

BIOSPECIFICS TECHNOLOGIES CORP  
Form 10-Q  
November 10, 2014

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

☐ 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 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☒ No ☐

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

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Large accelerated filer ☐ Accelerated filer ☒  
Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

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

Yes ☐ No ☒

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

<u>Class of Stock</u>	<u>Outstanding November 7, 2014</u>
Common Stock (\$.001 par value)	6,500,712

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BIOSPECIFICS TECHNOLOGIES CORP.

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Introductory Comments – Terminology

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

Introductory Comments – Forward-Looking Statements

This Report 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, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, expected revenue growth, and the assumptions underlying or relating to such statements, are “forward-looking statements”. The forward-looking statements in this Report include statements concerning, among other things, the market potential for the use of XIAFLEX to treat Dupuytren’s contracture and Peyronie’s disease and the likelihood of success of our partner’s, Auxilium Pharmaceuticals, Inc., plans for marketing and sales for those indications; the potential acquisition of Auxilium by Endo International plc; the market authorization for XIAPEX in the EU; payments associated with Auxilium’s exercise of its opt in rights for the canine lipoma indication; future payments for the approval of XIAFLEX for the treatment of Dupuytren’s contracture by the Japanese Pharmaceutical and Medical Device Agency; our ability and our partners ability to successfully commercialize our drug candidates; our current resources to advance current R&D; the timing to complete patient enrollment in our Phase 2 trial; the outcome of clinical trials including human and canine lipoma and uterine fibroids; the size of the market for Peyronie’s disease; the projected receipt of payments from Auxilium; changes in interest rates; the fair value of our carrying amounts; the credit risk on our cash; our revenue recognition policies; our milestone achievements and payments; the nature of our accounts receivable balance; increases in our third-party royalty expenses; expectations around approvals of new indications; and our accounting policies. In some cases, these statements can be identified by forward-looking words such as “believe,” “expect,” “anticipate,” “plan,” “estimate,” “likely,” “may,” “will,” “could,” “continue,” “project,” “predict,” “goal,” plural of these words, and other similar expressions. These forward-looking statements are predictions based on our current expectations and our projections about future events and various assumptions. There can be no assurance that we will realize our expectations or that our beliefs will prove correct. 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 timing of regulatory filings and action; the ability of Auxilium and its partners, Asahi Kasei Pharma Corporation, Actelion Pharmaceuticals Ltd. and Swedish Orphan Biovitrum AB, to achieve their objectives for XIAFLEX in their applicable territories; the market for XIAFLEX in, and timing, initiation and outcome of clinical trials for, additional indications including frozen shoulder, cellulite, human lipoma, canine lipoma and uterine fibroids, all of which will determine the amount of milestone, royalty, mark-up on cost of goods sold and sublicense income BioSpecifics may receive; the potential of collagenase clostridium histolyticum to be used in additional indications; the potential acquisition of Auxilium by Endo International plc; and other risk factors identified in BioSpecifics’ Annual Report on Form 10-K for the year ended December 31, 2013, its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014 and June 30, 2014 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, are expressly qualified in their entirety by the cautionary statements included in this Report and, except as may be required by law, we assume no obligation to update these forward-looking statements.

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## PART I – FINANCIAL INFORMATION

## Item 1: Condensed Consolidated Financial Statements

BioSpecifics Technologies Corp.  
Condensed Consolidated Balance Sheets

	September 30, 2014 (unaudited)	December 31, 2013 (audited)
Assets		
Current assets:		
Cash and cash equivalents	\$9,711,320	\$5,624,860
Short-term investments	7,794,683	6,966,964
Accounts receivable	3,089,229	5,004,418
Income tax receivable	751,151	255,708
Deferred tax assets	110,010	94,992
Prepaid expenses and other current assets	382,745	326,519
Total current assets	21,839,138	18,273,461
Deferred royalty buy-down	3,247,554	3,350,000
Deferred tax assets - long term	1,375,525	1,412,784
Patent costs, net	307,907	215,999
Total assets	26,770,124	23,252,244
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	517,228	634,277
Deferred revenue	62,546	69,130
Accrued liabilities of discontinued operations	78,138	78,138
Total current liabilities	657,912	781,545
Long-term deferred revenue	97,934	138,260
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 ; 6,830,167 and 6,655,168 shares issued at September 30, 2014 and December 31, 2013, respectively	6,830	6,655
Additional paid-in capital	22,657,340	20,951,796
Retained earnings	7,701,737	4,975,018
Treasury stock, 329,455 and 300,739 shares at cost at September 30, 2014 and December 31, 2013, respectively	(4,351,629 )	(3,601,030 )
Total stockholders' equity	26,014,278	22,332,439
Total liabilities and stockholders' equity	\$26,770,124	\$23,252,244

See accompanying notes to condensed consolidated financial statements



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Condensed Consolidated Income Statement  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Product revenues, net	\$ 15,468	\$ 2,651	\$ 29,595	\$ 32,394
Royalties	3,484,975	3,087,491	8,850,067	9,717,994
Licensing revenues	512,344	54,981	546,909	644,742
Total Revenues	4,012,787	3,145,123	9,426,571	10,395,130
Costs and expenses:				
Research and development	240,093	346,768	909,129	1,111,686
General and administrative	1,650,315	1,059,854	4,387,134	3,914,590
Total Cost and Expenses	1,890,408	1,406,622	5,296,263	5,026,276
Operating income	2,122,379	1,738,501	4,130,308	5,368,854
Other income:				
Interest income	8,121	7,134	22,444	19,510
Other income	-	-	1,150	-
	8,121	7,134	23,594	19,510
Income before expense for income tax	2,130,500	1,745,635	4,153,902	5,388,364
Income tax expense	(735,737 )	(566,860 )	(1,427,184 )	(1,828,319 )
Net income	\$ 1,394,763	\$ 1,178,775	\$ 2,726,718	\$ 3,560,045
Basic net income per share	\$0.21	\$0.19	\$0.42	\$0.56
Diluted net income per share	\$0.20	\$0.17	\$0.39	\$0.51
Shares used in computation of basic net income per share	6,489,758	6,338,901	6,433,013	6,346,978
Shares used in computation of diluted net income per share	7,074,154	6,924,363	7,039,225	6,916,485

Condensed Consolidated Statements of Comprehensive Income  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net income	\$ 1,394,763	\$ 1,178,775	\$ 2,726,718	\$ 3,560,045
Other comprehensive income	-	-	-	-
Comprehensive income	\$ 1,394,763	\$ 1,178,775	\$ 2,726,718	\$ 3,560,045

See accompanying notes to condensed consolidated financial statements





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BioSpecifics Technologies Corp.

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Nine Months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net income	\$2,726,718	\$3,560,045
Adjustments to reconcile net income to net cash provided By operating activities:		
Amortization of patent expense	94,230	48,242
Amortization of deferred royalty buydown	102,446	-
Stock-based compensation expense	16,062	106,621
Deferred tax expense	22,241	424
Gain on the sale of fixed assets	(1,150 )	-
Changes in operating assets and liabilities:		
Accounts receivable	1,915,189	37,678
Prepaid expenses and other current assets	(551,668 )	(294,715 )
Accounts payable and accrued expenses	(303,187 )	86,204
Deferred revenue	(46,910 )	(116,242 )
Net cash provided by operating activities	3,973,971	3,428,257
Cash flows from investing activities:		
Maturity of marketable investments	6,015,958	7,790,000
Purchases of marketable investments	(6,843,677)	(9,396,964)
Proceeds from sale of fixed asset	1,150	-
Net cash used in investing activities	(826,569 )	(1,606,964)
Cash flows from financing activities:		
Proceeds from stock option exercises	204,550	10,000
Payments for repurchase of common stock	(750,599 )	(608,052 )
Excess tax benefits from share-based payment arrangements	1,485,107	-
Net cash provided by (used in) financing activities	939,058	(598,052 )
Increase in cash and cash equivalents	4,086,460	1,223,241
Cash and cash equivalents at beginning of year	5,624,860	3,383,737
Cash and cash equivalents at end of period	\$9,711,320	\$4,606,978
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	\$-	\$-
Taxes	\$415,279	\$1,778,500

## 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, 2014, we accrued approximately \$186,000 related to certain patent costs of which we amortized approximately \$94,000 in the 2014 period. For the nine months ended September 30, 2013, we accrued approximately \$45,000 related to these costs of which approximately \$48,000 was amortized in the 2013 period.

See accompanying notes to condensed consolidated financial statements



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BIOSPECIFICS TECHNOLOGIES CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2014

(Unaudited)

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. (“Auxilium”) for injectable collagenase (which Auxilium has named XIAFLEX<sup>®</sup>) for marketed indications and collagenase clostridium histolyticum (“CCH”) for indications in development. Auxilium has an option to acquire additional indications that we may pursue, including human and canine lipoma. Auxilium is currently selling XIAFLEX in the U.S. for the treatment of Dupuytren’s contracture and Peyronie’s disease. Following the termination of the agreement between Auxilium and Pfizer, Inc. (“Pfizer”), Auxilium entered into an agreement with Swedish Orphan Biovitrum AB (“Sobi”) pursuant to which Sobi has marketing rights for XIAPEX<sup>®</sup> (the EU trade name for CCH) for Dupuytren’s contracture and Peyronie’s disease in Europe and certain Eurasian countries. Sobi is currently selling XIAPEX in Europe for the treatment of Dupuytren’s contracture. In addition, Auxilium has an agreement with Asahi Kasei Pharma Corporation (“Asahi”) pursuant to which Asahi has the right to commercialize XIAFLEX for the treatment of Dupuytren’s contracture and Peyronie’s disease in Japan. Auxilium also has an agreement with Actelion Pharmaceuticals Ltd. (“Actelion”) pursuant to which Actelion has the right to commercialize XIAFLEX for the treatment of Dupuytren’s contracture and Peyronie’s disease in Canada, Australia, Brazil and Mexico.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed 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 SEC for quarterly reporting.

The information included in this Report should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2013 and our Quarterly Reports on Form 10-Q for the first and second quarters of 2014 filed with the SEC.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its subsidiary, Advance Biofactures Corp. (“ABC-NY”). All intercompany balances and transactions have been eliminated.

Critical Accounting Policies, Estimates and Assumptions

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires the use of management’s estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. The Company makes certain assumptions and estimates for its deferred tax assets and deferred royalty buydown. For further details see footnote Provision for Income Taxes and Third Party Royalties and Royalty Buy-Down. Actual results could differ from those estimates.



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### Cash, Cash Equivalents and Investments

Cash equivalents and investments are stated on an amortized cost basis. 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 investments by placing its investments with banks it believes are highly creditworthy and with highly rated money market funds, certificates of deposit and pre-refunded municipal bonds. All investments are classified as held to maturity. As of September 30, 2014 and December 31, 2013, the aggregate fair value of these investments was \$7.8 million and \$7.0 million, respectively. No unrealized gains or losses were recorded in the balance sheet in either period.

### Fair Value Measurements

Management believes that the carrying amounts of the Company's financial instruments, including cash, cash equivalents, held to maturity investments, accounts receivable, accounts payable and accrued expenses approximate fair value due to the nature of those instruments.

### Concentration of Credit Risk and Major Customers

The Company maintains bank account balances, which, at times, may exceed insured limits. The Company has not experienced any losses with these accounts and believes that it is not exposed to any significant credit risk on cash.

The Company maintains its investment in FDIC insured certificates of deposits with several banks and pre-refunded municipal bonds.

At September 30, 2014, our accounts receivable balance of \$3.1 million was from one customer, Auxilium.

The Company is dependent on one customer who generates almost all its revenues. In the quarter ended September 30, 2014 and 2013, the licensing, sublicensing, milestones and royalty revenues from Auxilium were \$4.0 million and \$2.1, respectively.

### Revenue Recognition

We currently recognize revenues resulting from product sales, the licensing and sublicensing of the use of our technology and from services we sometimes perform in connection with the licensed technology under the guidance of Accounting Standards Codification 605, Revenue Recognition ("ASC 605").

If we determine that separate elements exist in a revenue arrangement under ASC 605, we recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete, when payment is reasonably assured and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement.

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

### Product Sales

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

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

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

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

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Under the Second Amended and Restated Development and License Agreement with Auxilium (“Auxilium Agreement”), we do not participate in the selling, marketing or manufacturing of products for which we receive royalties and a mark-up on 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.

Under the Asset Purchase Agreement, as amended with DFB (“DFB Agreement”), pursuant to which we sold our topical collagenase business to DFB, we had the right to receive earn-out payments based on sales of certain products. This right to receive payments on Santyl sales expired in August 2013. 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 had sold the royalty-bearing product. DFB provided us earn-out reports on a quarterly basis. In 2013, BioSpecifics recognized all income from the Santyl sales under the DFB agreement, and in March 2014 we received the corresponding cash payment for the income earned in 2013.

### Licensing Revenue

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

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.

### 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 FDA or other regulatory agencies require additional data or information, we would adjust our development period estimates accordingly. The impact on revenue of changes in our estimates and the timing thereof is recognized prospectively over the remaining estimated product development period.



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### Treasury Stock

The Company accounts for treasury stock under the cost method and includes treasury stock as a component of stockholders' equity. For the nine months ended September 30, 2014, we repurchased 28,716 shares at an average price of \$26.14 as compared to 36,568 shares at an average price of \$16.63 in the 2013 period.

### Receivables, Deferred Revenue 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 Auxilium, our one large pharmaceutical customer. Auxilium has historically paid timely and has been a financially stable organization. Due to the nature of the accounts receivable balance, we believe the risk of doubtful accounts is minimal. If the financial condition of our customer were to deteriorate, adversely affecting its 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.

At September 30, 2014, the accounts receivable balance of \$3.1 million was from one customer, Auxilium.

Deferred revenue of approximately \$160,000 consists of licensing fees related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected remaining development period of approximately 3 years for certain indications for XIAFLEX.

### Reimbursable Third Party Development Costs

We estimate our accrual for 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. As of September 30, 2014 and December 31, 2013, our net reimbursable third party patent cost was approximately \$13,000 and \$60,000, respectively.

### Third Party Royalties and Royalty Buy-Down

We have entered into licensing and royalty agreements with third parties and agreed to pay certain royalties on net sales of products for specific indications. The royalty rates differ from agreement to agreement and in certain cases have been redacted with the permission of the SEC. No assumptions should be made that the disclosed royalty rates payable to a particular third party is the same or similar with respect to the royalty rates payable to other third parties. We accrue third party royalty expenses on net sales reported to us by Auxilium. Third party royalty costs are generally expensed in the quarter that Auxilium provides the written reports and related information to us, that is, generally one quarter following the quarter in which the underlying sales by Auxilium occurred. For the three months ended September 30, 2014 and 2013, third party royalty expenses were \$210,161 and \$95,484 respectively. Third party royalty expenses were \$464,705 and \$287,386, respectively, for the nine months ended September 30, 2014 and 2013. We expect our third party royalty expense under general and administrative expenses will continue to increase as net sales by Auxilium for XIAFLEX increase and potential new indications for CCH are approved.

On March 31, 2012, we entered into an amendment to our existing agreement with Dr. Martin K. Gelbard, 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 of \$600,000, one of which was paid in December 2013. The Company amortizes long-term contracts with finite lives in a manner that reflects the pattern in which the economic benefits of the assets are consumed or otherwise used up. Dr. Gelbard's agreement is amortized based on an income forecast method by estimating sales of XIAFLEX for Peyronie's disease on an annual basis as measured by the proportion to the total estimated sales over the five year period. For the nine months ended September 30, 2014, we amortized approximately \$102,000 related to this agreement. As of September 30, 2014, the remaining capitalized balance was approximately \$3.2 million. We perform an evaluation of the recoverability of the carrying value to determine if facts and circumstances indicate that the carrying value of the assets may be impaired and if any adjustment is warranted. As of September 30, 2014, there was no indicator that an impairment existed.

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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 stock options 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 stock option 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 condensed consolidated statements of operations.

Under the ASC 718, we estimate the fair value of our employee stock option 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 option award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures) and the expected volatility of our common stock. As required under the accounting rules, we review our estimates at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. 15,000 stock options valued at approximately \$123,000 were granted to a new member of the Board of Directors (Max Link, Ph.D.) during the nine month period ended September 30, 2014. At the time of his sudden death on October 6, 2014, none of these options had vested and, in accordance with the applicable terms, they expired upon his death. During the nine months ended September 30, 2013, an aggregate 30,000 stock options were granted to one member of our Board of Directors, George Gould, and one of our consultants valued at approximately \$157,000. The following table presents the assumptions used to estimate the fair values of the stock options granted in the nine-month periods presented:

	September 2014		September 2013	
Risk-free interest rate	1.66	%	1.21	%
Expected volatility	32	%	35	%
Expected life (in years)	5		5	
Dividend yield	-		-	

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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.

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

	Three Months Ended September 30, 2014		Nine Months Ended September 30, 2014	
	2014	2013	2014	2013
Research and development	\$-	\$-	\$-	\$92,249
General and administrative	5,354	1,172	16,062	14,372
Total stock-based compensation expense	\$5,354	\$1,172	\$16,062	\$106,621

## Stock Option Activity

A summary of our stock option activity during the nine months ended September 30, 2014 is presented below:

	Total Number of Shares	Weighted-Average Exercise Price
Options Outstanding as of December 31, 2013	1,167,000	\$ 9.03
Granted	15,000	26.48
Forfeited	(15,000 )	26.48
Exercised	(175,000 )	1.17
Expired	-	-
Outstanding as of September 30, 2014	992,000	\$ 10.41
Exercisable as of September 30, 2014	960,750	\$ 9.93

During the nine months ended September, 2014 and 2013, the Company received \$204,550 and \$10,000, respectively, from stock options exercised by option holders.

The aggregate intrinsic value of options outstanding and exercisable as of September 30, 2014 was approximately \$24.4 million. Aggregate intrinsic value represents the total pre-tax intrinsic value based on the closing price of our common stock of \$35.30 on September 30, 2014, which would have been received by the option holders had all option holders exercised their options as of that date. We have approximately \$63,000 in unrecognized compensation cost related to stock options outstanding as of September 30, 2014. At the time of his sudden death on October 6, 2014, none of the 15,000 options granted to Dr. Link had vested and, in accordance with the applicable terms, they expired upon his death.

## Property and Equipment

Property 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.

As of September 30, 2014 and December 31, 2013, property and equipment were fully depreciated.

#### Provision for Income Taxes

Deferred tax assets and liabilities are recognized based on the expected future tax consequences, measured at the statutory rates enacted for future periods, 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.

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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.

## New Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (“FASB”) issued an Accounting Standards Update (“ASU”) on income taxes, which provides guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss, or tax credit carryforward exists. This guidance is effective for the Company beginning January 1, 2014. The Company adopted this guidance as of January 1, 2014 and its adoption did not have a material effect on the Company’s condensed consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which requires companies to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration it expects to be entitled in exchange for those goods or services. The standard will be effective for the Company beginning in the first quarter of 2017 and early adoption is not permitted. The new standard permits the use of either the retrospective or cumulative effect transition method on adoption. The Company is evaluating the effect that ASU 2014-09 will have on its condensed consolidated financial statements and related disclosures, including which transition method it will adopt.

## 3. NET INCOME PER SHARE

In accordance with Accounting Standards Codification 260, Earnings Per Share, basic net income per share amount is computed using the weighted-average number of shares of common stock outstanding during the periods presented, while diluted net income 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 treasury stock method.

The following table summarizes the number of common equivalent shares that were excluded for the calculation of diluted net income per share reported in the condensed consolidated statement of operations.

	Three Months Ended September 30, 2014		Nine Months Ended September 30, 2014	
	2014	2013	2014	2013
Stock options	20,000	272,500	60,000	302,500

## 4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	September 30, 2014	December 31, 2013
Trade accounts payable and accrued expenses	\$ 270,203	\$ 409,617
Accrued legal and other professional fees	51,441	61,538
Accrued payroll and related costs	195,584	163,122
Total	\$ 517,228	\$ 634,277

## 5. PATENT COSTS

We amortize intangible assets with definite lives on a straight-line basis over their remaining estimated useful lives, ranging from 1 to 13 years, and review for impairment on a quarterly basis and when events or changes in

circumstances indicate that the carrying amount of such assets may not be recoverable. As of September 30, 2014, there was no indicator that an impairment existed.



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For the nine months ended September 30, 2014, we capitalized legal patent costs related to patent prosecution and maintenance of approximately \$186,000 based on the most current information reported to us by Auxilium. As of September 30, 2014, the Company's estimated capitalized costs related to certain patent costs paid by Auxilium on behalf of the Company are approximately \$13,000, which are reimbursable to Auxilium under the Auxilium Agreement. These patent costs are creditable against future royalty revenues. For each period presented below net patent costs consisted of:

	September 30, 2014	December 31, 2013
Patents	\$658,513	\$472,375
Accumulated Amortization	(350,606)	(256,376)
	\$307,907	\$215,999

The amortization expense for patents for the nine months ended September 30, 2014 was approximately \$94,000. In the comparable period of 2013, the amortization expense for patents was approximately \$48,000. The estimated aggregate amortization expense for each of the next five years is approximately as follows:

2015	\$40,000
2016	34,000
2017	34,000
2018	34,000
2019	34,000

## 6. PROVISION FOR INCOME TAXES

In determining our provision for income taxes, we consider all available information, including operating results, ongoing tax planning, and forecasts of future taxable income. The significant components of the Company's deferred tax assets consist of stock-based compensation and deferred revenues. For the nine month period ended September 30, 2014, the provision for income taxes was \$1.4 million. For the nine month period ended September 30, 2014, the valuation allowance with respect to the Company's net deferred tax assets remained unchanged. As of September 30, 2014, our remaining deferred tax assets were approximately \$1.5 million. Our income tax liability was reduced by \$1.5 million due to the windfall associated with the disqualified sale of incentive stock options and the exercise of nonqualified options.

For the nine month period ended September 30, 2013, the provision for income taxes was \$1.8 million. For the nine month period ended September 30, 2013, the valuation allowance with respect to the Company's net deferred tax assets remained unchanged. As of September 30, 2013, our remaining deferred tax assets were approximately \$1.5 million.

## 7. SUBSEQUENT EVENTS

On October 10, 2014, the Company dismissed Friedman LLP as the auditor (although continuing to engage them for tax-related services) and appointed EisnerAmper LLP as its new independent registered public accounting firm for the year ending December 31, 2014 and for the quarter ending September 30, 2014

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

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

## Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. (“Auxilium”) for injectable collagenase (which Auxilium has named XIAFLEX®) for marketed indications and collagenase clostridium histolyticum (“CCH”) for indications in development. Auxilium has an option to acquire additional indications that we may pursue, including human and canine lipoma. Auxilium is currently selling XIAFLEX in the U.S. for the treatment of Dupuytren’s contracture and Peyronie’s disease. Following the termination of the agreement between Auxilium and Pfizer, Inc. (“Pfizer”), Auxilium entered into an agreement with Swedish Orphan Biovitrum AB (“Sobi”) pursuant to which Sobi has marketing rights for XIAPEX® (the EU trade name for CCH) for Dupuytren’s contracture and Peyronie’s disease in Europe and certain Eurasian countries. Sobi is currently selling XIAPEX in Europe for the treatment of Dupuytren’s contracture. In addition, Auxilium has an agreement with Asahi Kasei Pharma Corporation (“Asahi”) pursuant to which Asahi has the right to commercialize XIAFLEX for the treatment of Dupuytren’s contracture and Peyronie’s disease in Japan. Auxilium also has an agreement with Actelion Pharmaceuticals Ltd. (“Actelion”) pursuant to which Actelion has the right to commercialize XIAFLEX for the treatment of Dupuytren’s contracture and Peyronie’s disease in Canada, Australia, Brazil and Mexico.

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Operational Highlights

On July 10, 2014, the Company submitted its final study report of “A Double Blind Study to Evaluate the Efficacy and Safety of Collagenase Clostridium Histolyticum for the Treatment of Canine Lipoma” to Auxilium for review. Auxilium has 120 days to determine whether to exercise its additional indication option for canine lipoma under the Company’s Auxilium Agreement.

On July 31, 2014, the Company became entitled to receive 5% of the \$10 million regulatory milestone payment that Auxilium will receive from its partner Asahi for the successful submission of a regulatory application to the Japanese Pharmaceutical and Medical Device Agency (PMDA) for XIAFLEX® for the treatment of Dupuytren's contracture.

On August 5, 2014, the Company announced the appointment of Max Link, Ph.D. to its Board of Directors, effective August 15, 2014, with a term of office expiring and to be renewed at the 2016 Annual Meeting of Stockholders. On August 15, 2014, Henry G. Morgan retired from the Board of Directors after 24 years of service but will continue to act in a consulting capacity. Dr. Link was appointed Chairman of the Compensation Committee and as the financial expert on the Audit Committee following Henry Morgan’s retirement. After the reporting period, we announced with great sadness on October 8, 2014 that Dr. Link passed away suddenly on October 6, 2014. He was 74 years old. Dr. Link served as the Chair of the Compensation Committee, as the Audit Committee Financial Expert and as a member of the Board's Audit, Compensation and Nominating and Corporate Governance Committees. The Board of Directors of the Company is currently reviewing candidates to replace him on the Board and the three committees on which he served. To comply with the NASDAQ requirement that the Audit Committee consist of three independent members, on October 29, 2014, the Board of Directors appointed George Gould to fill the vacancy on the Audit Committee on an interim basis while the Board seeks a new independent member to permanently replace Dr. Link.

On August 7, 2014, the Audit Committee dismissed Tabriztchi & CO., CPA, P.C. as its independent registered public accounting firm, effective immediately following its completion of its review of the quarter ended June 30, 2014, and the Audit Committee engaged Friedman LLP as its new independent registered public accounting firm for the year ending December 31, 2014 and effective immediately and for the quarter ending September 30, 2014. This change in auditors was the result of the Company’s Audit Committee recently completing a competitive process to determine what audit firm would serve as the Company's independent registered public accounting firm beginning with the quarter ended September 30, 2014. Following the announcement of the change in auditors, the Securities and Exchange Commission (“SEC”) questioned the independence of Friedman LLP because of work they had previously done in preparing source materials relating to the tax footnotes in the Company’s financial information. Consequently, on October 10, 2014, after the reporting period and before Friedman LLP had commenced any audit-related work, the Company dismissed Friedman LLP as the auditor (although continuing to engage them for tax-related services) and appointed EisnerAmper LLP as its new independent registered public accounting firm for the year ending December 31, 2014 and for the quarter ending September 30, 2014.

On August 8, 2014, we announced that we injected the first patient in our placebo-controlled Phase 2 clinical trial of CCH for the treatment of human lipoma. We expect to complete patient enrollment in this trial during the first quarter of 2015.

On August 21, 2014, we announced positive, statistically significant results from a randomized, double-blind Phase 2a study of CCH for the potential treatment of cellulite, or edematous fibrosclerotic panniculopathy. The results showed that all three doses of CCH used in the study, including a low, medium and high dose, demonstrated an improvement in the appearance of cellulite as measured by the trial endpoints of physician and patient-assessed improvements. CCH was well-tolerated by all dose groups with most adverse events being mild to moderate and primarily limited to the local injection area.



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On September 18, 2014, we announced that positive safety and efficacy data from the MULTICORD (MULTiple Treatment Investigation of Collagenase Optimizing the Resolution of Dupuytren's) Phase 3b study was presented by BioSpecifics' partner, Auxilium Pharmaceuticals, Inc. (Auxilium) at the 69<sup>th</sup> Annual Meeting of the American Society for Surgery of the Hand (ASSH) being held in Boston on September 18-20, 2014. Positive data were also presented from an additional study evaluating the retreatment of recurrent contracture in joints that were previously treated with CCH.

After the reporting period, on October 9, 2014 Auxilium announced that it had entered into a definitive agreement with Endo International plc under which Endo would acquire all of the outstanding shares of common stock of Auxilium for a per share consideration of \$33.25 in a cash and stock transaction. The transaction is expected to close in the first half of 2015, subject to regulatory approval in the US, an affirmative vote of a majority of the stockholders of Auxilium and other customary closing conditions.

After the reporting period, on October 15, 2014, we announced that a paper titled, "Stiffness of Human Uterine Fibroids is Reduced After Treatment with Purified Clostridial Collagenase due to Collagen Degradation" was presented at the Mechanotransduction in the Reproductive Tract conference hosted by the Campion Fund of the Phyllis and Mark Leppert Foundation for Fertility Research in Durham, North Carolina. The data being presented show that highly purified collagenase can reduce the rigidity of human uterine fibroid tissue and potentially shrink uterine fibroid tumors by interrupting the accumulation of poorly aligned and altered collagen.

After the reporting period, on October 21, 2014, we announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) submitted by Auxilium for XIAFLEX for the treatment of up to two Dupuytren's contracture cords in the same hand during a single treatment visit. XIAFLEX obtained FDA approval in 2010 as the first and only nonsurgical treatment for adult Dupuytren's contracture patients with a palpable cord in the palm.

After the reporting period, on November 5, 2014, Auxilium exercised its exclusive option to expand its license right to CCH to include the potential treatment of canine lipomas under the Company's Auxilium Agreement. In accordance with the exercise of their option, Auxilium will pay BioSpecifics \$500,000 within ten business days of the date of exercise.

## Outlook

For the nine months ended September 30, 2014, we generated revenue from primarily one source, the Second Amended and Restated Development and License Agreement with Auxilium ("Auxilium Agreement"). Under the Auxilium Agreement, we receive license, sublicense income, royalties, milestones and mark-up on cost of goods sold payments related to the sale and approval of XIAFLEX 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 and Peyronie's disease, successfully develop CCH 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. For more information regarding the risks facing the Company, please see the risk factors discussed under the heading "Risk Factors" under Item 1A within this report and under item 1A of Part 1 of our Annual Report on Form 10-K for the year ended December 31, 2013.

## Critical Accounting Policies, Estimates and Assumptions

The preparation of condensed 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 condensed 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 financial information at September 30, 2014 and for the three and nine months ended September 30, 2014 and 2013 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, 2013 balance sheet amounts and disclosures included herein have been derived from the Company's December 31, 2013 audited condensed consolidated financial statements. The interim results are not necessarily indicative of results to be expected for the full fiscal year. These unaudited condensed consolidated financial statements should be read in conjunction with the audited condensed consolidated financial statements for the year ended December 31, 2013 included in the Company's Annual Report on Form 10-K and with the unaudited condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q for the first and second quarters of 2014 filed with the SEC. While our significant accounting policies are described in more detail in the notes to our unaudited condensed consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements. Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

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**Revenue Recognition.** We 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 on 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.

Under the Asset Purchase Agreement, as amended with DFB (“DFB Agreement”), pursuant to which we sold our topical collagenase business to DFB, we had the right to receive earn-out payments based on sales of certain products. This right to receive payments on Santyl sales expired in August 2013. 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 had sold the royalty-bearing product. DFB provided us earn-out reports on a quarterly basis. In 2013, BioSpecifics recognized all income from the Santyl sales under the DFB agreement, and, in March 2014 we received the corresponding cash payment for the income earned in 2013.

Reimbursable Third Party Development Costs. We accrue 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. As of September 30, 2014, our estimated net reimbursable third party patent costs accrual was approximately \$13,000.



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Receivables and Deferred Revenue. Accounts receivable as of September 30, 2014 is approximately \$3.1 million, which consists of royalties and mark-up on costs of goods sold due from Auxilium in accordance with the terms of the Auxilium Agreement. Deferred revenue of approximately \$160,000 consists 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.

Third Party Royalties and Royalty Buy-Down. We have entered into licensing and royalty agreements with third parties and agreed to pay certain royalties on net sales of products for specific indications. The royalty rates differ from agreement to agreement and in certain cases have been redacted with the permission of the SEC. No assumptions should be made that the disclosed royalty rates payable to a particular third party is the same or similar with respect to the royalty rates payable to other third parties. We accrue third party royalty expenses on net sales reported to us by Auxilium. Third party royalty costs are generally expensed in the quarter that Auxilium provides the written reports and related information to us, that is, generally one quarter following the quarter in which the underlying sales by Auxilium occurred. For the three months ended September 30, 2014 and 2013, third party royalty expenses was \$210,161 and \$95,484 respectively. Third party royalty expenses were \$464,705 and \$287,386, respectively, for the nine months ended September 30, 2014 and 2013. We expect our third party royalty expense under general and administrative expenses will continue to increase as net sales by Auxilium for XIAFLEX increase and potential new indications for CCH are approved.

On March 31, 2012, we entered into an amendment to our existing agreement with Dr. Martin K. Gelbard, dated August 27, 2008, related to our future royalty obligations. 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, one of which was paid in December 2013. The Company amortizes long-term contracts with finite lives in a manner that reflects the pattern in which the economic benefits of the assets are consumed or otherwise used up. Dr. Gelbard's agreement is amortized based on an income forecast method by estimating sales of XIAFLEX for Peyronie's disease on an annual basis as measured by the proportion to the total estimated sales over the five year period. For the nine months ended September 30, 2014, we amortized approximately \$102,000 related to this agreement. As of September 30, 2014, the remaining capitalized balance was \$3.20 million. We perform an evaluation of the recoverability of the carrying value to determine if facts and circumstances indicate that the carrying value of the assets may be impaired and if any adjustment is warranted. Based on our evaluation as of September 30, 2014, no impairment existed.

Stock Based Compensation. Under ASC 718, we estimate the fair value of our employee stock option 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 option award. Expected volatility is based on the historical volatility of our common stock. When establishing an estimate of the expected term of an option award, we consider the vesting period for the award, our historical experience of employee stock option exercises (including forfeitures) and the expected volatility of our common stock. We review our estimates at each grant date and, as a result, we are likely to change our valuation assumptions used to value future employee stock-based awards granted, to the extent any such awards are granted.

Further, ASC 718 requires that employee stock-based compensation costs 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, 2014 COMPARED TO THREE MONTHS ENDED SEPTEMBER 30, 2013

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, 2014 and 2013 product revenues were \$15,468 and \$2,651, respectively. This increase was primarily related to the amount of material required to perform testing and additional research by our customers.

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### 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 and mark-up on cost of goods sold for the three month period ended September 30, 2014 were \$3.5 million as compared to royalty, mark-up on cost of goods sold and earn-out revenues of \$3.1 million in the 2013 period, an increase of \$0.4 million or 13%. This increase in royalties and the mark-up on cost of goods sold revenue was mainly due to the increase in sales of XIAFLEX offset by the expiration of the right to receive earn-out payments on Santyl from DFB.

Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were \$3.5 million for the 2014 period compared to \$2.1 million in the 2013 period. The increase of \$1.4 million or 69% was mainly due to the increased sales of XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease.

Under the earn-out payment provision of the DFB Agreement, we had the right to receive earn-out revenues from DFB after certain net sales levels were achieved. This right to receive payments on Santyl sales expired in August 2013. Revenues recognized under the DFB Agreement were zero for the three months ended September 30, 2014 as compared to \$1.0 million in the 2013 period. The change in revenue was entirely due to the August 2013 expiration of the right to receive payments on Santyl.

### Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. For the three months ended September 30, 2014, we recognized total licensing revenue related to the development of XIAFLEX of approximately \$0.5 million, as compared to \$0.1 million in the 2013 period. We recognized certain licensing fees related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period. For the three months ended September 30, 2014, we recognized licensing revenue related to the development of XIAFLEX of approximately \$12,345 as compared to \$26,481 in the 2013 period. Milestone revenue recognized for the three months ended September 30, 2014 was \$0.5 million and as compared to \$28,500 for the 2013 period. The \$0.5 million milestone revenue recognized in the 2014 period related to a regulatory milestone for the successful submission in July 2014 of a regulatory application to the Japanese Pharmaceutical and Medical Device Agency (PMDA) for the potential approval of XIAFLEX for the treatment of Dupuytren's contracture in Japan by Asahi Kasei Pharma Corporation. The \$28,500 milestone revenue recognized in the 2013 period related to product approval for XIAFLEX for the treatment of Dupuytren's contracture in adults with a palpable cord in Australia granted to Actelion.

### 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 \$240,093 and \$346,768, respectively, for the three months ended September 30, 2014 and 2013, representing a decrease in 2014 of \$106,675, or 31%. This decrease in research and development expenses was primarily due to the completion of the human and canine lipoma trials and a decrease in pre-clinical costs associated with the uterine fibroid program.

We are working to develop CCH for the treatment of human and canine lipoma and have begun a pre-clinical study in uterine fibroids.

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

	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013
<u>Program</u>		
Canine Lipoma	\$ 45,127	\$ 79,482
Human Lipoma	61,060	152,229
Uterine Fibroids	5,378	49,722
Other	128,528	65,335

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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 we are 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 and CCH, 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 pre-clinical 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 \$1.7 million and \$1.1 million for the three months ended September 30, 2014 and 2013, respectively, an increase of approximately \$0.6 million, or 56%, from 2013. The increase in general and administrative expenses was mainly due to increased legal fees and consulting fees, third party royalty fees and the amortization of the deferred royalty buydown.

### Other Income

Other income for the three months ended September 30, 2014 was \$8,121 compared to \$7,134 in the 2013 period. Other income in both periods consisted mostly of interest earned on our investments.

Provision for 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.

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For the three month period ended September 30, 2014 our provision for income taxes was \$0.7 million. The provision for income taxes for the three month period ended September 30, 2014 is based on an estimated effective tax rate derived from an estimate of condensed consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for the fiscal year 2014. For the three month period ended September 30, 2014, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of September 30, 2014, our remaining deferred tax assets were approximately \$1.5 million.

For the three month period ended September 30, 2013 our provision for income taxes was \$0.6 million. The provision for income taxes for the three month period ended September 30, 2013 is based on an estimated effective tax rate derived from an estimate of condensed consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for fiscal year 2013. For the three month period ended September, 2013, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of September 30, 2013, our remaining deferred tax assets were approximately \$1.5 million.

### Net Income

For the three months ended September 30, 2014, we recorded net income of \$1.4 million, or \$0.21 per basic common share and \$0.20 per diluted common share, compared to a net income of \$1.2 million, or \$0.19 per basic and \$0.17 per diluted common share, for the same period in 2013.

### NINE MONTHS ENDED SEPTEMBER 30, 2014 COMPARED TO NINE MONTHS ENDED SEPTEMBER 30, 2013

#### 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, 2014 and 2013 product revenues were \$29,595 and \$32,394, 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 and mark-up on cost of goods sold for the nine month period ended September 30, 2014 were \$8.9 million as compared to royalty, mark-up on cost of goods sold and earn-out revenues of \$9.7 million in the 2013 period, a decrease of \$0.8 million or 9%. This decrease was mainly due to the expiration of the right to receive earn-out payments on Santyl partially offset by increased XIAFLEX royalties and the mark-up on cost of goods sold revenue from the sale of XIAFLEX.

Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were \$8.9 million for the 2014 period compared to \$6.2 million in the 2013 period. The increase of \$2.7 million or 43% was due to increased net sales of XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease during the 2014 period reported to us by Auxilium.

Under the earn-out payment provision of the DFB Agreement, we had the right to receive earn-out revenues from DFB after certain net sales levels were achieved. This right to receive payments on Santyl sales expired in August 2013. Revenues recognized under the DFB Agreement were zero for the nine months ended September 30, 2014 as

compared to \$3.5 million in the 2013 period. The change in revenue was entirely due to the August 2013 expiration of the right to receive payments on Santyl.



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## Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. For the nine months ended September 30, 2014 and 2013, we recognized total licensing and milestone revenue of approximately \$546,909 and \$644,742, respectively a decrease of \$0.1 million or 15%. Certain licensing fees recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period. For the nine months ended September 30, 2014, we recognized licensing revenue related to the development of XIAFLEX of approximately \$46,910 as compared to \$116,242 in the 2013 period, a decrease of \$69,332 or 60%. In the 2013 period, licensing fees recognized of \$0.5 million were related to the exercise by Auxilium of its exclusive option to expand the field of its license for injectable collagenase to include the potential treatment of adult patients with edematous fibrosclerotic panniculopathy, commonly known as cellulite. Milestone revenue recognized for the nine months ended September 30, 2014 was \$0.5 million and as compared to \$28,500 for the 2013 period. The \$0.5 million milestone revenue recognized in the 2014 period related to a regulatory milestone for the successful submission in July 2014 of a regulatory application to the Japanese Pharmaceutical and Medical Device Agency (PMDA) for the potential approval of XIAFLEX for the treatment of Dupuytren's contracture in Japan by Asahi Kasei Pharma Corporation. The \$28,500 milestone revenue recognized in the 2013 period related to product approval for XIAFLEX for the treatment of Dupuytren's contracture in adults with a palpable cord in Australia granted to Actelion.

## 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 \$1.1 million, respectively, for the nine months ended September 30, 2014 and 2013, representing a decrease in 2014 of approximately \$0.2 million, or 18%. This decrease in research and development expenses was primarily due to lower stock-based compensation, the completion of the human and canine lipoma trials and a decrease in pre-clinical costs associated with the uterine fibroid program.

We are working to develop CCH for the treatment of human and canine lipoma and have begun a pre-clinical study in uterine fibroids.

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

	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013	Accumulated Expenses Since January 1, 2010
<u>Program</u>			
Canine Lipoma	\$ 252,667	\$ 350,199	\$ 1,688,862
Human Lipoma	173,411	235,249	911,510
Uterine Fibroids	73,569	105,797	232,117
Other	409,482	420,441	1,782,889

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 and CCH, 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;

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- the scope, rate of progress of our pre-clinical 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 \$4.4 million and \$3.9 million for the nine months ended September 30, 2014 and 2013, respectively, an increase of approximately \$0.5 million, or 12%, from 2013. The increase in general and administrative expenses was mainly due to increased legal fees and consulting fees, third party royalty fees and the amortization of the deferred royalty buydown partially offset by lower third party licensing.

Other Income

Other income for the nine months ended September 30, 2014 was \$23,594 compared to \$19,510 in the 2013 period. Other income in both periods consisted mostly of interest earned on our investments.

Provision for 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 nine month period ended September 30, 2014 our provision for income taxes was \$1.4 million. The provision for income taxes for the nine month period ended September 30, 2014 is based on an estimated effective tax rate derived from an estimate of condensed consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for the fiscal year 2014. For the nine month period ended September 30, 2014, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of September 30, 2014, our remaining deferred tax assets were approximately \$1.5 million. Our taxes payable as September 30, 2014 were reduced by \$1.5 million due to the windfall associated with the disqualified sale of incentive stock options and the

exercise of nonqualified options.

For the nine month period ended September 30, 2013 our provision for income taxes was \$1.8 million. The provision for income taxes for the nine month period ended September 30, 2013 is based on an estimated effective tax rate derived from an estimate of condensed consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for fiscal year 2013. For the nine month period ended September 30, 2013, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of September 30, 2013, our remaining deferred tax assets were approximately \$1.5 million.

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### Net Income

For the nine months ended September 30, 2014, we recorded net income of \$2.7 million, or \$0.42 per basic common share and \$0.39 per diluted common share, compared to net income of \$3.6 million, or \$0.56 per basic common share and \$0.51 per diluted common share for the same period in 2013.

### 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, 2014 and December 31, 2013, we had cash and cash equivalents and investments in the aggregate of approximately \$17.5 million and \$12.6 million, respectively. We currently anticipate that our available funds and cash flow from operations will be sufficient to meet our operational cash needs for the next twelve months.

Net cash provided by operating activities for the nine months ended September 30, 2014 was \$4.0 and \$3.4 million in the 2013 period. Cash provided by operations in the 2014 period resulted primarily from our operating income for the period, a payment of earn-out royalties due under the DFB Agreement on an annual basis, royalties, mark-up on cost goods sold and milestone revenues under the Auxilium Agreement. Cash provided by operations in the 2013 period resulted primarily from our operating income for the period, a payment of earn-out royalties due under the DFB Agreement on an annual basis and licensing fees, milestones, royalties and mark-up on cost goods sold revenues under the Auxilium Agreement.

Net cash used in investing activities for the nine months ended September 30, 2014 was \$0.8 million as compared to \$1.6 million for the 2013 period. The net cash used in investing activities in the 2014 reflects the maturing of \$6.0 million and reinvestment of \$6.8 million in marketable securities. The net cash used in investing activities in the 2013 reflects the maturing of \$7.8 million and reinvestment of \$9.4 million in marketable securities.

Net cash provided by financing activities for the nine months ended September 30, 2014 was \$0.9 million as compared to net cash used in financing activities of \$0.6 million in the compared period of 2013. In the 2014 period, net cash provided by financing activities was mainly due to excess tax benefits related to share-based payments of \$1.5 million and proceeds received from stock option exercises of \$0.2 million partially offset by the repurchase of our common stock under our stock repurchase program of \$0.8 million. In the 2013 period, net cash used in financing activities was mainly due to the repurchase of our common stock under our stock repurchase program of \$0.6 million.

### Off-Balance Sheet Arrangements

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

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

We do not use derivative financial instruments or derivative commodity instruments for trading purposes. Our financial instruments consist of cash, cash equivalents, short-term investments, trade accounts receivable, accounts payable and long-term obligations. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents.

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 investments at September 30, 2014, amounting to approximately \$17.5 million, were maintained in bank demand accounts, money market accounts, certificates of deposit and pre-refunded municipal bonds. 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, 2013.

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Item 4: Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company, under the supervision and with the participation of Thomas L. Wegman, the Company's President, Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of its disclosure controls and procedures as of the end of the period covered by this Report. Based on that evaluation, management, including its Principal Executive Officer and Principal Financial Officer, concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by its in reports the Company files or submits 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 material information is accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, 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, the Company's 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 quarter ended September 30, 2014 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

In addition to the other information set forth below and other information contained elsewhere in this Report, you should carefully consider the risk factors discussed in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the SEC on March 7, 2014, which could materially affect our business, financial condition or future results.

A potential acquisition of Auxilium by Endo International plc may affect our working relationship with Auxilium pending the closing of transaction and may affect future option, milestone and contingent royalty payments from Auxilium.

On October 9, 2014 Auxilium announced that it had entered into a definitive agreement with Endo International plc under which Endo would acquire all of the outstanding shares of common stock of Auxilium for a per share consideration of \$33.25 in a cash and stock transaction. The transaction is expected to close in the first half of 2015, subject to regulatory approval in the US, an affirmative vote of a majority of the stockholders of Auxilium and other customary closing conditions. Until the closing, Endo and Auxilium will continue to operate as independent companies, although certain activities by Auxilium as defined in the definitive agreement require the consent of Endo pre-closing. While integration planning has commenced, no decisions will be made prior to the close of the transaction. It is unclear what effect the announcement of the Endo transaction will have on the Company's working

relationship with Auxilium or certain matters pending between the Company and Auxilium, including but not limited to the approval by Auxilium of the Company's conducting certain clinical trials or the on-going audit by the Company of the royalties paid by Auxilium, but it could potentially result in Endo's consent being required in connection with the resolution of these pending matters. Moreover, it is unclear what effect the Endo transaction will have, assuming it closes, on the support for the products currently being developed and marketed by Auxilium that generate milestone payments and royalties for the Company.

Our dependence upon revenue from Auxilium make us subject to the commercialization and other risk factors affecting Auxilium over which we have limited or no control, including the potential acquisition of Auxilium by Endo International plc.

Auxilium has disclosed in its securities filings a number of risk factors to consider when evaluating its business and future prospects, in addition to the potential acquisition of Auxilium by Endo. Given our dependence upon revenue from Auxilium, Auxilium's operating success or failure has a significant impact on our potential royalty stream and other payment rights and we could be similarly impacted by the potential acquisition of Auxilium by Endo. As such, we refer you to the full text of Auxilium's disclosed risk factors related to the Endo transaction, which were most recently included in Item 1A, Risk Factors, under "Risks Relating to the Endo Merger," included in Auxilium's Form 10-Q for the quarter ended September 30, 2014 as filed with the SEC on October 30, 2014.



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Our inability to successfully recruit and appoint a new independent member to the Board of Directors may result in our failure to meet NASDAQ listing standards.

On October 8, 2014, we announced with great sadness that Max Link, Ph.D., a member of our Board of Directors, passed away unexpectedly on October 6, 2014. He was 74 years old. Dr. Link served as the Chair of the Compensation Committee, as the Audit Committee Financial Expert and as a member of the Board's Audit, Compensation and Nominating and Corporate Governance Committees. Dr. Link's untimely passing has resulted in the Board of Directors failing to have a majority of independent directors. The Company has until the next annual meeting of stockholders to cure this deficiency or may be subject to delisting. The Board of Directors of the Company is currently reviewing candidates to replace Dr. Link on the Board and the three committees on which he served.

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

During the nine month period ended September 30, 2014, we did not issue any unregistered shares of securities.

Issuer Purchases of Equity Securities

During the quarter ended September 30, 2014, the Company did not have any purchases of equity securities.

Item 6. Exhibits

31\* Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-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.

The following materials from BioSpecifics Technologies Corp.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, are formatted in XBRL (Extensible Business Reporting Language): (i) 101\* the Consolidated Balance Sheet, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the Condensed Consolidated Financial Statements.

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\* filed herewith

\*\* furnished 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 10, 2014 /s/ Thomas L. Wegman

Thomas L. Wegman

President, Principal Executive Officer and

Principal Financial Officer