

BIOSPECIFICS TECHNOLOGIES CORP  
Form 10-Q  
November 09, 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 September 30, 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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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

Yes ☐ No ☒

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

Class of Stock	Outstanding November 4, 2011
Common Stock (\$.001 par value)	6,361,110

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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 “us” refer 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, and made pursuant to the safe harbor provisions of, The Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, expected revenue growth, and the assumptions underlying or relating to such statements, are forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "believe," "expect," "anticipate," "plan," "estimate," "likely," "may," "will," "could," "continue," "project," "predict", "goal," the negative or plural of these words, and other expressions. Our forward-looking statements are only predictions based on our current expectations and our projections about future events. There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements, including the statements made by us and by our partner Auxilium Pharmaceuticals, Inc. (“Auxilium”) regarding progress toward achievement of Auxilium’s objectives for the U.S. launch of XIAFLEX® for Dupuytren’s contracture, including, among other things, developments in the reimbursement process; the ability of Pfizer, Inc. to achieve its objectives for XIAPEX® in Europe; the ability of Asahi Kasei Pharma Corporation to achieve its objectives for XIAFLEX in Japan; the success of the Phase III trials for XIAFLEX for the treatment of Peyronie’s disease; the outcome of future clinical trials for additional indications including frozen shoulder, cellulite, human lipoma and canine lipoma, all of which will determine the amount of milestone, royalty and sublicense income we may receive; the potential of XIAFLEX to be used in additional indications; the receipt of any applicable milestone payments from Auxilium; and other risk factors identified in this Report, our Annual Report on Form 10-K for the year ended December 31, 2010 and our Current Reports on Form 8-K filed with the Securities and Exchange Commission. All forward-looking statements included in this Report are made as of the date hereof, and we assume no obligation to update these forward-looking statements.

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## PART I – FINANCIAL INFORMATION

## Item 1: Consolidated Financial Statements

BioSpecifics Technologies Corp.  
Consolidated Balance Sheets

	September 30, 2011 (unaudited)	December 31, 2010 (audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,795,763	\$ 2,470,852
Short-term investments	5,000,000	5,360,970
Accounts receivable, net	1,699,889	1,986,125
Income tax receivable	379,036	185,386
Deferred tax assets	1,289,065	-
Prepaid expenses and other current assets	122,082	91,925
Total current assets	12,285,835	10,095,258
Deferred royalty buy-down	1,250,000	1,250,000
Deferred tax assets –long term	1,762,132	-
Patent costs, net	164,027	173,443
Total assets	15,461,994	11,518,701
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	732,930	893,083
Accrued third-party development expenses	-	2,649,369
Deferred revenue	437,100	483,769
Accrued liabilities of discontinued operations	78,138	78,138
Total current liabilities	1,248,168	4,104,359
Long-term deferred revenue	385,795	713,619
Stockholders' equity:		
Series A Preferred stock, \$.50 par value, 700,000 shares authorized; none outstanding	-	-
Common stock, \$.001 par value; 10,000,000 shares authorized; 6,530,743 and 6,445,743 shares issued at September 30, 2011 and December 31, 2010, respectively	6,531	6,446
Additional paid-in capital	18,697,136	17,739,765
Accumulated deficit	(3,363,231 )	(9,893,530 )
Treasury stock, 169,633 and 151,875 shares at cost at September 30, 2011 and December 31, 2010, respectively	(1,512,405 )	(1,151,958 )
Total stockholders' equity	13,828,031	6,700,723
Total liabilities and stockholders' equity	\$ 15,461,994	\$ 11,518,701

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,	
	2011	2010	2011	2010
Revenues:				
Net sales	\$1,683	\$5,183	\$13,457	\$32,328
Royalties	1,810,436	819,639	4,461,683	1,358,773
Licensing revenues	109,276	109,275	4,265,327	2,916,835
Consulting fees	-	70,000	46,667	210,000
Total Revenues	1,921,395	1,004,097	8,787,134	4,517,936
Costs and expenses:				
Research and development	224,150	216,571	707,015	1,258,187
General and administrative	1,245,145	1,289,310	4,172,687	4,969,653
Total Cost and Expenses	1,469,295	1,505,881	4,879,702	6,227,840
Operating income (loss)	452,100	(501,784 )	3,907,432	(1,709,904)
Other income (expense):				
Interest income	7,813	17,487	41,061	69,262
Other income (expense)	-	-	14,479	-
	7,813	17,487	55,540	69,262
Income (loss) before expense for income tax	459,913	(484,297 )	3,962,972	(1,640,642)
Income tax benefit (expense)	(190,077 )	-	2,567,328	(8,067 )
Net income (loss)	\$269,836	\$(484,297 )	\$6,530,300	\$(1,648,709)
Basic net income (loss) per share	\$0.04	\$(0.08 )	\$1.03	\$(0.26 )
Diluted net income (loss) per share	\$0.04	\$(0.08 )	\$0.92	\$(0.26 )
Shares used in computation of basic net income (loss) per share	6,362,951	6,275,758	6,337,237	6,254,792
Shares used in computation of diluted net income (loss) per share	7,085,945	6,275,758	7,133,341	6,254,792

See accompanying notes to consolidated financial statements

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

	Nine Months Ended September 30,	
	2011	2010
Cash flows from operating activities:		
Net income (loss)	\$6,530,300	\$(1,648,709)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	32,349	9,770
Stock-based compensation expense	391,138	1,710,992
Changes in operating assets and liabilities:		
Accounts receivable	286,236	116,965
Deferred tax assets	(3,051,197)	-
Prepaid expenses and other current assets	(223,807 )	(67,679 )
Accounts payable and accrued expenses	(2,832,456)	457,547
Deferred revenue	(374,494 )	(651,836 )
Net cash provided by (used in) operating activities	758,069	(72,950 )
Cash flows from investing activities:		
Maturity of marketable investments	5,360,970	4,548,541
Purchases of marketable investments	(5,000,000)	(5,360,970)
Net cash provided by (used in) investing activities	360,970	(812,429 )
Cash flows from financing activities:		
Proceeds from stock option exercises	82,450	653,375
Payments for repurchase of common stock	(360,447 )	(418,757 )
Excess tax benefits from share-based payment arrangements	483,869	-
Net cash provided by (used in) financing activities	205,872	234,618
Increase (decrease) in cash and cash equivalents	1,324,911	(650,761 )
Cash and cash equivalents at beginning of year	2,470,852	3,950,389
Cash and cash equivalents at end of period	\$3,795,763	\$3,299,628
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	-	-
Taxes	\$190,000	\$9,851

## Supplemental disclosures of non-cash transactions:

Under our agreement with Auxilium certain patent costs paid by Auxilium on behalf of the Company are creditable against future royalties. As of September 30, 2011 we accrued \$22,933 related to these costs of which \$32,349 was amortized in the 2011 period. In 2010, the amortization expense for patents was \$9,160 for the nine months ended September 30, 2010.

See accompanying notes to consolidated financial statements





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BIOSPECIFICS TECHNOLOGIES CORP.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 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 (including all amendments, 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. Auxilium began selling XIAFLEX in the U.S. for the treatment of Dupuytren's contracture in the first quarter of 2010. 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). Pfizer is currently selling XIAPEX in the United Kingdom, Germany, Denmark, Sweden, Finland, Norway, Austria and Switzerland and received approval to market XIAPEX in Spain in the third quarter of 2011. 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 Santyl. 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 an August 31, 2011 joint press release, BioSpecifics and Auxilium announced that they amended and restated their development and license agreement (such amendment, the “Auxilium Amendment”) and that they entered into a settlement agreement pursuant to which they settled all pending litigation and resolved other outstanding disputes between them. The Auxilium Amendment clarified and changed certain rights and obligations of the parties. For example, Auxilium has been granted the right to initiate studies for the treatment of edematous fibrosclerotic panniculopathy, more commonly known as cellulite.

Also in their August 31, 2011 press release, BioSpecifics announced plans to move XIAFLEX forward in the clinic for human and canine lipoma as well as to collaborate with Auxilium on the initiation of further studies for XIAFLEX in additional indications. Auxilium expects to begin phase Ib clinical studies in early 2012 to assess the safety and efficacy of XIAFLEX in the treatment of cellulite and expects top line results for the cellulite Phase Ib dose escalation trial in the fourth quarter of 2012. BioSpecifics plans to initiate clinical studies for the indications of human and canine lipomas shortly. Auxilium will continue to have the option to exclusively license these indications upon completion of our development work.

Based on the terms of the Auxilium Amendment, Auxilium will pay us an opt-in fee at the time of completion by Auxilium of Stage I development of cellulite and will be responsible for all development costs associated with cellulite. Auxilium’s opt-in rights remain unchanged with respect to the two lipoma indications. In addition to the

opt-in fees, we will continue to be entitled to regulatory milestones, low double digit royalties and a mark-up of cost of goods on all indications.

In its September and October 2011 presentations, Auxilium provided updates on its clinical trials for Peyronie's disease and adhesive capsulitis commonly known as Frozen Shoulder. In September, Auxilium stated that the active dosing phase for its Peyronie's pivotal phase III clinical trials is complete, and they are entering a 34 week follow-up phase of studies, and in October, reaffirmed its belief that top line results in Peyronie's would be available in the second quarter of 2012. In October, Auxilium confirmed that it would initiate in the fourth quarter of 2011 a phase II study for Frozen Shoulder with top line results expected in the first quarter of 2013.

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On October 3, 2011 Auxilium announced that the first patients had been dosed in the Company's phase IIIb trial of XIAFLEX for the treatment of adult Dupuytren's contracture patients with multiple palpable cords. The study is expected to enroll approximately 60 patients at eight sites throughout the U.S. and Australia and patients will be monitored for 60 days following their last injection. It is estimated by SDI Health, LLC that up to 40% of annual Dupuytren's surgeries are performed to treat two or more cords concurrently.

The phase IIIb study is an open-label study that is designed to assess the safety and efficacy of concurrent administration of two injections of XIAFLEX into the same hand of subjects with at least two Dupuytren's contractures caused by palpable cords. Safety assessments, including immunogenicity testing, will be made during all study visits. Efficacy assessments will include measuring finger goniometry and range of motion of the treated joints on days 1, 8, 30, and 60, following the first cycle of two injections. Upon completion of the day 60 follow-up visit following the first treatment cycle, subjects who require additional treatment in the treated hand may receive XIAFLEX in other individual cords, up to a total of five injections.

In its October presentation, Auxilium announced that it earned in the third quarter of 2011 a \$7.5 million milestone payment from Pfizer due to the first sale of XIAPEX in Spain. Under the Auxilium Agreement, we are entitled to 8.5%, or \$637,500, of such milestone payment payable within 30 business days of Auxilium's receipt of the \$7.5 million from Pfizer.

On November 2, 2011, Auxilium announced that the Center for Medicare and Medicaid Services (CMS) released the payment rates for the 2012 Current Procedural Terminology (CPT®) codes that will be used with XIAFLEX for the treatment of adult Dupuytren's contracture patients with a palpable cord beginning January 1, 2012. The two new Category I CPT codes, issued by the American Medical Association (AMA) for 2012, are 20527 for the XIAFLEX injection procedure and 26341 for the finger extension or manipulation procedure, administered 24 hours following the XIAFLEX injection, as per the label. The finger extension code payment will cover any additional patient follow-up visits up to 10 days after the extension. The CPT codes will apply to the procedures only, and leave in place the separate J code for reimbursement of the product.

## 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 U.S. generally accepted accounting principles ("U.S. GAAP") has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for quarterly reporting.

The information included in this Report should be read in conjunction with our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2011 and June 30, 2011 filed with the SEC on May 10, 2011 and August 9, 2011, respectively, and 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. 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 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.

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## 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, U.S. 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 September 30, 2011:

	Level 1	Level 2	Level 3
Cash and cash equivalents	\$ 3,795,763	-	-
Certificates of Deposit	5,000,000	-	-

## 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 of lab reagents 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 and earn-out payment revenues are generally recognized in the quarter that the applicable licensee provides the written report and sufficient related information to us.

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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 and 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 Santyl. 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 Revenue

We include revenue recognized from upfront licensing and sublicensing fees 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 license and sublicense 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 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 U.S. Food and Drug Administration (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.

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### 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 September 30, 2011, accounts receivables included approximately \$1.7 million mainly due under our agreement with DFB.

### Reimbursable Third Party Development Costs

We accrued expenses for research and development that are reimbursable by us under the Auxilium Agreement. We capitalize certain patent costs related to estimated third party development costs that are reimbursable under the Auxilium Agreement. In August 2011, through the Auxilium Amendment, we have clarified the rights and responsibilities of the joint development of XIAFLEX. We resolved an on-going dispute with Auxilium concerning the appropriate amount of creditable third party development expenses related to the lyophilization of the injection formulation and certain patent expenses for research and development costs that are reimbursable under the Auxilium Agreement. We agreed to reimburse Auxilium by offsetting future royalties payable for the amount invoiced us for third party development costs related to the development of the lyophilization of the injection formulation.

In the third quarter of 2011, we recognized approximately \$1.0 million related to royalty revenue from the sale of XIAFLEX. Based upon the royalty revenue reported to us, we reduced our reimbursable third party development and certain patent costs accrual to zero.

### 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, product materials 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.

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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 nine month period ended September 30, 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development	\$ 22,138	\$ 27,116	\$ 74,711	\$ 82,269
General and administrative	104,093	362,104	316,427	1,628,723
Total stock-based compensation expense	\$ 126,231	\$ 389,220	\$ 391,138	\$ 1,710,992

## Stock Option Activity

A summary of our stock option activity during the nine months ended September 30, 2011 is presented below:

Options	Total Number of Shares	Weighted-Average Exercise Price
Outstanding as of December 31, 2010	1,346,425	\$ 7.81
Granted	-	-
Forfeited	-	-
Exercised	85,000	0.97
Expired	-	\$ -
Outstanding as of September 30, 2011	1,261,425	\$ 8.27
Exercisable as of September 30, 2011	1,163,925	\$ 7.16

During the nine months ended September 30, 2011 and 2010, \$82,450 and \$653,375, respectively, were received from stock options exercised by option holders.

The aggregate intrinsic value of options outstanding and exercisable as of September 30, 2011 was approximately \$10.5 million. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our

common stock of \$16.14 on September 30, 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 September 30, 2011 was approximately \$0.3 million which we expect to recognize over a weighted-average period of 1.2 years.

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### 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 May 2011, the Financial Accounting Standards Board ("FASB") issued ASU 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standard ("IFRS"), to converge fair value measurement and disclosure guidance in U.S. GAAP with the guidance in the International Accounting Standards Board's concurrently issued IFRS 13, Fair Value Measurement. The amendments in ASU 2011-04 do not modify the requirements for when fair value measurements apply; rather, they generally represent clarifications on how to measure and disclose fair value under ASC 820, Fair Value Measurement. The amendments in the ASU 2011-04 are effective prospectively for interim and annual periods beginning after December 15, 2011. Early adoption is not permitted for public entities. The Company is currently assessing the impact of ASU 2011-04 on its financial statements. Adoption of this standard is not expected to have a material impact on the financial statements.

In June 2011, the FASB issued Accounting Standards Update No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income ("ASU 2011-05"). Under ASU 2011-05, an entity will have the option to present comprehensive income on the income statement or as a separate financial statement. ASU 2011-05 is effective January 1, 2012 and requires retrospective adoption. ASU 2011-05 affects financial statement presentation only and has no effect on results of operations or financial position.

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 and nine months ended September 30, 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 those periods, as their effect would have been anti-dilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Stock options	722,994	902,134	796,104	936,615

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## 4. TOTAL COMPREHENSIVE INCOME (LOSS)

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net income (loss)	\$ 269,836	\$ (484,297 )	\$ 6,530,300	\$ (1,648,709)
Other comprehensive loss:				
Change in unrealized losses on marketable securities	-	-	-	-
Total Comprehensive Income (Loss)	\$ 269,836	\$ (484,297 )	\$ 6,530,300	\$ (1,648,709)

## 5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	September 30, 2011	December 31, 2010
Trade accounts payable and accrued expenses	\$ 473,162	\$ 674,917
Accrued legal and other professional fees	116,292	77,442
Accrued payroll and related costs	143,476	140,725
Total	\$ 732,930	\$ 893,084

## 6. PATENT COSTS

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 1 to 9 years, and review for impairment on a quarterly basis and when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

As of September 30, 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:

	September 30, 2011	December 31, 2010
Patents	\$ 273,554	\$ 250,621
Accumulated Amortization	(109,527 )	(77,178 )
	\$ 164,027	\$ 173,443

The amortization expense for patents was \$32,349 for the nine months ended September 30, 2011. In the comparable period of 2010, the amortization expense for patents was \$9,160 for the nine months September 30, 2010. The estimated aggregate amortization expense for each of the next five years is approximately as follows:



2012	\$39,000
2013	36,000
2014	29,000
2015	11,000
2016 through 2020	8,000

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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 nine month period ended September 30, 2011 net income tax benefit was \$2.6 million, primarily a non-cash credit. In the 2011 period, we reduced our tax assets valuation allowance and recorded net deferred tax assets of \$4.2 million 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 considered 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 an increase in the net operating loss carry-forward of approximately \$1.1 million which was applied to the current period's federal and state income taxes, \$1.1 million orphan tax credit, \$1.6 million stock based deferred tax asset and \$0.5 million tax asset from deferred revenues. We had \$2.2 million net operating loss carryforwards from windfall tax benefits from stock compensation awards and used \$0.4 million to reduce taxes payable for the nine month period of 2011.

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 plus utilities and real estate taxes. 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 notified the Landlord of our termination of the Lease Agreement effective March 31, 2011, but continue to hold over in the Premises.

On April 14, 2011, the Landlord entered into an agreement to sell the Premises to an unrelated third party named 35 Wilbur Street Associates, LLC. In October 2011, this agreement was terminated, and the sale did not occur. We are currently evaluating our options with respect to remaining in or leaving the Premises. Until that evaluation is complete, we will continue to hold over in the Premises on a month-to-month basis.

10. SUBSEQUENT EVENTS

In October 2011, Auxilium announced in its conference call that Pfizer had launched XIAPEx during the third quarter in Spain thereby achieving the third "first sale" milestone of \$7.5 million. We will be entitled to 8.5% of this milestone and will recognize \$637,500 in the fourth quarter of 2011.

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 November 8, 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.

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### Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement (including all amendments, 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. Auxilium began selling XIAFLEX in the U.S. for the treatment of Dupuytren's contracture in the first quarter of 2010. 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). Pfizer currently is selling XIAPEX in the United Kingdom, Germany, Denmark, Sweden, Finland, Norway, Austria and Switzerland and received approval to market XIAPEX in Spain in the third quarter of 2011. 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 Santyl. 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 an August 31, 2011 joint press release, BioSpecifics and Auxilium announced that they amended and restated their development and license agreement (such amendment, the “Auxilium Amendment”) and that they entered into a settlement agreement pursuant to which they settled all pending litigation and resolved other outstanding disputes between them. The Auxilium Amendment clarified and changed certain rights and obligations of the parties. For example, Auxilium has been granted the right to initiate studies for the treatment of edematous fibrosclerotic panniculopathy, more commonly known as cellulite.

Also in their August 31, 2011 press release, BioSpecifics announced plans to move XIAFLEX forward in the clinic for human and canine lipoma as well as to collaborate with Auxilium on the initiation of further studies for XIAFLEX in additional indications. Auxilium expects to begin phase Ib clinical studies in early 2012 to assess the safety and efficacy of XIAFLEX in the treatment of cellulite and expects top line results for the cellulite Phase Ib dose escalation trial in the fourth quarter of 2012. BioSpecifics plans to initiate clinical studies for the indications of human and canine lipomas shortly. Auxilium will continue to have the option to exclusively license these indications upon completion of our development work.

Based on the terms of the Auxilium Amendment, Auxilium will pay us an opt-in fee at the time of completion by Auxilium of Stage I development of cellulite and will be responsible for all development costs associated with cellulite. Auxilium’s opt-in rights remain unchanged with respect to the two lipoma indications. In addition to the opt-in fees, we will continue to be entitled to regulatory milestones, low double digit royalties and a mark-up of cost of goods on all indications.

In its September and October 2011 presentations, Auxilium provided updates on its clinical trials for Peyronie’s disease and adhesive capsulitis commonly known as Frozen Shoulder. In September, Auxilium stated that the active dosing phase for its Peyronie’s pivotal phase III clinical trials is complete, and they are entering a 34 week follow-up

phase of studies, and in October, reaffirmed its belief that top line results in Peyronie's would be available in the second quarter of 2012. In October, Auxilium confirmed that it would initiate in the fourth quarter of 2011 a phase II study for Frozen Shoulder with top line results expected in the first quarter of 2013.

On October 3, 2011 Auxilium announced that the first patients had been dosed in the Company's phase IIIb trial of XIAFLEX for the treatment of adult Dupuytren's contracture patients with multiple palpable cords. The study is expected to enroll approximately 60 patients at eight sites throughout the U.S. and Australia and patients will be monitored for 60 days following their last injection. It is estimated by SDI Health, LLC that up to 40% of annual Dupuytren's surgeries are performed to treat two or more cords concurrently.

The phase IIIb study is an open-label study that is designed to assess the safety and efficacy of concurrent administration of two injections of XIAFLEX into the same hand of subjects with at least two Dupuytren's contractures caused by palpable cords. Safety assessments, including immunogenicity testing, will be made during all study visits. Efficacy assessments will include measuring finger goniometry and range of motion of the treated joints on days 1, 8, 30, and 60, following the first cycle of two injections. Upon completion of the day 60 follow-up visit following the first treatment cycle, subjects who require additional treatment in the treated hand may receive XIAFLEX in other individual cords, up to a total of five injections.

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In its October presentation, Auxilium announced that it earned in the third quarter of 2011 a \$7.5 million milestone payment from Pfizer due to the first sale of XIAPEX in Spain. Under the Auxilium Agreement, we are entitled to 8.5%, or \$637,500, of such milestone payment payable within 30 business days of Auxilium's receipt of the \$7.5 million from Pfizer.

On November 2, 2011, Auxilium announced that the Center for Medicare and Medicaid Services (CMS) released the payment rates for the 2012 Current Procedural Terminology (CPT®) codes that will be used with XIAFLEX for the treatment of adult Dupuytren's contracture patients with a palpable cord beginning January 1, 2012. The two new Category I CPT codes, issued by the American Medical Association (AMA) for 2012, are 20527 for the XIAFLEX injection procedure and 26341 for the finger extension or manipulation procedure, administered 24 hours following the XIAFLEX injection, as per the label. The finger extension code payment will cover any additional patient follow-up visits up to 10 days after the extension. The CPT codes will apply to the procedures only, and leave in place the separate J code for reimbursement of the product.

## 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 Santyl. 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 September 30, 2011, we had an accumulated deficit from continuing operations of approximately \$3.4 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 U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are based on historical experience and on various other assumptions that we believe are reasonable under the circumstances. The information at September 30, 2011 and for the three and nine months ended September 30, 2011 and 2010 are 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 September 30, 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 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2011 and June 30, 2011 filed with the SEC on May 10, 2011 and August 9, 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.

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**Revenue Recognition.** We currently recognize revenues resulting from products sales, the licensing, sublicensing and use of our technology and from services we sometimes perform in connection with the licensed technology. 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 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 or our licensee has 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 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 and 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 and 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 Santyl. 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.

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**Reimbursable Third Party Development Costs.** We accrued expenses for research and development that are reimbursable by us under the Auxilium Agreement. We capitalize certain patent costs related to estimated third party development costs that are reimbursable under the Auxilium Agreement. In August 2011, through the Auxilium Amendment, we have clarified the rights and responsibilities of the joint development of XIAFLEX. We resolved an on-going dispute with Auxilium concerning the appropriate amount of creditable third party development expenses related to the lyophilization of the injection formulation and certain patent expenses for research and development cost that are reimbursable under the Auxilium Agreement. We agreed to reimburse Auxilium by offsetting future royalties payable for the amount invoiced us for third party development costs related to the development of the lyophilization of the injection formulation.

In the third quarter of 2011, we recognized approximately \$1.0 million related to royalty revenue from the sale of XIAFLEX. Based upon the royalty revenue reported to us, we reduced our reimbursable third party development and certain patent costs accrual to zero.

**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 September 30, 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 Accounting Standards Codification 718, Compensation-Stock Compensation ("ASC 718"), we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant 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 and NINE MONTHS ENDED SEPTEMBER 30, 2011 and 2010

Revenues

Product Revenues, net

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Product revenues include the sales of the collagenase for laboratory use recognized at the time it is shipped to customers. We recognized a small amount of revenue from the sale of collagenase for laboratory use. For the three months ended September 30, 2011 and 2010, product revenues were \$1,683 and \$5,183, respectively. For the nine months ended September 30, 2011 and 2010, product revenues were \$13,457 and \$32,328, respectively. The decreases in the 2011 periods as compared to 2010 were primarily related to the amount of material required to perform testing by our customers.

### Royalties/Earn-out/Mark-up on Cost of Goods Sold

We receive royalty, earn-out and mark-up on cost of goods sold revenues from two primary sources. We recognized royalties and the mark-up on cost of goods sold due to us under the terms of the Auxilium Agreement and royalty revenues from DFB under the earn-out payment provision of the DFB Agreement, after certain net sales levels are achieved.

Total royalty, earn-out and mark-up on cost of goods sold revenues for the three months ended September 30, 2011 was \$1.8 million as compared to \$0.8 million in the 2010 period. Total royalty, earn-out and mark-up on cost of goods sold revenues for the nine months ended September 30, 2011 was \$4.5 million as compared to \$1.4 million in the 2010 period.

Royalty and mark-up on cost of goods sold revenues recognized under the Auxilium Agreement for the three months ended September 30, 2011 totaled \$1.1 million and \$0.2 million in the comparable period of 2010. Royalty and mark-up on cost of goods sold revenues recognized under the Auxilium Agreement for the nine months ended September 30, 2011 totaled \$2.9 million and \$0.2 million in the comparable period of 2010. The increases were due to the increase in net sales of XIAFLEX during the 2011 periods reported to us by Auxilium. Auxilium began selling XIAFLEX in the first quarter of 2010 and Pfizer began selling XIAFLEX in the second quarter of 2011 for Dupuytren's contracture within certain European countries under the registered trademark XIAPEX.

Earn-out revenues recognized under the DFB Agreement for the three months ended September 30, 2011 were \$0.8 million and \$0.6 million for the same period in 2010. Earn-out revenues for the nine months ended September 30, 2011 were \$1.5 million and \$1.1 million for the same period in 2010. The increases in 2011 are mainly related to the increase in net sales of Santyl during the 2011 period reported to us by DFB.

### Licensing Revenues

Licensing revenues consist of licensing and sublicensing fees and milestone revenues. Licensing fees recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period. For the three months ended September 30, 2011 and 2010, we recognized in each period total licensing revenues of \$0.1 million related to the amortization of license fees received under the Auxilium Agreement.

For the nine months ended September 30, 2011 and 2010, we recognized total licensing revenue consisting of licensing and sublicensing fees and milestone revenues of \$4.3 million and \$2.9 million, respectively.

Licensing fees recognized for the nine months ended September 30, 2011 were \$0.3 million as compared to \$0.6 million in the 2010 period. Licensing fees recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period. The change was primarily due to the acceleration of license revenue recognized in connection with the marketing approval from the FDA for XIAFLEX for Dupuytren's contracture in the 2010 period. In the 2011 period, we recognized sublicensing fees of \$0.8 million related to a \$15 million payment to Auxilium by Asahi for the rights to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan as compared to none in the 2010 period. Total milestone

revenues recognized for the nine months ended September 30, 2011 and 2010 were \$3.2 million and \$2.3 million, respectively. Milestone revenues received and recognized in the 2011 period consist of \$2.6 million of the \$30 million regulatory milestone paid to Auxilium by Pfizer following the first sale of XIAPEX in a major EU market for Dupuytren's contracture in Europe and \$0.6 million of the \$7.5 million paid to Auxilium by Pfizer for the launch in Germany of XIAPEX. In the 2010 period, we received and recognized \$1.3 million of the \$15 million milestone paid to Auxilium by Pfizer for the scientific/technical review procedure of the Marketing Authorization Application for XIAFLEX for Dupuytren's contracture in Europe and a milestone of \$1.0 million related to the FDA's approval of XIAFLEX for Dupuytren's contracture.

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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. For the three months ended September 30, 2011 and 2010, consulting revenues were zero and \$70,000, respectively. For the nine months ended September 30, 2011 and 2010, consulting revenues were \$46,667 and \$210,000, respectively. The decreases in the 2011 periods were mainly due to the expiration of the consulting obligations under the DFB Agreement in March 2011.

## Costs and Expenses

## Research and Development Activities

Research and development expenses include, but are not limited to, internal costs, such as salaries and benefits, costs of materials, lab expense, facility costs and overhead. Research and development expenses also consist of third party costs, such as medical professional fees, product costs used in clinical trials, consulting fees and costs associated with clinical study arrangements.

Research and development expenses were \$0.2 million in each three month period ended September 30, 2011 and 2010. Research and development expenses were \$0.7 million and \$1.3 million, respectively, for the nine months ended September 30, 2011 and 2010. This decrease of approximately \$0.6 million or 44% in research and development expenses in the nine month period was primarily due to lower third party development costs partially offset by higher consulting services related to our animal study and research and development programs.

We are currently working to complete the regulatory requirements and obtain the applicable approvals from the FDA in order to initiate human and canine lipoma trials. Once we have submitted the required documentation and obtained the required approvals, we plan to conduct a placebo controlled clinical trial in dogs to assess the efficacy and safety of XIAFLEX as a non-surgical treatment for canine lipomas. We also plan to conduct a dose escalation clinical trial in human patients in order to assess the efficacy and safety of XIAFLEX as a non-surgical treatment for human lipoma.

Program	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2011	January 1, 2010 to September 30, 2011
Canine Lipoma	\$ 70,563	\$ 211,704	\$ 409,734
Human Lipoma	33,837	88,190	213,381

Successful development of drugs is inherently difficult and uncertain. Our business requires investments in research and development over many years, often for drug candidates that may fail during the research and development process. Even if the Company is able to successfully complete the development of our drug candidates, our long-term prospects depend upon our ability and the ability of our partners, particularly with respect to XIAFLEX, to continue to successfully commercialize these drug candidates.

There is significant uncertainty regarding our ability to successfully develop drug candidates in other indications. These risks include the uncertainty of:

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our preclinical studies and other research and development activities related to our drug candidate projects;

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- clinical trial results for our drug candidate projects;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our drug candidate projects;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our drug candidate projects;
  - the cost and timing of regulatory approvals with respect to our drug candidate projects; and
  - the cost of establishing clinical supplies for our drug candidate projects.

Our current resources and liquidity are sufficient to advance our significant current research and development projects and, Auxilium will have the option to exclusively license the canine and human lipoma indications upon completion of our development work.

### General and Administrative Expenses

General and administrative expenses were \$1.2 million and \$1.3 million, respectively, for the three months ended September 30, 2011 and 2010. The decrease in general and administrative expenses of approximately \$0.1 million was due to lower stock based compensation and consulting services partially offset by general legal expenses, director fees and third party royalties.

General and administrative expenses were \$4.2 million and \$5.0 million, respectively, for the nine months ended September 30, 2011 and 2010. The decrease in general and administrative expenses of approximately \$0.8 million or 16% was due to lower stock based compensation, consulting services and investor relations fees partially offset by increased legal fees, a reversal in the 2010 period of certain third party patent fees reimbursable under our agreement with Auxilium and director fees.

### Other Income (expense), net

Other income, net, was \$7,813 for the three months ended September 30, 2011 as compared to \$17,487 for the same period in 2010. This change was primarily due to lower interest income earned on our investments.

Other income, net, was \$55,540 for the nine months ended September 30, 2011 as compared to \$69,262 for the same period in 2010. Interest income earned on our investments for the 2011 period was \$41,061 as compared to \$69,262. Other income for the 2011 period was \$14,479 and zero in the comparable period of 2010 due to a refund of tax penalties associated with our prior years' tax filings.

### Income Tax Provision

For the three month period ended September 30, 2011 income tax expense was \$0.2 million, primarily a non-cash charge as compared to an income tax expense of zero in the 2010 period. Our income tax expense for the three month period ended September 30, 2011 is based on an estimated effective tax rate derived from an estimate of consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for fiscal year 2011.

For the nine month period ended September 30, 2011 net income tax benefit was \$2.6 million, primarily a non-cash credit, as compared to an income tax expense of \$8,067 in the 2010 period. In the 2011 period, we reduced our tax assets valuation allowance and recorded net deferred tax assets of \$4.2 million 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 considered 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 an increase in the net operating loss carry-forward of approximately \$1.1



million which was applied to the current period's federal and state income taxes, \$1.1 million orphan tax credit, \$1.6 million stock based deferred tax asset and \$0.4 million tax asset from deferred revenues. We had \$2.2 million net operating loss carryforwards from windfall tax benefits from stock compensation awards and used \$0.5 million to reduce taxes payable for the nine month period of 2011. The income tax expense for the 2010 period is primarily related to the payment of New York state taxes.

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### Net Income (Loss)

For the three months ended September 30, 2011 we recorded net income of \$0.3 million, or \$0.04 per basic and per diluted common share, compared to a net loss of \$0.5 million, or \$0.08 per basic and diluted common share, for the same period in 2010.

For the nine months ended September 30, 2011 we recorded net income of \$6.5 million or \$1.03 per basic and \$0.92 per diluted common share, compared to a net loss of \$1.6 million, or \$0.26 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 September 30, 2011 and December 31, 2010, we had cash and cash equivalents and investments in the aggregate of approximately \$8.8 million and \$7.8 million, respectively.

Net cash provided by operating activities for the nine months ended September 30, 2011 was \$0.8 million as compared to net cash used in operating activities of \$0.1 million for the same period in 2010. The change in the 2011 period as compared to the same period in 2010 was primarily attributable to our increased revenues during the period offset by a deferred tax asset recorded during the period and a reduction in accrued expenses associated with reimbursable third party development expenses.

Net cash provided by investing activities for the nine months ended September 30, 2011 was \$0.4 million as compared to \$0.8 million of net cash used in investing activities for the 2010 period. The change reflects the increase in maturing marketable securities and a slightly lower reinvestment in purchases of marketable securities during the 2011 period as compared to the 2010 period.

Net cash provided by financing activities for the nine months ended September 30, 2011 and 2010 was \$0.2 million in each period. In 2011, net cash provided by financing activities was mainly due to excess tax benefits related to share-based payments and proceeds received from stock option exercises partially offset by the repurchase of our common stock under our stock repurchase program during the period. In the 2010 period, net cash provided by financing activities was due to proceeds received from stock option exercises partially offset by repurchases of our common stock under our stock repurchase program.

### 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 eighteen months.

Our investment portfolio is subject to interest rate risk, although limited given the nature of the investments, and will fall in value in the event market interest rates increase. All our cash and cash equivalents and short-term investments at September 30, 2011, amounting to approximately \$8.8 million, were maintained in bank demand accounts, money market accounts, and certificates of deposit through the Certificate of Deposit Account Registry Service. 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.

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### 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, 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 August 31, 2011, the Company and Auxilium entered into a settlement agreement (the "Settlement Agreement") which resulted in the dismissals with prejudice with each party bearing its own expenses of the following previously reported litigation:

1. the lawsuit filed against the Company on June 28, 2011 by Auxilium and Cobra (as defined below) in the Court of Common Pleas in Chester County, Pennsylvania, seeking declaratory judgment on all of the counts contained in the May 2, 2011 lawsuit filed by the Company against them in New York.
2. the lawsuit filed by the Company on May 2, 2011 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 alleging that Auxilium, despite full knowledge of the terms of a Material Transfer Agreement ("MTA") between us and Cobra, wrongfully 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, which such rights were used by Auxilium to apply for and to obtain a manufacturing patent that did not name us as a co-owner or co-inventor.
3. the lawsuit filed against the Company on February 15, 2011 by Auxilium in the Court of Common Pleas in Chester County, Pennsylvania concerning our right to conduct clinical trials without the prior approval of the companies' Joint Development Committee.

Pursuant to the terms of the Settlement Agreement (which is more fully described in the Company's Current Report on Form 8-K filed on September 1, 2011 and is attached as Exhibit 10.2 thereto), the Company became a co-owner with Auxilium of the '560 patent and any continuations and divisionals thereof. The Company and Auxilium also agreed to certain clarifications as to intellectual property matters and amounts owed between the parties. The effectiveness of the Settlement Agreement was conditioned, in part, upon the parties' August 31, 2011 execution of the Auxilium Amendment described above in Part I, Item 2 of this Report. Under the Auxilium Amendment, the Company and Auxilium clarified and changed certain rights and obligations of the parties, including the respective rights of the parties to conduct clinical trials put at issue in the lawsuit filed by Auxilium on February 15, 2011. The Auxilium Amendment is more fully described in the Company's Current Report on Form 8-K filed on September 1, 2011 and is attached as Exhibit 10.1 thereto.

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Item 1A. Risk Factors

In addition to the other information set forth in this Report, you should carefully consider the factors discussed in Part I, “ITEM 1A. Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC on March 14, 2011. Except as set forth below, there have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010.

The following is an additional risk factor:

Successful development of drug candidates is inherently difficult and uncertain, and our long-term prospects depend upon our ability and the ability of our partners, particularly with respect to XIAFLEX, to continue to successfully commercialize these drug candidates.

Successful development of drugs is inherently difficult and uncertain. Our business requires investments in research and development over many years, often for drug candidates that may fail during the research and development process. Even if the Company is able to successfully complete the development of our drug candidates, our long-term prospects depend upon our ability and the ability of our partners, particularly with respect to XIAFLEX, to continue to successfully commercialize these drug candidates.

There is significant uncertainty regarding our ability to successfully develop drug candidates in other indications. These risks include the uncertainty of:

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our preclinical studies and other research and development activities related to our drug candidate projects;
- clinical trial results for our drug candidate projects;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our drug candidate projects;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our drug candidate projects;
- the cost and timing of regulatory approvals with respect to our drug candidate projects; and
- the cost of establishing clinical supplies for our drug candidate projects.

The following risk factor replaces and supersedes, in its entirety, the risk factor titled “Our ability to conduct clinical trials may be limited by the Auxilium Agreement” in our Annual Report on Form 10-K for the year ended December 31, 2010:

Our ability to conduct clinical trials may be limited by the Auxilium Agreement.

Under the Auxilium Agreement, we have the right to conduct trials, studies or development work for, among other things, indications in canine lipomas and human lipomas, and, upon approval by the parties’ joint development committee (“JDC”), additional indications. Auxilium has pre-approved our protocols for canine lipomas and human lipomas. However, certain material changes to the protocols must be approved by the JDC, and the JDC may decide not to approve such changes if the JDC has reasonable safety concerns. In addition, the JDC has the right to stop a study or trial in canine lipomas and human lipomas if the rate of serious adverse events exceeds certain thresholds. If

the JDC fails to approve changes to our protocols for canine lipomas and human lipomas or if the JDC stops our studies or trials in canine lipomas and human lipomas due to safety concerns, our ability to obtain option, milestone and royalty payments with respect to those indications would be limited. We may only conduct trials, studies or development work for additional indications beyond the pre-approved indications upon submission to and approval by the JDC of our development plan. In the case of indications in keloids, capsular contraction after breast augmentation, arthrofibrosis following total joint replacement in humans and equine suspensory ligament desmitis, the JDC may reject our submission only for reasonable safety concerns. The JDC may reject our submission for any other additional indications for safety or commercial concerns. If the JDC rejects our submissions in any additional indications, our ability to obtain option, milestone and royalty payments with respect to those additional indications would be limited.

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The following risk factor replaces and supersedes, in its entirety, the risk factor titled “We may have limited access to XIAFLEX under the Auxilium Agreement, which may limit our ability to conduct other clinical trials and to obtain the associated option, milestone and contingent royalty payments under the Auxilium Agreement” in our Annual Report on Form 10-K for the year ended December 31, 2010:

We are dependent on Auxilium for access to XIAFLEX, which may limit our ability to conduct clinical trials and to obtain the associated option, milestone and contingent royalty payments under the Auxilium Agreement.

Under the Auxilium Agreement, we have agreed to buy at cost plus a mark-up XIAFLEX from Auxilium for conducting our trials, studies and development work. If Auxilium does not supply XIAFLEX to us, our ability to conduct clinical trials using XIAFLEX would be limited because we do not have the right to make XIAFLEX or to purchase it from third parties. Moreover, our ability to use our own clinical material may be limited both by lack of availability and by certain potential regulatory restrictions. Without adequate supply of clinical material our ability to obtain additional option, milestone and royalty payments under the Auxilium Agreement would be limited.

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

During the nine month period ended September 30, 2011, we did not issue any unregistered shares of securities.

### Issuer Purchases of Equity Securities (1)

Period	Total Number of Shares Purchased During Period (2)	Average Price Paid Per Share (3)	Total Number of Shares Purchased as Part of Publicly Announced Plan	Maximum Dollar Value of Shares that may yet be Purchased under the Plan (4)
April 1, 2010 – June 30, 2010	18,718	\$22.37	18,718	\$1,581,242
July 1, 2010 – September 30, 2010	-	-	18,718	\$1,581,242
October 1, 2010 – December 31, 2010	1,890	\$20.76	20,608	\$1,541,999
January 1, 2011 – March 31, 2011	-	-	20,608	\$1,541,999
April 1, 2011 – June 30, 2011	8,777	\$23.51	29,385	\$1,335,651
				\$2,000,000 (5)
July 1, 2011 – September 30, 2011	8,981	\$17.18	38,366	\$1,845,900
<b>Total</b>	<b>38,366</b>			

(1) On June 4, 2010, we announced that our board of directors authorized a stock repurchase program under Rule 10b-18 of the Exchange Act of up to \$2.0 million of our outstanding common stock over a period of 12 months. On June 20, 2011, we announced that our Board of Directors had reauthorized this stock repurchase program.

(2) The purchases were made in open-market transactions.

(3) Includes commissions paid, if any, related to the stock repurchase transactions.

(4) Represents the difference between the original \$2.0 million of stock repurchases authorized by our board of directors on June 4, 2010 less the value of the stock repurchased for the indicated period.

(5) On June 20, 2011, our board of directors reauthorized the repurchase of up to \$2.0 million of our common stock under the stock repurchase program.



Item 3. Defaults Upon Senior Securities

None.

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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).
10.1	Second Amended and Restated Development and License Agreement, dated as of August 31, 2011, by and between BioSpecifics Technologies Corp. and Auxilium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed with the SEC on September 1, 2011).
10.2	Settlement Agreement, dated as of August 31, 2011, by and between BioSpecifics Technologies Corp. and Auxilium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed with the SEC on September 1, 2011).
<u>31</u> *	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).
<u>32</u> *	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002.
101.INS	Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

\* filed herewith

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SIGNATURES

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

BIOSPECIFICS TECHNOLOGIES CORP.  
(Registrant)

Date: November 8, 2011

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