

BIOSPECIFICS TECHNOLOGIES CORP
Form 10-Q
May 10, 2016

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 March 31, 2016

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

(State or Other Jurisdiction of Incorporation or Organization)

11-3054851

(I.R.S. Employer Identification No.)

35 Wilbur Street Lynbrook, NY 11563

(Address of Principal Executive Offices) (Zip Code)

516.593.7000

(Registrant's Telephone Number, Including Area Code)

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

Yes No

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

Yes No

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

Large accelerated filer

Accelerated filer

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

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

Yes No

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

<u>Class of Stock</u>	<u>Outstanding May 06, 2016</u>
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Common Stock (\$.001 par value)	7,019,604
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BIOSPECIFICS TECHNOLOGIES CORP.

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Introductory Comments – Terminology

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

Throughout this Quarterly Report on Form 10-Q, Endo Global Ventures, a Bermuda unlimited liability company, an affiliate of Endo International plc, and Endo International plc are referred to collectively as “Endo”.

Introductory Comments – Forward-Looking Statements

This Report includes “forward-looking statements” within the meaning of, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, expected revenue growth, and the assumptions underlying or relating to such statements, are “forward-looking statements.” The forward-looking statements in this Report include statements concerning, among other things, the 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, market and commercialize our drug candidates; the funding of research and development at medical institutions under agreements that are generally cancellable; Endo’s willingness to exclusively license the human lipoma indication upon completion of the appropriate opt-in study; Endo’s willingness to exercise its regular or early opt-in for additional indications; the future receipt of payments from Endo, including milestone and royalty payments, in connection with the License Agreement; the recognition of the \$8.25 million payment from Endo in connection with the First Amendment; Endo’s interest in new, unlicensed indications, including uterine fibroids, human lipoma, capsular contracture of the breast, Dercum’s disease, knee arthrofibrosis, urethral strictures, hypertrophic scars and keloids; the plans for the repurchase of stock and reacquired stock; the suspension or discontinuation of the stock repurchase plan; the risk of doubtful accounts and how we provide for estimates of uncollectable accounts; the adoption of new accounting pronouncements and their impact; which accounting policies we consider to be critical to the estimates and judgments used to prepare the unaudited condensed consolidated financial statements; 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 existence of significant uncertain tax positions and provision for income taxes; the sufficiency of the Company’s available funds and cash flow from operations to meet our operational cash needs; whether the carrying amounts of the Company’s financial instruments approximate fair value due to the nature of the instruments; the changes in the Company’s exposure to market risk; the fair value of the Company’s stock option awards; whether the Company’s bank account balances will exceed insured limits; whether the Company is exposed to any significant credit risk on our cash; our milestone achievements and payments; whether we will continue to make payments to buy down our future royalty obligations; whether we will experience uneven payment flows due to the variance in financial terms in contracts with third parties to perform clinical trial activities and ongoing development of potential drugs; estimates concerning our development period; our interpretation of the definition of milestone; whether the Company will choose to cancel the lease prior to the expiration of the term; and the nature of our accounts receivable balance. In some cases, these statements can be identified by forward-looking words such as “believe,” “expect,” “anticipate,” “estimate,” “likely,” “may,” “will,” “can,” and “could,” the negative or plural 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, uterine fibroids, plantar fibromatosis and lateral hip fat 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 XIAFLEX; and other risk factors identified in BioSpecifics' Annual Report on Form 10-K for the year ended December 31, 2015 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

	March 31, 2016 (unaudited)	December 31, 2015 (audited)
Assets		
Current assets:		
Cash and cash equivalents	\$9,514,493	\$5,137,875
Short term investments	32,277,242	28,347,542
Accounts receivable	3,787,155	2,547,920
Income tax receivable	928,843	916,843
Deferred royalty buy-down	1,184,225	1,017,981
Prepaid expenses and other current assets	467,130	383,810
Total current assets	48,159,088	38,351,971
Long-term investments	2,471,300	3,596,541
Deferred royalty buy-down – long term, net	2,411,141	2,851,423
Deferred tax assets	3,442,257	622,972
Patent costs, net	270,976	275,206
Total assets	\$56,754,762	\$45,698,113
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	637,749	611,009
Deferred revenue	1,464,638	149,378
Accrued liabilities of discontinued operations	78,138	78,138
Total current liabilities	2,180,525	838,525
Long-term deferred revenue	6,971,774	49,379
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; 7,405,167 and 7,290,167 shares issued, 7,022,964 and 6,918,579 outstanding as of March 31, 2016 and December 31, 2015, respectively	7,405	7,290
Additional paid-in capital	32,159,409	31,797,418
Retained earnings	22,067,734	19,238,610
Treasury stock, 382,203 and 371,588 shares at cost as of March 31, 2016 and December 31, 2015, respectively	(6,632,085)	(6,233,109)
Total stockholders' equity	47,602,463	44,810,209
Total liabilities and stockholders' equity	\$56,754,762	\$45,698,113

See accompanying notes to condensed consolidated financial statements.

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BioSpecifics Technologies Corp.
Condensed Consolidated Income Statements
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
Royalties	\$6,555,647	\$5,594,109
Licensing revenues	12,344	12,345
Total Revenues	6,567,991	5,606,454
Costs and expenses:		
Research and development	248,500	239,465
General and administrative	2,164,333	1,803,122
Total Cost and Expenses	2,412,833	2,042,587
Operating income	4,155,158	3,563,867
Other income:		
Interest income	52,703	13,720
Other income	21,358	4,633
	74,061	18,353
Income before income tax expense	4,229,219	3,582,220
Provision for income tax expense	(1,400,095)	(1,251,320)
Net income	\$2,829,124	\$2,330,900
Basic net income per share	\$0.40	\$0.35
Diluted net income per share	\$0.39	\$0.32
Shares used in computation of basic net income per share	7,011,664	6,739,047
Shares used in computation of diluted net income per share	7,274,966	7,218,033

See accompanying notes to condensed consolidated financial statements.

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BioSpecifics Technologies Corp.

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:	\$2,829,124	\$2,330,900
Net income		
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization	414,744	172,554
Stock-based compensation expense	33,476	5,354
Deferred tax expense	(2,819,285)	(841)
Changes in operating assets and liabilities:		
Accounts receivable	(1,239,234)	(717,785)
Income tax receivable	(12,000)	13,996
Investment interest receivable	(14,304)	(18,260)
Prepaid expenses and other current assets	(83,320)	(25,883)
Patent costs	(5,414)	-
Accounts payable and accrued expenses	26,739	239,885
Deferred revenue	8,237,655	(12,345)
Net cash provided by operating activities	7,382,485	1,987,575
Cash flows from investing activities:		
Maturity of marketable investments	12,233,583	5,197,986
Purchases of marketable investments	(15,169,104)	(7,343,620)
Net cash used in investing activities	(2,935,521)	(2,145,634)
Cash flows from financing activities:		
Proceeds from stock option exercises	177,250	37,200
Payments for repurchase of common stock	(398,976)	(114,263)
Excess tax benefits from share-based payment arrangements	151,380	1,158,165
Net cash (used in) provided by financing activities	(70,346)	1,081,102
Increase in cash and cash equivalents	4,376,618	923,043
Cash and cash equivalents at beginning of year	5,137,875	9,810,816
Cash and cash equivalents at end of period	\$9,514,493	\$10,733,859
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	-	-
Taxes	\$4,080,000	\$80,000

See accompanying notes to condensed consolidated financial statements.

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BIOSPECIFICS TECHNOLOGIES CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2016

(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 currently have a development and license agreement with Endo for injectable collagenase for marketed indications and indications in development. Endo assumed this agreement when Endo acquired Auxilium Pharmaceuticals, Inc. ("Auxilium") on January 29, 2015 (the "Acquisition"). CCH is marketed as XIAFLEX® (or XIAPEX® in Europe).

On February 5, 2016, we announced that we had entered into with Endo the First Amendment to the Second Amended and Restated Development and Licensing Agreement, by and between us and Auxilium, now a wholly-owned subsidiary of Endo (the "Auxilium Agreement"), to amend certain provisions of the Auxilium Agreement (the "First Amendment", and the Auxilium Agreement, as amended by the First Amendment, the "License Agreement"). The effective date of the First Amendment is January 1, 2016. Pursuant to the First Amendment, we and Endo mutually agreed that in exchange for a \$8.25 million lump sum payment, we will not receive future additional mark-up on cost of goods sold for sales by non-affiliated sublicensees of Endo outside of the U.S.; provided, however, that Endo will still be required to pay a mark-up on cost of goods sold for sales made in the "Endo Territory," which includes sales made in the U.S. and sales made in any other country where Endo sells the product directly or through affiliated sublicensees. We received this \$8.25 million lump sum payment in February 2016 and will recognize this income over time based on sales by non-affiliated sublicensees of Endo outside of the U.S. according to our revenue recognition policy beginning in the second quarter of 2016.

Additionally, we agreed that Endo may opt-in early to indications, prior to our submission of a clinical trial report, with our consent, such consent not to be unreasonably withheld. For early opt-ins, Endo will be required to make an opt-in payment of \$0.5 million on a per indication basis. For regular opt-ins, following our submission of a clinical trial report, Endo will be required to make an opt-in payment on a per indication basis.

The two marketed indications involving our injectable collagenase are Dupuytren's contracture and Peyronie's disease. Prior to the Acquisition, Auxilium had, and after the Acquisition, Endo has, opted-in to the following indications: frozen shoulder, cellulite, canine lipoma, lateral hip fat and plantar fibromatosis. With respect to human lipoma and uterine fibroids, BioSpecifics is currently conducting development work and Endo may opt-in for CCH for these two additional indications. Based on public statements made by Endo, Endo is also interested in several other new unlicensed indications, including: capsular contracture of the breast, Dercum's disease, knee arthrofibrosis, urethral strictures, hypertrophic scars and keloids.

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 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 and is currently selling 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 and Australia. Actelion has received regulatory approval for and is currently selling XIAFLEX in Canada and Australia for the treatment of

Dupuytren's contracture.

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.

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The information included in this Report should be read in conjunction with the risk factors discussed in “Part I, Item 1A. Risk Factors” in our Annual Report on Form 10-K for the period ended December 31, 2015 filed with the SEC on March 14, 2016.

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 buy-down. For further details see notes “Provision for Income Taxes” and “Third-Party Royalties and Royalty Buy-Down.” Actual results may differ from those estimates.

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 municipal bonds. All investments are classified as held to maturity. As of March 31, 2016 and December 31, 2015, the aggregate fair value of these investments was \$34.7 million and \$31.9 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 short-term nature of those instruments. As of March 31, 2016 and December 31, 2015, there were no recorded unrealized gains or losses on our investments as they are held to maturity. As of March 31, 2016, amortized cost basis of the investments approximate their fair value.

The authoritative literature for fair value measurements established a three-tier fair value hierarchy, which prioritizes the inputs in measuring fair value. These tiers are as follows: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than the quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as significant unobservable inputs (entity developed assumptions) in which little or no market data exists.

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As of March 31, 2016, the Company held certain investments that are required to be measured at fair value on a recurring basis. The following tables present the Company's fair value hierarchy for these financial assets as of March 31, 2016 and December 31, 2015:

<u>March 31, 2016</u>	<u>Type of Instrument</u>	<u>Fair Value</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash equivalents	Institutional Money Market	\$ 5,948,850	\$ 5,948,850	-	-
Investments	Municipal Bonds	4,375,538	-	4,375,538	-
Investments	Corporate Bonds	19,777,612	-	19,777,612	-
Investments	Certificates of Deposit	10,594,272	10,594,272	-	-
<u>December 31, 2015</u>	<u>Type of Instrument</u>	<u>Fair Value</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash equivalents	Institutional Money Market	\$715,784	\$715,784	-	-
Investments	Municipal Bonds	6,617,042	-	6,617,042	-
Investments	Corporate Bonds	11,480,000	-	11,480,000	-
Investments	Certificates of Deposit	13,847,041	13,847,041	-	-

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, pre-refunded municipal bonds, municipal bonds and corporate bonds.

The Company is currently dependent on one customer, Endo, who generates almost all its revenues. For the three months ended March 31, 2016 and 2015, licensing, sublicensing, milestones and royalty revenues under the License Agreement with Endo were approximately \$6.6 million and \$5.6 million, respectively.

At March 31, 2016 and December 31, 2015, our accounts receivable balances were \$3.8 million and \$2.5 million, respectively.

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.

Under the License 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. The royalty and mark-up on cost of goods sold 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 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.

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Pursuant to the First Amendment with Endo, in exchange for a \$8.25 million lump sum payment, we will not receive future additional mark-up on cost of goods sold for sales by non-affiliated sublicensees of Endo outside of the U.S.; provided, however, that Endo will still be required to pay a mark-up on cost of goods sold for sales made in the “Endo Territory,” which includes sales made in the U.S. and sales made in any other country where Endo sells the product directly or through affiliated sublicensees. We received this \$8.25 million lump sum payment in February 2016. We classified this payment as deferred revenue in our balance sheet and will recognize this income over time based on sales by non-affiliated sublicensees of Endo outside of the U.S. according to our revenue recognition policy beginning in the second quarter of 2016.

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 Quarterly Report on Form 10-Q.

Upfront License and Sublicensing Fees

We generally recognize revenue from upfront licensing and sublicensing fees when the license or sublicense 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 \$12,345 for the three months ended March 31, 2016 and 2015, 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 license or sublicense agreement, 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, are 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. We did not recognize any milestone revenue in either three month period ended March 31, 2016 and 2015.

Treasury Stock

The Company accounts for treasury stock under the cost method and includes treasury stock as a component of stockholders’ equity. For the three months ended March 31, 2016, we repurchased 10,615 shares at an average price of \$37.59 as compared to the repurchase of 2,910 shares at an average price of \$39.27 in the corresponding 2015 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. Our accounts receivable balance is typically due from Endo, our one large specialty pharmaceutical customer. Endo has historically paid timely and has been a financially stable organization. Due to the nature of the accounts receivable balance, we believe the risk of doubtful accounts is minimal. If the financial condition of our customer were to deteriorate, adversely affecting its ability to make payments, additional allowances would be required. We 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 charge to the valuation allowance and a credit to accounts receivable. At March 31, 2016 and December 31, 2015 our accounts receivable balance was \$3.8 million and \$2.5 million, respectively, and was from one customer, Endo.

Deferred Revenue

Deferred revenue consists of the \$8.25 million related to the First Amendment with Endo of mark-up on cost of goods sold revenue for sales by non-affiliated sublicensees, \$86,412 related to nonrefundable upfront product license fees for product candidates for which we are providing continuing services related to product development and \$100,000 related to a milestone payment withheld by Endo due to a foreign tax withholding which remains uncollected. Currently, the Company expects to recover the full amount. As of March 31, 2016 and December 31, 2015, deferred revenue was \$8.4 million and \$0.2 million, respectively.

Reimbursable Third-Party Development Costs

We accrued patent expenses for research and development (“R&D”) that are reimbursable by us under the License Agreement. We capitalize certain patent costs related to estimated third-party development costs that are reimbursable under the License Agreement. As of March 31, 2016 and December 31, 2015, our net reimbursable third party patent expense accrual was approximately \$25,000 and \$20,000, respectively.

Third-Party Royalties

We have entered into licensing and royalty agreements with third parties and agreed to pay certain royalties on net sales of products for specific indications. The royalty rates differ from agreement to agreement and, in certain cases, have been redacted with the permission of the SEC. No assumptions should be made that any disclosed royalty rate payable to a particular third party is the same or similar with respect to any royalty rate payable to any other third parties. We accrue third-party royalty expenses on net sales reported to us by Endo. Third-party royalty costs are generally expensed in the quarter that Endo provides the written reports and related information to us; that is, generally one quarter following the quarter in which the underlying sales by Endo occurred. For each of the three month periods ended March 31, 2016 and 2015, third-party royalty expenses were \$0.4 million. Our third-party royalty expense under general and administrative expenses may increase if net sales by Endo and its partners for XIAFLEX and XIAPEX 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 in connection with 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, three of which have been paid as of March 31, 2016. 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 of the total estimated sales over the five year period. Related to this agreement, we amortized approximately \$274,000 and \$126,000 for the three months ended March 31, 2016 and 2015, respectively. The remaining capitalized balance as of March 31, 2016 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 March 31, 2016, no impairment existed and no adjustment was warranted.

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R&D Expenses

R&D expenses include, but are not limited to, internal costs, such as salaries and benefits, costs of materials, lab expenses, 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, and other 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. No stock options were granted during the three months ended March 31, 2016 and 2015.

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 \$5,300 for the three months ended March 31, 2016 and 2015, respectively.

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Stock Option Activity

A summary of our stock option activity during the three months ended March 31, 2016 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2016	562,000	\$ 11.91	2.51	17,456,220
Grants	-	-	-	
Exercised	(115,000)	1.54	-	
Forfeitures or expirations	-	-	-	
Outstanding at March 31, 2016	447,000	\$ 14.58	2.84	\$9,133,470
Exercisable at March 31, 2016	389,500	\$ 11.98	2.23	\$8,894,445

During the three months ended March 31, 2016 and 2015, the Company received \$177,250 and \$37,200, 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 \$34.82 on March 31, 2016, which would have been received by the option holders had all option holders exercised their options as of that date. We have approximately \$368,000 in unrecognized compensation cost related to stock options outstanding as of March 31, 2016, which we expect to recognize over the next 2.93 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 March 31, 2016 and December 31, 2015, property and equipment were fully depreciated.

Comprehensive Income

For the three months ended March 31, 2016 and 2015, 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 March 31, 2016 and 2015, the Company has not recorded any unrecognized tax benefits.

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Commitments and Contingencies

On August 14, 2015, the Company entered into an agreement with the Landlord to extend the term of the lease to the Headquarters for an additional one year period (the “Extended Lease Agreement”). The one year extension will end on November 30, 2016. Pursuant to the Extended Lease Agreement, the Landlord took occupancy of 1,000 square feet in the front of the building, the base rent is \$10,213 per month and the Company may cancel the lease with three months’ prior written notice to the Landlord at any time during the term. The Extended Lease Agreement was filed with the SEC as Exhibit 10.1 to the Company’s Quarterly Report on Form 10Q on November 9, 2015.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, further amended in August 2015, March 2016 and April 2016, Accounting Standards Updates No. 2014-09, No. 2015-14, No. 2016-08, and No. 2016-10 (the “ASUs”). These ASUs were issued in connection with revenue from contracts with customers. The new standard provides a five-step approach to be applied to all contracts with customers and also requires expanded disclosures about revenue recognition. In August 2015, the FASB deferred the effective date of the guidance to reporting periods, including interim periods, beginning after December 15, 2017, and will be applied retrospectively. Early adoption is not permitted. We are currently evaluating the timing, method of adoption and the expected impact that the standard could have on our consolidated financial statements and related disclosures. We expect to complete our analysis by December 31, 2016.

In November 2015, the FASB issued final guidance that requires companies to classify all deferred tax assets and liabilities as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. This guidance allows for adoption on either a prospective or retrospective basis. This guidance will be effective on January 1, 2017. Early adoption is permitted and can be applied prospectively or retrospectively. We adopted this standard retrospectively in the first quarter of 2016 resulting in a reclassification of approximately \$16,000 for the year ended December 31, 2015 from current to non-current deferred tax assets.

In January 2016, the FASB issued new guidance on recognition and measurement of financial assets and financial liabilities. The new guidance will impact the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. All equity investments in unconsolidated entities (other than those accounted for under the equity method of accounting) will generally be measured at fair value with changes in fair value recognized through earnings. There will no longer be an available-for-sale classification (changes in fair value reported in other comprehensive income (loss)) for equity securities with readily determinable fair values. In addition, the FASB clarified the need for a valuation allowance on deferred tax assets resulting from unrealized losses on available-for-sale debt securities. In general, the new guidance will require modified retrospective application to all outstanding instruments, with a cumulative effect adjustment recorded to opening retained earnings. This guidance will be effective for us on January 1, 2018. We are currently evaluating the expected impact that the standard could have on our consolidated financial statements and related disclosures.

In February 2016, FASB issued Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the lease commencement date: a lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. Under the new guidance, lessor accounting is largely unchanged. Certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and Topic 606, Revenue from Contracts with Customers. The new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. Lessees will no longer be provided with a source of off-balance sheet financing. Public business entities

should apply the amendments in ASU 2016-02 for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years (i.e., January 1, 2019, for a calendar year entity). Early application is permitted. Lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees and lessors may not apply a full retrospective transition approach.

In March 2016, FASB issued ASU No. 2016-09 related to stock-based compensation. The new guidance simplifies the accounting for stock-based compensation transactions, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This update is effective in fiscal years, including interim periods, beginning after December 15, 2016, and early adoption is permitted. We are currently evaluating this guidance and the impact it will have on the consolidated financial statements and disclosures.

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3. NET INCOME PER SHARE

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

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

	Three Months Ended	
	March 31,	
	2016	2015
Stock options	50,000	20,000

At March 31, 2016, the Company had 50,000 options outstanding, of which 30,000 options had an exercise price of \$37.64 which was higher than the average market price for the first quarter of 2016. These options expire on April 21, 2025. The remaining 20,000 options, which have an exercise price of \$29.21, will vest upon the achievement of certain performance criteria, which has not yet been met. These options expire on December 2, 2019.

4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	March 31, 2016	December 31, 2015
Trade accounts payable and accrued expenses	\$ 402,227	\$ 372,367
Accrued legal and other professional fees	46,141	74,138
Accrued payroll and related costs	189,381	164,504
Total	\$ 637,749	\$ 611,009

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 March 31, 2016, there was no indicator that an impairment existed.

We capitalized legal patent costs related to patent prosecution and maintenance. For the three months ended March 31, 2016, we increased our capitalized patent costs by approximately \$5,400, based on reports provided to us by Endo. These patent costs are creditable against future royalty revenues. For each period presented below, net patent costs consisted of:

	March 31, 2016	December 31, 2015
Patents	\$ 702,674	\$ 697,260
Accumulated Amortization	(431,698)	(422,054)
	\$ 270,976	\$ 275,206

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The amortization expense for patents for the three months ended March 31, 2016 and 2015 was approximately \$9,600 and \$11,000, respectively. The estimated aggregate amortization expense for the remaining nine months of 2016 and each of the years below is approximately as follows:

April 1, 2016 to December 31, 2016	\$28,600
2017	38,100
2018	38,100
2019	38,100
2020	26,800
Thereafter	\$101,100

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 months ended March 31, 2016 and 2015, the provision for income taxes was \$1.4 million and \$1.3 million, respectively. As of March 31, 2016 and December 31, 2015, our remaining deferred tax assets were approximately \$3.4 million and \$0.6 million, respectively. As of March 31, 2016, the Company believes that there are no significant uncertain tax positions and no amounts have been recorded for interest and penalties.

7. SUBSEQUENT EVENTS

None

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 currently have a development and license agreement with Endo for injectable collagenase for marketed indications and indications in development. Endo assumed this agreement when Endo acquired Auxilium Pharmaceuticals, Inc. ("Auxilium") on January 29, 2015 (the "Acquisition"). CCH is marketed as XIAFLEX® (or XIAPEX® in Europe).

The two marketed indications involving our injectable collagenase are Dupuytren's contracture and Peyronie's disease. Prior to the Acquisition, Auxilium had, and after the Acquisition, Endo has, opted-in to the following indications: frozen shoulder, cellulite, canine lipoma, lateral hip fat and plantar fibromatosis. With respect to human lipoma and uterine fibroids, BioSpecifics is currently conducting development work and Endo may opt-in for CCH for these two additional indications. Based on public statements made by Endo, Endo is also interested in several other new unlicensed indications, including: capsular contracture of the breast, Dercum's disease, knee arthrofibrosis, urethral strictures, hypertrophic scars and keloids.

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 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 and is currently selling 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 and Australia. Actelion has received regulatory approval and is currently selling in Canada and Australia for the treatment of Dupuytren’s contracture.

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Operational Highlights

On February 5, 2016, we announced that we had entered into with Endo the First Amendment to the Second Amended and Restated Development and Licensing Agreement, by and between us and Auxilium, now a wholly-owned subsidiary of Endo (the “Auxilium Agreement”), to amend certain provisions of the Auxilium Agreement (the “First Amendment”, and the Auxilium Agreement, as amended by the First Amendment, the “License Agreement”). The effective date of the First Amendment is January 1, 2016. Pursuant to the First Amendment, we and Endo mutually agreed that in exchange for a \$8.25 million lump sum payment, we will not receive future additional mark-up on cost of goods sold for sales by non-affiliated sublicensees of Endo outside of the U.S.; provided, however, that Endo will still be required to pay a mark-up on cost of goods sold for sales made in the “Endo Territory,” which includes sales made in the U.S. and sales made in any other country where Endo sells the product directly or through affiliated sublicensees. We received this \$8.25 million lump sum payment in February 2016 and will recognize this income over time based on sales by non-affiliated sublicensees of Endo outside of the U.S. according to our revenue recognition policy beginning in the second quarter of 2016.

Additionally, we agreed that Endo may opt-in early to indications, prior to our submission of a clinical trial report, with our consent, such consent not to be unreasonably withheld. For early opt-ins, Endo will be required to make an opt-in payment of \$0.5 million on a per indication basis. For regular opt-ins, following the submission of a clinical trial report, Endo will be required to make an opt-in payment on a per indication basis.

Outlook

We generated revenue from primarily one source, the License Agreement. Under the License 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.

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, pre-refunded municipal bonds and corporate bonds.

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, 2015 filed with the SEC on March 14, 2016.

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

March 31, 2016 and for the three months ended March 31, 2016 and 2015 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, 2015 balance sheet amounts and disclosures included herein have been derived from the Company's December 31, 2015 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, 2015 included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2016. While our significant accounting policies are described in more detail in the notes to our unaudited condensed consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements. Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

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Revenue Recognition

We 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 deliverables should be treated as separate units, 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.

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 are generally recognized in the quarter that the applicable licensee provides the written report and related information to us.

Under the License 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. The royalty and mark-up on cost of goods sold 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 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.

Pursuant to the First Amendment with Endo, in exchange for a \$8.25 million lump sum payment, we will not receive future additional mark-up on cost of goods sold for sales by non-affiliated sublicensees of Endo outside of the U.S.; provided, however, that Endo will still be required to pay a mark-up on cost of goods sold for sales made in the "Endo Territory," which includes sales made in the U.S. and sales made in any other country where Endo sells the product

directly or through affiliated sublicensees. We received this \$8.25 million lump sum payment in February 2016. We classified this payment as deferred revenue in our balance sheet and will recognize this income over time based on sales by non-affiliated sublicensees of Endo outside of the U.S. according to our revenue recognition policy beginning in the second quarter of 2016.

Reimbursable Third-Party Development Costs

We accrue patent expenses for research and development (“R&D”) that are reimbursable by us under the License Agreement. We capitalize certain patent costs related to estimated third-party development costs that are reimbursable under the License Agreement. As of March 31, 2016 and December 31, 2015, our estimated net reimbursable third party patent costs accrual were approximately \$25,000 and \$20,000, respectively.

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Receivables

At March 31, 2016 and December 31, 2015 our accounts receivable balance which consists of royalties, mark-up on costs of goods sold and a portion of a milestone payment from Endo due to a foreign tax withholding was \$3.8 million and \$2.5 million, respectively, and was from one customer, Endo.

Deferred Revenue

Deferred revenue consists of the mark-up on cost of goods sold for sales by non-affiliated sublicensees and will be recognized as income over time based on sales by non-affiliated sublicensees of Endo outside of the U.S in accordance with our revenue recognition policy beginning in the second quarter of 2016. In addition, deferred revenue consists of licensing fees related to the cash payments received under the License Agreement in prior years and amortized over the expected development period of certain indications for XIAFLEX and a portion of a milestone payment withheld by Endo due to a foreign tax withholding which remains uncollected. As of March 31, 2016 and December 31, 2015, deferred revenue was approximately \$8.4 million and \$0.2 million, respectively.

Third-Party Royalties

We have entered into licensing and royalty agreements with third parties 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 any disclosed royalty rate payable to any particular third party are the same or similar with respect to any royalty rate payable to any other third parties. We accrue third-party royalty expenses on net sales reported to us by Endo. Third-party royalty costs are generally expensed in the quarter that Endo provides the written reports and related information to us; that is, generally one quarter following the quarter in which the underlying sales by Endo occurred. For each of the three months ended March 31, 2016 and 2015, third-party royalty expenses were \$0.4 million. Our third-party royalty expense under general and administrative expenses may increase if net sales by Endo and its partners for XIAFLEX and XIAPEX 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 in connection with 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, three of which have been paid as of March 31, 2016. 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 of the total estimated sales over the five year period. Related to this agreement, we amortized approximately \$274,000 and \$126,000 for the three months ended March 31, 2016 and 2015, respectively, 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 March 31, 2016, no impairment existed and no adjustment was warranted.

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.

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Further, ASC 718 requires that employee stock-based compensation costs be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. The allocation of employee stock-based compensation costs to each operating expense line are estimated based on specific employee headcount information at each grant date and estimated stock option forfeiture rates and 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 MARCH 31, 2016 COMPARED TO THREE MONTHS ENDED MARCH 31, 2015

Revenues

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the License Agreement. Total royalty and mark-up on cost of goods sold for the three month period ended March 31, 2016 were \$6.6 million as compared to \$5.6 million in the corresponding 2015 period, an increase of \$1.0 million or 18%. This increase in royalties and the mark-up on cost of goods sold was primarily due to the increase in sales of XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease.

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 each of the three month periods ended March 31, 2016 and 2015, we recognized licensing revenue related to the development of injectable collagenase of approximately \$12,000.

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 expenses, 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. For the three months ended March 31, 2016 and 2015, R&D expenses were \$0.2 million in each period.

We are currently working to develop CCH for the treatment of human lipoma and uterine fibroids. We expect to release top-line results from our Phase 2 study in human lipoma the second quarter of 2016. We expect to initiate a trial in uterine fibroids in the second half of 2016.

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

<u>Program</u>	Three Months Ended March 31, 2016	Three Months Ended March 31, 2015
Human Lipoma	\$ 35,969	\$ 56,767
Uterine Fibroids	16,337	-
Pre-clinical/other research projects	196,194	182,698

The 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 the Company is able to successfully complete the development of our drug candidates, our long-term prospects depend upon our ability and the ability of our partners, particularly with respect to XIAFLEX and CCH, to continue to successfully commercialize these drug candidates.

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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 R&D activities related to our drug candidate projects;
- the 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, partnership, joint venture, 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.

We believe that 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.

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 for the three months ended March 31, 2016 and 2015 were \$2.2 million and \$1.8 million, respectively. The increase in general and administrative expenses was mainly due to the amortization of the deferred royalty buy-down, legal fees and director fees.

Other Income

Other income for the three months ended March 31, 2016 was approximately \$74,000 compared to \$18,000 in the corresponding 2015 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 March 31, 2016, our provision for income taxes was \$1.4 million. Our taxes payable as March 31, 2016 were reduced by \$0.2 million due to the windfall associated with the disqualified sale of incentive stock options and the exercise of nonqualified options. Our deferred tax assets increased by \$2.8 million due to the receipt of \$8.3 million under the First Amendment with Endo which will be recognized as income over time based on sales by non-affiliated sublicensees of Endo outside of the U.S. according to our revenue recognition policy beginning in the second quarter of 2016.

For the three month period ended March 31, 2015, the provision for income taxes was \$1.3 million.

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Net Income

For the three months ended March 31, 2016, we recorded net income of \$2.8 million, or \$0.40 per basic common share and \$0.39 per diluted common share, compared to a net income of \$2.3 million, or \$0.35 per basic common share and \$0.32 per diluted common share, for the same period in 2015.

Liquidity and Capital Resources

To date, we have financed our operations primarily through product sales, licensing revenues and royalties under agreements with third parties and sales of our common stock. At March 31, 2016 and December 31, 2015, we had cash and cash equivalents and investments in the aggregate of approximately \$44.3 million and \$37.1 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 12 months.

Net cash provided by operating activities for the three months ended March 31, 2016 and 2015 was \$7.4 million and \$2.0 million, respectively. Net cash provided by operating activities in the 2016 period was primarily attributable our net income of \$2.8 million, an increase in operating assets and liabilities of \$6.9 million of which \$8.3 million was related to the First Amendment with Endo for mark-up on cost of goods sold for sales by non-affiliated sublicensees of Endo outside of the U.S. Non-cash items included amortization, stock-based compensation expense, deferred taxes, deferred revenue which was reduced by adjustments to reconcile net income to net cash provided by operating activities of \$2.4 million. Net cash provided by operating activities in the 2015 period was primarily attributable our net income of \$2.3 million, adjustments to reconcile net income to net cash provided by operating activities of \$0.2 million and changes in operating assets and liabilities of \$0.5 million. Non-cash items included amortization, stock-based compensation expense, deferred taxes and deferred revenue.

Net cash used in investing activities for the three months ended March 31, 2016 was \$2.9 million as compared to \$2.1 million for the corresponding 2015 period. The net cash used in investing activities in the 2016 reflects the maturing of \$12.2 million and investment of \$15.2 million in marketable securities. The net cash used in investing activities in the 2015 period reflects the maturing of \$5.2 million and investment of \$7.3 million in marketable securities.

Net cash used in by financing activities for the three months ended March 31, 2016 was \$0.1 million as compared to net cash provided by financing activities of \$1.1 million in the corresponding 2015 period. In the 2016 period, net cash used in financing activities was mainly due to the repurchase of \$0.4 million of our common stock under our stock repurchase program partially offset by the excess tax benefits related to share-based payments of \$0.2 million and the proceeds received from stock option exercises of approximately \$0.2 million. In the 2015 period, net cash provided by financing activities was mainly due to the excess tax benefits related to share-based payments of \$1.2 million and the proceeds received from stock option exercises of approximately \$37,000 partially offset by the repurchase of \$0.1 million of our common stock under our stock repurchase program.

Off-Balance Sheet Arrangements

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

Item 3: Quantitative and Qualitative Disclosures About Market Risk.

We do not use derivative financial instruments or derivative commodity instruments for trading purposes. Our financial instruments consist of cash, cash equivalents, investments, trade accounts receivable, accounts payable and long-term obligations. We consider investments that, when purchased, have a remaining maturity of three months 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 of our cash and cash equivalents and investments at March 31, 2016, amounting to approximately \$44.3 million, were maintained in bank demand accounts, money market accounts, certificates of deposit, corporate bonds 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, 2015.

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Item 4: Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company, under the supervision and with the participation of Thomas L. Wegman, the Company's President, Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of its disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, Thomas L. Wegman, in his capacity as the sole named executive officer of the Company, the Company's Principal Executive Officer and the Company's 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 such 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 March 31, 2016 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

Due to our dependence on Endo for future royalty, milestone, cost of goods mark up and sublicense income payments and the commercialization of licensed indications and further development of future indications of XIAFLEX, the restructuring of Endo's business and Endo's failure to achieve projected revenues as reflected in its revised guidance announced on May 5, 2016, could have a material adverse effect on our business.

Our performance is substantially dependent on Endo's performance, stability and success. Endo's operations are substantially dependent on the continued services and performance of its senior management and other key personnel as well as the stability and performance of its various business units. Although the revised guidance on projected revenues and internal restructuring of Endo's business units announced by Endo on May 5, 2016 are principally related to the generics business, they could have the effect of distracting the attention of management and other resources away from the commercialization and further development of XIAFLEX, thereby materially and adversely our financial condition by slowing down the growth of, or reducing, XIAFLEX sales and development and payments by Endo to us for royalties, cost of goods sold, milestones, and sublicense income.

In addition to the other information contained elsewhere in this Report, you should carefully consider the risk factors discussed in “Part I, Item 1A. Risk Factors” in our Annual Report on Form 10-K for the period ended December 31, 2015 filed with the SEC on March 4, 2016, 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 March 31, 2016, 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 March 31, 2016.

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 \$ 1,620,011 ⁽¹⁾
January 1, 2016 – January 31, 2016	5,130	\$ 38.77	240,798	1,421,146
February 1, 2016-February 29, 2016	3,715	36.61	244,513	1,285,155
March 1, 2016 – March 31, 2016	1,770	36.23	246,283	1,221,035

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- (1) On August 17, 2015, we announced that our Board of Directors had authorized the repurchase of up to \$2.5 million of our common stock under the stock repurchase program.
- (2) The purchases were made in open-market transactions in compliance with rule 10b-18 or under the company's 10b-18 plan.
- (3) Includes commissions paid, if any, related to the stock repurchase transactions.

Item 6. Exhibits

- First Amendment to Second Amended and Restated Development and License Agreement, by and between the Company and Endo Global Ventures, entered into as of February 1, 2016, with an effective date of January 1, 2016 (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on February 5, 2016)
- 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.
- 101* The following materials from BioSpecifics Technologies Corp.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, (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.

+ Indicates confidential treatment was requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

* 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: May 10, 2016 /s/ Thomas L. Wegman

Thomas L. Wegman

President, Principal Executive Officer and Principal Financial Officer