BIOSPECIFICS TECHNOLOGIES CORP
Form 10-Q
August 10, 2015

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, 2015

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____to _____

001-34236
(Commission file number)

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

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

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

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

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

Yes No

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

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

company" in Rule 12b-2 of the Exchange Act.

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

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

Yes No

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

| Class of Stock | Outstanding August 5, 2015 |
|---|---|
| Common Stock ($.001 par value) | 6,846,850 |

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" re to BioSpecifics Technologies Corp. and its subsidiary, Advance Biofactures Corp.

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, successful commercialization of XIAFLEX to treat Dupuytren's contracture and Peyronie's disease; Endo's ability to obtain required regulatory approvals; Endo's ability to manufacture XIAFLEX at an acceptable cost, in a timely manner and with appropriate quality; successful development of CCH for additional indications; the ability to successfully develop and commercialize our drug candidates; the funding of research and development at medical institutions; Endo's willingness to exclusively license the human lipoma indication upon completion of the appropriate opt-in study; future development of CCH for the treatment of uterine fibroids; the projected receipt of royalty, milestone and opt-in payments from Endo including when commercial launch will occur in Japan following regulatory approval and when the Company will receive the corresponding milestone payment; the provision for estimated uncollectible accounts and income taxes; cost accrual amounts; the adoption of new accounting pronouncements and their impact; the effect of changes in interest rates on the Company's results of operations, financial position and cash flow; changes in internal controls; the ability of internal controls and procedures to achieve desired control objectives; the certainty of tax positions; the sufficiency of the Company's available funds to meet our operational cash needs; the fair value of the Company's carrying amounts and stock option awards; whether the Company's bank account balances will exceed insured limits; the Company's maintenance of allowances for doubtful accounts; the measurement of costs charged to research and development; the increase in general and administrative expenses; the increase in royalties and costs of goods sold; the decrease in R&D expenses; the recognition of currently unrecognized compensation cost related to stock options; the valuation assumptions used to value employee stock-based awards; the credit risk on our cash; our revenue recognition policies; our milestone achievements and payments; the timing and length of our development period; the nature of our accounts receivable balance; increases in our third-party royalty expenses; and our accounting policies. In some cases, these statements can be identified by forward-looking words such as "believe," "expect," "anticipate," "assume," "potential," "plan," "estimate," "likely," "may," "will," "can," "could," "continue," "project," "predict," "goal," "should," the negative or p 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 Endo and its partners, Asahi Kasei Pharma Corporation, Actelion Pharmaceuticals Ltd. and Swedish Orphan Biovitrum AB, to achieve their objectives for XIAFLEX in their applicable territories; the market for XIAFLEX in, and timing, initiation and outcome of clinical trials for, additional indications including frozen shoulder, cellulite, human lipoma, canine lipoma and uterine fibroids, all of which will determine the amount of milestone, royalty, mark-up on cost of goods sold, license and sublicense income BioSpecifics may receive; the potential of CCH to be used in additional indications; Endo modifying its objectives or allocating resources other than to CCH; and other risk factors identified in BioSpecifics' Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, its Annual Report on Form 10-K for the year ended December 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: Condensed Consolidated Financial Statements

BioSpecifics Technologies Corp.
Condensed Consolidated Balance Sheets

| | June 30, 2015 (unaudited) | December 31, 2014 (audited) |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $8,547,199 | $9,810,816 |
| Short term investments | 19,245,847 | 10,900,436 |
| Accounts receivable, net | 3,001,975 | 2,938,731 |
| Investment interest receivable | 119,382 | 48,316 |
| Income tax receivable | 708,237 | 653,116 |
| Deferred tax asset | 16,907 | 16,907 |
| Deferred royalty buy-down | 640,587 | 569,641 |
| Prepaid expenses | 469,037 | 210,847 |
| Total current assets | 32,749,171 | 25,148,810 |
| | | |
| Long-term Investments | 1,437,000 | 1,250,000 |
| Deferred royalty buy-down – long term, net | 3,001,489 | 3,271,120 |
| Deferred tax assets –long term | 821,236 | 1,061,864 |
| Patent costs, net | 289,783 | 295,030 |
| | | |
| Total assets | $38,298,679 | $31,026,824 |
| | | |
| Liabilities and stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | 831,389 | 543,696 |
| Deferred revenue | 49,379 | 49,378 |
| Accrued liabilities of discontinued operations | 78,138 | 78,138 |
| Total current liabilities | 958,906 | 671,212 |
| | | |
| Long-term deferred revenue | 74,068 | 98,757 |
| | | |
| 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; 7,197,475 and 7,062,209 shares issued, 6,847,945 and 6,730,622 outstanding as of June 30, 2015 and December 31, 2014, respectively | 7,197 | 7,062 |
| Additional paid-in capital | 28,681,190 | 25,059,458 |
| Retained earnings | 13,709,082 | 9,620,978 |
| Treasury stock, 349,530 and 331,587 shares at cost as of June 30, 2015 and December 31, 2014, respectively | (5,131,764 ) | (4,430,643 ) |
| Total stockholders' equity | 37,265,705 | 30,256,855 |
| | | |
| Total liabilities and stockholders' equity | $38,298,679 | $31,026,824 |

See accompanying notes to condensed consolidated financial statements

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BioSpecifics Technologies Corp.
Condensed Consolidated Income Statements
(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Revenues: | | | | |
| Royalties | $4,702,631 | $2,624,774 | $10,296,740 | $5,365,092 |
| Licensing revenues | 12,344 | 17,282 | 24,689 | 34,565 |
| Total Revenues | 4,714,975 | 2,642,056 | 10,321,429 | 5,399,657 |
| | | | | |
| Costs and expenses: | | | | |
| Research and development | 256,736 | 286,332 | 496,201 | 669,036 |
| General and administrative | 1,795,265 | 1,490,514 | 3,598,387 | 2,736,819 |
| Total Cost and Expenses | 2,052,001 | 1,776,846 | 4,094,588 | 3,405,855 |
| | | | | |
| Operating income | 2,662,974 | 865,210 | 6,226,841 | 1,993,802 |
| | | | | |
| Other income: | | | | |
| Interest income | 18,482 | 7,352 | 32,202 | 14,323 |
| Other income | - | 10,449 | 4,633 | 15,277 |
| | 18,482 | 17,801 | 36,835 | 29,600 |
| | | | | |
| Income before income tax expense | 2,681,456 | 883,011 | 6,263,676 | 2,023,402 |
| Income tax expense | (924,252 ) | (305,045 ) | (2,175,572 ) | (691,447 ) |
| | | | | |
| Net income | $1,757,204 | $577,966 | $4,088,104 | $1,331,955 |
| | | | | |
| Basic net income per share | $0.26 | $0.09 | $0.61 | $0.21 |
| Diluted net income per share | $0.24 | $0.08 | $0.57 | $0.19 |
| | | | | |
| Shares used in computation of basic net income per share | 6,759,147 | 6,429,203 | 6,749,153 | 6,404,170 |
| Shares used in computation of diluted net income per share | 7,233,133 | 7,009,625 | 7,225,806 | 7,018,533 |

See accompanying notes to condensed consolidated financial statements

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

| | Six Months Ended June 30, | |
|---|---|---|
| Cash flows from operating activities: | 2015 | 2014 |
| Net income | $4,088,104 | $1,331,955 |
| Adjustments to reconcile net income to net cash provided By operating activities: | | |
| Amortization | 319,582 | 108,595 |
| Stock-based compensation expense | 38,830 | 10,708 |
| Deferred tax expense | 240,628 | 30,742 |
| Gain on the sale of fixed assets | - | (1,150) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (63,244) | 2,959,252 |
| Income tax receivable | (55,121) | (1,016,778) |
| Investment interest receivable | (71,066) | 2,549 |
| Prepaid expenses | (258,189) | 35,078 |
| Patent costs | (17,381) | (151,454) |
| Accounts payable and accrued expenses | 287,693 | 84,917 |
| Deferred revenue | (24,689) | (34,565) |
| Net cash provided by operating activities | 4,485,147 | 3,359,849 |
| | | |
| Cash flows from investing activities: | | |
| Maturity of marketable investments | 8,302,605 | 4,811,964 |
| Purchases of marketable investments | (16,933,286) | (5,638,002) |
| Proceeds from sale of fixed asset | - | 1,150 |
| Net cash used in investing activities | (8,630,681) | (824,888) |
| | | |
| Cash flows from financing activities: | | |
| Proceeds from stock option exercises | 1,672,973 | 169,000 |
| Payments for repurchase of common stock | (701,121) | (750,598) |
| Excess tax benefits from share-based payment arrangements | 1,910,065 | 1,262,483 |
| Net cash provided by financing activities | 2,881,917 | 680,885 |
| | | |
| (Decrease) increase in cash and cash equivalents | (1,263,617) | 3,215,846 |
| Cash and cash equivalents at beginning of year | 9,810,816 | 5,624,860 |
| Cash and cash equivalents at end of period | $8,547,199 | $8,840,706 |
| | | |
| Supplemental disclosures of cash flow information: | | |
| Cash paid during the year for: | | |
| Interest | - | - |
| Taxes | $80,000 | $415,000 |

See accompanying notes to condensed consolidated financial statements

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BIOSPECIFICS TECHNOLOGIES CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2015
(Unaudited)

## 1. ORGANIZATION AND DESCRIPTION OF BUSINESS

We are a biopharmaceutical company involved in the development of an injectable collagenase clostridium histolyticum, or CCH, for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. ("Auxilium") for injectable collagenase (named XIAFLEX®) for marketed indications and CCH for indications in development. On January 29, 2015, Auxilium was acquired by Endo International plc ("Endo") (the "Acquisition") and is now a wholly owned subsidiary of Endo. Endo is currently selling XIAFLEX in the U.S. for the treatment of Dupuytren's contracture and Peyronie's disease and has an agreement with Swedish Orphan Biovitrum AB ("Sobi"), pursuant to which Sobi has marketing rights for XIAPEX® (the EU trade name for XIAFLEX) 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 and Peyronie's disease. In addition, Endo 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. Asahi has received regulatory approval for the sale of XIAFLEX for the treatment of Dupuytren's contracture in Japan. Endo 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. Endo has an option to acquire the rights to additional indications that we may pursue, including human lipoma, and acquired this option in connection with the Acquisition. Prior to the Acquisition, Auxilium had this option and exercised its option to acquire the rights to frozen shoulder, cellulite and canine lipoma indications.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited, but include all adjustments (consisting only of normal, recurring adjustments) which we consider necessary for a fair presentation of our financial position at such dates and the operating results and cash flows for those periods. Although we believe that the disclosures in our financial statements are adequate to make the information presented not misleading, certain information normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") has been condensed or omitted pursuant to the rules and regulations of the 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 period ended March 31, 2015 and our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC.

### Reclassification

Certain reclassifications have been made to prior year balances to conform to the current year's presentation.

### Principles of Consolidation

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

Critical Accounting Policies, Estimates and Assumptions

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

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Cash, Cash Equivalents and Investments

Cash equivalents include only securities having a maturity of three months or less at the time of purchase. Investments are stated on an amortized cost basis. The Company limits its credit risk associated with cash, cash equivalents and investments by placing its investments with banks it believes are highly creditworthy and with highly rated money market funds, certificates of deposit and pre-refunded municipal bonds. All investments are classified as held to maturity. As of June 30, 2015 and December 31, 2014, the aggregate fair value of these investments was $20.7 million and $12.2 million, respectively. No unrealized gains or losses were recorded in the balance sheet in either period.

Fair Value Measurements

Management believes that the carrying amounts of the Company's financial instruments, including cash, cash equivalents, held to maturity investments, accounts receivable, accounts payable and accrued expenses, approximate fair value due to the nature of those instruments. As of June 30, 2015 and 2014, there were no recorded unrealized gains or losses on our held to maturity investments as they are held to maturity.

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 investments in FDIC insured certificates of deposits with several banks and pre-refunded municipal bonds.

At June 30, 2015 and December 31, 2014, our accounts receivable balances were $3.0 million and $2.9 million, respectively. Our accounts receivables until January 29, 2015 were from one customer, Auxilium, and due to the Acquisition, our accounts receivables from January 29, 2015 on have been from one customer, Endo.

The Company is dependent on one customer who generates almost all its revenues. This one customer was Auxilium until the Acquisition on January 29, 2015. From January 29, 2015 on, this one customer has been Endo. Licensing, sublicensing, milestones and royalty revenues were $4.7 million and $10.3 million for the three and six months ended June 30, 2015 and $2.6 million and $5.4 million for the three and six months ended June 30, 2014.

Revenue Recognition

We currently recognize revenues resulting from 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:

Royalty / Mark-Up on Cost of Goods Sold

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

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Under our Second Amended and Restated Development and Licensing Agreement with Auxilium (the "Auxilium Agreement"), which Endo assumed in the Acquisition, 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 Endo 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 Endo occurred. The royalties payable by Endo to us are subject to set-off for certain patent costs.

Licensing Revenue

We include revenue recognized from upfront licensing, sublicensing and milestone payments in "License Revenues" in our condensed consolidated statements of income 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 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. We recognized deferred revenue of $12,344 and $24,689 for the three and six months ended June 30, 2015 and $17,282 and $34,565 for the three and six months ended June 30, 2014. At June 30, 2015 and December 31, 2014, our remaining deferred revenue balances were $123,446 and $148,135, respectively.

Milestones

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

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

Treasury Stock

The Company accounts for treasury stock under the cost method and includes treasury stock as a component of stockholders' equity. For the six months ended June 30, 2015, we repurchased 17,943 shares at an average price of $39.07 as compared to 28,716 shares at an average price of $26.14 in the 2014 period.

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Receivables and Doubtful Accounts

Trade accounts receivable are stated at the amount the Company expects to collect. We may maintain allowances for doubtful accounts for estimated losses resulting from the inability of our 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. Prior to January 29, 2015, our accounts receivable balance was typically due from Auxilium and from January 29, 2015 on, due to the Acquisition, our accounts receivable balance has been due from Endo, our one large pharmaceutical customer. Auxilium and Endo 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 customer were to deteriorate, adversely affecting its ability to make payments, additional allowances would be required. We may 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 credit to accounts receivable.

Reimbursable Third Party Development Costs

We accrued patent expenses for research and development ("R&D") 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, 2015 and December 31, 2014 our net reimbursable third party patent expense accrual was approximately $15,000 and $34,000, respectively.

Third Party Royalties

We have entered into licensing and royalty agreements with the Research Foundation of the State University of New York at Stony Brook and Dr. Martin K. Gelbard and have agreed to pay certain royalties on net sales of products for specific indications. The royalty rates differ from agreement to agreement and, in certain cases, have been redacted with the permission of the SEC. No assumptions should be made that the disclosed royalty rates payable to a particular third party are the same or similar with respect to the royalty rates payable to other third parties. We accrued third party royalty expenses on net sales reported to us by Auxilium through January 29, 2015 and we have accrued third party royalty expenses on net sales reported to us by Endo since January 29, 2015. Third party royalty costs are generally expensed in the quarter that Auxilium provided or Endo provides the written reports and related information to us; that is, generally one quarter following the quarter in which the underlying sales by Auxilium, or Endo due to the Acquisition, occurred. Third party royalty expenses were $0.3 million and $0.7 million for the three and six months ended June 30, 2015 and $0.1 million and $0.3 million for the three and six months ended June 30, 2014. We expect our third party royalty expenses under general and administrative expenses will continue to increase if net sales by Endo for XIAFLEX increase and potential new indications for CCH are approved.

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 of $600,000, two of which have been paid as of June 30, 2015. We are currently making the payments to buy down the future royalty obligations, which royalty obligations terminate five years after first commercial sale. 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. Related to this agreement, we amortized approximately $72,000 and $199,000 for the three and six months ended June 30, 2015 and $41,000 for the

three and six months ended June 30, 2014. As of June 30, 2015, the remaining capitalized balance was $3.6 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, 2015, no impairment existed.

R&D Expenses

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.

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

Under ASC 718, we estimate the fair value of our employee stock option awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of an award. When establishing an estimate of the expected term of an option award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures) and the expected volatility of our common stock. As required under the accounting rules, we review our estimates at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. On April 22, 2015, we granted a total of 30,000 stock options to new members of our Board of Directors, valued at approximately $450,000. We used the Black-Scholes valuation model to estimate the value of options using 38.6% volatility, a risk free rate of 1.41% and an expected term of 6.25 years. No options were granted in 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.

Stock-based compensation expense recognized in general and administrative expenses was approximately $33,000 and $39,000 for the three and six months ended June 30, 2015, respectively, and approximately $5,000 and $11,000 for the three and six months ended June 30, 2014, respectively.

Stock Option Activity

A summary of our stock option activity during the six months ended June 30, 2015 is presented below:

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at January 1, 2015 | 759,958 | $ 11.04 | 3.12 | $23,483,235 |
| Grants | 30,000 | 37.64 | 9.82 | - |
| Exercised | (135,266) | 12.37 | - | - |
| Forfeitures or expirations | - | - | - | - |
| Outstanding at June 30, 2015 | 654,692 | 11.98 | 2.47 | 25,938,175 |
| | | | | |
| Exercisable at June 30, 2015 | 593,442 | $ 9.99 | 2.91 | $24,692,561 |

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During the six months ended June 30, 2015 and 2014, the Company received $1.7 million and $0.2 million, respectively, from stock options exercised by option holders.

Aggregate intrinsic value represents the total pre-tax intrinsic value based on the closing price of our common stock of $51.60 on June 30, 2015, which would have been received by the option holders had all option holders exercised their options as of that date. We have approximately $469,000 in unrecognized compensation cost related to stock options outstanding as of June 30, 2015, which we expect to recognize over 3.65 years.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Machinery and equipment, furniture and fixtures, and autos are depreciated on the straight-line basis over their estimated useful lives of five to ten years. Leasehold improvements are amortized over the lesser of their estimated useful lives or the remaining life of the lease. As of June 30, 2015 and December 31, 2014, property and equipment were fully depreciated.

Comprehensive Income

For the three and six months ended June 30, 2015 and 2014, we had no components of other comprehensive income other than net income itself.

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. 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. We classify interest associated with income taxes under interest expense and tax penalties under other.

The Company recognizes a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements from such position is measured based on the largest benefit that has a greater than 50% likelihood of being realized upon the ultimate settlement. As of June 30, 2015 and 2014, the Company has not recorded any unrecognized tax benefits.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued a new standard related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The new standard will replace most of the existing revenue recognition standards in U.S. GAAP and is effective for the annual reporting periods beginning after December 31, 2016, including interim periods within that reporting period. Early adoption is not permitted. On July 9, 2015, the FASB agreed to delay the effective date by one year. In accordance with the agreed upon delay, the new standard is effective beginning the first quarter of 2018. Early adoption is permitted, but not before the original effective date of the standard. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application in retained earnings. The Company is assessing the potential impact of the new standard on financial reporting and has not yet

selected a transition method.

3. NET INCOME PER SHARE

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Stock options | 20,000 | 105,000 | 20,000 | 105,000 |

At June 30, 2015, the Company had 20,000 options outstanding which vest upon the achievement of certain performance criteria, which has not yet been met. These options expire on December 2, 2019 and have an exercise price of $29.21.

4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

| | June 30, 2015 | December 31, 2014 |
|---|---|---|
| Trade accounts payable and accrued expenses | $579,402 | $ 309,188 |
| Accrued legal and other professional fees | 65,407 | 65,205 |
| Accrued payroll and related costs | 186,580 | 169,303 |
| Total | $831,389 | $ 543,696 |

5. PATENT COSTS

We amortize intangible assets with definite lives on a straight-line basis over their remaining estimated useful lives, ranging from one to twelve 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, 2015, there was no indicator that an impairment existed.

We capitalized legal patent costs related to patent prosecution and maintenance. For the six months ended June 30, 2015, we increased our capitalized patent costs by approximately $17,000 as reported to us by Auxilium through January 29, 2015 or Endo from January 29, 2015 on. These patent costs are creditable against future royalty revenues. For each period presented below, net patent costs consisted of:

| | June 30, 2015 | December 31, 2014 |
|---|---|---|
| Patents | $688,707 | $ 671,326 |
| Accumulated Amortization | (398,924) | (376,296) |
| | $289,783 | $ 295,030 |

The amortization expense for patents for the three and six months ended June 30, 2015 was approximately $12,000 and $23,000 and $23,000, respectively and $68,000 for the three and six months ended June 30, 2014, respectively. The estimated aggregate amortization expense for the remaining six months of 2015 and each of the years below is approximately as follows:

| | |
|---|---|
| 2015 | $22,000 |
| 2016 | 37,000 |

| | |
|---|---|
| 2017 | 37,000 |
| 2018 | 37,000 |
| 2019 | 37,000 |
| Thereafter, | 119,000 |

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6. PROVISION FOR INCOME TAXES

In determining our provision for income taxes, we consider all available information, including operating results, ongoing tax planning, and forecasts of future taxable income. The significant components of the Company's deferred tax assets consist of stock-based compensation and deferred revenues. For the three and six month period ended June 30, 2015, the provision for income taxes was $0.9 million and $2.2 million, respectively. As of June 30, 2015 and December 31, 2014, our remaining deferred tax assets were approximately $0.8 million and $1.1 million, respectively.

For the three and six month period ended June 30, 2014, the provision for income taxes was $0.3 million and $0.7 million, respectively. As of June 30, 2014, our remaining deferred tax assets were approximately $1.5 million.

As of June 30, 2015, the Company believes that there are no significant uncertain tax positions and no amounts have been recorded for interest and penalties.

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

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

Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase clostridium histolyticum, or CCH, for multiple indications. We have a development and license agreement with Auxilium for injectable collagenase (named XIAFLEX®) for marketed indications and CCH for indications in development. On January 29, 2015, Auxilium was acquired by Endo and is now a wholly owned subsidiary of Endo. Endo is currently selling XIAFLEX in the U.S. for the treatment of Dupuytren's contracture and Peyronie's disease and has an agreement with Sobi, pursuant to which Sobi has marketing rights for XIAPEX® (the EU trade name for XIAFLEX) 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 and Peyronie's disease. In addition, Endo has an agreement with Asahi, pursuant to which Asahi has the right to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan. Asahi has received regulatory approval for the sale of XIAFLEX for the treatment of Dupuytren's contracture in Japan. Endo also has an agreement with 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. Endo has an option to acquire the rights to additional indications that we may pursue, including human lipoma, and acquired this option in connection with the Acquisition. Prior to the Acquisition, Auxilium had this option and exercised its option to acquire the rights to frozen shoulder, cellulite and canine lipoma indications.

Operational Highlights

On April 22, 2015, we announced the appointment of two new members to our Board of Directors, Ms. Jennifer Chao and Jyrki Mattila, M.D., Ph.D.

At the American Urological Association (AUA) 2015 Annual Meeting in New Orleans, LA, the AUA presented the first ever treatment guidelines for Peyronie's disease, a condition in which the presence of inelastic collagen on the shaft of the penis causes the penis to curve during erection, and may make sexual intercourse difficult or impossible in advanced cases. The guidelines recommended the use of XIAFLEX for the treatment of Peyronie's disease. Investigator's sponsored by Endo also presented data at the AUA 2015 Annual Meeting in New Orleans, LA, evaluating the efficacy of XIAFLEX treatment for Peyronie's disease as well as the impact of Peyronie's disease on erectile dysfunction (ED) and female partners.

On July 20, 2015, we announced that Asahi Kasei has received approval for its regulatory application to the Japanese Pharmaceutical and Medical Device Agency (PMDA) for XIAFLEX® (collagenase clostridium histolyticum) for the treatment of patients with Dupuytren's contracture in Japan. Asahi has the rights to develop and market XIAFLEX in Japan through an agreement with BioSpecifics' partner, Endo. BioSpecifics will receive a milestone payment upon commercial launch in Japan.

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Outlook

We generated revenue from primarily one source, 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, Endo, 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 2 within this report and under item 1A of Part 1 of our Annual Report on Form 10-K for the year ended December 31, 2014.

Critical Accounting Policies, Estimates and Assumptions

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are based on historical experience and on various other assumptions that we believe are reasonable under the circumstances. The financial information at June 30, 2015 and for the three and six months ended June 30, 2015 and 2014 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, 2014 balance sheet amounts and disclosures included herein have been derived from the Company's December 31, 2014 audited consolidated financial statements. The interim results are not necessarily indicative of results to be expected for the full fiscal year. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K and with the unaudited condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the first quarter of 2015 filed with the SEC. While our significant accounting policies are described in more detail in the notes to our unaudited condensed consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements. Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

Revenue Recognition

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.

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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.

We recognize revenues from product sales in other income when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and payment is reasonably assured.

Royalty / Mark-up on Cost of Goods Sold

For those arrangements for which royalty and mark-up on cost of goods sold 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 and mark-up on cost of goods sold cannot be made, the royalty and mark-up on cost of goods sold 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 Endo 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 Endo occurred. The royalties payable by Endo to us are subject to set-off for certain patent costs.

Reimbursable Third Party Development Costs

We accrue patent expenses for R&D 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, 2015 and December 31, 2014, our estimated net reimbursable third party patent costs accrual was approximately $15,000 and $34,000, respectively.

Receivables and Deferred Revenue

Accounts receivable as of June 30, 2015 was approximately $3.0 million, which consists of royalties and mark-up on costs of goods sold due from Endo in accordance with the terms of the Auxilium Agreement. Deferred revenue of approximately $123,000 consists of licensing fees related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period of certain indications for XIAFLEX.

Third Party Royalties

We have entered into licensing and royalty agreements with the Research Foundation of the State University of New York at Stony Brook and Dr. Martin K. Gelbard and have agreed to pay certain royalties on net sales of products for specific indications. The royalty rates differ from agreement to agreement and in certain cases have been redacted with the permission of the SEC. No assumptions should be made that the disclosed royalty rates payable to a particular third party are the same or similar with respect to the royalty rates payable to other third parties. We accrued third party royalty expenses on net sales reported to us by Auxilium until January 29, 2015 and have accrued third party royalty expenses on net sales reported to us by Endo from January 29, 2015 on. Third party royalty costs are generally expensed in the quarter that Auxilium or Endo provided the written reports and related information to us,

that is, generally one quarter following the quarter in which the underlying sales by Auxilium or Endo, due to the Acquisition, occurred. Third party royalty expenses were $0.3 million and $0.7 million for the three and six months ended June 30, 2015 and $0.1 million and $0.3 million for the three and six months ended June 30, 2014. We expect our third party royalty expenses under general and administrative expenses will continue to increase if net sales by Endo for XIAFLEX increase and potential new indications for CCH are approved.

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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 of $600,000, two of which have been paid as of June 30, 2015. We are currently making the payments to buy down the future royalty obligations, which royalty obligations terminate five years after first commercial sale. 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. Related to this agreement, we amortized approximately $72,000 and $199,000 for the three and six months ended June 30, 2015 and $41,000 for the three and six months ended June 30, 2014. As of June 30, 2015, the remaining capitalized balance was $3.6 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, 2015, no impairment existed.

Stock Based Compensation

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

Further, ASC 718 requires that employee stock-based compensation costs be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. The allocation of employee stock-based compensation costs to each operating expense line are estimated based on specific employee headcount information at each grant date and estimated stock option forfeiture rates and are 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, 2015 COMPARED TO THREE MONTHS ENDED JUNE 30, 2014

Revenues

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the Auxilium Agreement. Total royalty and mark-up on cost of goods sold for the three month period ended June 30, 2015 were $4.7 million as compared to $2.6 million in the 2014 period, an increase of $2.1 million or 81%. This increase in royalties and the mark-up on cost of goods sold revenue was primarily due to the increase in sales of XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease, which, in the case of Peyronie's disease, Auxilium began selling in the first quarter of 2014 in the United States.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. We recognized certain licensing fees related to the cash payments received under the Auxilium Agreement in prior years and amortized them over the expected development period. For the three months ended June 30, 2015, we recognized licensing revenue related to the development of injectable collagenase clostridium histolyticum, or CCH, of $12,344, as compared to $17,282 in the 2014 period.

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Research and Development Activities and Expenses

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. R&D expenses were $0.3 million for each of the three months ended June 30, 2015 and 2014.

We are currently working to develop CCH for the treatment of human lipoma and have completed a pre-clinical study in uterine fibroids. Our development work related to CCH for the treatment of canine lipoma has been completed and Auxilium exercised its exclusive option to expand the field of its license for CCH to include the potential treatment of canine lipomas.

The following table summarizes our R&D expenses related to our clinical development programs:

| | Three Months Ended June 30, 2015 | Three Months Ended June 30, 2014 |
|---|---|---|
| Program | | |
| Canine Lipoma | $- | $90,675 |
| Human Lipoma | 68,331 | 36,036 |
| Uterine Fibroids | 6,943 | 17,232 |
| Other | 181,462 | 142,389 |

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

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our pre-clinical studies and other R&D 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 R&D projects and Endo will have the option to exclusively license the human lipoma indication upon completion of the current opt-in study.

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General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, third party royalty fees, amortization of deferred royalty buy-down, consultant costs, legal fees, investor relations, professional fees and overhead costs. General and administrative expenses were $1.8 million and $1.5 million for the three months ended June 30, 2015 and 2014, respectively, an increase of approximately $0.3 million, or 20%, from 2014. The increase in general and administrative expenses was mainly due to increased third party royalty fees, consulting fees, the amortization of the deferred royalty buy-down and stock-based compensation expense partially offset by lower legal fees.

Other Income

Other income for the three months ended June 30, 2015 was $18,482 compared to $17,801 in the 2014 period. Other income consists of product sales of collagenase for laboratory use and interest earned on our investments.

Provision for Income Taxes

Our deferred tax liabilities and deferred tax assets are impacted by events and transactions arising in the ordinary course of business, R&D activities, vesting of nonqualified options, deferred revenues and other items. The provision for income taxes is based on an estimated effective tax rate derived from an estimate of condensed consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for the fiscal year

For the three month period ended June 30, 2015, our provision for income taxes was $0.9 million. Our taxes payable as June 30, 2015 were reduced by $1.9 million due to the windfall associated with the disqualified sale of incentive stock options and the exercise of nonqualified options.

For the three month period ended June 30, 2014, the provision for income taxes was $0.3 million.

Net Income

For the three months ended June 30, 2015, we recorded net income of $1.8 million, or $0.26 per basic common share and $0.24 per diluted common share, compared to a net income of $0.6 million, or $0.09 per basic and $0.08 per diluted common share, for the same period in 2014.

SIX MONTHS ENDED JUNE 30, 2015 COMPARED TO SIX MONTHS ENDED JUNE 30, 2014

Revenues

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the Auxilium Agreement. Total royalty and mark-up on cost of goods sold for the six month period ended June 30, 2015 were $10.3 million as compared to $5.4 million in the 2014 period, an increase of $4.9 million or 91%. This increase in royalties and the mark-up on cost of goods sold revenue was primarily due to the increase in sales of XIAFLEX for the treatment of Dupuytren’s contracture and Peyronie’s disease, which, in the case of Peyronie’s disease, Auxilium began selling in the first quarter of 2014 in the United States.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. We recognized certain licensing fees related to the cash payments received under the Auxilium Agreement in prior years and amortized them over the expected development period. For the six months ended June 30, 2015, we recognized licensing revenue related to the development of injectable collagenase clostridium histolyticum, or CCH of $24,689, as compared to $34,565 in the 2014 period.

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Research and Development Activities and Expenses

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. R&D expenses were $0.5 million and $0.7 million, respectively, for the six months ended June 30, 2015 and 2014, representing a decrease in 2015 of $0.2 million, or 29%. This decrease in R&D expenses was primarily due to the completion of the canine lipoma trials, the completion of the human lipoma phase I clinical trial and a decrease in pre-clinical costs associated with the uterine fibroid program, which was partially offset by the initiation of the phase II clinical trial of CCH for the treatment of human lipoma.

We are currently working to develop CCH for the treatment of human lipoma and have completed a pre-clinical study in uterine fibroids. Our development work related to CCH for the treatment of canine lipoma has been completed and Auxilium exercised its exclusive option to expand the field of its license for CCH to include the potential treatment of canine lipomas.

The following table summarizes our R&D expenses related to our clinical development programs:

| | Six Months Ended June 30, 2015 | Six Months Ended June 30, 2014 |
|---|---|---|
| Program | | |
| Canine Lipoma | $- | $207,540 |
| Human Lipoma | 125,098 | 112,350 |
| Uterine Fibroids | 6,943 | 68,191 |
| Other | 364,160 | 280,955 |

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

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our pre-clinical studies and other R&D 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 R&D projects and Endo will have the option to exclusively license the human lipoma indication upon completion of the current opt-in study.

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General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, third party royalty fees, amortization of deferred royalty buy-down, consultant costs, legal fees, investor relations, professional fees and overhead costs. General and administrative expenses were $3.6 million and $2.7 million for the six months ended June 30, 2015 and 2014, respectively, an increase of approximately $0.9 million, or 33%, from 2014. The increase in general and administrative expenses was mainly due to increased third party royalty fees, consulting fees, the amortization of the deferred royalty buy-down and stock-based compensation expense partially offset by lower legal fees and the amortization of certain patents costs.

Other Income

Other income for the six months ended June 30, 2015 was $36,835 compared to $29,600 in the 2014 period. Other income consists of product sales of collagenase for laboratory use and interest earned on our investments.

Provision for Income Taxes

Our deferred tax liabilities and deferred tax assets are impacted by events and transactions arising in the ordinary course of business, R&D activities, vesting of nonqualified options, deferred revenues and other items. The provision for income taxes is based on an estimated effective tax rate derived from an estimate of condensed consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for the fiscal year

For the six month period ended June 30, 2015, our provision for income taxes was $2.2 million. Our taxes payable as of June 30, 2015 were reduced by $1.9 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, 2014 our provision for income taxes was $0.7 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.

Net Income

For the six months ended June 30, 2015, we recorded net income of $4.1 million, or $0.61 per basic common share and $0.57 per diluted common share, compared to a net income of $1.3 million, or $0.21 per basic and $0.19 per diluted common share, for the same period in 2014.

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, 2015 and December 31, 2014, we had cash and cash equivalents and investments in the aggregate of approximately $29.2 million and $22.0 million, respectively. We currently anticipate that our available funds and cash flow from operations will be sufficient to meet our operational cash needs for at least the next twelve months.

Net cash provided by operating activities for the six months ended June 30, 2015 and 2014 was $4.5 million and $3.4 million, respectively. Net cash provided by operating activities in the 2015 period was primarily attributable our net income of $4.1 million, adjustments to reconcile net income to net cash provided by operating activities of $0.6 million and changes in operating assets and liabilities of $0.2 million. Non-cash items included amortization, stock-based compensation expense, deferred taxes and deferred revenue. Net cash provided by operating activities in the 2014 period was primarily attributable our net income of $1.3 million, adjustments to reconcile net income to net

cash provided by operating activities of $0.1 million and changes in operating assets and liabilities of $1.9 million. Non-cash items included amortization, stock-based compensation expense, deferred taxes and deferred revenue.

Net cash used in investing activities for the six months ended June 30, 2015 was $8.6 million as compared to $0.8 million for the comparable 2014 period. The net cash used in investing activities in the 2015 reflects the maturing of $8.3 million and investment of $16.9 million in marketable securities. The net cash used in investing activities in the 2014 reflects the maturing of $4.8 million and investment of $5.6 million in marketable securities.

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Net cash provided by financing activities for the six months ended June 30, 2015 was $2.9 million as compared to $0.7 million in the comparable period of 2014. In the 2015 period, net cash provided by financing activities was mainly due to the excess tax benefits related to share-based payments of $1.9 million and the proceeds received from stock option exercises of approximately $1.7 million partially offset by the repurchase of our common stock under our stock repurchase program of $0.7 million. 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 approximately $0.2 million partially offset by the repurchase of our common stock under our stock repurchase program of $0.8 million.

Off-Balance Sheet Arrangements

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

Item 3: Quantitative and Qualitative Disclosures About Market Risk.

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

Our investment portfolio is subject to interest rate risk, although limited given the nature of the investments, and will fall in value in the event market interest rates increase. All our cash and cash equivalents and investments at June 30, 2015, amounting to approximately $29.2 million, were maintained in bank demand accounts, money market accounts, certificates of deposit and pre-refunded municipal bonds. We do not hedge our interest rate risks, as we believe reasonably possible near-term changes in interest rates would not materially affect our results of operations, financial position or cash flows.

We are subject to market risks in the normal course of our business, including changes in interest rates. There have been no significant changes in our exposure to market risks since December 31, 2014.

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, 2015 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.

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Item 1A Risk Factors

In addition to the other information contained elsewhere in this Report and our Quarterly Report on Form 10-Q for the first quarter of 2015, you should carefully consider the risk factors discussed in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the SEC on March 16, 2015, which could materially affect our business, financial condition or future results.

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

During the three month period ended June 30, 2015, we did not issue any unregistered shares of securities.

Issuer Purchases of Equity Securities

The following table presents a summary of share repurchases made by us during the quarter ended June 30, 2015.

| 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) |
|---|---|---|---|---|
| | | | | $ 1,056,124 |
| April 1, 2015 – April 30, 2015 | 10,330 | $ 38.53 | 213,560 | 658,062 |
| May 1, 2015 – May 31, 2015 | 4,100 | 38.79 | 217,660 | 499,015 |
| June 1, 2015 – June 30, 2015 | 603 | 49.33 | 218,263 | $ 469,266 |

(1) 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.
(2) The purchases were made under the company's 10b-18 plan.
(3) Includes commissions paid, if any, related to the stock repurchase transactions.

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Item 6. Exhibits

| | |
|---|---|
| 31* | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule13a-14(a)/15d-14(a). |
| 32** | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of-Sarbanes-Oxley Act of 2002. |
| 101* | The following materials from BioSpecifics Technologies Corp.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, are formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheet, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the Condensed Consolidated Financial Statements. |

* 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 10, 2015 /s/ Thomas L. Wegman
Thomas L. Wegman
President, Principal Executive Officer and
Principal Financial Officer