 3,691,123	\$ (254,180)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	10,610	9,914
Stock-based compensation expense	133,698	775,068
Changes in operating assets and liabilities:		
Deferred revenue	(155,943)	(143,284)
Deferred tax assets	(3,539,240)	-
Accounts receivable	970,098	1,067,847
Prepaid expenses and other current assets	11,436	(12,105)
Accounts payable and accrued expenses	(447,275)	1,303,171
<b>Net cash provided by operating activities</b>	<b>674,507</b>	<b>2,746,431</b>
<b>Cash flows from financing activities:</b>		
Proceeds from stock option exercises	-	36,800
<b>Net cash provided by financing activities</b>	<b>-</b>	<b>36,800</b>
Increase (decrease) in cash and cash equivalents	674,507	2,783,231
Cash and cash equivalents at beginning of year	2,470,852	3,950,389
<b>Cash and cash equivalents at end of year</b>	<b>\$ 3,145,359</b>	<b>\$ 6,733,620</b>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid during the year for:		
Interest	\$ -	\$ -
Taxes	\$ -	\$ 9,851
<b>Supplemental disclosures of non-cash transactions:</b>		

Under our agreement with Auxilium certain patent costs paid by Auxilium on behalf of the Company are creditable against future royalties. As of March 31, 2011 we accrued \$13,844 related to these costs of which \$10,610 was amortized in the 2011 period and \$9,710 in the 2010 comparable period.

**See accompanying notes to consolidated financial statements**



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

**March 31, 2011**  
**(Unaudited)**

**1. ORGANIZATION AND DESCRIPTION OF BUSINESS**

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement (the *Auxilium Agreement*) with Auxilium Pharmaceuticals, Inc. (*Auxilium*) for injectable collagenase (which Auxilium has named XIAFLEX (collagenase clostridium histolyticum)) 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 human and canine lipoma and cellulite. Auxilium has an agreement with Pfizer, Inc. (*Pfizer*), pursuant to which Pfizer has the right to market XIAFLEX for Dupuytren's contracture and Peyronie's disease in 27 member countries of the European Union and 19 other European and Eurasian countries, and will do so under the registered trademark XIAPEX (collagenase clostridium histolyticum). In addition, Auxilium has an agreement with Asahi Kasei Pharma Corporation (*Asahi*) pursuant to which Asahi has the right to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan.

Until March 2011, we received, pursuant to a March 2006 agreement (the *DFB Agreement*) between the Company and DFB Biotech, Inc. (*DFB*), payments for certain technical assistance and certain transition services that we provided to DFB. Under the DFB Agreement, we continue to receive earn out payments based on the sales of certain products. Our right to receive earn out payments with respect to the marketed topical product sold to DFB expires in June 2013, but earn out payments for second generation collagenase products, if any, continue indefinitely.

*Operational Highlights*

In April 2011, Auxilium announced it will receive a \$30 million regulatory milestone payment from its EU partner, Pfizer, following the first sale of XIAPEX in a major EU market. XIAPEX is a new non-surgical treatment option for Dupuytren's contracture in adult patients with a palpable cord and is the first injectable treatment to be approved in the EU for the treatment of Dupuytren's contracture. The sale in the first major EU market occurred in the United Kingdom. We will recognize \$2.55 million of the \$30 million regulatory milestone paid to Auxilium by Pfizer under our agreement with Auxilium in the second quarter of 2011. We will receive 8.5% of the \$365 million in potential additional milestone payments that may be made by Pfizer to Auxilium under the Pfizer Agreement. For example, we will receive 8.5% of each additional \$7.5 million milestone payment (\$30 million in aggregate) made as a result of the first commercial sale in each of the following additional major European markets: France, Italy, Germany and Spain. In addition, we will receive 8.5% of all additional sublicense income Auxilium receives from Pfizer, a markup on the cost of goods sold and low double digit royalties as a percent of net sales independent of clinical indication, territory and sales volume.

In March 2011, Auxilium and Asahi announced that they had entered into a long-term strategic alliance for the development, commercialization and supply of XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease. Under the terms of the agreement, Asahi paid Auxilium a \$15 million upfront fee and received rights to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan. We recognized in the first quarter of 2011 \$0.75 million related to the upfront fee paid to Auxilium, although we dispute the calculation of this amount. Asahi will also make up to \$247 million in potential milestone payments which we will be entitled to a certain percentage of, with \$37 million tied to development and regulatory milestones and \$210 million based on sales milestones. Asahi will be primarily responsible for the clinical development, regulatory and commercialization activities for XIAFLEX in Japan. In addition, we will receive a different percentage depending upon the indication of all additional sublicense income Auxilium receives from Asahi, a markup on the cost of goods

sold and low double digit royalties as a percent of net sales independent of clinical indication and sales volume in Japan.

In March 2011, Auxilium announced it had reached the target enrollment for the double-blind placebo-controlled phase III program of XIAFLEX for the treatment of Peyronie's disease. Peyronie's disease is the development of a collagen plaque on the penis that can cause the penis to curve during erection, often interfering with or preventing intercourse and resulting in psychological distress or bother for the patient.

In February 2011, we announced that our Board of Directors amended its Rights Agreement. The amendment increases the ownership threshold for determining Acquiring Person status under the rights Agreement from 15%-18% and extends the Final Expiration Date for an additional two years, to May 31, 2014.

On January 6, 2011, we announced promising results from our study Chien-802 showing reductions in canine lipoma following injections with purified injectable collagenase. These results build upon an earlier dose escalation study from which the Company selected the dose for Chien-802. The Company also announced the initiation of a larger clinical trial, Chien-803, for the same indication. However, Auxilium filed a complaint against BioSpecifics (Court of Common Pleas in Chester County, Pennsylvania) concerning its right to conduct clinical trials without Auxilium's approval. In response to the lawsuit, BioSpecifics voluntarily agreed to suspend Chien-803 and will not be initiating any new trials using injectable collagenase in animals or humans pending resolution of dispute.

## **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 Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC on March 14, 2011.

### **Principles of Consolidation**

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

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

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles 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 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. Actual results could differ from those estimates. While our significant accounting policies are described in more detail in the notes to our consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

### **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. 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 March 31, 2011:

	Level 1	Level 2	Level 3
Cash and cash equivalents	\$ 3,145,359	-	-
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. 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. The royalties payable by Auxilium to us are subject to set-off for certain third party development and patent costs.

Under the DFB Agreement, pursuant to which we sold our topical collagenase business to 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.

### ***License and Sublicense Fees***

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

#### ***Consulting and Technical Assistance Services***

We recognize revenues from 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 and technical assistance obligations to DFB expired in 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.

As of March 31, 2011, accounts receivables included approximately \$0.75 million mainly due from Auxilium related to a sublicense fee.

#### **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 the first quarter of 2011, we recognized approximately \$0.8 million related to royalty revenue from the sale of XIAFLEX. Based upon the royalty revenue reported to us, we reduced our estimates for reimbursable third party development and certain patent costs to approximately \$1.9 million. Any amount ultimately agreed or determined 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 have an ongoing dispute with Auxilium concerning the appropriate amount of creditable lyophilization and patent expenses.

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. We have classified accrued third party development costs as current liabilities on our balance sheet as of March 31, 2011.

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

### **Research and Development Expenses**

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

### **Clinical Trial Expenses**

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

### **Stock-Based Compensation**

The Company has two stock-based compensation plans in effect. Accounting Standards Codification 718, *Compensation - Stock Compensation* ( ASC 718 ) requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based awards including stock options and common stock issued to our

employees and directors under our stock plans. It requires companies to estimate the fair value of share-based awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service periods in our Consolidated Statements of Operations.

Under the 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. 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 stock options during the first quarter of 2011.

Further, ASC 718 requires that employee stock-based compensation costs to be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. The allocation of employee stock-based compensation costs to each operating expense line are estimated based on specific employee headcount information at each grant date and estimated stock option forfeiture rates and revised, if necessary, in future periods if actual employee headcount information or forfeitures differ materially from those estimates. As a result, the amount of employee stock-based compensation costs we recognize in each operating expense category in future periods may differ significantly from what we have recorded in the current period.

Stock-based compensation expense recognized under ASC 718 was as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Research and development	\$ 27,116	\$ 23,637
General and administrative	106,582	751,431
<b>Total stock-based compensation expense</b>	<b>\$ 133,698</b>	<b>\$ 775,068</b>

*Stock Option Activity*

A summary of our stock option activity during the three months ended March 31, 2011 is presented below:

<b>Options</b>	<b>Total Number of Shares</b>	<b>Weighted- Average Exercise Price</b>
Outstanding as of December 31, 2010	1,346,425	\$ 7.81
Granted	-	-
Forfeited	-	-
Exercised	-	-
Expired	-	-
<b>Outstanding as of March 31, 2011</b>	<b>1,346,425</b>	<b>\$ 7.81</b>

<b>Exercisable as of March 31, 2011</b>	<b>1,231,425</b>	<b>\$ 6.66</b>
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During the three months ended March 31, 2011 and 2010, zero and \$36,800, respectively, were received from stock options exercised by option holders.

The aggregate intrinsic value of options outstanding and exercisable as of March 31, 2011 was approximately \$23.2 million. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our common stock of \$25.50 on March 31, 2011, which would have been received by the option holders had all option

holders exercised their options as of that date. Total unrecognized compensation cost related to non-vested stock options outstanding as of March 31, 2011 was approximately \$0.5 million which we expect to recognize over a weighted-average period of 1.1 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.

## **Income Taxes**

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the appropriate period.

We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. In making such determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations.

## **Future Impact of Recently Issued Accounting Standards**

In March 2010, the Financial Accounting Standards Board ( FASB ) amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We adopted this amended guidance for the fiscal year beginning January 1, 2011. The adoption of this amendment did not have any impact on our consolidated financial statements.

In February 2010, the FASB issued update No. 2010-09, *Subsequent Events (Topic 855): Amendments to Certain Recognition and Disclosure Requirements*. This update provides amendments to Subtopic 855-10 for an entity that is an SEC filer and is required to evaluate subsequent events through the date that the financial statements are issued. An entity that is an SEC filer is not required to disclose the date through which subsequent events have been evaluated. The adoption of this update did not have any impact on our consolidated financial statements.

In January 2010, the FASB issued ASU 2010-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements* . ASU 2010-06 amends the fair value disclosure guidance to include new disclosures and changes to clarify existing disclosure requirements. These amended standards require disclosures about inputs and valuation techniques used to measure fair value as well as disclosures about significant transfers, beginning in the first quarter of 2010. Additionally, these amended standards require presentation of disaggregated activity within the reconciliation for fair value measurements using significant unobservable inputs (Level 3), beginning in the first quarter of 2011. The adoption of these new standards did not materially impact our consolidated financial statements.

There were various other updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to have a material impact on the on our consolidated financial statements.

## **3. NET INCOME (LOSS) PER SHARE**

In accordance with Accounting Standards Codification 260, *Earnings Per Share*, basic net income (loss) per share amount is computed using the weighted-average number of shares of common stock outstanding during the periods

presented, while diluted net income (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.

The following table summarizes the number of common equivalent shares that may be included for the calculation of diluted net income purposes from continuing operations reported in the consolidated statement of operations. For the three months ended March 31, 2010, 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 for that period, as their effect would have been anti-dilutive.

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Stock options</b>	<b>909,456</b>	<b>930,625</b>
<b>4. TOTAL COMPREHENSIVE INCOME (LOSS)</b>		

Comprehensive loss is comprised of net income (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 income (loss). The following table presents the calculation of our comprehensive income (loss):

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Net income (loss)	\$ 3,691,123	\$ (254,180)
Other comprehensive loss:		
Change in unrealized losses on marketable securities	-	-
<b>Total Comprehensive Income (Loss)</b>	<b>\$ 3,691,123</b>	<b>\$ (254,180)</b>
<b>5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES</b>		

Accounts payable and accrued expenses consisted of the following:

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
Trade accounts payable and accrued expenses	\$ 994,031	\$ 674,917
Accrued legal and other professional fees	37,016	77,442
Accrued payroll and related costs	146,608	140,725
<b>Total</b>	<b>\$ 1,177,655</b>	<b>\$ 893,084</b>

#### **6. PATENT COSTS**

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 10 years, and review for impairment on a quarterly basis and when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

As of March 31, 2011, 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:

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
Patents	\$ 264,465	\$ 250,621
Accumulated Amortization	(87,788)	(77,178)
	<b>\$ 176,677</b>	<b>\$ 173,443</b>

The amortization expense for patents was \$10,610 for the three months ended March 31, 2011. (See Note 1: **Reimbursable Third Party Development Costs** for a more detailed description of the change) In the comparable period of 2010, the amortization expense for patents was \$9,710. The estimated aggregate amortization expense for each of the next five years is approximately as follows:



2012	\$	37,000
2013		35,000
2014		27,000
2015		10,000
2016		10,000

## 7. INCOME TAXES

The significant components of the Company's deferred tax assets, pursuant to Accounting Standards Codification 740-10-50 consist of net operating losses, orphan tax credits, stock-based compensation and deferred revenues. For the three month period ended March 31, 2011, the valuation allowance reversed by approximately \$3.6 million with respect to the Company's net deferred tax assets and corresponding tax benefit reduced the Company's statutory tax rate of 34% and resulted in net benefit of \$3,539,240. The Company has determined that it is more likely than not that these deferred tax assets would be realized based on the Company's projected annual profitability of operations driven by our revenues under our agreement with Auxilium. Included in the valuation adjustment is a decrease in the net operating loss carry-forward of approximately \$0.1 million which was applied to the current period's federal and state income taxes. The remaining balance of deferred tax assets as of March 31, 2011 is approximately \$3.5 million.

## 8. QUALIFYING THERAPEUTIC DISCOVERY PROJECT PROGRAM

In November 2010, we were notified that we had been awarded a total cash grant of approximately \$426,000 under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code, of which approximately \$102,000 relates to qualifying expenses we had previously incurred during the 2009 fiscal year which was received during the fourth quarter of fiscal 2010. The remainder of the grant of approximately \$324,000 was received in February 2011 based on qualifying expenses that we incurred during the 2010 fiscal year. We recognized the full \$426,000 of the grant as of the date of notification since we had already incurred all of the qualifying expenses. Since this program is non-recurring, we elected to classify this payment as other income in the Consolidated Statement of Operations for the year ended December 31, 2010.

## 9. RELATED PARTY TRANSACTIONS

Our subsidiary, ABC-NY (together with the Company, the "Tenant") and Wilbur St. Corp. (the "Landlord") were parties to a lease agreement initially dated as of January 30, 1998 and modified as of June 24, 2009 (the "Lease Agreement"), pursuant to which the Landlord leased to the Tenant the premises located at 35 Wilbur Street, Lynbrook, NY 11563 (the "Premises") until June 30, 2010 and for a monthly rental price of \$11,250 (exclusive of real estate taxes) plus utilities. Following the expiration of the Lease Agreement, the Tenant has continued to lease the Premises from the Landlord on a month-to-month basis. We have notified the Landlord of our termination of the Lease Agreement effective March 31, 2011, but continue to hold over pending the closing of the sale described below.

On April 14, 2011, Landlord entered into an agreement to sell the Premises to an unrelated third party named 35 Wilbur Street Associates, LLC ("Third Party Buyer"). The agreement is subject to a 45-day contingency period. Pending the closing of the sale, the Company and the Third Party Buyer have engaged in negotiations concerning entering into a new lease at the reduced rental price of \$10,000 per month (inclusive of current real estate taxes), plus utilities, for a period of six months with an option to renew for an additional six months. If the closing of the sale does not occur or the Third Party Buyer and the Company cannot agree on the terms of the new lease, the Company will need to relocate.

## 10. SUBSEQUENT EVENTS

We have evaluated subsequent events for recognition or disclosure through the time of filing these consolidated financial statements on Form 10-Q with the U.S. Securities and Exchange Commission on May 10, 2011.



## 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 the 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 a development and license agreement (the Auxilium Agreement) with Auxilium Pharmaceuticals, Inc. (Auxilium) for injectable collagenase (which Auxilium has named XIAFLEX (collagenase clostridium histolyticum)) 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 human and canine lipoma and cellulite. Auxilium has an agreement with Pfizer Inc. (Pfizer), pursuant to which Pfizer has the right to market XIAFLEX for Dupuytren's contracture and Peyronie's disease in 27 member countries of the European Union and 19 other European and Eurasian countries, and will do so under the registered trademark XIAPEX (collagenase clostridium histolyticum). In addition, Auxilium has an agreement with Asahi Kasei Pharma Corporation (Asahi) pursuant to which Asahi has the right to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan.

Until March 2011, we received, pursuant to a March 2006 agreement (the DFB Agreement) between the Company and DFB Biotech, Inc. (DFB), payments for certain technical assistance and certain transition services that we provided to DFB. Under the DFB Agreement, we continue to receive earn out payments based on the sales of certain products. Our right to receive earn out payments with respect to the marketed topical product sold to DFB expire in June 2013, but earn out payments for second generation collagenase products, if any, continue indefinitely.

### Operational Highlights

In April 2011, Auxilium announced it will receive a \$30 million regulatory milestone payment from its EU partner, Pfizer, following the first sale of XIAPEX in a major EU market. XIAPEX is a new non-surgical treatment option for Dupuytren's contracture in adult patients with a palpable cord and is the first injectable treatment to be approved in the EU for the treatment of Dupuytren's contracture. The sale in the first major EU market occurred in the United Kingdom. We will recognize \$2.55 million of the \$30 million regulatory milestone paid to Auxilium by Pfizer under our agreement with Auxilium in the second quarter of 2011. We will receive 8.5% of the \$365 million in potential additional milestone payments that may be made by Pfizer to Auxilium under the Pfizer Agreement. For example, we will receive 8.5% of each additional \$7.5 million milestone payment (\$30 million in aggregate) made as a result of the first commercial sale in each of the following additional major European markets: France, Italy, Germany and Spain. In addition, we will receive 8.5% of all additional sublicense income Auxilium receives from Pfizer, a markup on the cost of goods sold and low double digit royalties as a percent of net sales independent of clinical indication, territory and sales volume.

In March 2011, Auxilium and Asahi announced that they had entered into a long-term strategic alliance for the development, commercialization and supply of XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease. Under the terms of the agreement, Asahi paid Auxilium a \$15 million upfront fee and received rights to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan. We recognized in the first quarter of 2011 \$0.75 million related to the upfront fee paid to Auxilium, although we dispute the calculation of this amount. Asahi will also make up to \$247 million in potential milestone payments which we will be entitled to a certain percentage of, with \$37 million tied to development and regulatory milestones and \$210 million based on sales milestones. Asahi will be primarily responsible for the clinical development, regulatory and commercialization activities for XIAFLEX in Japan. In addition, we will receive a different percentage depending upon the indication of all additional sublicense income Auxilium receives from Asahi, a markup on the cost of goods sold and low double digit royalties as a percent of net sales independent of clinical indication and sales volume in

Japan.

In March 2011, Auxilium announced it had reached the target enrollment for the double-blind placebo-controlled phase III program of XIAFLEX for the treatment of Peyronie's disease. Peyronie's disease is the development of a collagen plaque on the penis that can cause the penis to curve during erection, often interfering with or preventing intercourse and resulting in psychological distress or bother for the patient.

In February 2011, we announced that our Board of Directors amended its Rights Agreement. The amendment increases the ownership threshold for determining Acquiring Person status under the rights Agreement from 15% to 18% and

extends the Final Expiration Date for an additional two years, to May 31, 2014.

On January 6, 2011, we announced promising results from our study Chien-802 showing reductions in canine lipoma following injections with purified injectable collagenase. These results build upon an earlier dose escalation study from which the Company selected the dose for Chien-802. The Company also announced the initiation of a larger clinical trial, Chien-803, for the same indication. However, Auxilium filed a complaint against BioSpecifics (Court of Common Pleas in Chester County, Pennsylvania) concerning its right to conduct clinical trials without Auxilium's approval. In response to the lawsuit, BioSpecifics voluntarily agreed to suspend Chien-803 and will not be initiating any new trials using injectable collagenase in animals or humans pending resolution of dispute.

## **Outlook**

Currently, we generate revenue from two primary sources: in connection with the DFB Agreement and in connection with the Auxilium Agreement. Under the DFB Agreement, until March 2011, we received revenue related to certain technical assistance and certain transition services that we provided to DFB. Under the DFB Agreement, we continue to receive earn-out payments from DFB based on the sales of certain products. Under the Auxilium Agreement, we receive sublicense income, royalties, milestones and mark-up on cost of goods sold payments related to the sale and approval of XIAFLEX/XIAPEX as described above.

## **Significant Risks**

In recent history we have had operating losses but expect to achieve sustained profitability on an on-going annual basis. As of March 31, 2011, we had an accumulated deficit from continuing operations of approximately \$6.2 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, which will affect our profitability.

## **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 March 31, 2011 and for the three months ended March 31, 2011 and 2010 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 March 31, 2011 balance sheet amounts and disclosures included herein have been derived from the Company's December 31, 2010 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, 2010 included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2011. 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. 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. The royalties payable by Auxilium to us are subject to set-off for certain third party development and patent costs.

Under the DFB Agreement, pursuant to which we sold our topical collagenase business to 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 and technical assistance obligations to DFB expired in 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 the first quarter of 2011, we recognized approximately \$0.75 million related to royalty revenue from the sale of XIAFLEX. Based upon the royalty revenue reported to us, we reduced our estimates for reimbursable third party development and certain patent costs to approximately \$1.9 million. 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 have an ongoing dispute with Auxilium over the appropriate calculation of the amount of creditable lyophilization and patent expenses.



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. We have classified accrued third party development costs as current liabilities on our balance sheet as of March 31, 2011.

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 and technical assistance obligations expired in 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 March 31, 2011, 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 future employee stock-based awards granted, to the extent any such awards are granted.

Further, ASC 718 requires that employee stock-based compensation costs to be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. The allocation of employee stock-based compensation costs to each operating expense line are estimated based on specific employee headcount information at each grant date and estimated stock option forfeiture rates and revised, if necessary, in future periods if actual employee headcount information or forfeitures differ materially from those estimates. As a result, the amount of employee stock-based compensation costs we recognize in each operating expense category in future periods may differ significantly from what we have recorded in the current period.

## RESULTS OF OPERATIONS

### THREE-MONTHS ENDED MARCH 31, 2011 and 2010

#### 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 March 31, 2011 and 2010, product revenues were \$5,892 and \$8,936, respectively. This decrease of \$3,044, or 34%, 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 March 31, 2011 were \$945,081 as compared to \$31,812 in the 2010 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 March 31, 2011 were \$165,630 and \$31,812 for the same period in 2010. This increase of \$133,818 or 421% is mainly related to the increase in net sales during the 2011 period reported to us by DFB.

We recognized royalties and the mark-up on cost of goods sold due to us under the terms of the Auxilium Agreement during the first quarter of 2011. Royalty and cost of goods sold revenues recognized under the Auxilium Agreement for the three months ended March 31, 2011 were \$779,451 and zero in the comparable period of 2010. This change was due to the net sales of XIAFLEX during the first quarter of 2011 reported to us by Auxilium as they began selling XIAFLEX in March 2010. 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 March 31, 2011 and 2010, we recognized total licensing, sublicensing and milestone revenue of \$859,275 and \$2,548,284, 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 March 31, 2011 was \$109,276 and \$423,284 for the same period in 2010. The decrease of \$314,008, or 74%, was mainly due to accelerating the recognition of the licensing revenue under the Auxilium Agreement in the 2010 quarter that was allocated to the development of XIAFLEX for Dupuytren's contracture. Auxilium received marketing approval from the FDA for XIAFLEX for the treatment of Dupuytren's contracture on February 2, 2010.

Sublicensing income recognized in the period ended March 31, 2011 was \$750,000 compared to zero in the 2010 period. In the 2011 period, we recognized \$750,000 of the \$15 million paid to Auxilium by Ashai for the rights to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan. We dispute the basis for the calculation of this amount.

Milestone revenue recognized for the three months ended March 31, 2011 and 2010 was zero and \$2.275 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 \$850,000 related to the FDA's approval of XIAFLEX for 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 expired in March 2011. For the three months ended March 31, 2011 and 2010 consulting revenues were \$46,667 and \$70,000, respectively.

## **Costs and Expenses**

### *Research and Development Activities*

Research and development expenses were \$212,066 and \$896,817, respectively, for the three months ended March 31, 2011 and 2010. This decrease of \$684,751 or 76% in research and development expenses was primarily due to lower third party development costs incurred in 2011 that were reimbursable under the Auxilium Agreement partially offset by higher preclinical expenses and consulting services related to our animal study.

*General and Administrative Expenses*

General and administrative expenses were \$1,509,526 and \$2,034,178, respectively, for the three months ended March 31, 2011 and 2010. The decrease in general and administrative expenses of \$524,652 or 26% was due to lower stock based compensation and consulting services partially offset by higher legal expenses.

*Other Income (expense), net*

Other income, net, was \$16,560 for the three months ended March 31, 2011 as compared to \$25,850 for the same period in 2010. This decrease of \$9,290 or 36% was primarily due to lower interest received on our invested balances during the 2011 period.

*Income Tax Provision*

Income tax benefit for the three months ended March 31, 2011 was \$3.5 million and as compared to an income tax expense of \$8,067 in the 2010 period. In the 2011 period, we record net deferred tax assets that we believe will more likely than not be realized as we expect to achieve sustained profitability on an on-going annual basis. In making such determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations. Included in the valuation adjustment is a decrease in the net operating loss carry-forward of approximately \$0.1 million which was applied to the current period's federal and state income taxes. The income tax expense for the 2010 period is primarily related to the payment of New York state taxes.

*Net Income (Loss)*

As a result of the above discussion, we recorded a net income of \$3.7 million for the three months ended March 31, 2011, or \$0.59 per basic and \$0.51 per diluted common share, compared to a net loss of \$0.3 million, or \$0.04 per basic and diluted common share, for the same period in 2010.

**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 March 31, 2011 and December 31, 2010, we had cash and cash equivalents and investments in the aggregate of approximately \$8.5 million and \$7.8 million, respectively.

*Continuing Operations*

Net cash provided by operating activities for three months ended March 31, 2011 was \$0.7 million as compared to \$2.7 million for the same period in 2010. The decrease in the 2011 period as compared to the same period in 2010 was primarily attributable to a reduction in accrued expenses associated with reimbursable third party development expenses.

Net cash used in investing activities for the three months ended March 31, 2011 and 2010 was zero in each period.

Net cash provided by financing activities for the three months ended March 31, 2011 and 2010 was zero and \$36,800, respectively. The net cash provided by financing activities in the 2010 period was due to proceeds received from stock option exercises.

*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 March 31, 2011, amounting to approximately \$8.5 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, 2010.

#### **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 March 31, 2011 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**

On May 2, 2011, we filed a complaint against Recipharm AB (Recipharm), Recipharmcobra Holdings Limited (Recipharmcobra) and together with Recipharm, Cobra) and Auxilium in the Supreme Court of the State of New York in Nassau County, New York. We are seeking monetary damages, declaratory judgment and injunctive relief arising out of a Material Transfer Agreement (the MTA) between us and Cobra. Our complaint asserts that Auxilium, despite full knowledge of the terms of the MTA, wrongfully and in breach of an agreement with us that we would benefit from the assignments, caused Cobra to instruct its employees to assign to Auxilium alone instead of to us the rights to inventions that belong to us under the MTA. These assignments were used by Auxilium to apply for and to obtain a manufacturing patent, which did not name us as a co-owner or co-inventor.

On February 15, 2011, Auxilium filed a complaint against us in the Court of Common Pleas in Chester County, Pennsylvania. The complaint concerns our right to conduct clinical trials without the prior approval of the companies Joint Development Committee. The complaint seeks declaratory and injunctive relief and does not seek monetary damages. The dispute has been sealed pending further order of the court. In response to the complaint, we have voluntarily agreed to suspend Chien-803, our clinical trial testing the use of injectable collagenase in canine lipoma, and will not be initiating any new trials using injectable collagenase in animals or humans pending a resolution of the dispute with Auxilium unless Auxilium consents. The outcome of the dispute will have no effect on the amounts due to us from Auxilium for exercised indications (Dupuytren's contracture, Peyronie's disease and Frozen Shoulder). However, if the court rules in a manner that is detrimental to our interests or interprets our agreement with Auxilium in a way that limits the scope of our rights under that agreement, we may be precluded from pursuing additional indications and, if Auxilium does not pursue such additional indications, we may also be precluded from the opportunity to receive from Auxilium license fees for the rights to, as well as potential milestone, royalty and other payments with respect to, such additional indications.



**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 14, 2011.

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

\* filed herewith

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

**BIOSPECIFICS TECHNOLOGIES CORP.**

(Registrant)

Date: May 10, 2011

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

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