

BIOSPECIFICS TECHNOLOGIES CORP
Form 10-Q
August 11, 2014

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 June 30, 2014

☐ 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 (I.R.S. Employer
of Incorporation or Organization) Identification No.)

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

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

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

Yes ☒ No ☐

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

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

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

Yes ☐ No ☒

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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 August 7, 2014</u>
Common Stock (\$.001 par value)	6,477,012

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 market authorization for XIAPEX in the EU; the likelihood that Auxilium will exercise its opt in rights for the canine lipoma indication; payments for the successful submission of the application XIAFLEX for the treatment of Dupuytren’s contracture to 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 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; 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,” the negative versions 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 and 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 CCH to be used in additional indications; and other risk factors identified in BioSpecifics’ Annual Report on Form 10-K for the year ended December 31, 2013, its Quarterly Report on Form 10-Q for the quarter ended March 31, 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: Consolidated Financial Statements

BioSpecifics Technologies Corp.
Consolidated Balance Sheets

	June 30, 2014 (unaudited)	December 31, 2013 (audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,840,706	\$ 5,624,860
Short-term investments	7,793,002	6,966,964
Accounts receivable, net	2,042,617	5,004,418
Income tax receivable	1,272,486	255,708
Deferred tax assets	99,244	94,992
Prepaid expenses and other current assets	291,441	326,519
Total current assets	20,339,496	18,273,461
Deferred royalty buy-down	3,309,146	3,350,000
Deferred tax assets - long term	1,377,790	1,412,784
Patent costs, net	299,711	215,999
Total assets	25,326,143	23,252,244
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	719,194	634,277
Deferred revenue	69,130	69,130
Accrued liabilities of discontinued operations	78,138	78,138
Total current liabilities	866,462	781,545
Long-term deferred revenue	103,695	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 ; 6,806,467 and 6,655,168 shares issued at June 30, 2014 and December 31, 2013, respectively	6,806	6,655
Additional paid-in capital	22,393,836	20,951,796
Retained earnings	6,306,973	4,975,018
Treasury stock, 329,455 and 300,739 shares at cost at June 30, 2014 and December 31, 2013, respectively	(4,351,629)	(3,601,030)
Total stockholders' equity	24,355,986	22,332,439
Total liabilities and stockholders' equity	\$ 25,326,143	\$ 23,252,244

See accompanying notes to consolidated financial statements

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BioSpecifics Technologies Corp.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenues:				
Net sales	\$10,449	\$27,500	\$14,127	\$29,743
Royalties	2,624,774	3,197,603	5,365,092	6,630,503
Licensing revenues	17,282	44,880	34,565	589,761
Total Revenues	2,652,505	3,269,983	5,413,784	7,250,007
Costs and expenses:				
Research and development	286,332	470,044	669,036	764,918
General and administrative	1,490,514	1,236,254	2,736,819	2,854,736
Total Cost and Expenses	1,776,846	1,706,298	3,405,855	3,619,654
Operating income	875,659	1,563,685	2,007,929	3,630,353
Other income (expense):				
Interest income	7,352	6,510	14,323	12,376
Other income	-	-	1,150	-
	7,352	6,510	15,473	12,376
Income before expense for income tax	883,011	1,570,195	2,023,402	3,642,729
Income tax benefit (expense)	(305,045)	(542,009)	(691,447)	(1,261,459)
Net income	\$577,966	\$1,028,186	\$1,331,955	\$2,381,270
Basic net income per share	\$0.09	\$0.16	\$0.21	\$0.37
Diluted net income per share	\$0.08	\$0.15	\$0.19	\$0.34
Shares used in computation of basic net income per share	6,429,203	6,345,277	6,404,170	6,351,083
Shares used in computation of diluted net income per share	7,009,625	6,968,057	7,018,533	6,966,045

Consolidated Statements of Comprehensive Income

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net income	\$577,966	\$1,028,186	1,331,955	\$2,381,270
Other comprehensive income (loss)	-	-	-	-
Comprehensive income	\$577,966	\$1,028,186	1,331,955	\$2,381,270

See accompanying notes to consolidated financial statements

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

	Six Months Ended June 30,	
	2014	2013
Cash flows from operating activities:		
Net income	\$1,331,955	\$2,381,270
Adjustments to reconcile net income to net cash provided By operating activities:		
Depreciation and amortization	108,595	32,162
Stock-based compensation expense	10,708	105,449
Deferred tax assets	30,742	1,060
Gain on the sale of fixed assets	(1,150)	-
Changes in operating assets and liabilities:		
Accounts receivable	2,961,801	1,178,418
Prepaid expenses and other current assets	(981,700)	(261,387)
Accounts payable and accrued expenses	(66,537)	147,694
Accrued taxes payable	-	382,704
Deferred revenue	(34,565)	(89,761)
Net cash provided by operating activities	3,359,849	3,877,609
Cash flows from investing activities:		
Maturity of marketable investments	4,811,964	4,430,000
Purchases of marketable investments	(5,638,002)	(7,276,964)
Proceeds from sale of fixed asset	1,150	-
Net cash used in investing activities	(824,888)	(2,846,964)
Cash flows from financing activities:		
Proceeds from stock option exercises	169,000	-
Payments for repurchase of common stock	(750,598)	(396,851)
Excess tax benefits from share-based payment arrangements	1,262,483	-
Net cash used in in financing activities	680,885	(396,851)
Increase in cash and cash equivalents	3,215,846	633,794
Cash and cash equivalents at beginning of year	5,624,860	3,383,737
Cash and cash equivalents at end of period	\$8,840,706	\$4,017,531
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	\$-	\$-
Taxes	\$415,000	\$888,500

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 six month period ended June 30, 2014, we accrued approximately \$151,000 related to certain patent costs of which we amortized approximately \$68,000 in the 2014 period. For the six months ended June 30, 2013, we accrued approximately \$30,000 related to these costs of which approximately \$32,000 was amortized in the 2013 period.

See accompanying notes to consolidated financial statements

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BIOSPECIFICS TECHNOLOGIES CORP.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

June 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®) 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.

Operational Highlights

On April 7, 2014, our partner Auxilium and Sobi announced that Sobi became the Market Authorisation Holder (“MAH”) for XIAPEX in 28 EU member countries, Norway, and Iceland on April 3, 2014. As the MAH, Sobi has now elected to file for market authorization for XIAPEX for the treatment of Peyronie’s disease and work is on-going for that filing in the EU.

On April 14, 2014, our partner Auxilium and Sobi announced that encore data were presented from multiple clinical trials evaluating the use of XIAFLEX /XIAPEX in adult patients with Peyronie’s disease. This data were presented at the 29th Annual European Association of Urology Congress held April 11-15, 2014 in Stockholm, Sweden.

On May 19, 2014, our partner Auxilium announced that new analyses of data evaluating the use of XIAFLEX in adult men with Peyronie's disease were presented at the 2014 Annual Meeting of the American Urological Association being held in Orlando, Florida on May 16-21, 2014.

On June 25, 2014, our partner Auxilium announced that Sobi has filed for an extension of the label for XIAPEX (the EU trade name for CCH) with the European Medicines Agency to include the indication of Peyronie's disease. XIAPEX is currently approved for the treatment of Dupuytren's contracture in adult patients with a palpable cord. Auxilium, has partnered with Sobi for the marketing of XIAPEX in 71 Eurasian and African countries for the treatment of Dupuytren's contracture, and Peyronie's disease pending applicable regulatory approvals.

On June 27, 2014, we announced that effective at the close of the U.S. markets on June 27, 2014, BioSpecifics will be added to the Russell 3000® and Russell Global Indexes as part of Russell Investments' annual reconstitution of its U.S. and global equity indexes.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

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

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Principles of Consolidation

The audited consolidated financial statements include the accounts of the Company and its subsidiary, Advance Biofactures Corp. (“ABC-NY”).

Critical Accounting Policies, Estimates and Assumptions

The preparation of 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 consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Cash, Cash Equivalents and Short-term Investments

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

Fair Value Measurements

Management believes that the carrying amounts of the Company’s financial instruments, including cash, cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short-term 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.

At June 30, 2014, our accounts receivable balance of \$2.0 million was from one customer, Auxilium.

The Company is dependent on one customer who generates almost all its revenues. In the quarter ended June 30, 2014, the licensing and royalty revenues from Auxilium were \$2.0 million.

Revenue Recognition

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

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

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

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Product Sales

We recognize revenue from product sales 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.

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 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 recognized in 2013.

Licensing Revenue

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

Upfront License and Sublicensing Fees

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

Milestones

Milestones, in the form of additional license fees, typically represent nonrefundable payments to be received in conjunction with the achievement of a specific event identified in the contract, such as completion of specified development activities and/or regulatory submissions and/or approvals. We believe that a milestone represents the culmination of a distinct earnings process when it is not associated with ongoing research, development or other

performance on our part. We recognize such milestones as revenue when they become due and collection is reasonably assured. When a milestone does not represent the culmination of a distinct earnings process, we recognize revenue in a manner similar to that of an upfront license fee.

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

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 June 30, 2014, the accounts receivable balance of \$2.0 million was from one customer, Auxilium.

Deferred revenue of \$0.2 million 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.

We recorded no material bad debt expense for the period ended June 30, 2014. The allowance for doubtful accounts balance was approximately \$30,000 at June 30, 2014 and 2013.

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 June 30, 2014, our net reimbursable third party patent cost was approximately \$15,000.

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. 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. Third party royalty expenses were \$254,545 and \$191,902, respectively, for the six months ended June 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 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, 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 quarter ended June 30, 2014, we amortized approximately \$40,000 related to this agreement. As of June 30, 2014, the remaining capitalized balance was \$3.30 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 June 30, 2014, no 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 share-based awards including stock options and common stock issued to our employees and directors under our stock plans. It requires companies to estimate the fair value of share-based awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service periods in our consolidated statements of operations.

Under the ASC 718, we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of an award. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures) and the expected volatility. When there is uncertainty in the factors used to determine the expected term of an award, we use the simplified method. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. No stock options were granted during the six month period ended June 30, 2014.

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.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
Research and development	\$-	\$79,049	\$-	\$92,249
General and administrative	5,354	-	10,708	13,200
Total stock-based compensation expense	\$5,354	\$79,049	\$10,708	\$105,449

Stock Option Activity

A summary of our stock option activity during the three months ended June 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	-	-
Forfeited	-	-
Exercised	(151,300)	1.12
Expired	-	-
Outstanding as of June 30, 2014	1,015,700	\$ 10.21
Exercisable as of June 30, 2014	980,700	\$ 9.70

During the three months ended June 30, 2014 and 2013, the Company received \$169,000 and zero, respectively, from stock options exercised by option holders.

The aggregate intrinsic value of options outstanding and exercisable as of June 30, 2014 was approximately \$16.9 million. Aggregate intrinsic value represents the total pre-tax intrinsic value based on the closing price of our common stock of \$26.96 on June 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 \$68,000 in unrecognized compensation cost related to stock options outstanding as of June 30, 2014.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation. Machinery and equipment, furniture and fixtures, and autos are depreciated on the straight-line basis over their estimated useful lives of 5 to 10 years. Leasehold improvements are amortized over the lesser of their estimated useful lives or the remaining life of the lease.

Provision for Income Taxes

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

We use the asset and liability method of accounting for income taxes, as set forth in Accounting Standards Codification 740-10-25-2. Under this method, deferred income taxes, when required, are provided on the basis of the

difference between the financial reporting and income tax basis of assets and liabilities at the statutory rates enacted for future periods. In accordance with Accounting Standards Codification 740-10-45-25, Income Statement Classification of Interest and Penalties, we classify interest associated with income taxes under interest expense and tax penalties under other.

3. NET INCOME (LOSS) PER SHARE

In accordance with Accounting Standards Codification 260, Earnings Per Share, basic net income (loss) per share amount is computed using the weighted-average number of shares of common stock outstanding during the periods presented, while diluted net income (loss) per share is computed using the sum of the weighted-average number of common and common equivalent shares outstanding. Common equivalent shares used in the computation of diluted earnings per share result from the assumed exercise of stock options using the converted method.

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The following table summarizes the number of common equivalent shares that were included for the calculation of diluted net income purposes from continuing operations reported in the consolidated statement of operations.

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
Stock options	580,422	622,780	614,363	614,962

4. COMPREHENSIVE INCOME (LOSS)

For the three months ended June 30, 2014 and 2013, we had no components of other comprehensive income or loss other than net income itself.

5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	June 30,	December
	2014	31, 2013
Trade accounts payable and accrued expenses	\$308,378	\$409,617
Accrued legal and other professional fees	220,703	61,538
Accrued payroll and related costs	190,113	163,122
Total	\$719,194	\$634,277

6. PATENT COSTS

We amortize intangible assets with definite lives on a straight-line basis over their 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.

For the six months ended June 30, 2014, we capitalized patent costs of \$151,000 based on the most current information reported to us by Auxilium. As of June 30, 2014, the Company's estimated capitalized costs related to certain patent costs paid by Auxilium on behalf of the Company are approximately \$15,000, 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:

	June 30,	December
	2014	31, 2013
Patents	\$623,828	\$472,375
Accumulated Amortization	(324,117)	(256,376)
	\$299,711	\$215,999

The amortization expense for patents for the six months ended June 30, 2014 was approximately \$68,000. In the comparable period of 2013, the amortization expense for patents was approximately \$32,000. The estimated aggregate amortization expense for each of the next five years is approximately as follows:

2015	\$38,000
2016	32,000
2017	32,000
2018	32,000
2019	32,000

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7. 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 pursuant to Accounting Standards Codification 740-10-50 consist of stock-based compensation and deferred revenues. For the six month period ended June 30, 2014, the provision for income taxes was \$0.7 million. For the six month period ended June 30, 2014, the valuation allowance with respect to the Company's net deferred tax assets remained unchanged. As of June 30, 2014, our remaining deferred tax assets were approximately \$1.5 million. Our taxes payable were reduced by \$1.3 million due to the windfall associated with the disqualified sale of incentive stock options and the exercise of nonqualified options.

For the six month period ended June 30, 2013, the provision for income taxes was \$1.3 million. For the six month period ended June 30, 2013, the valuation allowance with respect to the Company's net deferred tax assets remained unchanged. As of June 30, 2013, our remaining deferred tax assets were approximately \$1.5 million.

8. SUBSEQUENT EVENTS

We have evaluated subsequent events for recognition or disclosure through the time of filing these consolidated financial statements on Form 10-Q with the SEC on August 11, 2014.

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 is 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 4, 2014, with a term of office expiring and to be renewed at the 2016 Annual Meeting of Stockholders. We also announced that as of August 15, 2014, Henry G. Morgan will retire from the Board of Directors after 24 years of service but will continue to act in a consulting capacity. Max Link will serve as Chairman of the Compensation Committee and as the financial expert on the Audit Committee following Henry Morgan's retirement.

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.

On August 8, 2014, the Company announced that it has injected the first patient in its placebo-controlled Phase 2 clinical trial of CCH for the treatment of lipoma. The Company expects to complete patient enrollment in this trial during the first quarter of 2015. The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled study to assess the safety and efficacy of CCH for the treatment of lipoma. Lipomas are encapsulated benign fatty tumors often detected as bulges under the skin. The study will be conducted at two centers in the U.S. and is expected to enroll 20 adult men and women presenting with at least two benign lipomas of similar size. Subjects will be randomized to have two lipomas treated in immediate succession; one with CCH and one with placebo.

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

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

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Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement 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.

Operational Highlights

On April 7, 2014, our partner Auxilium and Sobi announced that Sobi became the Market Authorisation Holder (“MAH”) for XIAPEX in 28 EU member countries, Norway, and Iceland on April 3, 2014. As the MAH, Sobi has now elected to file for market authorization for XIAPEX for the treatment of Peyronie’s disease and work is on-going for that filing in the EU.

On April 14, 2014, our partner Auxilium and Sobi announced that encore data were presented from multiple clinical trials evaluating the use of XIAFLEX /XIAPEX in adult patients with Peyronie’s disease. This data were presented at the 29th Annual European Association of Urology Congress held April 11-15, 2014 in Stockholm, Sweden.

On May 19, 2014, our partner Auxilium announced that new analyses of data evaluating the use of XIAFLEX in adult men with Peyronie's disease were presented at the 2014 Annual Meeting of the American Urological Association being held in Orlando, Florida on May 16-21, 2014.

On June 25, 2014, our partner Auxilium announced that Sobi has filed for an extension of the label for XIAPEX (the EU trade name for CCH) with the European Medicines Agency to include the indication of Peyronie's disease. XIAPEX is currently approved for the treatment of Dupuytren's contracture in adult patients with a palpable cord. Auxilium has partnered with Sobi for the marketing of XIAPEX in 71 Eurasian and African countries for the treatment of Dupuytren's contracture, and Peyronie's disease pending applicable regulatory approvals.

On June 27, 2014, we announced that effective at the close of the U.S. markets on June 27, 2014, BioSpecifics will be added to the Russell 3000® and Russell Global Indexes as part of Russell Investments' annual reconstitution of its U.S. and global equity indexes.

Outlook

For the quarter ended June 30, 2014, we generated revenue from one primary source: in connection with the 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 of Part 1 of our Annual Report on Form 10-K for the year ended December 1, 2013.

Critical Accounting Policies, Estimates and Assumptions

The preparation of unaudited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are based on historical experience and on various other assumptions that we believe are reasonable under the circumstances. The information at June 30, 2014 and for the three and six months ended June 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 consolidated financial statements. The interim results are not necessarily indicative of results to be expected for the full fiscal year. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2013 included in the Company's Annual Report on Form 10-K and with the unaudited consolidated financial statements included in our Quarterly Report on Form 10-Q for the first quarter of 2014 filed with the SEC. While our significant accounting policies are described in more detail in the notes to our unaudited consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our unaudited consolidated financial statements. Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

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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.

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Under the 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 recognized 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 June 30, 2014, our estimated net reimbursable third party patent costs accrual was approximately \$15,000.

Receivables and Deferred Revenue. Accounts receivable as of June 30, 2014 is approximately \$2.0 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 \$0.2 million 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. 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. Third party royalty expenses were \$254,545 and \$191,902, respectively, for the six months ended June 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 quarter ended June 30, 2014, we amortized approximately \$40,000 related to this agreement. As of June 30, 2014, the remaining capitalized balance was \$3.30 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 June 30, 2014, no impairment existed.

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

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

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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 June 30, 2014 and 2013 product revenues were \$10,449 and \$27,500, 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 three month period ended June 30, 2014 were \$2.6 million as compared to royalty, mark-up on cost of goods sold and earn-out revenues of \$3.2 million in the 2013 period, a decrease of \$0.6 million or 18%. This decrease was mainly due to the expiration of the right to receipt earn-out payments on Santyl partially offset by increased XIAFLEX royalties and the mark-up on cost of goods sold revenue.

Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were \$2.6 million for the 2014 period compared to \$1.7 million in the 2013 period. The increase of \$0.9 million or 53% was due to increased net sales of XIAFLEX during 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 three months ended June 30, 2014 as compared to \$1.5 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.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. For the three months ended June 30, 2014, we recognized total licensing revenue related to the development of XIAFLEX of approximately \$17,282 as compared to \$44,880 in the 2013 period. 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.

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

Research and Development Activities and Expenses

Research and development expenses include, but are not limited to, internal costs, such as salaries and benefits, costs of materials, lab expense, facility costs and overhead. Research and development expenses also consist of third party costs, such as medical professional fees, product costs used in clinical trials, consulting fees and costs associated with clinical study arrangements. Research and development expenses were \$286,332 and \$470,044, respectively, for the three months ended June 30, 2014 and 2013, representing a decrease in 2014 of \$183,712, or 39%. This decrease in research and development expenses was primarily due to the completion of the canine lipoma trial, pre-clinical costs associated with the uterine fibroid program and stock-based compensation.

We are currently 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 June 30, 2014	Three Months Ended June 30, 2013
Program		
Canine Lipoma	\$90,675	\$180,646
Human Lipoma	36,036	39,184
Uterine Fibroids	17,232	54,435

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Successful development of drugs is inherently difficult and uncertain. Our business requires investments in research and development over many years, often for drug candidates that may fail during the research and development process. Even if the Company is able to successfully complete the development of our drug candidates, our long-term prospects depend upon our ability and the ability of our partners, particularly with respect to XIAFLEX 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 preclinical studies and other research and development activities related to our drug candidate projects;
- clinical trial results for our drug candidate projects;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our drug candidate projects;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our drug candidate projects;
- the cost and timing of regulatory approvals with respect to our drug candidate projects; and
- the cost of establishing clinical supplies for our drug candidate projects.

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, consultant costs, legal fees, investor relations, professional fees and overhead costs. General and administrative expenses were \$1.5 million and \$1.2 million for the three months ended June 30, 2014 and 2013, respectively, an increase of approximately \$0.3 million, or 21%, from 2013. The increase in general and administrative expenses was mainly due to increased legal fees, third party royalty fees and consulting services partially offset by professional fees and investor relations.

Other Income and expense

Other income for the three months ended June 30, 2014 was \$7,352 compared to \$6,510 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.

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For the three month period ended June 30, 2014 our provision for income taxes was \$0.3 million. The provision for income taxes for the three month period ended June 30, 2014 is based on an estimated effective tax rate derived from an estimate of consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for the fiscal year 2014. For the three month period ended June 30, 2014, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of June 30, 2014, our remaining deferred tax assets were approximately \$1.5 million.

For the three month period ended June 30, 2013 our provision for income taxes was \$0.5 million. The provision for income taxes for the three month period ended June 30, 2013 is based on an estimated effective tax rate derived from an estimate of consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for fiscal year 2013. For the three month period ended June 30, 2013, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of June 30, 2013, our remaining deferred tax assets were approximately \$1.5 million.

Net Income

For the three months ended June 30, 2014 we recorded net income of \$0.6 million, or \$0.09 per basic common share and \$0.08 per diluted common share, compared to a net income of \$1.0 million, or \$0.16 per basic and \$0.15 per diluted common share, for the same period in 2013.

SIX MONTHS ENDED JUNE 30, 2014 COMPARED TO SIX MONTHS ENDED JUNE, 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 six months ended June 30, 2014 and 2013 product revenues were \$14,127 and \$29,743, 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 six month period ended June 30, 2014 were \$5.4 million as compared to royalty, mark-up on cost of goods sold and earn-out revenues of \$6.6 million in the 2013 period, a decrease of \$1.2 million or 19%. This decrease was mainly due to the expiration of the right to receipt earn-out payments on Santyl partially offset by increased XIAFLEX royalties and the mark-up on cost of goods sold revenue.

Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were \$5.4 million for the 2014 period compared to \$4.1 million in the 2013 period. The increase of \$1.3 million or 32% 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 six months ended June 30, 2014 as compared to \$2.5 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.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. For the six months ended June 30, 2014 and 2013, we recognized total licensing and milestone revenue of approximately \$34,565 and \$589,761, respectively a decrease of \$555,196 or 94%. 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 six months ended June 30, 2014, we recognized licensing revenue related to the development of XIAFLEX of approximately \$34,565 as compared to \$89,761 in the 2013 period, a decrease of \$55,196 or 61%. 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.

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

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 \$0.7 million and \$0.8 million, respectively, for the six months ended June 30, 2014 and 2013, representing a decrease in 2014 of approximately \$0.1 million, or 20%. This decrease in research and development expenses was primarily due to lower stock-based compensation.

We are currently 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.

	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013	Accumulated Expenses Since January 1, 2010
<u>Program</u>			
Canine Lipoma	\$207,540	\$270,717	\$1,643,735
Human Lipoma	\$112,350	\$83,021	\$850,450
Uterine Fibroids	\$68,191	\$56,075	\$225,821

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;
- the scope, rate of progress of our preclinical studies and other research and development activities related to our drug candidate projects;
- clinical trial results for our drug candidate projects;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our drug candidate projects;

the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our drug candidate projects;

the cost and timing of regulatory approvals with respect to our drug candidate projects; and

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·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 \$2.7 million and \$2.9 million for the six months ended June 30, 2014 and 2013, respectively, a decrease of approximately \$0.2 million, or 10%, from 2013. The decrease in general and administrative expenses was mainly due to lower third party licensing fees, investor relations and professional fees partially offset by increased third party royalty fees and patent amortization.

Other Income and expense

Other income for the six months ended June 30, 2014 was \$15,473 compared to \$12,376 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 six month period ended June 30, 2014 our provision for income taxes was \$0.7 million. The provision for income taxes for the six month period ended June 30, 2014 is based on an estimated effective tax rate derived from an estimate of consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for the fiscal year 2014. For the six month period ended June 30, 2014, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of June 30, 2014, our remaining deferred tax assets were approximately \$1.5 million. Our taxes payable as June 30, 2014 were reduced by \$1.3 million due to the windfall associated with the disqualified sale of incentive stock options and the exercise of nonqualified options

For the six month period ended June 30, 2013 our provision for income taxes was \$1.3 million. The provision for income taxes for the six month period ended June 30, 2013 is based on an estimated effective tax rate derived from an estimate of consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for fiscal year 2013. For the six month period ended June 30, 2013, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of June 30, 2013, our remaining deferred tax assets were approximately \$1.5 million.

Net Income

For the six months ended June 30, 2014 we recorded net income of \$1.3 million, or \$0.21 per basic common share and \$0.19 per diluted common share, compared to net income of \$2.4 million, or \$0.37 per basic common share and \$0.34 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 June 30, 2014 and December 31, 2013, we had cash and cash equivalents and investments in the aggregate of approximately \$16.6 million and \$12.6 million, respectively.

Net cash provided by operating activities for the six months ended June 30, 2014 was \$3.4 and \$3.9 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 and royalties and mark-up on cost goods sold 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.

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Net cash used in investing activities for the six months ended June 30, 2014 was \$0.8 million as compared to \$2.8 million for the 2013 period. The net cash used in investing activities in the 2014 reflects the maturing of \$4.8 million and reinvestment of \$5.6 million in marketable securities. The net cash used in investing activities in the 2013 reflects the maturing of \$4.4 million and reinvestment of \$7.3 million in marketable securities.-

Net cash provided by financing activities for the six months ended June 30, 2014 was \$0.7 million as compared to net cash used in financing activities of \$0.4 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 \$1.3 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.

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 short-term investments at June 30, 2014, amounting to approximately \$16.6 million, were maintained in bank demand accounts, money market accounts, and certificates of deposit. We do not hedge our interest rate risks, as we believe reasonably possible near-term changes in interest rates would not materially affect our results of operations, financial position or cash flows.

We are subject to market risks in the normal course of our business, including changes in interest rates. There have been no significant changes in our exposure to market risks since December 31, 2013.

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 June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K filed with the SEC on March 7, 2014.

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

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

Issuer Purchases of Equity Securities (1)

<u>Period</u>	Total Number of Shares Purchased (2)	Average Price Paid Per Share (3)	Total Number of Shares Purchased as Part of Publicly Announced Plan	Maximum Number (or Dollar Value) of Shares that may yet be Purchased under the Plan
				\$1,919,028
April 1, 2014 – April 30, 2014	5,673	\$ 24.92	178,370	\$1,777,648
May 1, 2014 – May 31, 2014	15,018	\$ 26.52	193,388	\$1,379,435
June 1, 2014 – June 30, 2014	4,800	\$ 27.09	198,188	\$1,249,400

On June 4, 2010, we announced that our Board of Directors authorized a stock repurchase program under Rule 10b-18 of the Exchange Act of up to \$2.0 million of our outstanding common stock over a period of 12 months. Our Board of Directors reauthorized this stock repurchase program on June 20, 2011. Again, on November 15, (1)2012, we announced that our Board of Directors had reauthorized the repurchase of up to \$2.0 million of our common stock under the stock repurchase program. On December 10, 2013, we announced that our Board of Directors had reauthorized the repurchase of up to \$2.0 million of our common stock under the stock repurchase program until such time the program is terminated by our Board of Directors.

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

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

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.

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

* 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: August 11, 2014 /s/ Thomas L. Wegman

Thomas L. Wegman

President, Principal Executive Officer and

Principal Financial Officer
