

## 10-Q 1 d75325\_10-q.htm QUARTERLY REPORT

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2008**

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

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

**0-19879**

(Commission file number)

**BIOSPECIFICS TECHNOLOGIES CORP.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

**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  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

Yes  No

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

Class of StockOutstanding November 4, 2008

Common Stock (\$.001 par value)

**6,006,801**

**BIOSPECIFICS TECHNOLOGIES CORP.**

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**Introductory Comments – Terminology**

Throughout this quarterly report on Form 10-Q (this “Report”), the terms “BioSpecifics,” “Company,” “we,” “our,” and “us” refer to BioSpecifics Technologies Corp. and its subsidiary, Advance Biofactures Corporation (“ABC-NY”). We also owned two dormant companies, BioSpecifics of Curacao N.V. and Biota N.V., which were liquidated in January 2007.

**Introductory Comments – Forward-Looking Statements**

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

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## PART I – FINANCIAL INFORMATION

## Item 1: Consolidated Financial Statements

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

	<b>As of September 30, 2008</b>	<b>Fiscal Year Ended December 31, 2007</b>
	(unaudited)	(audited)
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 3,735,568	\$ 68,564
Short-term investments	1,375,000	975,000
Accounts receivable, net	70,259	108,809
Prepaid expenses and other current assets	305,055	73,158
	<hr/>	<hr/>
<b>Total current assets</b>	<b>5,485,882</b>	<b>1,225,531</b>
Deferred royalty buydown	1,250,000	—
Property, plant and equipment, net	9,728	35,680
	<hr/>	<hr/>
<b>Total assets</b>	<b>6,745,610</b>	<b>1,261,211</b>
	<hr/>	<hr/>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	674,145	873,460
Accrued third-party development expenses	2,272,969	2,272,969
Accrued tax liability	—	453,553
Deferred revenue	1,341,792	1,437,116
Accrued tax and other accrued liabilities of discontinued operations	78,138	78,138
	<hr/>	<hr/>
<b>Total current liabilities</b>	<b>4,367,044</b>	<b>5,115,236</b>
Long-term deferred revenue	2,168,113	2,881,633
<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; 6,138,068 shares and 5,480,768 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	6,138	5,481
Additional paid-in capital	12,550,156	4,751,447
Accumulated deficit	(11,651,884)	(10,172,855)
Treasury stock, 131,267 shares at cost at September 30, 2008 and December 31, 2007	(693,957)	(693,957)
Notes receivable from former CEO and Chairman and other related party	—	(625,774)
	<hr/>	<hr/>
<b>Total stockholders' equity</b>	<b>210,453</b>	<b>(6,735,658)</b>
	<hr/>	<hr/>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 6,745,610</b>	<b>\$ 1,261,211</b>
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**See accompanying notes to consolidated financial statements**

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

	Three Months Ended September 30,		Nine Months Ended September 30	
	2008	2007	2008	2007
<b>Revenues:</b>				
Net sales	\$ 13,042	\$ 10,128	\$ 29,841	\$ 22,060
Royalties	—	—	2,028	—
Licensing fees	266,281	289,279	798,844	867,837
Consulting fees	70,000	70,000	354,185	210,000
<b>Total Revenues</b>	<b>349,323</b>	<b>369,407</b>	<b>1,184,898</b>	<b>1,099,897</b>
<b>Costs and expenses:</b>				
General and administrative	866,574	1,001,384	2,840,346	2,911,798
Research and development	71,737	142,582	260,440	601,001
<b>Total Cost and Expenses</b>	<b>938,311</b>	<b>1,143,966</b>	<b>3,100,786</b>	<b>3,512,799</b>
<b>Operating loss from continuing operations</b>	<b>(588,988)</b>	<b>(774,559)</b>	<b>(1,915,888)</b>	<b>(2,412,902)</b>
<b>Other income (expense):</b>				
Interest income	31,511	29,253	89,314	107,396
Interest expense	46,979	—	46,528	—
Other, net	104,203	—	108,730	—
	182,693	29,253	244,572	107,396
Loss from continuing operations before benefit (expense) for income tax	(406,295)	(745,306)	(1,671,316)	(2,305,506)
Income tax benefit (expense)	192,287	—	192,287	(3,600)
<b>Net loss from continuing operations</b>	<b>\$ (214,008)</b>	<b>\$ (745,306)</b>	<b>\$ (1,479,029)</b>	<b>\$ (2,309,106)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.04)</b>	<b>\$ (0.14)</b>	<b>\$ (0.25)</b>	<b>\$ (0.44)</b>
<b>Shares used in computation of basic and diluted net loss per share</b>	<b>5,976,937</b>	<b>5,317,324</b>	<b>5,803,497</b>	<b>5,276,238</b>

See accompanying notes to consolidated financial statements

**BIOSPECIFICS TECHNOLOGIES CORP.**  
**Consolidated Statements of Cash Flows**  
(unaudited)

	<b>Nine Months Ended September 30</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (1,479,029)	\$ (2,309,106)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Gain on disposal of fixed asset	(5,535)	—
Depreciation and amortization	23,487	24,106
Stock-based compensation expense	1,054,147	477,363
Changes in operating assets and liabilities:		
Accounts receivable	38,550	(24,190)
Prepaid expenses and other current assets	(231,897)	(69,541)
Accounts payable and accrued expenses	(652,868)	353,234
Deferred revenue	(808,844)	(702,837)
	<b>(2,061,989)</b>	<b>(2,250,971)</b>
<b>Net cash used in operating activities from continuing operations</b>	<b>(2,061,989)</b>	<b>(2,250,971)</b>
<b>Net cash used in discontinued operations</b>	<b>—</b>	<b>(321,037)</b>
<b>Cash flows from investing activities:</b>		
Maturities of marketable securities	1,600,000	—
Purchases of marketable securities	(2,000,000)	—
Payment for royalty buydown	(1,250,000)	—
Proceeds from sale of fixed asset	8,000	—
	<b>(1,642,000)</b>	<b>—</b>
<b>Net cash used in investing activities</b>	<b>(1,642,000)</b>	<b>—</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of capital stock	6,007,047	—
Proceeds from stock option exercises	247,388	87,062
Proceeds from pay-off of notes receivable from former CEO and Chairman	1,116,558	—
	<b>7,370,993</b>	<b>87,062</b>
<b>Net cash provided by financing activities from continuing operations</b>	<b>7,370,993</b>	<b>87,062</b>
Increase in cash and cash equivalents	3,667,004	(2,484,946)
Cash and cash equivalents at beginning of year	68,564	4,367,178
	<b>\$ 3,735,568</b>	<b>\$ 1,882,232</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 3,735,568</b>	<b>\$ 1,882,232</b>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid during the periods for:		
Interest	\$ 33,880	\$ —
Taxes	\$ 225,824	\$ 3,600

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

In March 2007, in full repayment of the \$304,398 loan owed to the Company by Wilbur Street Corporation (“WSC”), WSC offset \$304,398 in back rent due from the Company in repayment of the loan. The transaction was recorded by reducing the rent payable by \$304,398 and the receivable from the Company’s former CEO and Chairman by \$98,253 and increasing additional paid in capital by \$206,145.

**See accompanying notes to consolidated financial statements**

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

**September 30, 2008  
(Unaudited)**

**1. ORGANIZATION AND DESCRIPTION OF BUSINESS**

We are a biopharmaceutical company that has been involved in the development of injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. (“Auxilium”) for injectable collagenase (which Auxilium has named “XIAFLEX™” (formerly known as “AA4500”)) for clinical indications in Dupuytren’s disease, Peyronie’s disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas. In June 2008, Auxilium announced positive top-line efficacy and safety results from the CORD I and CORD II Phase III clinical trials for XIAFLEX™ in the treatment of Dupuytren’s contracture. In October 2008, Auxilium confirmed that it remains on track to submit a Biologics License Application (“BLA”) for XIAFLEX™ in Dupuytren’s contracture in early 2009.

**DISCONTINUED OPERATIONS**

Prior to March 2006, we were a party to an exclusive license agreement with Abbott Laboratories, Inc. and its subsidiaries (“Abbott”), for the production of the active pharmaceutical ingredient (“API” or “API Enzyme”) for topical collagenase. In March 2006, we sold our topical collagenase business to DFB Biotech, Inc. and its affiliates (“DFB”), including all rights to the exclusive license agreement and we were released of any obligations thereunder.

In addition, DFB acquired all of the issued and outstanding shares of Advance Biofactures of Curacao, N.V. (“ABC-Curacao”), pursuant to the Asset Purchase Agreement (the “Asset Purchase Agreement”) between us, DFB and Advance Biofactures Corp. (“ABC-NY”). The operating results of ABC-Curacao and certain operations of ABC-NY have been classified as discontinued operations in the consolidated financial statements for all periods presented.

As consideration for the purchased assets including our API inventory we received \$8 million in cash, DFB’s assumption of certain liabilities, and the right to receive earn out payments in the future based on sales of certain products. In connection with the closing of the Asset Purchase Agreement, we agreed to provide certain technical assistance and certain transition services to DFB in consideration of fees and costs totaling over \$1.4 million. At the closing, DFB paid to us a partial payment of \$400,000 in respect of the technical assistance to be provided by us. To date, we have received a total of \$1,000,000 in payments from DFB. The consulting obligations generally expire during March 2011.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

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

The information included in this Report should be read in conjunction with our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2008 and June 30, 2008 filed with the SEC on May 15, 2008 and August 12, 2008 and our Annual Report on Form 10-KSB for the year ended December 31, 2007 filed with the SEC on May 2, 2008.

### **Principles of Consolidation**

The unaudited consolidated financial statements include the accounts of the Company and its subsidiaries, ABC-NY, BioSpecifics of Curacao N.V. and Biota N.V., and its wholly-owned subsidiary. BioSpecifics of Curacao N.V. and Biota N.V. were both liquidated in January 2007. Due to the sale of ABC-Curacao in March 2006 to DFB all accounts of this former subsidiary and certain operations of ABC-NY are classified as discontinued operations in the 2007 periods presented.

### **Management Estimates**

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

### **Cash, Cash Equivalents and Marketable Securities**

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

### **Fair Value Measurements**

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

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

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

The following table sets forth the fair value of our financial assets that were measured on a recurring basis as of September 30, 2008:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash and cash equivalents	\$ 3,735,568	—	—
Auction rate securities	—	\$ 1,375,000	—

### **Auction Rate Securities**

In October 2008, the Company received notice from UBS of a solution that provided us the option to continue to hold our Auction Rate Securities (“ARS”) or sell the securities back to UBS at par value plus any accrued interest. On October 24, 2008 we accepted UBS’s offer and will instruct UBS if and when we want to exercise our rights and sell our ARS to UBS during the period January 2, 2009 through January 4, 2011.

In the first six months of 2008, we classified our auction rate securities as long-term investments in our consolidated balance sheet as our ability to liquidate such securities in the short-term was uncertain. The cost value of these securities held as of September 30, 2008 amounted to approximately \$1.4 million with a current market value of approximately \$1.0 million. We previously had recorded a temporary impairment within other accumulated comprehensive loss of approximately \$0.4 million related to these auction rate securities which we subsequently reversed as of September 30, 2008 due to the solution provided by UBS in October 2008. We currently expect to sell our ARS to UBS within the next 12 months and therefore have reclassified our ARS to short-term investments at our original cost value.

### **Revenue Recognition**

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

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

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

#### ***Product Sales***

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

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

#### ***Royalty Revenue***

We recognize royalties under the earn out provision of the Asset Purchase Agreement with DFB. We have the right to receive earn out payments in the future based on sales of certain products. Generally,

under this agreement we would receive royalty payments and a report within ninety (90) days from the end of each calendar year; after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured. Accordingly, we recognize royalty revenues in the quarter reported to us by our licensee.

### ***License Fees***

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

#### ***Upfront License Fees***

We generally recognize revenue from upfront 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 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***

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 a nonrefundable upfront license fee.

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

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

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

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

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

If conditions or other circumstances change, we may take actions to revise our reimbursable third-party development cost estimates. These revisions could result in an incremental increase in research and development costs. Amendment No.1 to the Development and License Agreement, dated May 5, 2006 provides that Auxilium and BioSpecifics will share equally in third-party costs for the development of the lyophilization of the injection formulation. On April 11, 2008, we received an invoice for approximately \$2.3 million from Auxilium, which represents an amount that Auxilium believes is owed by us through year end 2007 under this provision. Based on the information available, we are not able to verify the accuracy or the validity of the charges and have informed Auxilium that we cannot pay the invoice until we have done so. Based on our preliminary review, we believe that only a portion of the amount charged actually relates to the development of the lyophilization of the injection formulation and, therefore, reserve all rights related to this matter, including but not limited to our right to contest the amount charged by Auxilium. For the three and nine month periods ended September 30, 2008, there has been no change to the estimated amount owed and is still currently under review

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

### **Research and Development Expenses**

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

### **Clinical Trial Expenses**

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

### **Stock-Based Compensation**

Under the provisions of Statement of Financial Accounting Standards (SFAS) No. 123(R), we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures) and the expected volatility. As required under the accounting rules, we review our

valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. The weighted-average assumptions used were as follows:

	<b>Quarter Ended September 30, 2008</b>	<b>Year Ended December 31, 2007</b>
<b>Stock Option Plans</b>		
Expected life, in years	5.0	5.0
Risk free interest rate	2.6%	5.0%
Volatility	73%	106%
Dividend yield	—	—

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

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

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
Research and development	\$ 20,468	\$ 4,979	\$ 30,426	\$ 9,219
General and administrative	295,888	224,240	1,023,721	468,144
<b>Total stock-based compensation expense</b>	<b>\$ 316,356</b>	<b>\$ 229,219</b>	<b>\$ 1,054,147</b>	<b>\$ 477,363</b>

#### *Stock Option Activity*

A summary of our stock option and warrant activity during the nine months ended September 30, 2008 is presented below:

<b>Option</b>	<b>Total Number of Shares</b>	<b>Weighted-Average Exercise Price</b>
Outstanding as of December 31, 2007	1,409,700	\$ 1.86
Granted	232,500	\$ 16.00
Forfeited	—	—
Exercised	(207,300)	\$ 1.20
Expired	(1,500)	\$ 4.38
<b>Outstanding as of September 30, 2008</b>	<b>1,433,400</b>	<b>\$ 4.25</b>
<b>Exercisable as of September 30, 2008</b>	<b>1,150,900</b>	<b>\$ 2.54</b>

The weighted-average grant-date fair value for options granted during the nine months ended September 30, 2008 was \$16.00 per share and \$4.50 per share in the corresponding nine month period of 2007.

During the nine months ended September 30, 2008 and 2007, \$247,388 and \$87,062 were received from stock options exercised by employees, respectively.

The aggregate intrinsic value of options outstanding and exercisable as of September 30, 2008 was approximately \$21.9 million. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our common stock of \$19.00 on September 30, 2008, 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, 2008 was approximately \$1.7 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 being amortized over the lesser of their estimated useful lives or the life of the lease, which is approximately 8 to 10 years.

### **Recent Accounting Pronouncements**

In June 2007, the Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received to Be Used in Future Research and Development Activities" (EITF No. 07-3). EITF No. 07-3 requires companies that are involved in research and development activities to defer nonrefundable advance payments for future research and development activities and to recognize those payments as goods and services are delivered. The Company will be required to assess on an ongoing basis whether or not the goods or services will be delivered and to expense the nonrefundable advance payments immediately if it is determined that delivery is unlikely. EITF No. 07-3 is effective for new arrangements entered into subsequent to the beginning of the Company's fiscal year 2009. The adoption of this EITF did not have a material effect on our consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133." SFAS No. 161 requires enhanced disclosures about an entity's derivative and hedging activities. Entities will be required to provide enhanced disclosures about: (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related hedge items are accounted for under SFAS No. 133 and its related interpretations; and (c) how derivative instruments and related hedge items affect an entity's financial position, financial performance and cash flows. The Company is required to adopt SFAS No. 161 beginning in fiscal year 2009. We do not expect the adoption of this FAS statement to have a material effect on our consolidated financial statements.

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

In May 2008, the FASB issued Staff Position No. APB 14-1, "Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)" (the "FSP"), which clarifies the accounting for convertible debt instruments that may be settled in cash (including partial cash settlement) upon conversion. The FSP requires issuers to account separately for the

liability and equity components of certain convertible debt instruments in a manner that reflects the issuer's nonconvertible debt (unsecured debt) borrowing rate when interest cost is recognized. The FSP requires bifurcation of a component of the debt, classification of that component in equity and the accretion of the resulting discount on the debt to be recognized as part of interest expense in our consolidated statement of operations. The FSP requires retrospective application to the terms of instruments as they existed for all periods presented. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We do not expect the adoption of this FSP to have a material effect on our consolidated financial statements.

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

In May 2008, the FASB issued SFAS No. 163, "Accounting for Financial Guarantee Insurance Contracts, an interpretation of FASB Statement No. 60." The scope of this Statement is limited to financial guarantee insurance (and reinsurance) contracts, as described in this Statement, issued by enterprises included within the scope of Statement 60. Accordingly, this Statement does not apply to financial guarantee contracts issued by enterprises excluded from the scope of Statement 60 or to some insurance contracts that seem similar to financial guarantee insurance contracts issued by insurance enterprises (such as mortgage guaranty insurance or credit insurance on trade receivables). This Statement also does not apply to financial guarantee insurance contracts that are derivative instruments included within the scope of FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities." We do not expect the adoption of this FAS statement to have a material effect on our consolidated financial statements.

In June 2008, the FASB issued Emerging Issues Task Force Issue 07-5 "Determining whether an Instrument (or Embedded Feature) is indexed to an Entity's Own Stock" ("EITF No. 07-5"). This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early application is not permitted. Paragraph 11(a) of Statement of Financial Accounting Standard No 133 "Accounting for Derivatives and Hedging Activities" ("SFAS 133") specifies that a contract that would otherwise meet the definition of a derivative but is both (a) indexed to the Company's own stock and (b) classified in stockholders' equity in the statement of financial position would not be considered a derivative financial instrument. EITF No.07-5 provides a new two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock and thus able to qualify for the SFAS 133 paragraph 11(a) scope exception. We do not expect the adoption of this EITF to have a material effect on our consolidated financial statements.

In June 2008, FASB issued EITF Issue No. 08-4, "Transition Guidance for Conforming Changes to Issue No. 98-5 ("EITF No. 08-4"). The objective of EITF No.08-4 is to provide transition guidance for conforming changes made to EITF No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios", that result from EITF No. 00-27 "Application of Issue No. 98-5 to Certain Convertible Instruments", and SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity". This Issue is effective for financial statements issued for fiscal years ending after December 15, 2008. Early application is permitted. We do not expect the adoption of this EITF to have a material effect on our consolidated financial statements.

### 3. NET LOSS PER SHARE

In accordance with SFAS No. 128, "Earnings Per Share" (SFAS 128), basic net loss per share amount is computed using the weighted-average number of shares of common stock outstanding during the periods presented, while diluted net loss per share is computed using the sum of the weighted-average number of common and common equivalent shares outstanding. Common equivalent shares used in the computation of diluted earnings per share result from the assumed exercise of stock options, and warrants using the if converted method. For the three and nine months ended September 30, 2008 and 2007, we incurred a net loss from continuing operations and, as such, we did not include the effect of outstanding stock options or warrants 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,	
	2008	2007	2008	2007
Stock options	1,355,912	1,074,531	1,270,527	1,061,844
Warrants	—	10,000	—	10,000
<b>Total</b>	<b>1,355,912</b>	<b>1,084,531</b>	<b>1,270,527</b>	<b>1,071,844</b>

### 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 change in other comprehensive income is the direct result of the offer to repurchase our auction rate securities by UBS described more fully under **Note 2 Summary of Significant Accounting Policies - Auction Rate Securities**. The following table presents the calculation of our comprehensive income (loss):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net loss	\$ (214,008)	\$ (478,002)	\$ (1,479,029)	\$ (1,563,800)
Other comprehensive income:				
Change in unrealized gains on marketable securities	354,572	—	—	—
<b>Total Comprehensive gain (loss)</b>	<b>\$ 140,564</b>	<b>\$ (478,002)</b>	<b>\$ (1,479,029)</b>	<b>\$ (1,563,800)</b>

### 5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	September, 2008	December 31, 2007
Trade accounts payable and accrued expenses	\$ 470,463	\$ 686,742
Accrued legal and other professional fees	87,592	98,438

Accrued payroll and related costs	116,090	88,280
	<u>          </u>	<u>          </u>
<b>Total</b>	<b>\$ 674,145</b>	<b>\$ 873,460</b>
	<u>          </u>	<u>          </u>

## 6. INCOME TAXES

In September 2008, we filed our delinquent federal and state tax returns for the years ended 2003, 2004, 2005, 2006 and 2007. Prior to finalizing our tax returns for the aforementioned periods, we had accrued approximately \$198,000 in federal and state taxes, \$175,000 in penalties and \$80,000 in interest under our original estimates through December 31, 2007.

After finalizing our tax filings in 2008, we had a change in estimates related to federal and state taxes, penalties and interest for the prior annual periods based on a clarification of our intercompany transactions. We accrued an additional tax expense of approximately \$28,000 for federal and state taxes in third quarter of 2008 related to prior years and postponed the recognition of a tax benefit of \$220,000 for the 2007 period due to net operating loss carrybacks. We have applied for a refund of this tax benefit and have recorded a receivable under prepaid expenses and other current assets on our Balance Sheet as of September 30, 2008. This tax benefit also resulted in a reduction to penalties and interest of approximately \$103,000 and \$47,000 respectively. For the three and nine month period ended September 30, 2008 we had a net tax benefit of \$192,287.

## 7. RELATED PARTY TRANSACTIONS

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

In March 2007, in full repayment of the \$304,398 loan owed to the Company by Wilbur Street Corporation ("WSC"), WSC offset \$304,398 in back rent due from the Company in repayment of the loan.

## 8. SUBSEQUENT EVENTS

None.

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

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

#### **Overview**

We are a biopharmaceutical company that has been involved in the development of injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. ("Auxilium") for injectable collagenase (which Auxilium has named "XIAFLEX<sup>TM</sup>" (formerly known as "AA4500")) for clinical indications in Dupuytren's disease, Peyronie's disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas. In June 2008, Auxilium announced positive top-line efficacy and safety results from the CORD I and CORD II Phase III clinical trials for XIAFLEX<sup>TM</sup> in the treatment of Dupuytren's contracture. In October 2008, Auxilium confirmed that it remains on track to submit a Biologics License Application ("BLA") for XIAFLEX<sup>TM</sup> in Dupuytren's contracture in early 2009.

## Outlook

We foresee the potential to generate income from limited sources in the next several years. Under the terms of our agreement with DFB Biotech, Inc. and its affiliates (“DFB”), we are scheduled to receive certain contractual anniversary payments and, if DFB exceeds a certain sales target, we would be entitled to an earn out on sales. Under the terms of our agreement with Auxilium, we may receive milestone payments upon their achieving certain regulatory progress and if Auxilium elects to pursue additional indications for injectable collagenase (“Additional Indications”).

Based on our current business model, we expect to have adequate cash reserves until the third quarter of 2010 depending on the amount actually owed to Auxilium, as discussed in Item 1A, “Risk Factors”, included in our Annual Report on Form 10-KSB for the year ended December 31, 2007. 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, 2008, we had an accumulated deficit from continuing operations of \$11,651,884.

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

In October 2008, the Company received notice from UBS of a solution that provided us the option to continue to hold our ARS or sell the securities back to UBS at par value plus any accrued interest. On October 24, 2008 we accepted UBS’s offer and will instruct UBS if and when we want to exercise our rights and sell our ARS to UBS during the period January 2, 2009 through January 4, 2011.

In the first six months of 2008, we classified our auction rate securities as long-term investments in our consolidated balance sheet as our ability to liquidate such securities in the short-term was uncertain. The cost value of these securities held as of September 30, 2008 amounted to approximately \$1.4 million with a current market value of approximately \$1.0 million. We previously had recorded a temporary impairment within other accumulated comprehensive loss of approximately \$0.4 million related to these auction rate securities which we subsequently reversed as of September 30, 2008 due to the solution provided by UBS in October 2008. We currently expect to sell our ARS to UBS within the next 12 months and therefore have reclassified our ARS to short-term investments at our original cost value.

## Critical Accounting Policies, Estimates and Assumptions

The preparation of unaudited consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are based on historical experience and on various other assumptions that we believe are reasonable under the circumstances. The information at September 30, 2008 and for the three and nine months ended September 30, 2008 and 2007 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, 2007 balance sheet amounts and disclosures included herein have been derived from the Company’s December 31, 2007

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 years ended December 31, 2007 and 2006 included in the Company's Form 10-KSB filed with the SEC on May 2, 2008 and our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2008 and June 30, 2008. While our significant accounting policies are described in more detail in the notes to our unaudited consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our unaudited consolidated financial statements.

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

We recognize royalties under the earn out provision of the Asset Purchase Agreement with DFB. We have the right to receive earn out payments in the future based on sales of certain products. Royalties are recognized as earned in accordance with the contract terms when royalties can be reliably measured, and collectibility is reasonably assured, such as upon the receipt of a royalty statement from our licensees.

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

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

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

We recognize revenues from a consulting and technical assistance contract primarily as a result of the Asset Purchase Agreement. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations under the Asset Purchase Agreement generally expire during March 2011.

**Receivables and Deferred Revenue.** Under our agreement with DFB, we agreed to provide certain technical assistance and transitional services in consideration of fees and costs totaling over \$1.4 million. At the closing, DFB paid to us a partial payment of \$400,000 in respect of the technical assistance to be provided by us. To date, we have received a total of \$1,000,000 in payments from DFB. The consulting

obligations generally expire during March 2011. As of September 30, 2008 the remaining accounts receivable balance due was \$400,000 for future services and was offset by the associated deferred revenues to be recognized in future periods of \$400,000.

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

As of September 30, 2008, we capitalized \$1,250,000 which will be amortized over approximately five years beginning on the date of the first commercial sale of XIAFLEX(TM), for Peyronie's disease, which represents the period estimated to be benefited, using the straight-line method. In accordance with SFAS No. 142, *Goodwill and Other Intangibles*, the Company amortizes intangible assets with finite lives in a manner that reflects the pattern in which the economic benefits of the assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the assets are amortized using the straight-line method.

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

If conditions or other circumstances change, we may take actions to revise our reimbursable third-party development cost estimates. These revisions could result in an incremental increase in research and development costs. For example, Amendment No.1 to the Development and License Agreement, dated May 5, 2006 provides that Auxilium and BioSpecifics will share equally in third-party costs for the development of the lyophilization of the injection formulation. On April 11, 2008, we received an invoice for approximately \$2.3 million from Auxilium, which represents an amount that Auxilium believes is owed by us through year end 2007 under this provision. Based on the information available, we are not able to verify the accuracy or the validity of the charges and have informed Auxilium that we cannot pay the invoice until we have done so. Based on our preliminary review, we believe that only a portion of the amount charged actually relates to the development of the lyophilization of the injection formulation and, therefore, reserve all rights related to this matter, including but not limited to our right to contest the amount charged by Auxilium. For the three and nine month periods ended September 30, 2008, there has been no change to the estimated amount owed and is still currently under review.

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.

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

Further, SFAS 123(R) requires that employee stock-based compensation costs 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, 2008 AND 2007

#### Revenues

##### *Product Revenues, net*

Product revenues include the sales of the API Enzyme recognized at the time it is shipped to customers. We recognized a small amount of revenue from the sale of collagenase for laboratory use. For the three months ended September 30, 2008 and 2007 product revenues were \$13,042 and \$10,128, respectively. This increase of \$2,914 or 29% was primarily related to the amount of material required to perform testing by our customers.

##### *Royalties*

We received all of our royalty revenues from DFB under the earn out payment provision of the Asset Purchase Agreement. Royalty revenues recognized under our agreement with DFB for the three months ended September 30, 2008 and 2007 were zero.

##### *Licensing Revenues*

For the three months ended September 30, 2008 and 2007, we recognized licensing revenue of \$266,281 and \$289,279, respectively. This decrease of \$22,998 or 8% was primarily related to the extension of the development timeline for a certain indication for injectable collagenase under the Auxilium Agreement. Licensing revenues recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period.

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

##### *Consulting Services*

We recognize revenues from consulting and technical assistance contracts primarily as a result of the Asset Purchase Agreement and an Auxilium consulting agreement. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations under the Asset Purchase Agreement generally expire during March 2011. For the three months ended September 30, 2008 and 2007 consulting revenues were \$70,000 in each period.

## Costs and Expenses

### *Research and Development Activities*

Research and development expenses were \$71,737 and \$142,582 respectively, for the three months ended September 30, 2008 and 2007. This decrease of \$70,845 or 50% in research and development expenses was primarily due to certain external study development costs partially offset by an increase in stock-based compensation.

### *General and Administrative Expenses*

General and administrative expenses were \$866,574 and \$1,001,384 for the three months ended September 30, 2008 and 2007, respectively. The decrease in general and administrative expenses of \$134,810 or 13% was primarily due to lower outside consulting expense and legal fees partially offset by an increase in stock-based compensation expense.

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

Other income, net, was \$182,693 and \$29,253 for the three months ended September 30, 2008 and 2007, respectively. Components of other income, net, consist of investment income, a reduction in interest expense and other, net. Investment income for the three months ended September 30, 2008 was \$31,511 as compared to \$29,253 in the comparable period of 2007. This increase of \$2,258 or 8% was primarily due to higher invested balances during the 2008 period. Interest expense reduction for the three months ended September 30, 2008 was \$46,980 as compared to zero in the 2007 period. This reduction in interest expense is primarily the result of lower than previously estimated accrued interest associated with our delinquent federal and state tax returns. Other, net for the three months ended September 30, 2008 was \$104,203 as compared to zero in the 2007 period. The increase in other, net was primarily due to lower than previously estimated tax penalties due in connection with our delinquent federal and state tax returns.

### *Income Taxes*

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

## **NINE-MONTHS ENDED SEPTEMBER 30, 2008 AND 2007**

### **Revenues**

#### *Product Revenues, net*

Product revenues include the sales of the API Enzyme recognized at the time it is shipped to customers. We recognized a small amount of revenue from the sale of collagenase for laboratory use. For the nine months ended September 30, 2008 and 2007 product revenues were \$29,841 and \$22,060, respectively. This increase of \$7,781 or 35% was primarily related to the amount of material required to perform testing by our customers.

*Royalties*

We receive all of our royalty revenues from DFB under the earn out payment provision of the Asset Purchase Agreement. Royalty revenues recognized under our agreement with DFB for the nine months ended September 30, 2008 were \$2,028 and zero in the comparable period of 2007. This increase for the 2008 was due to certain foreign sales levels achieved and reported to us in the second quarter of 2008 by DFB in connection with the sale of topical collagenase.

*Licensing Revenues*

For the nine months ended September 30, 2008 and 2007, we recognized licensing revenue of \$798,844 and \$867,837, respectively. This decrease of \$68,993 or 8% was primarily related to the extension of the development timeline for a certain indication for injectable collagenase under the Auxilium Agreement. Licensing revenues recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period.

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

*Consulting Services*

We recognize revenues from consulting and technical assistance contracts primarily as a result of the Asset Purchase Agreement and an Auxilium consulting agreement. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations under the Asset Purchase Agreement generally expire during March 2011. For the nine months ended September 30, 2008 and 2007 consulting revenues were \$354,185 and \$210,000, respectively. This increase of \$144,185 or 67% was primarily due to the recognition of revenues earned in connection with the October 2007 consulting agreement with Auxilium.

**Costs and Expenses***Research and Development Activities*

Research and development expenses were \$260,440 and \$601,001 respectively, for the nine months ended September 30, 2008 and 2007. This decrease of \$340,561 or 57% in research and development expenses was primarily due to lower third-party development costs and certain external study development expenses partially offset by an increase in stock-based compensation.

*General and Administrative Expenses*

General and administrative expenses were \$2,840,346 and \$2,911,798 for the nine months ended September 30, 2008 and 2007, respectively. The decrease in general and administrative expenses of \$71,452 or 2% was primarily due to lower administrative personnel costs, legal fees and consulting expenses partially offset by stock-based compensation.

*Other Income (expense), net*

Other income, net, was \$244,572 and \$107,396 for the nine months ended September 30, 2008 and 2007, respectively. Components of other income, net consist of investment income, a reduction in interest expense and other, net. Investment income for the nine months ended September 30, 2008 was \$89,314 as compared to \$107,396 in the comparable period of 2007. This decrease of \$18,082 or 17% was primarily due to a lower return on the invested balances during the 2008 period. Interest expense reduction for the nine months ended September 30, 2008 was \$46,529 as compared to zero in the 2007



period. This reduction in interest expense is primarily the result of lower than previously estimated accrued interest associated with our delinquent federal and state tax returns. Other, net for the nine months ended September 30, 2008 was \$108,730 as compared to zero in the 2007 period. The increase in other, net was primarily due to lower than previously estimated tax penalties due in connection with our delinquent federal and state tax returns and a small gain from proceeds received from the sale of a company owned vehicle.

#### *Income Taxes*

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

#### **Liquidity and Capital Resources**

To date, we have financed our operations primarily through product sales, debt instruments, licensing revenues, royalties under agreements with third parties and sales of our common stock. At September 30, 2008 and December 31, 2007, we had cash and cash equivalents in the aggregate of \$3,735,568 and \$68,564, respectively.

#### ***Continuing Operations***

Net cash used in operating activities for the nine months ended September 30, 2008 was \$2,061,989 as compared to net cash used in operating activities in the 2007 period of \$2,250,971. In the 2008 period, as compared to the 2007 period, the changes in net cash used in operating activities was primarily attributable to a lower net loss for the period, non-cash stock compensation expense partially offset by payments related to accounts payable, accrued expenses related to income taxes paid, prepaid expenses and other current assets and deferred revenue.

Net cash used in investing activities for the nine months ended September 30, 2008 was \$1,642,000 as compared to net cash used in investing activities in the 2007 period of zero. The increase in net cash used in investing activities for the 2008 period, reflect our investment in marketable securities of \$2,000,000, a one-time cash payment related to our future royalty obligations for Peyronie's disease of \$1,250,000, offset by maturities of investments of \$1,600,000.

Net cash provided by financing activities for the nine months ended September 30, 2008 was \$7,370,993 as compared to the 2007 period of \$87,062. The increase in net cash provided by financing activities for the 2008 consisted of proceeds from the sale of our common stock of \$6,007,047, repayment of an outstanding loan from our former Chairman and CEO of \$1,116,558 and proceeds received from stock option exercises of \$247,388. Net cash provided by financing activities in the 2007 period was from proceeds received from stock option exercises.

#### ***Discontinued Operations***

Net cash used in operating activities from discontinued operations for the nine months ended September 30, 2008 was zero as compared to \$321,037 in the comparable period of 2007.

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

Pursuant to Item 305(c) of Regulation S-K, the information under this Item 3 is not required to be disclosed until after the first fiscal year end in which Item 305 is applicable. Item 305 will be first applicable to the Company in its annual report for the fiscal year ended December 31, 2008.

**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 nine month period ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II: OTHER INFORMATION****Item 1. Legal Proceedings**

None.

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

On August 19, 2008, the Company closed on the sale of 50,000 shares of its common stock in a private placement offering to a private investment fund at a purchase price of \$22.50 per share, for aggregate proceeds to the Company of \$1,125,000. The shares were offered and sold in reliance on Section 4(2) of the Act as private placements of securities exempt from the registration requirements of the Act. The shares were sold to financially sophisticated investors who had access to the sort of information which registration under the Act would disclose. Additionally, no commissions were paid and no general solicitation was made to any person or entity in connection with the sale of the shares.

**Item 3. Defaults Upon Senior Securities**

None.

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

Our 2008 Annual Meeting of Stockholders was held on September 9, 2008 at the offices of Thelen Reid Brown Raysman & Steiner LLP in New York, New York, in accordance with the Notice of Annual Meeting of Stockholders sent on or about August 14, 2008. The tables below present the voting results of the matters voted upon by our stockholders at the meeting:

##### *Proposal 1: Election of Directors*

At the meeting, each of the nominees listed below was elected to our Board of Directors to serve as director until the end of his or her respective term and received the number votes set forth after their respective names below.

Nominee*	Number of Shares		
	For	Against	Abstain
Toby Wegman	4,555,895	544,653	0
Dr. Mark Wegman	4,354,850	645,698	100,000

\* The Board is divided into three classes, each of which serves for a term of three years, with only one class of directors being elected in each year. Each director holds office for the term for which elected and until his or her successor shall be elected and shall qualify and be subject to such director's earlier death, resignation or removal. The term of office of the first class of directors, presently consisting of Thomas L. Wegman, Dr. Paul A. Gitman and Matthew Geller, Ph.D. is scheduled to expire at the annual meeting for the year 2009; the term of office of the second class of directors, presently consisting of Henry Morgan and Michael Schamroth is scheduled to expire on the date of the annual meeting for the year 2010; and the third class of directors, which was elected at our 2008 Annual Meeting of Stockholders, consisting of Toby Wegman and Dr. Mark Wegman is now scheduled to expire at the 2011 Annual Meeting. Matthew Geller, Ph.D was appointed to the Board on September 22, 2008 to serve in the first class until the end of the applicable term.

##### *Proposal 2: Ratification of the selection of Tabriztchi & Co. CPA, P.C. as our independent registered public accounting firm for the fiscal year ending December 31, 2008.*

At the meeting, our stockholders ratified by the vote set forth below the selection of Tabriztchi & Co. CPA, P.C. as our independent registered public accounting firm for the fiscal year ending December 31, 2008.

For	Number of Shares		Broker Non-Votes
	Against	Abstain	
4,661,430	245,713	193,405	0

The number of shares of our common stock eligible to vote as of the record date of July 23, 2008 was 5,950,801 shares.

#### Item 5. Other Information

None.

#### Item 6. Exhibits

- 3.1 Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-KSB for the fiscal years ended December 31, 2005, 2004 and 2003).

3.2 Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-KSB for the fiscal years ended December 31, 2005, 2004 and 2003).

[31\\* Certification of Principal Executive Officer and Principal Financial Officer pursuant to 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.\\*](#)

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\* 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.**

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(Registrant)

Date: November 11, 2008

/s/ Thomas L. Wegman

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