

BIOSPECIFICS TECHNOLOGIES CORP
Form 10-Q
August 09, 2013

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, 2013

☐ 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 ☒

Edgar Filing: BIOSPECIFICS TECHNOLOGIES CORP - Form 10-Q

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, 2013</u>
Common Stock (\$.001 par value)	6,339,815

BIOSPECIFICS TECHNOLOGIES CORP.

TABLE OF CONTENTS

	Page
PART I – FINANCIAL INFORMATION	
ITEM 1. <u>Consolidated Financial Statements</u>	4
<u>Consolidated Balance Sheet as of June 30, 2013 and December 31, 2012</u>	4
<u>Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2013 and 2012</u>	5
<u>Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2013 and 2012</u>	6
<u>Notes to Consolidated Financial Statements</u>	7
ITEM 2. <u>Management’s Discussion and Analysis</u>	13
ITEM 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
ITEM 4. <u>Controls and Procedures</u>	22
PART II – OTHER INFORMATION	
ITEM 1. <u>Legal Proceedings</u>	22
ITEM 1A. <u>Risk Factors</u>	22
ITEM 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	22
ITEM 3. <u>Defaults Upon Senior Securities</u>	23
ITEM 4. <u>Reserved</u>	23
ITEM 5. <u>Other Information</u>	23
ITEM 6. <u>Exhibits</u>	23

Table of Contents

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 – Bingham to Update

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 include statements concerning, among other things, the timing of reporting top-line data from BioSpecifics’ phase II clinical trial of XIAFLEX for the treatment of human lipoma and its placebo controlled randomized study to evaluate the efficacy of XIAFLEX for the treatment of canine lipoma; and the timing for receiving the final earn-out payments under BioSpecifics’ agreement with DFB Biotech, Inc. and its affiliates. 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 or plural of these words, and other similar expressions. These forward-looking statements are predictions based on BioSpecifics’ current expectations and its projections about future events. There are a number of important factors that could cause BioSpecifics’ actual results to differ materially from those indicated by such forward-looking statements, including the timing of regulatory filings and action; the ability of BioSpecifics’ partner, Auxilium Pharmaceuticals, Inc., and its partners, Swedish Orphan Biovitrum AB, Asahi Kasei Pharma Corporation and Actelion Pharmaceuticals Ltd., to achieve their objectives for XIAFLEX in their applicable territories; the market for XIAFLEX in, and initiation and outcome of clinical trials for, additional indications including frozen shoulder, cellulite, human lipoma and canine lipoma, all of which will determine the amount of milestone, royalty and sublicense income BioSpecifics may receive; the potential of XIAFLEX to be used in additional indications; the timing of results of any clinical trials; the receipt of any applicable milestone payments from Auxilium Pharmaceuticals, Inc.; whether royalty payments BioSpecifics is entitled to receive will exceed set-offs; and other risk factors identified in BioSpecifics’ Annual Report on Form 10-K for the year ended December 31, 2012, its Quarterly Report on Form 10-Q for the first quarter of 2013 and its Current Reports on Form 8-K filed with the Securities and Exchange Commission. All forward-looking statements included in this Report are made as of the date hereof, and BioSpecifics assumes no obligation to update these forward-looking statements.

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1: Consolidated Financial Statements

BioSpecifics Technologies Corp.
Consolidated Balance Sheets

	June 30, 2013 (unaudited)	December 31, 2012 (audited)
Assets		
Current assets:		
Cash and cash equivalents	\$4,017,531	\$3,383,737
Short-term investments	7,966,964	5,120,000
Accounts receivable, net	3,903,942	5,082,360
Income tax receivable	51,070	51,070
Deferred tax assets	79,482	88,910
Prepaid expenses and other current assets	411,110	149,724
Total current assets	16,430,099	13,875,801
Deferred royalty buy-down	2,750,000	2,750,000
Deferred tax assets - long term	1,492,509	1,484,141
Patent costs, net	248,160	280,322
Total assets	20,920,768	18,390,264
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	660,560	512,866
Deferred tax liability	382,704	-
Deferred revenue	78,328	133,524
Accrued liabilities of discontinued operations	78,138	78,138
Total current liabilities	1,199,730	724,528
Long-term deferred revenue	172,825	207,390
Stockholders' equity:		
Series A Preferred stock, \$.50 par value, 700,000 shares authorized; none outstanding	-	-
Common stock, \$.001 par value; 10,000,000 shares authorized ; 6,625,168 shares issued at June 30, 2013 and December 31, 2012, respectively	6,625	6,625
Additional paid-in capital	20,794,154	20,688,706
Retained earnings (deficit)	2,070,441	(310,829)
Treasury stock, 285,352 and 260,632 shares at cost at June 30, 2013 and December 31, 2012, respectively	(3,323,007)	(2,926,156)
Total stockholders' equity	19,548,213	17,458,346
Total liabilities and stockholders' equity	\$20,920,768	\$18,390,264

See accompanying notes to consolidated financial statements

Table of Contents

BioSpecifics Technologies Corp.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenues:				
Net sales	\$27,500	\$1,246	\$29,743	\$8,750
Royalties	3,197,603	2,491,313	6,630,503	4,391,282
Licensing revenues	44,880	109,275	589,761	788,550
Total Revenues	3,269,983	2,601,834	7,250,007	5,188,582
Costs and expenses:				
Research and development	470,044	404,346	764,918	653,898
General and administrative	1,236,254	1,149,926	2,854,736	2,238,648
Total Cost and Expenses	1,706,298	1,554,272	3,619,654	2,892,546
Operating income	1,563,685	1,047,562	3,630,353	2,296,036
Other income (expense):				
Interest income	6,510	9,771	12,376	19,264
	6,510	9,771	12,376	19,264
Income before expense for income tax	1,570,195	1,057,333	3,642,729	2,315,300
Income tax benefit (expense)	(542,009)	(390,651)	(1,261,459)	(906,228)
Net income	\$1,028,186	\$666,682	\$2,381,270	\$1,409,072
Basic net income per share	\$0.16	\$0.11	\$0.37	\$0.22
Diluted net income per share	\$0.15	\$0.10	\$0.34	\$0.20
Shares used in computation of basic net income per share	6,345,277	6,343,356	6,351,083	6,339,930
Shares used in computation of diluted net income per share	6,968,057	6,971,687	6,966,045	6,984,258

Consolidated Statements of Comprehensive Income

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Net income	\$1,028,186	\$666,682	\$2,381,270	\$1,409,072
Other comprehensive income (loss)	-	-	-	-
Comprehensive income	\$1,028,186	\$666,682	\$2,381,270	\$1,409,072

See accompanying notes to consolidated financial statements

Table of ContentsBioSpecifics Technologies Corp.
Consolidated Statements of Cash Flows
(unaudited)

	Six Months Ended June 30,	
	2013	2012
Cash flows from operating activities:		
Net income	\$2,381,270	\$1,409,072
Adjustments to reconcile net income to net cash provided By operating activities:		
Depreciation and amortization	32,162	29,019
Stock-based compensation expense	105,449	175,685
Deferred tax assets	1,060	416,055
Changes in operating assets and liabilities:		
Accounts receivable	1,178,418	416,072
Prepaid expenses and other current assets	(261,387)	72,403
Accounts payable and accrued expenses	147,694	(5,033)
Accrued taxes payable	382,704	102,471
Deferred revenue	(89,761)	(218,550)
Net cash provided by operating activities	3,877,609	2,397,194
Cash flows from investing activities:		
Maturity of marketable investments	4,430,000	2,000,000
Purchases of marketable investments	(7,276,964)	(2,000,000)
Payment for royalty buy down	-	(1,500,000)
Net cash used in investing activities	(2,846,964)	(1,500,000)
Cash flows from financing activities:		
Proceeds from stock option exercises	-	78,000
Payments for repurchase of common stock	(396,851)	(485,904)
Excess tax benefits from share-based payment arrangements	-	102,052
Net cash used in in financing activities	(396,851)	(305,852)
Increase in cash and cash equivalents	633,794	591,342
Cash and cash equivalents at beginning of year	3,383,737	3,196,831
Cash and cash equivalents at end of period	\$4,017,531	\$3,788,173
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	\$-	\$-
Taxes	\$888,500	\$92,000

Supplemental disclosures of non-cash transactions:

Under our agreement with Auxilium certain patent costs paid by Auxilium on behalf of the Company are creditable against future royalties. For the six month period ended June 30, 2013, we accrued approximately \$30,000 related to certain patent costs of which we amortized approximately \$16,100 in the 2013 period. For the six months ended June 30, 2012, we accrued approximately \$64,000 related to these costs of which approximately \$29,000 was amortized in the 2012 period.

See accompanying notes to consolidated financial statements

6

Table of Contents

BIOSPECIFICS TECHNOLOGIES CORP.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2013

(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® (collagenase clostridium histolyticum)) for clinical indications in Dupuytren’s contracture, Peyronie’s disease, frozen shoulder (adhesive capsulitis) and cellulite (edematous fibrosclerotic panniculopathy) (the “Auxilium Agreement”). 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. 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. Auxilium has been granted a Notice of Compliance (approval) by Health Canada for XIAFLEX for the treatment of Dupuytren’s contracture in adults with a palpable cord in Canada. In July 2013 Auxilium entered into a long-term collaboration with Swedish Orphan Biovitrum AB (“Sobi”) for the development, supply and commercialization of XIAPEX (collagenase clostridium histolyticum) for the treatment of Dupuytren’s contracture. In addition, work is on-going to file for approval of XIAPEX for the treatment of Peyronie’s disease in the EU.

Pursuant to a March 2006 agreement (the “DFB Agreement”) between the Company and DFB Biotech, Inc. (“DFB”), we continue to receive earn-out payments based on the sales of Santyl. Our right to receive earn-out payments with respect to the marketed topical product sold to DFB expires in August 2013, and we expect to receive our final earn-out payment for Santyl by the end of the year.

Operational Highlights

On July 23, 2013 we presented a poster titled “Biomechanical Evaluation of Human Uterine Fibroids after Exposure to Purified Clostridial Collagenase” at the Society for the Study of Reproduction 46th Annual Meeting in Montreal, Quebec, Canada. The poster provided data which showed that highly purified collagenase can reduce the stiffness of human uterine fibroid tissue in laboratory experiments. Increased tissue rigidity has been implicated as a cause of the morbidity associated with uterine fibroids. The results of this ex vivo study show that treatment of fibroids with determined doses of purified collagenase caused a statistically significant decrease in the stiffness of the tissue. This hypothesis was tested in fibroid tissue obtained after hysterectomy or myomectomy surgery from patients. Tissues were injected with collagenase and compared to control-injected tissue.

On July 16, 2013, Auxilium announced that it has entered into a long-term collaboration with Sobi for the development, supply and commercialization of XIAPEX (collagenase clostridium histolyticum) for the treatment of Dupuytren’s contracture. In addition, Auxilium stated that work is on-going to file for approval of XIAPEX for the treatment of Peyronie’s disease in the EU. Under the terms of the collaboration agreement, Sobi will receive exclusive rights to commercialize XIAPEX for Dupuytren’s contracture and Peyronie’s disease, subject to applicable regulatory approvals, in 28 EU member countries, Switzerland, Norway, Iceland, 18 Central Eastern Europe/Commonwealth of Independent countries, including Russia and Turkey, and 22 Middle Eastern & North African countries. Since 2011, XIAPEX has been approved for the treatment of Dupuytren’s contracture in 28 EU member countries, Switzerland, and Norway. Sobi, via its Partner Products business unit, will be primarily responsible for the applicable regulatory,

clinical and commercialization activities for XIAPEX in Dupuytren's contracture and Peyronie's disease in these countries.

In April 2013, we completed enrollment in our placebo-controlled, randomized Phase II trial, Chien-804, to evaluate the efficacy of XIAFLEX for the treatment of subcutaneous benign lipomas in 32 canines randomized 1:1 XIAFLEX to placebo. The lipoma volume will be measured at baseline, 1 month and 3 months with the primary efficacy endpoint being the relative change in lipoma volume from baseline to 3 months, as determined by CT scan.

Table of Contents

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

The information included in this Report should be read in conjunction with our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 and our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC.

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, U.S. government securities, or short-term commercial paper.

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, 2013, the accounts receivable balance of \$3.9 million was primarily from two customers, comprised of \$2.5 million (64% of total) from DFB and \$1.4 million (36% of total) from Auxilium.

The Company has been dependent in each year on two customers who generate almost all its revenues. In the quarter ended June 30, 2013, the licensing and royalty revenues from Auxilium were \$4.7 million (65% of total) and royalty revenues from DFB were \$2.5 million (35% of total).

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”).

8

Table of Contents

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.

Under the Auxilium Agreement, we do not participate in the selling, marketing or manufacturing of products for which we receive royalties and a mark-up of the cost of goods sold revenues. The royalty and mark-up on cost of goods sold revenues will generally be recognized in the quarter that Auxilium provides the written reports and related information to us, that is, royalty and mark-up on cost of goods sold revenues are generally recognized one quarter following the quarter in which the underlying sales by Auxilium occurred. The royalties payable by Auxilium to us are subject to set-off for certain patent costs.

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

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.

9

Table of Contents

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

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 our two large pharmaceutical customers. These companies have historically paid timely and have been financially stable organizations. Due to the nature of the accounts receivable balance, we believe the risk of doubtful accounts is minimal. If the financial condition of our customers were to deteriorate, adversely affecting their ability to make payments, additional allowances would be required. We provide for estimated uncollectible amounts through a charge to earnings and a credit to a valuation allowance. Balances that remain outstanding after we have used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to accounts receivable.

At June 30, 2013, the accounts receivable balance of \$3.9 million was primarily from two customers, comprised of \$2.5 million from DFB and \$1.4 million from Auxilium.

Deferred revenue of \$0.5 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 in each of the last three years. The allowance for doubtful accounts balance was approximately \$30,000 at June 30, 2013 and 2012.

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, 2013 our net reimbursable third party patent costs accrual was approximately \$30,000.

Royalty Buy-Down

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 payable upon the occurrence of a milestone event.

As of June 30, 2013, we have capitalized \$2.75 million related to this agreement which will be amortized over approximately five years beginning on the date of the first commercial sale of XIAFLEX for the treatment of Peyronie's disease, which represents the period estimated to be benefited using the straight-line method. In accordance with Accounting Standards Codification 350, Intangibles, Goodwill and Other, the Company amortizes intangible assets with finite lives in a manner that reflects the pattern in which the economic benefits of the assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the assets are amortized using the straight-line method.

10

Table of Contents

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. We granted to one of our consultants 15,000 stock options, valued at approximately \$79,000, during the three month period ended June 30, 2013. We used the Black-Scholes valuation model to estimate the value of options using 37% volatility, a risk free rate of 0.68% and average exercise period of five years.

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.

Table of Contents

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2013	2012	2013	2012
Research and development	\$79,049	\$122,679	\$92,249	\$144,817
General and administrative	-	13,200	13,200	30,868
Total stock-based compensation expense	\$79,049	\$135,879	\$105,449	\$175,685

Stock Option Activity

A summary of our stock option activity during the six months ended June 30, 2013 is presented below:

	Total Number of Shares	Weighted-Average Exercise Price
Options Outstanding as of December 31, 2012	1,182,000	\$ 8.90
Granted	15,000	15.85
Forfeited	-	-
Exercised	-	-
Expired	-	-
Outstanding as of June 30, 2013	1,197,000	\$ 8.99
Exercisable as of June 30, 2013	1,177,000	\$ 8.64

During the six months ended June 30, 2013 and 2012, zero and \$78,000, respectively, were received from stock options exercised by option holders.

The aggregate intrinsic value of options outstanding and exercisable as of June 30, 2013 was approximately \$8.2 million. Aggregate intrinsic value represents the total pre-tax intrinsic value based on the closing price of our common stock of \$15.60 on June 28, 2013, which would have been received by the option holders had all option holders exercised their options as of that date. We have no unrecognized compensation cost related to stock options outstanding as of June 30, 2013.

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.

Table of Contents

3. NET INCOME (LOSS) PER SHARE

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Stock options	622,780	628,331	614,962	644,328

4. COMPREHENSIVE INCOME (LOSS)

For the three and six months ended June 30, 2013 and 2012, 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, 2013	December 31, 2012
Trade accounts payable and accrued expenses	\$365,054	\$304,635
Accrued legal and other professional fees	129,822	61,147
Accrued payroll and related costs	165,684	147,084
Total	\$660,560	\$512,866

6. PATENT COSTS

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 2 to 14 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 June 30, 2013, the Company's capitalized costs related to certain patent costs paid by Auxilium on behalf of the Company, 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, 2013	December 31, 2012
Patents	\$472,375	\$472,375
Accumulated Amortization	(224,215)	(192,053)

\$248,160 \$280,322

The amortization expense for patents for the six months ended June 30, 2013 was approximately \$32,000. In the comparable period of 2012, the amortization expense for patents was approximately \$29,000. The estimated aggregate amortization expense for each of the next five years is approximately as follows:

2014	\$53,000
2015	25,000
2016	20,000
2017	20,000
2018	20,000

Table of Contents

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, 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.

For the six month period ended June 30, 2012 our provision for income taxes was \$0.9 million, primarily a non-cash charge. For the six month period ended June 30, 2012, the valuation allowance with respect to the company's net deferred tax assets remained unchanged. Our remaining deferred tax assets decreased by \$0.4 million to approximately \$2.6 million, primarily because we used our Orphan Drug Tax Credit to reduce our taxes payable, during six months ended June 30, 2012.

8. RELATED PARTY TRANSACTIONS

Our corporate headquarters are currently located at 35 Wilbur St., Lynbrook, NY 11563. As previously reported, our previous lease for our headquarters terminated on June 30, 2010. Our subsidiary, ABC-NY (together with the Company, the "Tenant") and Wilbur St. Corp. (the "Landlord") were parties to a lease agreement initially dated as of January 30, 1998 and modified as of June 24, 2009 (the "Lease Agreement"), pursuant to which the Landlord leased to the Tenant the premises located at 35 Wilbur Street, Lynbrook, NY 11563 (the "Premises") until June 30, 2010 and for a monthly rental price of \$11,250 plus utilities and real estate taxes. Following the expiration of the Lease Agreement, the Tenant continued to lease the Premises from the Landlord on a month-to-month basis. We notified the Landlord of our termination of the Lease Agreement effective March 31, 2011, but continue to hold over in the Premises.

9. SUBSEQUENT EVENTS

We have evaluated subsequent events for recognition or disclosure through the time of filing these consolidated financial statements on Form 10-Q with the SEC on August 9, 2013.

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

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

Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. ("Auxilium") for injectable collagenase (which Auxilium has named XIAFLEX® (collagenase clostridium histolyticum)) for clinical indications in Dupuytren's contracture, Peyronie's disease, frozen shoulder (adhesive capsulitis) and cellulite (edematous fibrosclerotic panniculopathy) (the "Auxilium Agreement"). 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. 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. Auxilium has been granted a Notice of Compliance (approval) by Health Canada for XIAFLEX for the treatment of Dupuytren's

contracture in adults with a palpable cord in Canada. In July 2013 Auxilium entered into a long-term collaboration with Swedish Orphan Biovitrum AB (“Sobi”) for the development, supply and commercialization of XIAPEX[®] (collagenase clostridium histolyticum) for the treatment of Dupuytren's contracture. In addition, work is on-going to file for approval of XIAPEX for the treatment of Peyronie's disease in the EU.

Pursuant to a March 2006 agreement (the “DFB Agreement”) between the Company and DFB Biotech, Inc. (“DFB”), we continue to receive earn-out payments based on the sales of Santyl. Our right to receive earn-out payments with respect to the marketed topical product sold to DFB expires in August 2013, and we expect to receive our final earn-out payment for Santyl by the end of the year.

14

Table of Contents

Operational Highlights

On July 23, 2013 we, presented a poster titled “Biomechanical Evaluation of Human Uterine Fibroids after Exposure to Purified Clostridial Collagenase” at the Society for the Study of Reproduction 46th Annual Meeting in Montreal, Quebec, Canada. The poster provided data which showed that highly purified collagenase can reduce the stiffness of human uterine fibroid tissue in laboratory experiments. Increased tissue rigidity has been implicated as a cause of the morbidity associated with uterine fibroids. The results of this ex vivo study show that treatment of fibroids with determined doses of purified collagenase caused a statistically significant decrease in the stiffness of the tissue. This hypothesis was tested in fibroid tissue obtained after hysterectomy or myomectomy surgery from patients. Tissues were injected with collagenase and compared to control-injected tissue.

On July 16, 2013, Auxilium announced that it has entered into a long-term collaboration with Sobi for the development, supply and commercialization of XIAPEX (collagenase clostridium histolyticum) for the treatment of Dupuytren's contracture. In addition, work is on-going to file for approval of XIAPEX for the treatment of Peyronie's disease in the EU. Under the terms of the collaboration agreement, Sobi will receive exclusive rights to commercialize XIAPEX for Dupuytren's contracture and Peyronie's disease, subject to applicable regulatory approvals, in 28 EU member countries, Switzerland, Norway, Iceland, 18 Central Eastern Europe/Commonwealth of Independent countries, including Russia and Turkey, and 22 Middle Eastern & North African countries. Since 2011, XIAPEX has been approved for the treatment of Dupuytren's contracture in 28 EU member countries, Switzerland, and Norway.

Sobi, via its Partner Products business unit, will be primarily responsible for the applicable regulatory, clinical and commercialization activities for XIAPEX in Dupuytren's contracture and Peyronie's disease in these countries.

In April 2013, we completed enrollment in our placebo-controlled, randomized Phase II trial, Chien-804, to evaluate the efficacy of XIAFLEX for the treatment of subcutaneous benign lipomas in 32 canines randomized 1:1 XIAFLEX to placebo. The lipoma volume will be measured at baseline, 1 month and 3 months with the primary efficacy endpoint being the relative change in lipoma volume from baseline to 3 months, as determined by CT scan.

Outlook

Currently, we generate revenue from two primary sources: in connection with the DFB Agreement and in connection with the Auxilium Agreement. Under the DFB Agreement, our right to receive earn-out payments with respect to the marketed topical product sold to DFB expires in August 2013, and we expect to receive our final earn-out payment for Santyl by the end of the year. 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, successfully develop XIAFLEX for additional indications, obtain required regulatory approvals, manufacture XIAFLEX at an acceptable cost, in a timely manner and with appropriate quality, or successfully market products or maintain desired margins for products sold, and as a result we may not achieve sustained profitable operations.

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, 2013 and for the three and six months ended June 30, 2013 and 2012 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, 2012 balance sheet amounts and disclosures included herein have been derived from the Company's December 31, 2012 audited consolidated financial statements. The interim results are not necessarily indicative of results to be expected for the full fiscal year. These unaudited consolidated financial statements should be read in conjunction with the unaudited consolidated financial statements for the period ended March 31, 2013 included in the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2013 and the audited consolidated financial statements for the year ended December 31, 2012 included in the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2013. 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.

Table of Contents

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 DFB Agreement, pursuant to which we sold our topical collagenase business to DFB, we have the right to receive earn-out payments in the future based on sales of certain products. Generally, under the DFB Agreement we would receive payments and a report within ninety (90) days from the end of each calendar year after DFB has sold the royalty-bearing product. Currently, DFB is providing us earn-out reports on a quarterly basis. We expect to receive the final earn-out payment under the DFB Agreement at the end of 2013.

Table of Contents

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, 2013 our net reimbursable third party patent costs accrual was approximately \$30,000.

Receivables and Deferred Revenue. Accounts receivable as of June 30, 2013 is approximately \$3.9 million, which consists of approximately \$2.5 million due from DFB in accordance with the earn-out under the DFB Agreement and approximately \$1.4 million in royalties and mark-up on costs of goods sold due from Auxilium in accordance with the terms of the Auxilium Agreement. Deferred revenue of \$0.5 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.

Royalty Buy-Down. 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 payable upon the occurrence of a milestone event.

As of June 30, 2013, we have capitalized \$2.75 million related to this agreement which will be amortized over approximately five years beginning on the date of the first commercial sale of XIAFLEX for the treatment of Peyronie's disease, which represents the period estimated to be benefited using the straight-line method. In accordance with Accounting Standards Codification 350, Intangibles, Goodwill and Other, the Company amortizes intangible assets with finite lives in a manner that reflects the pattern in which the economic benefits of the assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the assets are amortized using the straight-line method.

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

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, 2013 AND 2012

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, 2013 and 2012 product revenues were \$27,500 and \$1,246, respectively. This increase was primarily related to the amount of material required to perform testing and additional research by our customers.

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the Auxilium Agreement and earn-out revenues associated with the DFB Agreement. Total royalty, mark-up on cost of goods sold and earn-out revenues for the three month period ended June 30, 2013 were \$3.2 million as compared to \$2.5 million in the 2012 period, an increase of \$0.7 million or 28%. Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were \$1.7 million for the 2013 period compared to \$1.5 million in the 2012 period. The increase of \$0.2 million was due to increased net sales of XIAFLEX during 2013 reported to us by Auxilium.

17

Table of Contents

We receive earn-out revenues from DFB under the earn-out payment provision of the DFB Agreement after certain net sales levels are achieved. Revenues recognized under the DFB Agreement were \$1.5 million for the three months ended June 30, 2013 as compared to \$0.9 million in the 2012 period. The increase of \$0.6 million was due to increased net sales of Santyl during 2013 reported to us by DFB. DFB's Santyl assets were purchased by Smith & Nephew plc at the end of the fourth quarter of 2012.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. 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 three months ended June 30, 2013, we recognized total licensing revenue related to the development of XIAFLEX of approximately \$44,881 as compared to \$109,275 in the 2012 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 \$470,044 and \$404,346, respectively, for the three months ended June 30, 2013 and 2012, representing an increase in 2013 of \$65,698, or 16%. This increase in research and development expenses was primarily due to expenses related to our clinical development and research programs partially offset by lower stock based compensation expense.

We are currently working to develop XIAFLEX for the treatment of human and canine lipoma. We have initiated a placebo controlled randomized study to evaluate the efficacy of XIAFLEX for the treatment of subcutaneous benign lipomas in canines. The study will consist of 32 canines randomized at 1:1 XIAFLEX or placebo. The treatment is a single injection of XIAFLEX or placebo. The primary efficacy endpoint will be the relative change in lipoma volume from baseline to 3 months, as determined by CT scan. We have completed enrollment for this study, and top-line data is expected in the second half of 2013.

Also, we have initiated a 14-patient, single center dose escalation, phase II clinical trial of XIAFLEX for the treatment of human lipomas. The study is a single injection, open-label trial, and XIAFLEX is being administered in four ascending doses (0.058 mg to 0.44 mg). The primary efficacy endpoint will be a change in the visible surface area of the target lipoma, as determined at six months post-injection. We have completed enrollment for this study, and top-line data is expected in the second half of 2013.

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

	Three Months Ended June 30, 2013	Three Months Ended June 30, 2012
<u>Program</u>		
Canine Lipoma	\$180,646	\$127,510

Human Lipoma \$39,184 \$74,155

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

18

Table of Contents

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 \$1.2 million and \$1.1 million for the three months ended June 30, 2013 and 2012, respectively, an increase of approximately \$0.1 million, or 8%, from 2012. The increase in general and administrative expenses was due to increased professional fees, investor relations and consulting services.

Other Income and expense

Other income for the three months ended June 30, 2013 was \$6,510 compared to \$9,771 in the 2012 period. Other income in both periods consisted 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 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.

For the three month period ended June 30, 2012 our provision for income taxes was \$0.4 million, primarily a non-cash charge. Our income tax expense for the three month period ended June 30, 2012 is based on an estimated effective tax rate derived from an estimate of consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for fiscal year 2012. For the three month period ended June 30, 2012, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of June 30, 2012, our remaining deferred tax assets decreased by \$0.4 million to approximately \$2.6 million.

Table of Contents

Net Income

For the three months ended June 30, 2013 we recorded net income of \$1.0 million, or \$0.16 per basic common share and \$0.15 per diluted common share, compared to a net income of \$0.7 million, or \$0.11 per basic and \$0.10 per diluted common share, for the same period in 2012.

SIX MONTHS ENDED JUNE 30, 2013 AND 2012

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, 2013 and 2012 product revenues were \$29,743 and \$8,750, respectively. This increase was primarily related to the amount of material required to perform testing and additional research by our customers.

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the Auxilium Agreement and earn-out revenues associated with the DFB Agreement. Total royalty, mark-up on cost of goods sold and earn-out revenues for the six month period ended June 30, 2013 were \$6.6 million as compared to \$4.4 million in the 2012 period, an increase of \$2.2 million or 51%. Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were \$4.1 million for the 2013 period compared to \$3.1 million in the 2012 period. The increase of \$1.0 million was due to increased net sales of XIAFLEX during 2013 reported to us by Auxilium.

We receive earn-out revenues from DFB under the earn-out payment provision of the DFB Agreement after certain net sales levels are achieved. Revenues recognized under the DFB Agreement were \$2.5 million for the six months ended June 30, 2013 as compared to \$1.3 in the 2012 period. The increase of \$1.2 million was due to increased net sales of Santyl during 2013 reported to us by DFB. DFB's Santyl assets were purchased by Smith & Nephew plc at the end of the fourth quarter of 2012.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. 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, 2013, we recognized total licensing revenue of approximately \$0.6 million as compared to \$0.8 million in the 2012 period. 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. License fees recognized related to development were \$88,761 as compared to \$218,550 in the comparable period of 2012. Sublicensing fees recognized in 2013 were zero and \$570,000 in the comparable period of 2012. In the 2012 period, sublicensing fees recognized were related to the \$10.0 million paid to Auxilium by Actelion for the rights to develop and commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico.

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 \$764,918 and \$653,898, respectively, for the six months ended June 30, 2013 and 2012, representing an increase in 2013 of \$111,020, or 17%. This increase in research and development expenses was primarily due to expenses related to our clinical development and research programs partially offset by lower stock based compensation expense.

20

Table of Contents

We are currently working to develop XIAFLEX for the treatment of human and canine lipoma. We have initiated a placebo controlled randomized study to evaluate the efficacy of XIAFLEX for the treatment of subcutaneous benign lipomas in canines. The study will consist of 32 canines randomized at 1:1 XIAFLEX or placebo. The treatment is a single injection of XIAFLEX or placebo. The primary efficacy endpoint will be the relative change in lipoma volume from baseline to 3 months, as determined by CT scan. We have completed enrollment for this study, and top-line data is expected in the second half of 2013.

Also, we have initiated a 14-patient, single center dose escalation, phase II clinical trial of XIAFLEX for the treatment of human lipomas. The study is a single injection, open-label trial, and XIAFLEX is being administered in four ascending doses (0.058 mg to 0.44 mg). The primary efficacy endpoint will be a change in the visible surface area of the target lipoma, as determined at six months post-injection. We have completed enrollment for this study, and top-line data is expected in the second half of 2013.

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

Six Months Ended June 30, 2013	Six Months Ended June 30, 2012	Accumulated Expenses Since January 1, 2010
--	--	--

Program

Canine Lipoma	\$270,717	\$209,801	\$1,243,705
Human Lipoma	\$83,021	\$102,433	\$487,890

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

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

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

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

of the appropriate opt-in study.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, consultant costs, legal fees, investor relations, professional fees and overhead costs. General and administrative expenses were \$2.9 million and \$2.2 million for the six months ended June 30, 2013 and 2012, respectively, an increase of approximately \$0.7 million, or 28%, from 2012. The increase in general and administrative expenses was due to increased third party licensing and royalty fees, investor relations, legal fees, consulting services and professional fees.

21

Table of Contents

Other Income and expense

Other income for the six months ended June 30, 2013 was \$12,376 compared to \$19,264 in the 2012 period. Other income in both periods consisted 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, 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.

Our provision for income taxes was \$0.9 million for the six month period ended June 30, 2012. We paid \$0.1 million of cash and applied \$0.2 million of its tax refunds receivable to reduce its income taxes payable. We also used \$0.4 million, of tax assets (primarily Orphan Tax Credit) and availed itself of \$0.1 million tax deductible expense related to exercise of stock options to further reduce its tax liability. Our income tax expense for the six month period ended June 30, 2012 is based on an estimated effective tax rate derived from an estimate of consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for fiscal year 2012. For the six month period ended June 30, 2012, the valuation allowance with respect to our net deferred tax assets remained unchanged. As of June 30, 2012, our remaining deferred tax assets decreased by \$0.4 million to approximately \$2.6 million.

Net Income

For the six months ended June 30, 2013 we recorded net income of \$2.4 million, or \$0.37 per basic common share and \$0.34 per diluted common share, compared to a net income of \$1.4 million, or \$0.22 per basic and \$0.20 per diluted common share, for the same period in 2012.

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, 2013 and December 31, 2012, we had cash and cash equivalents and investments in the aggregate of approximately \$12.0 million and \$8.5 million, respectively.

Net cash provided by operating activities for the six months ended June 30, 2013 was \$3.9 million as compared to \$2.4 million for the same period in 2012. 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. Cash provided by operations in the 2012 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 sublicensing fees, royalties and mark-up on cost goods sold revenues under the Auxilium Agreement.

Net cash used in investing activities for the six months ended June 30, 2013 was \$2.8 million as compared to \$1.5 million for the 2012 period. 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. The net cash used in investing activities in the 2012 reflects the maturing and reinvestment of \$2.0 million in marketable securities and a one-time cash payment related to our future royalty obligations for Peyronie's disease of \$1.5 million.

22

Table of Contents

Net cash used in financing activities for the six months ended June 30, 2013 was \$0.4 million as compared \$0.3 million in the compared period of 2012. 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. In 2012, net cash used in financing activities was mainly due to the repurchase of our common stock under our stock repurchase program during the period partially offset by excess tax benefits related to share-based payments and proceeds received from stock option exercises.

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, 2013, amounting to approximately \$11.9 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, 2012.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company, under the supervision and with the participation of Thomas L. Wegman, the Company's President, Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of its disclosure controls and procedures as of the end of the period covered by this Report. Based on that evaluation, management has concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to the Company's management to allow timely decisions regarding required disclosure. Because of the inherent limitations in all control systems, any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Furthermore, our controls and procedures can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control, and misstatements due to error or fraud may occur and not be detected on a timely basis.

Changes in Internal Controls

There were no changes in our internal controls over financial reporting during the six month period ended June 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial

reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K filed with the SEC on March 15, 2013.

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

During the six month period ended June 30, 2013, we did not issue any unregistered shares of securities.

23

Table of Contents

Issuer Purchases of Equity Securities (1)

Period	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
				\$1,672,146
January 1, 2013 – January 31, 2013	6,271	\$ 15.15	135,636	\$1,577,114
February 1, 2013 – February 28, 2013	3,615	\$ 15.83	139,251	\$1,519,874
March 1, 2013 – March 31, 2013	3,206	\$ 16.74	142,457	\$1,466,196
April 1, 2013 – April 30, 2013	4,081	\$ 17.08	146,538	\$1,396,488
May 1, 2013 – May 31, 2013	4,320	\$ 15.94	150,858	\$1,327,616
June 1, 2013 – June 30, 2013	3,227	\$ 16.21	154,085	\$1,275,294

On June 4, 2010, we announced that our board of directors authorized a stock repurchase program under Rule 10b-18 of the Exchange Act of up to \$2.0 million of our outstanding common stock over a period of 12 months. On (1) June 20, 2011, we announced that our Board of Directors had reauthorized this stock repurchase program. On November 15, 2012, we announced that our Board of Directors had reauthorized this stock repurchase program.

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

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

3.2 Registrant's Amended and Restated By-laws (incorporated by reference to Exhibit 3.2 of the Registrant's Form 10-KSB filed with the Commission on March 2, 2007)

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.

* filed herewith

Table of Contents

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 9, 2013 /s/ Thomas L. Wegman
Thomas L. Wegman
President, Principal Executive Officer and
Principal Financial Officer