BIOSPECIFICS TECHNOLOGIES CORP
Form 10-Q
November 09, 2012

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

FORM 10-Q

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

For the quarterly period ended September 30, 2012

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

For the transition period from _____to _____

001-34236
(Commission file number)

BIOSPECIFICS TECHNOLOGIES CORP.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	11-3054851
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

35 Wilbur Street Lynbrook, NY 11563
(Address of Principal Executive Offices) (Zip Code)

516.593.7000
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

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

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

Yes o No x

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

Class of Stock	Outstanding November 2, 2012
Common Stock ($.001 par value)	6,391,617

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" to BioSpecifics Technologies Corp. and its subsidiary, Advance Biofactures Corp. ("ABC-NY").

Introductory Comments – Forward-Looking Statements

This Report includes "forward-looking statements" within the meaning of, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are "forward-looking statements." The forward-looking statements include statements concerning, among other things, the timing of the FDA's review of the sBLA for XIAFLEX for the potential treatment of Peyronie's disease; the potential for XIAFLEX to be a break through option in Peyronie's disease; the potential for Auxilium to receive approval to expand the label for Dupuytren's contracture; the timing of results from Auxilium's clinical trials for Dupuytren's contracture (phase IIIb for concurrent treatment of multiple palpable cords and phase IV retreatment), cellulite, and frozen shoulder; and the timing of making XIAFLEX available in Canada. In some cases, these statements can be identified by forward-looking words such as "believe," "expect," "anticipate," "plan," "estimate," "likely," "will," "could," "continue," "project," "predict," "goal," the negative or plural of these words, and other similar expressions. Th forward-looking statements are predictions based on BioSpecifics' current expectations and its projections about future events. There are a number of important factors that could cause BioSpecifics' actual results to differ materially from those indicated by such forward-looking statements, including the ability of BioSpecifics' partner, Auxilium, and its partners, Pfizer Inc., Asahi Kasei Pharma Corporation and Actelion Pharmaceuticals Canada Inc., to achieve their objectives for XIAFLEX in their applicable territories; the potential market for XIAFLEX in a given indication, the potential of XIAFLEX to be used in additional indications, and the initiation, timing and outcome of clinical trials of XIAFLEX for additional indications; the timing of regulatory filings and action; the receipt of any applicable milestone payments from Auxilium; and other risk factors identified in BioSpecifics' Annual Report on Form 10-K for the year ended December 31, 2011, its Quarterly Reports on Form 10-Q for the first and second quarters of 2012, and its 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 BioSpecifics assumes 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, 2012 (unaudited)	December 31, 2011 (audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 3,823,860	$ 3,196,831
Short-term investments	5,190,000	5,000,000
Accounts receivable, net	3,205,394	3,236,917
Income tax receivable	71,132	244,720
Deferred tax assets	637,399	1,309,801
Prepaid expenses and other current assets	161,167	98,234
Total current assets	13,088,952	13,086,503
Deferred royalty buy-down	2,750,000	1,250,000
Deferred tax assets - long term	1,791,146	1,738,154
Patent costs, net	210,684	190,416
Total assets	17,840,782	16,265,073
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	680,406	601,002
Deferred revenue	161,122	437,099
Accrued liabilities of discontinued operations	78,138	78,138
Total current liabilities	919,666	1,116,239
Long-term deferred revenue	224,673	276,520
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 ; 6,625,168 and 6,530,743 shares issued at September 30, 2012 and December 31, 2011, respectively	6,625	6,531
Additional paid-in capital	20,667,613	20,049,196
Accumulated deficit	(1,411,785)	(3,291,904)
Treasury stock, 233,551 and 194,604 shares at cost at September 30, 2012 and December 31, 2011, respectively	(2,566,010)	(1,891,509)
Total stockholders' equity	16,696,443	14,872,314
Total liabilities and stockholders’ equity	$ 17,840,782	$ 16,265,073

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,	
	2012	2011	2012	2011
Revenues:				
Net sales	$3,378	$1,683	$12,128	$13,457
Royalties	2,307,073	1,810,436	6,698,355	4,461,683
Licensing revenues	137,774	109,276	926,324	4,265,327
Consulting fees	-	-	-	46,667
Total Revenues	2,448,225	1,921,395	7,636,807	8,787,134
Costs and expenses:				
Research and development	293,221	224,150	947,119	707,015
General and administrative	1,375,477	1,245,145	3,614,125	4,172,687
Total Cost and Expenses	1,668,698	1,469,295	4,561,244	4,879,702
Operating income	779,527	452,100	3,075,563	3,907,432
Other income (expense):				
Interest income	8,292	7,813	27,556	41,061
Other income (expense)	-	-	-	14,479
	8,292	7,813	27,556	55,540
Income before expense for income tax	787,819	459,913	3,103,119	3,962,972
Income tax benefit (expense)	(316,772)	(190,077)	(1,223,000)	2,567,328
Net income	$471,047	$269,836	$1,880,119	$6,530,300
Basic net income per share	$0.07	$0.04	$0.30	$1.03
Diluted net income per share	$0.07	$0.04	$0.27	$0.92
Shares used in computation of basic net income per share	6,343,210	6,362,951	6,341,031	6,337,237
Shares used in computation of diluted net income per share	6,961,652	7,085,945	6,985,290	7,133,341

Consolidated Statements of Comprehensive Income

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income	$471,047	$269,836	$1,880,119	$6,530,300
Other comprehensive income (loss)	-	-	-	-
Comprehensive income	$471,047	$269,836	$1,880,119	$6,530,300

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,	
Cash flows from operating activities:	2012	2011
Net income	$1,880,119	$6,530,300
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	43,529	32,349
Stock-based compensation expense	202,085	391,138
Deferred tax assets	619,410	(3,051,197)
Changes in operating assets and liabilities:		
Accounts receivable	31,523	286,236
Prepaid expenses and other current assets	110,655	(223,807)
Accounts payable and accrued expenses	15,607	(2,832,456)
Deferred revenue	(327,824)	(374,494)
Net cash provided by operating activities	2,575,104	758,069
Cash flows from investing activities:		
Maturity of marketable investments	5,000,000	5,360,970
Purchases of marketable investments	(5,190,000)	(5,000,000)
Payment for royalty buy down	(1,500,000)	-
Net cash provided by (used in) investing activities	(1,690,000)	360,970
Cash flows from financing activities:		
Proceeds from stock option exercises	148,425	82,450
Payments for repurchase of common stock	(674,501)	(360,447)
Excess tax benefits from share-based payment arrangements	268,001	483,869
Net cash provided by (used in) in financing activities	(258,075)	205,872
Increase in cash and cash equivalents	627,029	1,324,911
Cash and cash equivalents at beginning of year	3,196,831	2,470,852
Cash and cash equivalents at end of period	$3,823,860	$3,795,763
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	$-	$-
Taxes	162,000	190,000

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. For the nine month period ended September 30, 2012, we accrued approximately $64,000 related to certain patent costs of which we amortized approximately $44,000 in the 2012 period. For the nine months ended September 30, 2011, we accrued approximately $23,000 related to these costs of which approximately $33,000 was amortized in the 2011 period.

See accompanying notes to consolidated financial statements

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BIOSPECIFICS TECHNOLOGIES CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2012
(Unaudited)

1.ORGANIZATION AND DESCRIPTION OF BUSINESS

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We are a party to a development and license 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). Auxilium has an option to acquire additional indications that we may pursue, including cellulite, for which we have granted Auxilium the right to initiate early development studies at its cost, and human and canine lipoma. Auxilium is currently selling XIAFLEX in the U.S. for the treatment of Dupuytren’s contracture. Auxilium has an agreement with Pfizer, Inc. (“Pfizer”) pursuant to which Pfizer has marketing rights for XIAPEX® (the EU trade name for collagenase clostridium histolyticum) for Dupuytren’s contracture and Peyronie’s disease in Europe and certain Eurasian countries through April 24, 2013. 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 Duputyren’s contracture and Peyronie’s disease in Japan. Auxilium also has an agreement with Actelion Pharmaceuticals Ltd. (“Actelion”) pursuant to which Actelion has the right to commercialize XIAFLEX for the treatment of Duputyren’s contracture and Peyronie’s disease in Canada, Australia, Brazil and Mexico. Actelion was granted a Notice of Compliance (approval) by Health Canada for XIAFLEX for the treatment of Dupuytren's contracture in adults with a palpable cord in Canada.

Pursuant to a March 2006 agreement (the “DFB Agreement”) between the Company and DFB Biotech, Inc. (“DFB”), 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

On November 7, 2012, Auxilium announced that it has submitted a supplemental Biologics License Application (“sBLA”) to the U.S. Food and Drug Administration (“FDA”) for XIAFLEX for the potential treatment of Peyronie’s disease. Auxilium has requested Priority Review designation for the sBLA and expects to hear back from the FDA regarding that designation within approximately 60 days from the filing date. Under Prescription Drug User Fee Act guidelines, if Priority Review designation is granted for the submission, the FDA’s goal for completing the Priority Review is six months from the date of receipt. Adrian Adams, Chief Executive Officer and President of Auxilium, noted in Auxilium’s announcement that the sBLA submission “‘is a significant regulatory milestone for XIAFLEX and Auxilium and further demonstrates our strong commitment to addressing unmet medical needs by potentially providing patients with the only FDA-approved biologic therapy to treat this devastating disease’”. He added that Auxilium believes that “‘if approved by the FDA for the treatment of Peyronie’s disease, XIAFLEX has the clinical profile to become a potential breakthrough option in a therapeutic area that currently has limited treatment options’”.

Also on November 7, 2012, Auxilium and Pfizer announced that they have amended their collaboration agreement for the development, commercialization and supply of XIAPEX for the treatment of Dupuytren’s contracture and the potential treatment of Peyronie’s disease in the European Union and certain other European and Eurasian countries to include a mutual termination date of April 24, 2013. After the termination date, rights to commercialize XIAPEX and responsibility for regulatory activities for XIAPEX in these countries will revert to Auxilium. Adrian Adams stated in the announcement that “‘Auxilium remains committed to addressing the unmet needs of adult Dupuytren’s contracture

patients in the EU, and we now have the strategic flexibility to evaluate all of our options for the continuing commercialization of XIAPEX for the treatment of Dupuytren's contracture and for gaining approval for XIAPEX for the treatment of Peyronie's disease in the EU and other specified markets'".

In a September 5, 2012 press release, we announced a safety update following 30 months of post-approval use in the U.S. of XIAFLEX for the treatment of adult Dupuytren's contracture patients with a palpable cord. As reported by Auxilium, after approximately 27,000 injections were administered to approximately 21,000 patients in the U.S., there was no clinically meaningful change in the nature of events expected relative to the clinical trial safety profile.

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In an August 27, 2012 press release, we announced the presentation of additional data from the Phase III clinical program of XIAFLEX for the treatment of Peyronie's disease conducted by Auxilium and known as IMPRESS (The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies). These data were presented at two oral presentations at the Sexual Medicines Society of North America/International Society for Sexual Medicine Joint Annual Meeting on August 27 and 29, 2012 in Chicago, IL. These data highlighted the psychological severity of Peyronie's disease, which currently has no FDA-approved pharmaceutical therapy and complemented the positive top-line Phase III results from the two IMPRESS clinical trials reported in June 2012.

In a July 30, 2012 press release, Auxilium announced positive top-line data from its open-label phase IIIb trial evaluating XIAFLEX for the treatment of adult Dupuytren's contracture patients with multiple palpable cords. Auxilium enrolled 60 patients at eight sites throughout the U.S. and Australia. In the third quarter of 2012, Auxilium initiated a larger study with XIAFLEX for the concurrent treatment of multiple palpable cords that, if successful, may allow the Company to seek FDA approval and expansion of the Dupuytren's label. Auxilium expects topline results in the first half of 2014.

Also in the third quarter of 2012, Auxilium completed enrollment in its cellulite phase Ib, Frozen Shoulder phase IIa and phase IV Dupuytren's retreatment clinical trials. Auxilium expects top-line data from these XIAFLEX studies in the fourth quarter of 2012, first quarter of 2013 and fourth quarter of 2013, respectively.

In a July 9, 2012 press release, Auxilium and Actelion announced that Auxilium was granted a Notice of Compliance (approval) by Health Canada for XIAFLEX for the treatment of Dupuytren's contracture in adults with a palpable cord in Canada. Under the terms of the Collaboration Agreement between Actelion and Auxilium, Actelion received exclusive rights to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico upon receipt of the respective regulatory approvals. Pursuant to the Collaboration Agreement, Auxilium intends to transfer regulatory sponsorship of the dossier to Actelion and Actelion will be primarily responsible for the applicable regulatory and commercialization activities for XIAFLEX in Canada and, upon approval, in the remainder of these countries. Actelion expects to make XIAFLEX available to patients in Canada in the first half of 2013.

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 quarters ended March 31, 2012 and June 30, 2012 and our Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC.

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

The Fair Value Measurements and Disclosures Topic of the Accounting Standards Codification defines fair value, establishes a framework for measuring fair value in applying generally accepted accounting principles, and expands disclosures about fair value measurements. This Codification topic identifies two kinds of inputs that are used to determine the fair value of assets and liabilities: observable and unobservable. Observable inputs are based on market data or independent sources while unobservable inputs are based on our own market assumptions. Once inputs have been characterized, this Codification topic requires us to prioritize the inputs used to measure fair value into one of three broad levels. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values identified by Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities. Fair values identified by Level 3 inputs are unobservable data points and are used to measure fair value to the extent that observable inputs are not available. Unobservable inputs reflect our own assumptions about the assumptions that market participants would use in pricing the asset or liability.

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis for the period presented and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

September 30, 2012	Fair Value	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3
Cash and cash equivalents	$ 3,823,860	$ 3,823,860	-	-
Certificates of Deposit	5,190,000	5,190,000	-	-

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:

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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.

Under our development and license agreement with Auxilium (as amended and restated on each of December 11, 2008 and August 31, 2011, 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 patent costs.

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

License Revenue

We include revenue recognized from upfront licensing, sublicensing and milestone payments in "License Revenues" in our consolidated statements of operations in this Report.

Upfront License and Sublicensing Fees

We generally recognize revenue from upfront licensing and sublicensing fees when the agreement is signed, we have completed the earnings process and we have no ongoing performance obligation with respect to the arrangement. Nonrefundable upfront technology license for product candidates for which we are providing continuing services related to product development are deferred and recognized as revenue over the development period.

Milestones

Milestones, in the form of additional license fees, typically represent nonrefundable payments to be received in conjunction with the achievement of a specific event identified in the contract, such as completion of specified

development activities and/or regulatory submissions and/or approvals. We believe that a milestone represents the culmination of a distinct earnings process when it is not associated with ongoing research, development or other performance on our part. We recognize such milestones as revenue when they become due and collection is reasonably assured. When a milestone does not represent the culmination of a distinct earnings process, we recognize revenue in a manner similar to that of an upfront license fee.

The timing and amount of revenue that we recognize from licenses of technology, either from upfront fees 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 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.

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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.

Treasury Stock

The Company accounts for treasury stock under the cost method and includes treasury stock as a component of stockholders' equity.

Accounts receivable and Allowance for Doubtful Accounts

Trade accounts receivable are stated at the amount the Company expects to collect. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. We consider the following factors when determining the collectability of specific customer accounts: customer credit-worthiness, past transaction history with the customer, current economic industry trends, and changes in customer payment terms. Our accounts receivable balance is typically due from its two large pharmaceutical customers. These companies have historically paid timely and have been financially stable organizations. Due to the nature of the accounts receivable balance, we believe the risk of doubtful accounts is minimal. If the financial condition of our customers were to deteriorate, adversely affecting their ability to make payments, additional allowances would be required. We provide for estimated uncollectible amounts through a charge to earnings and a credit to a valuation allowance. Balances that remain outstanding after we have used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to accounts receivable. We recorded no material bad debt expense in the quarter ended September 30, 2012. The allowance for doubtful accounts balance as of September 30, 2012 and 2011 was $30,095.

Accounts receivable as of September 30, 2012 is approximately $3.2 million, which consists of approximately $2.1 million due from DFB in accordance with the earn-out under the DFB Agreement and approximately $1.1 million in royalties and mark-up on cost of goods sold due from Auxilium in accordance with the terms of the Auxilium Agreement.

Reimbursable Third Party Development Costs

We accrue 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 amendment and restatement of our development and license agreement with Auxilium, we have clarified the rights and responsibilities of the joint development of XIAFLEX. We resolved what had been 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 were reimbursable under the Auxilium Agreement. We do not expect any additional third party development cost related to the lyophilization of the injection formulation. Any estimates of patent costs are based on contractual terms, historical costs, reviewing third party data and expectations regarding future development for certain products.

If conditions or other circumstances change, we may take actions to revise our reimbursable third party patent cost estimates. These revisions could result in an incremental increase or decrease in research and development costs. For example, the Auxilium Agreement provides that Auxilium and BioSpecifics will share equally certain patent expenses which are creditable against future royalty revenues.

As of September 30, 2012 our net reimbursable third party patent costs accrual was approximately $90,000.

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Research and Development Expenses

Research and development ("R&D") expenses include, but are not limited to, internal costs, such as salaries and benefits, costs of materials, lab expense, facility costs and overhead. R&D 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. We may fund R&D at medical research institutions under agreements that are generally cancelable. All of these costs are charged to R&D as incurred, which may be measured by percentage of completion, contract milestones, patient enrollment, or the passage of time.

Clinical Trial Expenses

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

Stock-Based Compensation

The Company has two stock-based compensation plans in effect. Accounting Standards Codification 718, Compensation - Stock Compensation ("ASC 718") requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based awards including stock options and common stock issued to our employees and directors under our stock plans. It requires companies to estimate the fair value of share-based awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service periods in our consolidated statements of operations.

Under the ASC 718, we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of an award. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures) and the expected volatility. When there is uncertainty in the factors used to determine the expected term of an award, we use the simplified method. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. The Company did not grant stock options during the three month period ended September 30, 2012.

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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development	$ 13,200	$ 22,138	$ 158,017	$ 74,711
General and administrative	13,200	104,093	44,068	316,427
Total stock-based compensation expense	$ 26,400	$ 126,231	$ 202,085	$ 391,138

Stock Option Activity

A summary of our stock option activity during the nine months ended September 30, 2012 is presented below:

Options	Total Number of Shares	Weighted-Average Exercise Price
Outstanding as of December 31, 2011	1,261,425	$ 8.27
Granted	15,000	15.75
Forfeited	-	-
Exercised	94,425	1.57
Expired	-	-
Outstanding as of September 30, 2012	1,182,000	$ 8.90
Exercisable as of September 30, 2012	1,102,000	$ 7.90

During the nine months ended September 30, 2012 and 2011, $148,425 and $82,450, respectively, were received from stock options exercised by option holders.

The aggregate intrinsic value of options outstanding and exercisable as of September 30, 2012 was approximately $13.6 million. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our common stock of $19.42 on September 28, 2012, 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, 2012 was approximately $55,000 which we expect to recognize over a weighted-average period of six months.

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

Deferred tax assets and liabilities are recognized based on the expected future tax consequences, using current tax rates, of temporary differences between the financial statement carrying amounts and the income tax basis of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We use the asset and liability method of accounting for income taxes, as set forth in Accounting Standards Codification 740-10-25-2. Under this method, deferred income taxes, when required, are provided on the basis of the difference between the financial reporting and income tax basis of assets and liabilities at the statutory rates enacted for future periods. In accordance with Accounting Standards Codification 740-10-45-25, Income Statement Classification of Interest and Penalties, we classify interest associated with income taxes under interest expense and tax penalties under other.

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Future Impact of Recently Issued Accounting Standards

In June 2011, the Financial Accounting Standards Board (“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 is required to present comprehensive income on the income statement or as a separate financial statement. ASU 2011-05 is effective January 1, 2012. ASU 2011-05 affects financial statement presentation only and has no effect on results of operations or financial position. We adopted this new guidance effective March 31, 2012 and chose to use the two separate but consecutive statements presentation approach.

In May 2011, the 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. Adoption of this standard did not have a material impact on the 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 were included for the calculation of diluted net income purposes from continuing operations reported in the consolidated statement of operations.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Stock options	618,442	722,994	644,259	796,104

4.COMPREHENSIVE INCOME (LOSS)

For the three and nine months ended September 30, 2012 and 2011, we had no components of other comprehensive income or loss other than net income itself.

5.ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	September 30, 2012	December 31, 2011
Trade accounts payable and accrued expenses	$ 465,153	$ 407,954
Accrued legal and other professional fees	65,192	50,000
Accrued payroll and related costs	150,061	143,048

Total	$ 680,406	$ 601,002

6.PATENT COSTS

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 1 to 8 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.

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As of September 30, 2012, 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, 2012	December 31, 2011
Patents	$ 382,076	$ 318,280
Accumulated Amortization	(171,392)	(127,863)
	$ 210,684	$ 190,417

The amortization expense for patents for nine months ended September 30, 2012 was approximately $44,000. In the comparable period of 2011, the amortization expense for patents was approximately $33,000. The estimated aggregate amortization expense for each of the next five years is approximately as follows:

2013	52,000
2014	42,000
2015	17,000
2016	14,000
2017 through 2027	71,000

7.INCOME TAXES

The significant components of the Company's deferred tax assets, pursuant to Accounting Standards Codification 740-10-50 consist of net operating losses, orphan tax credits, stock-based compensation and deferred revenues. For the nine month period ended September 30, 2012 net income tax expense was $1.2 million, primarily a non-cash charge. For the nine month period ended September 30, 2012, the valuation allowance with respect to the company’s net deferred tax assets remained unchanged. Our remaining deferred tax assets decreased by $0.6 million to approximately $2.4 million, primarily because we used our Orphan Drug Tax Credit to reduce our taxes payable, during nine months ended September 30, 2012.

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.

8.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. 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.

9.SUBSEQUENT EVENTS

We have evaluated subsequent events for recognition or disclosure through the time of filing these consolidated financial statements on Form 10-Q with the U.S. Securities and Exchange Commission on November 9, 2012.

On November 7, 2012, Auxilium announced that it has submitted a supplemental Biologics License Application ("sBLA") to the U.S. Food and Drug Administration ("FDA") for XIAFLEX for the potential treatment of Peyronie's disease. Auxilium has requested Priority Review designation for the sBLA and expects to hear back from the FDA regarding that designation within approximately 60 days from the filing date. Under Prescription Drug User Fee Act guidelines, if Priority Review designation is granted for the submission, the FDA's goal for completing the Priority Review is six months from the date of receipt.

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Also on November 7, 2012, Auxilium and Pfizer announced that they have amended their collaboration agreement for the development, commercialization and supply of XIAPEX for the treatment of Dupuytren's contracture and the potential treatment of Peyronie's disease in the European Union and certain other European and Eurasian countries to include a mutual termination date of April 24, 2013. After the termination date, rights to commercialize XIAPEX and responsibility for regulatory activities for XIAPEX in these countries will revert to Auxilium.

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

The following discussion should be read in conjunction with the consolidated financial statements and the related notes thereto included elsewhere in this Report, and is qualified by reference to them.

Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We are a party to the Auxilium Agreement, our development and license agreement with 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). Auxilium has an option to acquire additional indications that we may pursue, including cellulite, for which we have granted Auxilium the right to initiate early development studies at its cost, and human and canine lipoma. Auxilium is currently selling XIAFLEX in the U.S. for the treatment of Dupuytren's contracture. Auxilium has an agreement with Pfizer pursuant to which Pfizer has marketing rights for XIAPEX® (the EU trade name for collagenase clostridium histolyticum) for Dupuytren's contracture and Peyronie's disease in Europe and certain Eurasian countries through April 24, 2013. In addition, Auxilium has an agreement with Asahi pursuant to which Asahi has the right to commercialize XIAFLEX for the treatment of Duputyren's contracture and Peyronie's disease in Japan. Auxilium also has an agreement with Actelion pursuant to which Actelion has the right to commercialize XIAFLEX for the treatment of Duputyren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico. Actelion was granted a Notice of Compliance (approval) by Health Canada for XIAFLEX for the treatment of Dupuytren's contracture in adults with a palpable cord in Canada.

Pursuant to 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

On November 7, 2012, Auxilium announced that it has submitted a sBLA to the FDA for XIAFLEX for the potential treatment of Peyronie's disease. Auxilium has requested Priority Review designation for the sBLA and expects to hear back from the FDA regarding that designation within approximately 60 days from the filing date. Under Prescription Drug User Fee Act guidelines, if Priority Review designation is granted for the submission, the FDA's goal for completing the Priority Review is six months from the date of receipt. Adrian Adams, Chief Executive Officer and President of Auxilium, noted in Auxilium's announcement that the sBLA submission "'is a significant regulatory milestone for XIAFLEX and Auxilium and further demonstrates our strong commitment to addressing unmet medical needs by potentially providing patients with the only FDA-approved biologic therapy to treat this devastating disease'". He added that Auxilium believes that "'if approved by the FDA for the treatment of Peyronie's disease, XIAFLEX has the clinical profile to become a potential breakthrough option in a therapeutic area that currently has limited treatment options'".

Also on November 7, 2012, Auxilium and Pfizer announced that they have amended their collaboration agreement for the development, commercialization and supply of XIAPEX for the treatment of Dupuytren's contracture and the

potential treatment of Peyronie's disease in the European Union and certain other European and Eurasian countries to include a mutual termination date of April 24, 2013. After the termination date, rights to commercialize XIAPEX and responsibility for regulatory activities for XIAPEX in these countries will revert to Auxilium. Adrian Adams stated in the announcement that "'Auxilium remains committed to addressing the unmet needs of adult Dupuytren's contracture patients in the EU, and we now have the strategic flexibility to evaluate all of our options for the continuing commercialization of XIAPEX for the treatment of Dupuytren's contracture and for gaining approval for XIAPEX for the treatment of Peyronie's disease in the EU and other specified markets'".

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In a September 5, 2012 press release, we announced a safety update following 30 months of post-approval use in the U.S. of XIAFLEX for the treatment of adult Dupuytren's contracture patients with a palpable cord. As reported by Auxilium, after approximately 27,000 injections were administered to approximately 21,000 patients in the U.S., there was no clinically meaningful change in the nature of events expected relative to the clinical trial safety profile.

In an August 27, 2012 press release, we announced the presentation of additional data from the Phase III clinical program of XIAFLEX for the treatment of Peyronie's disease conducted by Auxilium and known as IMPRESS (The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies). These data were presented at two oral presentations at the Sexual Medicines Society of North America/International Society for Sexual Medicine Joint Annual Meeting on August 27 and 29, 2012 in Chicago, IL. These data highlighted the psychological severity of Peyronie's disease, which currently has no FDA-approved pharmaceutical therapy and complemented the positive top-line Phase III results from the two IMPRESS clinical trials reported in June 2012.

In a July 30, 2012 press release, Auxilium announced positive top-line data from its open-label phase IIIb trial evaluating XIAFLEX for the treatment of adult Dupuytren's contracture patients with multiple palpable cords. Auxilium enrolled 60 patients at eight sites throughout the U.S. and Australia. In the third quarter of 2012, Auxilium initiated a larger study with XIAFLEX for the concurrent treatment of multiple palpable cords that, if successful, may allow the Company to seek FDA approval and expansion of the Dupuytren's label. Auxilium expects topline results in the first half of 2014.

Also in the third quarter of 2012, Auxilium completed enrollment in its cellulite phase Ib, Frozen Shoulder phase IIa and phase IV Dupuytren's retreatment clinical trials. Auxilium expects top-line data from these XIAFLEX studies in the fourth quarter of 2012, first quarter of 2013 and fourth quarter of 2013, respectively.

In a July 9, 2012 press release, Auxilium and Actelion announced that Auxilium was granted a Notice of Compliance (approval) by Health Canada for XIAFLEX for the treatment of Dupuytren's contracture in adults with a palpable cord in Canada. Under the terms of the Collaboration Agreement between Actelion and Auxilium, Actelion received exclusive rights to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico upon receipt of the respective regulatory approvals. Pursuant to the Collaboration Agreement, Auxilium intends to transfer regulatory sponsorship of the dossier to Actelion and Actelion will be primarily responsible for the applicable regulatory and commercialization activities for XIAFLEX in Canada and, upon approval, in the remainder of these countries. Actelion expects to make XIAFLEX available to patients in Canada in the first half of 2013.

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, 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. 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

We are dependent to a significant extent on third parties, and our principal licensee, Auxilium, may not be able to continue successfully commercializing XIAFLEX for Dupuytren's contracture, successfully develop XIAFLEX for additional indications, obtain required regulatory approvals, manufacture XIAFLEX at an acceptable cost, in a timely manner and with appropriate quality, or successfully market products or maintain desired margins for products sold,

and as a result we may not achieve sustained profitable operations.

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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, 2012 and for the three and nine months ended September 30, 2012 and 2011 is unaudited but includes all adjustments (consisting only of normal recurring adjustments) which, in the opinion of management, are necessary to state fairly the financial information set forth herein. The December 31, 2011 balance sheet amounts and disclosures included herein have been derived from the Company's December 31, 2011 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 unaudited consolidated financial statements for the period ended March 31, 2012 and June 30, 2012 included in the Company's Quarterly Reports on Form 10-Q filed with the SEC and the audited consolidated financial statements for year ended December 31, 2011 included in the Company's Annual Report on Form 10-K filed with the SEC. While our significant accounting policies are described in more detail in the notes to our unaudited consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our unaudited consolidated financial statements. Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

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

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

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

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

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

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

Under the Auxilium Agreement, we do not participate in the selling, marketing or manufacturing of products for which we receive royalties and a mark-up of the cost of goods sold revenues. The royalty 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 the underlying sales by Auxilium occurred. The royalties payable by Auxilium to us are subject to set-off for certain patent costs.

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

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

Reimbursable Third Party Development Costs. We accrued patent 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 amendment and restatement of our development and license agreement with Auxilium, we have clarified the rights and responsibilities of the joint development of XIAFLEX. We resolved what had been 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 and have reimbursed 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. We do not expect any additional third party development cost related to the lyophilization of the injection formulation.

As of September 30, 2012 our net reimbursable third party patent costs accrual was approximately $90,000.

Receivables and Deferred Revenue. Accounts receivable as of September 30, 2012 is approximately $3.2 million, which consists of approximately $2.1 million due from DFB in accordance with the earn-out under the DFB Agreement and approximately $1.1 million in royalties and mark-up on costs of goods sold due from Auxilium in accordance with the terms of the Auxilium Agreement. Deferred revenue of $0.4 million consist of licensing fees related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period of certain indications for XIAFLEX.

Royalty Buy-Down. On March 31, 2012, we entered into an amendment to our existing agreement, dated August 27, 2008, related to our future royalty obligations for Peyronie’s disease. The amendment enables us to buy down a portion of our future royalty obligations in exchange for an initial cash payment of $1.5 million and five additional cash payments payable upon the occurrence of a milestone event.

As of September 30, 2012, we have capitalized $2.75 million related to this agreement which will be amortized over approximately five years beginning on the date of the first commercial sale of XIAFLEX for the treatment of Peyronie’s disease, which represents the period estimated to be benefited using the straight-line method. In accordance with Accounting Standards Codification 350, Intangibles, Goodwill and Other, the Company amortizes intangible assets with finite lives in a manner that reflects the pattern in which the economic benefits of the assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the assets are amortized using the straight-line method.

Stock Based Compensation. Under ASC 718, we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of an award. Expected volatility is based on the historical volatility of our common stock. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our historical experience of employee stock option exercises (including forfeitures) and the expected volatility. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, we are likely to change

our valuation assumptions used to value future employee stock-based awards granted, to the extent any such awards are granted.

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

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

Revenues

Product Revenues, net

Product revenues include the sales of the collagenase for laboratory use recognized at the time it is shipped to customers. We had a small amount of revenue from the sale of collagenase for laboratory use. For the three months ended September 30, 2012 and 2011 product revenues were $3,378 and $1,683, respectively. This increase was primarily related to the amount of material required to perform testing and additional research by our customers.

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the Auxilium Agreement and earn-out revenues associated with the DFB Agreement. Total royalty, mark-up on cost of goods sold and earn-out revenues for the three month period ended September 30, 2012 were $2.3 million as compared to $1.8 million in the 2011 period, an increase of $0.5 million or 27%. Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were $1.5 million for the 2012 period compared to $1.1 million in the 2011 period. The increase of $0.4 million was due to increased net sales of XIAFLEX during 2012 reported to us by Auxilium.

We receive earn-out revenues from DFB under the earn-out payment provision of the DFB Agreement after certain net sales levels are achieved. Revenues recognized under the DFB Agreement were $0.8 million in each of the three month periods ended September 30, 2012 and 2011.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. For the three months ended September 30, 2012 and 2011, we recognized total licensing and milestone revenue of approximately $0.1 million in each period. Certain licensing revenues recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period. Licensing fees revenue recognized for the three months ended September 30, 2012 and 2011 was $0.1 million in each period. Milestone revenue recognized for the three months ended September 30, 2012 and 2011 was $28,500 and zero, respectively. The $28,500 milestone revenue recognized in the 2012 period related to the Notice of Compliance (approval) by Health Canada for XIAFLEX for the treatment of Dupuytren's contracture in adults with a palpable cord in Canada granted to Actelion.

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.

Research and Development Activities and Expenses

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 $0.3 million and $0.2 million, respectively, for the three months ended September 30, 2012 and 2011, representing an increase in 2012 of $0.1 million or 31%. This increase in research and development expenses was primarily due to expenses related to our clinical development programs.

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We are currently working to develop XIAFLEX for the treatment of human and canine lipoma. We have designed a placebo controlled randomized study to evaluate the efficacy of XIAFLEX for the treatment of subcutaneous benign lipomas in canines. This single injection study will evaluate 32 dogs randomized 1:1 XIAFLEX to placebo. We initiated this trial in the second quarter of 2012. Also, we have designed a phase II dose escalation clinical study of XIAFLEX for the treatment of human lipomas. This study is a single injection, open label trial and is planned to enroll 14 patients with four dosage groups for the treatment of benign subcutaneous lipomas. We initiated this trial in the second quarter of 2012.

The following table summarizes our research and development expenses related to our clinical development programs.

	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011
Program		
Canine Lipoma	$ 122,638	$ 70,563
Human Lipoma	$ 26,758	$ 33,837

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.

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 the appropriate opt-in study.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, consultant costs, legal fees, investor relations, professional fees and overhead costs. General and administrative expenses were $1.4 million and $1.2 million for the three months ended September 30, 2012 and 2011, respectively, an increase of

approximately $0.2 million, or 10%, from 2011. The increase in general and administrative expenses was due to increased legal fees, consulting services and third party royalty fees partially offset by lower stock based compensation.

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Other Income and expense

Other income for the three months ended September 30, 2012 was $8,292 compared to $7,813 in the 2011 period. Other income in both periods consisted of interest earned on our investments.

Income Taxes

Our deferred tax liabilities, deferred tax assets and related valuation allowances are impacted by events and transactions arising in the ordinary course of business, research and development activities, vesting of nonqualified options, deferred revenues and other items. Deferred tax assets are affected by the valuation allowance which is dependent upon several factors, including estimates of the realization of deferred income tax assets, and the impact of estimated future taxable income. Significant judgment is required to determine the estimated amount of valuation allowance to record. Changes in the estimate of the valuation allowance could materially increase or decrease our provision for income taxes in future periods.

For the three month period ended September 30, 2012 income tax expense was $0.3 million, primarily a non-cash charge. Our income tax expense for the three month period ended September 30, 2012 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 2012. For the three month period ended September 30, 2012, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of September 30, 2012, our remaining deferred tax assets decreased by $0.6 million to approximately $2.4 million.

For the three month period ended September 30, 2011 income tax expense was $0.2 million, primarily a non-cash charge. 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.

Net Income

For the three months ended September 30, 2012 we recorded net income of $0.5 million, or $0.07 per basic and diluted common share, compared to a net income of $0.2 million, or $0.04 per basic and diluted common share, for the same period in 2011.

NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

Revenues

Product Revenues, net

Product revenues include the sales of the collagenase for laboratory use recognized at the time it is shipped to customers. We had a small amount of revenue from the sale of collagenase for laboratory use. For the nine months ended September 30, 2012 and 2011 product revenues were $12,128 and $13,457, respectively. This decrease was primarily related to the amount of material required to perform testing and additional research by our customers.

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the Auxilium Agreement and earn-out revenues associated with the DFB Agreement. Total royalty, mark-up on cost of goods sold and earn-out revenues for the nine month period ended September 30, 2012 were $6.7 million as compared to $4.5 million in the 2011 period, an

increase of $2.2 million or 50%. Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were $4.6 million for the 2012 period compared to $2.9 million for the 2011 period. The increase of $1.7 million was due to increased net sales of XIAFLEX during 2012 reported to us by Auxilium.

We receive earn-out revenues from DFB under the earn-out payment provision of the DFB Agreement after certain net sales levels are achieved. Revenues recognized under the DFB Agreement were $2.1 million for the nine months ended September 30, 2012 and $1.5 million for the same period in 2011. This increase of $0.6 million was mainly related to the increase in net sales during the 2012 period reported to us by DFB.

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Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. For the nine months ended September 30, 2012 and 2011, we recognized total licensing, sublicensing and milestone revenue of $0.9 million and $4.3 million, respectively, a decrease of $3.4 million or 78%. Certain licensing revenues recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period. Licensing revenue recognized for the nine months ended September 30, 2012 and 2011 was $0.3 million in each period. Sublicensing fees recognized in 2012 were $0.6 million compared to $0.8 million in the same period in 2011. In the 2012 period, sublicensing fees recognized were related to the $10.0 million paid to Auxilium by Actelion for the rights to develop and commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico. In 2011, sublicensing fees recognized were related to the $15.0 million paid to Auxilium by Asahi for the rights to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan.

Milestone revenue recognized for the nine months ended September 30, 2012 and 2011 was $28,500 and $3.2 million, respectively. The $28,500 milestone revenue recognized in the 2012 period related to the Notice of Compliance (approval) by Health Canada for XIAFLEX for the treatment of Dupuytren's contracture in adults with a palpable cord in Canada granted to Actelion. In the 2011 period we received and recognized $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. We recognized a milestone of $0.6 million of the $7.5 million paid to Auxilium by Pfizer for the launch in Germany of XIAPEX in the second quarter of 2011.

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 recognized 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 nine months ended September 30, 2012 and 2011 consulting fees recognized were zero and $46,667, respectively. The consulting and technical assistance obligations to DFB expired during March 2011.

Research and Development Activities and Expenses

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 $0.9 million and $0.7 million, respectively, for the nine months ended September 30, 2012 and 2011, representing an increase in 2012 of $0.2 million or 34%. This increase in research and development expenses was primarily due to expenses related to our clinical development programs.

We are currently working to develop XIAFLEX for the treatment of human and canine lipoma. We have designed a placebo controlled randomized study to evaluate the efficacy of XIAFLEX for the treatment of subcutaneous benign lipomas in canines. This single injection study will evaluate 32 dogs randomized 1:1 XIAFLEX to placebo. We initiated this trial in the second quarter of 2012. Also, we have designed a phase II dose escalation clinical study of XIAFLEX for the treatment of human lipomas. This study is a single injection, open label trial and is planned to enroll

14 patients with four dosage groups for the treatment of benign subcutaneous lipomas. We initiated this trial in the second quarter of 2012.

The following table summarizes our research and development expenses related to our clinical development programs.

	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Accumulated Expenses Since January 1, 2010
Program			
Canine Lipoma	$ 332,439	$ 211,704	$ 862,687
Human Lipoma	129,192	88,190	365,182

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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.

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 the appropriate opt-in study.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, consultant costs, legal fees, investor relations, professional fees and overhead costs. General and administrative expenses were $3.6 million and $4.2 million for the nine months ended September 30, 2012 and 2011, respectively, a decrease of $0.6 million, or 13%, from 2011. The decrease in general and administrative expenses was due to lower general legal fees and stock based compensation partially offset by third party royalty fees.

Other Income and expense

Other income for the nine months ended September 30, 2012 was $27,556 compared to $55,540 in the 2011 period. Other income in the 2012 period consisted of interest earned on our investments. Other income in the 2011 period consisted of interest earned on our investments of $41,061 and a refund of tax penalties of $14,479.

Income Taxes

Our deferred tax liabilities, deferred tax assets and related valuation allowances are impacted by events and transactions arising in the ordinary course of business, research and development activities, vesting of nonqualified options, deferred revenues and other items. Deferred tax assets are affected by the valuation allowance which is dependent upon several factors, including estimates of the realization of deferred income tax assets, and the impact of estimated future taxable income. Significant judgment is required to determine the estimated amount of valuation

allowance to record. Changes in the estimate of the valuation allowance could materially increase or decrease our provision for income taxes in future periods.

The provision for income taxes and corresponding taxes payable was $1.3 million. The company paid $0.2 million of cash and applied $0.2 million of its tax refunds receivable to reduce its income taxes payable. The company also used $0.6 million, of tax assets (primarily Orphan Tax Credit) and availed itself of $0.3 million tax deductible expense related to exercise of stock options to further reduce its tax liability. Our income tax expense for the nine month period ended September 30, 2012 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 2012. For the nine month period ended September 30, 2012, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of September 30, 2012, our remaining deferred tax assets decreased by $0.6 million to approximately $2.4 million.

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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 $0.4 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.

Net Income

For the nine months ended September 30, 2012 we recorded net income of $1.9 million, or $0.30 per basic and $0.27 per diluted common share, compared to a net income of $6.5 million, or $1.03 per basic and $0.92 per diluted common share, for the same period in 2011.

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, 2012 and December 31, 2011, we had cash and cash equivalents and investments in the aggregate of approximately $9.0 million and $8.2 million, respectively.

Net cash provided by operating activities for the nine months ended September 30, 2012 was $2.6 million as compared to $0.8 million for the same period in 2011. Cash provided by operations in the 2012 period resulted primarily from the operating income for the period and a payment of earn-out royalties due under the DFB agreement on an annual basis. Cash provided by operations in the 2011 period resulted primarily from the operating income for the period and a payment of earn-out royalties due under the DFB Agreement on an annual basis partially offset by deferred income taxes and a reduction in accrued expenses.

Net cash used in investing activities for the nine months ended September 30, 2012 was $1.7 million as compared to net cash provided by investing activities of $0.4 million for the 2011 period. The net cash used in investing activities in the 2012 period reflects the maturing of investments of $5.0 million and reinvestment of $5.2 million in marketable securities and a one-time cash payment related to our future royalty obligations for Peyronie's disease of $1.5 million. The net cash provided by investing activities in the 2011 period reflects the maturing of investments of $5.4 million and reinvestment of $5.0 million in marketable securities

Net cash used in financing activities for the nine months ended September 30, 2012 was $0.3 million as compared to net cash provided by financing activities of $0.2 million in the comparable period of 2011. In the 2012 period, net cash used in financing activities was mainly due to the repurchase of our common stock under our stock repurchase program during the period partially offset by excess tax benefits related to share-based payments and proceeds received from stock option exercises. In the 2011 period, 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.

Off-Balance Sheet Arrangements

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

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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, 2012, amounting to approximately $9.0 million, were maintained in bank demand accounts, money market accounts, and certificates of deposit. 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, 2011.

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, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K filed with the SEC on March 13, 2012.

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

During the nine month period ended September 30, 2012, 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)	
January 1, 2011 – March 31, 2011	0	0	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	
October 1, 2011 – December 31, 2011	24,971	$ 15.18	63,337	$ 1,466,796	
January 1, 2012 – March 31, 2012	12,247	$ 16.24	75,584	$ 1,267,935	
April 1, 2012 – June 30, 2012	16,340	$ 17.57	91,924	$ 980,841	
July 1, 2012 – September 30, 2012	10,360	$ 18.20	102,284	$ 792,296	

(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.

Item 4. (Removed and Reserved).

Item 5. Other Information

None.

Item 6. Exhibits

3.1 Registrant’s Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 of the Registrant's Form 10-KSB filed with the SEC on March 2, 2007).

3.2 Registrant’s Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Registrant’s Form 10-KSB filed with the SEC on March 2, 2007

31*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule13a-14(a)/15d-14(a).
32*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002.

*filed herewith

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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 9, 2012

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